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Original Article

Incidence of Anesthesia-Related Medication Errors Over a 15-Year Period in a University Hospital

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Abstract To clarify the incidence of anesthesia-related medication errors in Kyushu University Hospital, a retrospective analysis of anesthesia-related incidents from 1993 to 2007 was conducted based on the "Investigation of anesthesia-related medication incidents" by the Japanese Society of Anesthesiologists. Out of a total of 64,285 anesthesia cases, drug errors occurred in 50 cases (0.078%), but none of the incidents led to serious sequelae. Wrong medication was the most common type of drug error (48%), followed by overdose (38%), underdose (4%), omission (2%), and incorrect administration route (8%). The most commonly involved drugs were opioids, cardiac stimulants, and vasopressors. Syringe swap was the leading cause of wrong medication, accounting for 42%, drug ampoule swap occurred in 33%, and the wrong choice of drug was made in 17%. The first, second, and third most frequent causes of overdose involved a misunderstanding or preconception of the dose (53%), pump misuse (21%), and dilution error (5%). The error frequency did not decrease over the 15-year period. The responsible anesthesiologists were most likely to be doctors with a little experience. To reduce anesthesia-related medication errors, improvements of protocols for handling medication and instruction, and an improved education system for the anesthesia trainees are essential.

Key words : medication error, anesthesia, incidence

Introduction

Anesthetics and anesthesia-related medication which anesthesiologists administer are powerful and potentially toxic drugs that act directly on levels of consciousness, respiration, and circulation. Therefore, wrong medication, overdose, or drug administration via an incorrect route could seriously harm the patients. Data collected prospectively by the Japanese Society of Anesthesiologists from 1999 to 2002 showed that overdose, incorrect drug choice, and a syringe or an ampoule swap accounted for 46.4% of all critical

incidents totally attributable to anesthesia¹⁾. Other data from overseas also indicated that the incorrect administration of medications constituted 29–52% of all anesthesia-related critical incidents^{2)–4)}. The Japanese Society of Anesthesiologists started a 3-year prospective study, called 'Investigation of anesthesia-related medication incidents', from 2005, to determine the frequency of the incorrect administration, overdose, and incorrect administration route of anesthesia-related drugs including incidents that did not lead to a critical outcome, and to identify the factors related to these incidents.

In the Department of Anesthesiology and Critical Care Medicine of Kyushu University, we have been registering all incidents, including those that did not lead to a critical outcome, since 1993, when the Japanese Society of Anesthesiolog-

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ists initiated the investigation of anesthesia-related mortality and morbidity, in an attempt to improve the quality of anesthesia. The aim of this study was to clarify the frequency and characteristics of incidents due to anesthesia-related medication error by using data collected in this hospital over a period of 15 years.

Material and Methods

A retrospective study of incidents due to anesthesia-related medication error registered in Kyushu University Hospital from 1993 to 2007 was conducted regarding questions extracted from 'Investigation of anesthesia-related medication incidents'.

1. Type of incident.
2. In cases of wrong medication, the drugs that should have been and those that were actually administered.
3. In cases of wrong medication, causes of the incidents.
4. In cases of overdose/underdose, the drug that was administered.
5. In cases of overdose/underdose, causes of the incidents.
6. In cases of an incorrect route, the drug administered, route mistakenly used, and the route that should have been taken.
7. The outcome of the incidents.
8. Qualification of the anesthesiologist responsible for the incidents.
9. The number of incidents divided by the year

and types.

Furthermore, an analysis of the factors that may be associated with the incidents, such as those of the responsible anesthesiologist, surrounding environment, education system (orientation), and training was conducted.

Results

Out of a total of 64,285 anesthesia-related procedures in Kyushu University Hospital performed from 1993 to 2007, drug errors occurred in 50 cases (0.078%). None of them were registered as critical incidents. Wrong medication was the most common type of drug error (24 cases, 48%), with overdose (the correct drug was administered but the dosage was more than appropriate: 19 cases, 38%) being the second common type of error, together constituting 86%. There were 2 cases (4%) of underdose (the correct drug was administered but the dosage was less than appropriate), and 1 case (2%) of omission (the drug that should have been administered was not). The administration route was incorrect in 4 cases (8%) (Fig. 1).

Of 24 cases of wrong medication, the first, second, and third most frequent drugs that should have been administered were opioids (8 cases), local anesthetics (4 cases), and muscle relaxants (3 cases). One case each involving intravenous anesthetics, cardiac stimulants/vasopressors, electrolyte-correcting drugs, and antibiotics, and 5 other cases were reported. The drugs actually

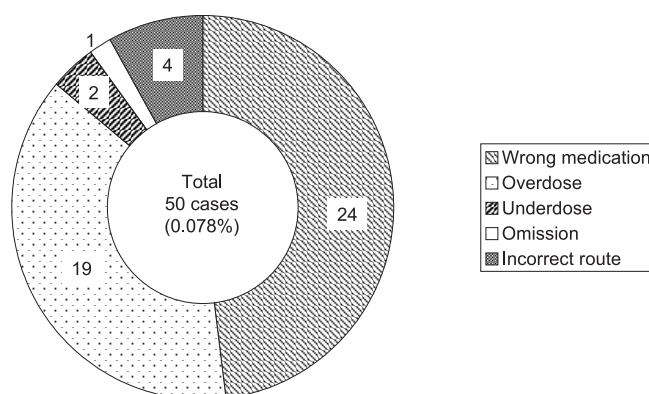


Fig. 1 Types of anesthesia-related medication errors over a 15-year period in the Kyushu University Hospital

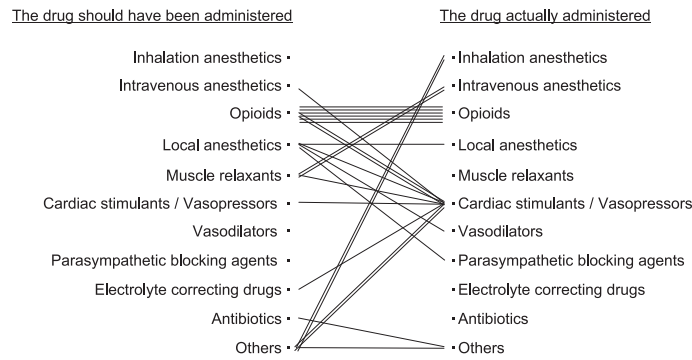


Fig. 2 The drug that should have been administered versus that actually administered

administered were as follows: cardiac stimulants/vasopressors (9 cases), opioids (6 cases), inhalation anesthetics and intravenous anