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Analysis of 30 anaesthesia-related deaths in Germany between 2006 and 2015

Short title: Anaesthesia-related deaths in Germany

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Abstract

BACKGROUND Anaesthesiology can be described as one of the safest fields in medicine today in relation to mortality. Deaths purely due to anaesthesia have fortunately now become rare exceptions. However, important findings can still be inferred from the rare cases of anaesthesia-related death.

OBJECTIVE The aim of this study was to identify and analyse the causes of deaths related to anaesthesia alone over a 10-year period.

DESIGN Retrospective structured analysis of a database of medical liability claims.

SETTING Institutions at all levels of care in Germany.

PATIENTS The database of a large insurance broker included data for 81,413 completed liability claims over the 10-year period from 2006 to 2015. Among 1914 cases associated with anaesthetic procedures, 56 deaths were identified. Of these, 30 clearly involved anaesthesia-related mortality (Edwards category 1) and were included in the evaluation.

INTERVENTIONS None (retrospective database analysis).

MAIN OUTCOME MEASURES Causes of anaesthesia-related death identified from medical records, court records, expert opinions, and autopsy reports.

RESULTS The 30 deaths were analysed in detail at the case and document level. They included high proportions of 'potentially avoidable' anaesthesia-related deaths, at 86.6%, and what are termed 'never events', at 66.7%. Problems with the airways were the cause in 40% of these cases and problems with correct monitoring in 20%. In addition, communication problems were identified as a 'human factor' in 50% of the cases.

CONCLUSION The majority of the anaesthesia-related deaths investigated could very probably have been avoided with simple anaesthesiological measures if the currently valid standard and routine guidelines had been followed. Actions to be taken are inferred from these results, and recommendations are made. In the future, greater care must be taken to ensure that the level of safety already achieved in anaesthesiology can be maintained despite demographic developments and increasing economic pressures.

Introduction

Tremendous improvements have been made in recent decades in relation to patient safety in anaesthesiology. Today, anaesthesiology is the only medical specialty that can claim to meet the 'six sigma defect rate' used in the industrial field in relation to mortality.[1] This means that the 'end product is free of defects' in 99.99966% of cases. Although the United States Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System,*[2] published in 2000, is usually thought of as representing the start of the patient safety movement in medicine, anaesthesiology can claim to have already been placing a high value on patient safety for several decades before that.[3] Figure 1 shows that major improvements in safety and the associated reductions in mortality in anaesthesiology had already been achieved before the IOM report. This was due to the initially high mortality rate associated with anaesthesia. In the period 1948–1952, for example, the anaesthesia-related mortality was 64/100,000 anaesthetic procedures, representing a mortality rate of 3.3/100,000 inhabitants relative to the total population mit und ohne Narkosen.[4,5] The anaesthesia-related mortality was even higher than the mortality caused by the contemporary poliomyelitis epidemic.[6] In diesen frühen Zeiten der Fachentwicklung waren hauptsächlich technische und medikamentöse Probleme für die meisten Zwischenfälle in der Anästhesie verantwortlich[7]. Through numerous technical advances (pulse oximetry, capnography, etc.) and improvements in drugs and training, as well as the introduction of systematic optimisation measures such as systematic error analyses, standards for anaesthesia administration, simulation and crew resource management training, as well as the introduction of national incident reporting systems,[8] it was possible to reduce the anaesthesia-related mortality rate to 12.6/100,000 by 1986.[9] In 2006, Lienhardt *et al.* reported a mortality rate solely due to anaesthesia of only 0.69/100,000.[10] In an analysis of 1.37 million anaesthesia procedures conducted between 1999 and 2010, Schiff *et al.* noted anaesthesia-associated mortality rates of 0.73/100,000 or 0.00073% in patients in American Society of Anesthesiologists (ASA) classes I and II.[11]

In terms of mortality, an anaesthetic procedure in an ASA I or II patient is now as safe as a holiday flight. According to Boehm[12] and Gottschalk *et al.*,[6] fundamental distinctions need to be made between the following terms: anaesthesia-related, anaesthesia-associated, and perioperative mortality (Table 1). Despite the marked reduction in anaesthesia-associated and anaesthesia-related mortality over the last 20 years, perioperative mortality is reported to have hardly changed, at between 0.4% and 0.8%.[13–15]

Although these developments in the field of anaesthesia are in principle encouraging, it means that it is becoming all the more difficult to identify purely anaesthesia-related deaths and to analyse their causes. The aim of the present study was to identify and analyse purely anaesthesia-related deaths in the period 2006–2015 in the claims database of a large German insurance claims broker.

Methods

Ecclesia Versicherungsdienst GmbH is an insurance claims broker that holds an extensive database of medical liability cases in Germany. Die versicherten Krankenhäuser und Ärzte sind gleichmässig über Deutschland verteilt. From 1996 to 2017, the claims database recorded a total of around 215,000 claims from 950 public liability policies of German hospitals and physicians in private practice.[16] Thanks to a cooperation agreement, it was possible to evaluate this claims database in a structured manner to analyse anaesthesia-related deaths between 2006 and 2015. What is known as the Edwards classification[17,18] was used to identify purely anaesthesia-related mortality (Table 2). Only Edwards category 1 cases, in which the event was most likely caused by anaesthesia, were included in the evaluation. The period between 2006 and 2015 was chosen so that only closed liability cases were included in the analysis. Since anaesthesiology was not encoded in the claims database as a separate main specialty field – in the same way as trauma surgery, for example – and instead was assigned to another main specialty in each case, structural adjustments first had to be made to the database to identify the anaesthesia-related deaths. After identification, it was also possible to analyse the corresponding underlying original files in addition to the descriptive evaluations, with strict data protection and security precautions at the broker's head office in Detmold. In addition to the copies of the medical records, including anaesthesia records, minutes from memory of those involved, file notes, available expert opinions, and autopsy reports were analysed in a structured way. The data were deliberately not re-evaluated, and instead the findings and decisions made by experts and/or courts were included in the evaluation. Structured items as listed in Table 3 were included in the evaluation.

The data were analysed using IBM SPSS Statistics, version 25.0 (IBM Corporation, Armonk, New York, USA). The evaluation included descriptive statistics (means, standard deviations, relative frequencies). Structural differences between preventable and non-preventable deaths were tested for inferential statistical differences using a contingency table and χ^2 test or, in the case of interval scale levels (e.g., time of day), using a *t*-test. In case of significant differences, the parameters used for each of the applied analyses are given.

Ethics

Ethical approval for this study (registry number 2013-17) was provided by the ethics committee of Martin Luther University of Halle–Wittenberg, Halle, Germany (Chairperson Prof. Dr. Hermann M. Behre) on 12 February 2013.

Results

A total of 81,413 claims were recorded during the period from 2006 to 2015 that was analysed (Fig. 2). A total of 1914 (2.4%) of the claims were made in connection with anaesthetic procedures. Fifty-six deaths were identified among these 1914 cases. When these 56 cases were analysed at the document level, 16 cases were found to be anaesthesia-associated deaths, two cases had been assessed by the experts or the court as involving a ‘fateful course’, and eight cases could not be taken into consideration due to missing or incomplete documentation. A total of 26 cases were thus excluded, and the analysis showed that 30 cases clearly involved anaesthesia-related mortality corresponding to Edwards category 1 (Table 2). In der Tabelle 4 sind die wichtigsten Merkmale der 30 analysierten Todesfälle komprimiert zusammengefasst.

Analysable documents

For each person who died, a mean of 2.5 full medical reports were available for analysis (range 0–5). At least one set of minutes from memory from one participant was present in 93.3% of these cases (n = 28), and from at least two participants in 73.3% of the cases (mean 1.9 sets of minutes from memory per case, maximum three). An expert committee or medical council arbitration board was involved in parallel in only 10% of the cases (n = 3). Investigations by public prosecutors had been initiated in 21 cases

(70%), and autopsies, including the corresponding reports, were available in 13 of the 30 cases (43.3%).

General framework

Ninety per cent of the cases (n = 27) involved in-patient interventions and three occurred in the outpatient setting. Twenty-three cases (76.7%) were planned elective procedures and only seven cases were stated to be emergencies. It is therefore not surprising that 90% of the events (n = 27) occurred on regular working days and 83.3% (n = 25) were during core working hours, between 8 a.m. and 4 p.m. A statistically significant difference ($P = 0.034$) in times of death was noted here: potentially preventable deaths tended to occur later in the course of the day (mean 12:56, SD 3:22 h), while more unpreventable ones tended to occur earlier in the course of the day (mean 10:37, SD 1:21 h; $t[df = 28] = 2.438$; $P = 0.034$). The distribution of cases relative to hospital size was as follows: eight cases (26.7%) occurred in hospitals with up to 200 beds, 10 (33.3%) in hospitals with 201–500 beds, five (16.7%) in hospitals with 501–1000 beds, and six (20%) in hospitals with more than 1000 beds.

The most common cases were in the fields of trauma surgery/orthopaedics and ear, nose and throat (ENT), with six deaths each (20% each), followed by general surgery with five cases (16.7%), gynaecology with four (13.3%) and obstetrics with three cases (10%).

Patient data

The patients who died were 50% female and 50% male, with ages ranging from a 6-week-old premature baby to an 81-year-old man (mean 43.5 years). Seventy per cent of the deaths (n = 21) were in the 18–65 year age group, 13.3% were in patients under

4 years of age and 16.7% were in patients aged over 65. The patients' ASA classifications showed low ASA grades: six patients were assigned to ASA I (20%), 14 to ASA II (46%), eight to ASA III (27%) and two to ASA IV (7%). None of the patients who died were in ASA V or VI (Fig. 3).

Anaesthesia-specific data

The majority of cases (83.2%) involved general anaesthesia (n = 25; 23 intubations, two laryngeal masks). In three cases, spinal anaesthesia was administered (in one case with additional analgesia), and peripheral regional anaesthesia with a catheter and analgosedation were performed. Sixty per cent of the fatal complications (n = 18) occurred in the operating room (11 during induction, three during ongoing anaesthesia and four during the recovery phase) and 40% postoperatively (n = 12; six in the intensive-care unit and three each in the recovery room and the normal ward). The procedures had 'consultant status' in 76.7% of the cases (n = 23).

Anaesthesia-related causes of death

Analysis of anaesthesia-related causes of death showed that failure to secure the airway was most frequent (40%, n = 12). In addition to cases in which there was a lack of management preparation for difficult airways that could have been expected (entweder war nicht die nötige fachliche Expertise und/oder das nötige Spezialmaterial von Beginn an im Einsatz), there were seven cases of unrecognised incorrect intubation (23.3%). Davon kam eine Kapnometrie in vier Fällen gar nicht zum Einsatz und in drei Fällen wurden die angezeigten Werte falsch interpretiert. The second most frequent anaesthesia-related cause found in the analysis was inadequate or insufficient routine monitoring during or after anaesthesia, in 20% (n = 6). Dabei wurde dreimal auf das

Standardüberwachungsmonitoring (Sauerstoffstättigung, Blutdruck, EKG) verzichtet, einmal kam es zu einem Muskelrelaxansüberhang bei fehlender Relaxometrie und in zwei Fällen fehlte eine adäquate personelle Überwachung. Incorrect performance of the anaesthetic technique selected (n = 4, 13.3%), medication errors, or inadequate preoperative preparation were each present in 10% (n = 3 each).

Assessment and avoidability

Two-thirds of the cases (66.7%, n = 20) involved what have been termed 'never events'.[19,20] The events were classified as 'potentially avoidable' by the experts in 86.7% of the cases (n = 26). A major communication problem between the team members was considered to be the cause in every second case (n = 15), and the experts considered that help had been called for too late in 60% (n = 18).

Limitations

Closed claims data analysis has distinct limitations that differ from outcome research[21].The incidence and risk of anaesthetic-related adverse outcomes are unknown due to the absence of numerator data for the total number of anaesthetic procedures performed. Therefore, closed claims data does not provide a denominator for calculating the risk of anaesthetic injury[22]. *In addition, some relatives (e.g. patient ASA IV and higher) do not file claims, even when it as a fatal complication.*

As anaesthesia-related deaths have now become extremely rare, it was necessary to make a suitable data pool usable. The insurance claims data pool that was used, including data for more than 155,000 medical claims at the end of 2015, can be described as uniquely extensive in Germany, as it covers approximately 50% of all insured hospital beds in Germany. A critical point that should be noted is that the data pool was not primarily created for medical evaluations and that anaesthesiology is not listed as a separate main specialty in the database. Cases with anaesthesiological involvement therefore first had to be linked using a database adjustment. This made it possible to assign 2.4% of the claims to anaesthesiological activities. If one analyses the statistical survey of the expert commissions and state medical councils' arbitration boards on questions of medical liability[23,24] over the same period, the proportion of anaesthesiological/intensive-care liability cases in the same period lies between 2.2% and 2.9%, with a mean of around 2.6%. It can therefore be assumed that the anaesthesiological cases present in the database were detected successfully. In addition, the main specialties found to be most frequently involved in the database are consistent with those noted by the expert commissions and arbitration boards: the most frequent events occurred in the specialties of trauma surgery/orthopaedics, followed by general surgery. This also argues in favour of a realistic reflection of the data in the database. Analysis of *anaesthesia-related causes* showed that failure to secure the airway (40%), incorrect performance of the anaesthetic technique selected (13.3%), medication errors (10%) and inadequate preoperative preparation (10%) were most frequent, with rates analogous to those reported in the literature.[12,25] In addition, the analysis found that inadequate routine monitoring during or after anaesthesia was present at an above-average rate, in 20%.

Discussion

In 86.7% (n = 26) of all deaths (Fig. 4), the experts concluded that the events would have been *'potentially avoidable'* if the safety standards currently in force at the time had been observed. This figure is markedly higher than that given in the literature for unexpected events in medicine. In highly developed health-care systems, potential avoidability rates for adverse events of between 25% and 70% have been reported when the treatment standards applicable in each case are observed.[26–28] However, these are data from retrospective studies of medical records – i.e., events that in many cases did not ultimately lead to liability claims. The 'potentially avoidable' causes of death identified in the present study included, for example, unrecognised incorrect intubations due to failure to use capnometry/capnography, incomplete staffing and/or inadequate technical monitoring. All of these deaths could potentially have been avoided with simple routine measures: constant attendance by anaesthesia specialists and correct monitoring and surveillance in accordance with the currently valid recommendations of the national specialist associations.[29] Other simple and effective measures would have been correct use of capnometry/capnography, neuromuscular monitoring, bedside testing, safety checks on medication and adequate preoperative preparation. The potentially avoidable deaths would thus not have required elaborate procedures or procedures that could not be carried out in routine conditions, but only adherence to established standards. The effectiveness of these routine measures has been well documented (Table 5).[30]

A specialist was present ('consultant status') at the time of the event in 76.7% (n = 23) of the cases, so that a lack of individual professional competence or experience cannot be assumed. In 60% (n = 18) of the cases, however, the experts found that there had been a delayed request for help in spite of obvious problems. Die Anforderung um weitere Hilfe nach Aufreten der Komplikation erfolgte im Schnitt nach 13 Minuten (minimum 5 min, maximum 24 min) und es dauerte durchschnittlich weitere 6 Minuten, bis die Hilfe eintraf. Warum die Hilfe erst mit dieser Verzögerung angefordert wurde, konnte aus den Unterlagen nicht eindeutig beantwortet werden. In half of the cases, they also identified a major communication problem in the team that made problem-solving difficult. Dies waren häufig multifaktoriell und betrafen in erster Linie nicht erfolgte oder unstrukturierte Übergaben mit nachfolgendem Informationsdefiziten (n = 11), falsche Annahmen (n = 9) und nicht explizit geklärte Rollen- oder Führungsverständnisse zwischen den Teammitgliedern (n = 7). This appears to confirm the fact that it is often not a lack of professional expertise, but rather so-called 'human factors' – including the quality of collaboration in the team – that play a major role, particularly in connection with solving and overcoming problems. In medicine, the contribution made by 'human factors' to the causes of incidents is 60–80%.[30,31]

The positive effects of high-quality teamwork on clinical performance[33] and on rates of adverse events[34–36] are regularly reported on. In a study on perioperative mortality including 84,730 patients, Ghaferi *et al.* found that serious complications occurred at similar frequencies in hospitals of different sizes that were included in the study.[37] It was only when the consequences were analysed – in this case specifically the mortality associated with the complications – that clear differences emerged in relation to what is termed 'failure to rescue'. In concrete terms, this means that the number of complications does not correlate automatically with the mortality. Differences in mortality only arise from qualitative differences between treatment teams in relation to routine and professional management of the complications. Structured teams and structured communications can thus help to reduce complications and deaths.[38,39] No significant correlations with hospital sizes were observed in the present analysis, due to the small number of cases.

In addition, two-thirds of the deaths (n = 20) were rated by the experts as so-called 'never events' (Fig. 5), all of which were consequently classified as 'potentially avoidable'. General anaesthesia was used in 17 of these cases, and the cause of death was also attributed to a respiratory cause in 17 cases. The main causes were identified as unrecognised incorrect intubation in seven cases, and a lack of management preparation for difficult airways and medication errors in four cases each. In this group, the procedure also had ‘consultant status’ in 70% of the cases at the time of the event. Here, too, the experts identified a communications problem in the team in half of the cases and a delay in requesting help despite obvious problems in 60%.

Some studies have shown that both age and ASA classification represent patient-associated risks.[10,40] The risk for anaesthesia-associated mortality was found to increase starting from age > 45 and from ASA risk class III. The present analysis did not show any evidence of these likely associations (Fig. 3). In fact, it even showed the contrary: six patients (20%) were in ASA class I and thus belonged by definition to the so-called ‘never event’ group. Another 14 patients (46%) were classified as belonging to the ASA II group. That means that 66.7% (n = 20) of those who died were thus in the supposedly lowest ASA risk categories. Only eight (ASA III) and two (ASA IV) patients were in the higher risk grades, and none of those who died were in risk classes V or VI at all. One explanation for this might be that the analysis involved an insurance claims database – so that deaths in individuals with higher-grade ASA classifications may be underrepresented here, weil diese Fälle ggf. in der Versicherungsdatenbank nicht gemeldet wurden.

A subgroup analysis of the ‘never events’ in ASA class I shows that they included four elective and two emergency procedures exclusively in younger patients (ages 3, 3.5, 5, 26, 35 and 39), two of which occurred in the field of traumatology (two with knee arthroscopy) and four in the ENT field (two tonsillectomies, one adenotonsillectomy and one intraoral abscess incision). Intubation anaesthesia was performed in all six cases, and the primary cause of death was respiratory in each case. The experts assessed all of these deaths as ‘potentially avoidable’ if the currently valid safety standards had been applied. In all, there were three unrecognised incorrect intubations (twice with a lack of capnography and once with incorrect interpretation of the available capnography curve) and in two cases inadequate preparation for an expected ‘difficult airway’. In one case, postoperative monitoring was assessed as inadequate.

Due to the small number of cases, it was not possible to identify any relevant statistical risk patterns using the items recorded in relation to ‘potentially avoidable’ deaths or so-called ‘never events’. Only the differences in deaths at later times of the day in connection with potentially avoidable deaths were statistically significant ($P = 0.034$). This finding is consistent with results from a study in Germany,[41] in which the lowest rates of complications and mortality were associated with operations starting between 7 a.m. and 11 a.m. and the highest rates were in those starting between 1 p.m. and 5 p.m. Potential reasons for this might be the patient’s biorhythms, the urgency of the operation, or potential fatigue on the part of the surgical team, for example.

Im Gegensatz zu früheren Untersuchungen[7] zeigen sich in dieser Analyse also weniger technische oder medikamentöse Ursachen für die tödlichen Komplikationen, sonder in erster Linie in hohem Masse vermeidbare “human factors” Probleme bei grundsätzlich jungen und gesunden Patienten. Dies spricht dafür, neben den technischen Errungenschaften weiterhin vermehrt auf die sog. human factors (z.B. crew resource management trainings, high reliability organizations) zu focussieren, um derartige Todesfälle künftig noch häufiger vermeiden zu können. Eine ideale Grundlage für diese Weiterentwicklung wurde bereits 2010 durch das European Board of

Anaesthesiology der European Society of Anaesthesiology mit der Helsinki Declaration on Patient Safetey in Anaesthesiology[42] geschaffen und 2020 um ein Expertenupdate erweitert. [43]

In the future – with demographic developments leading to increasingly older patients with increasing numbers of comorbidities being treated with ever more complex interventions, and with health-care facilities being exposed to increasing economic pressures – it is imperative to ensure that the anaesthesiological safety standards that have been achieved are not endangered, leading once again to increased complication rates and thus indirectly to higher anaesthesia-related and anaesthesia-associated mortality.[44]

Conclusion

Anaesthesiology is justifiably regarded as having been pioneering in the field of patient safety. Purely anaesthesia-related deaths are extremely rare today. Among the anaesthesia-related deaths investigated, 86.7% (n = 26) were 'potentially avoidable'. So-called 'never events' were involved in 66.7% (n = 20) of the anaesthesia-related deaths investigated. The 'potentially avoidable' deaths and 'never events' could have been prevented with simple anaesthesiological measures in accordance with the current standards in each case. In the context of increasing economic pressures, patients' constantly increasing age and increasing comorbidities, with ever more complex interventions, anaesthesiology must maintain the level of safety that has been achieved and, ideally, further improve it.

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Legends

Fig. 1

Deaths per 100,000 anaesthesia procedures per decade since 1950. The Institute of Medicine (IOM) report[2] was published in 2000.

Fig. 2

Anaesthesia-associated and anaesthesia-related mortality in Germany, 2006–2015, as represented by claims in the Ecclesia insurance service database.

Fig. 3

American Society of Anesthesiologists (ASA) classifications of 30 patients with anesthesia-related deaths in Germany, 2006–2015.

Fig. 4

Cases of potentially avoidable death among 30 anaesthesia-related deaths in Germany, 2006–2015.

Fig. 5

'Never events' among 30 anesthesia-related deaths in Germany, 2006–2015.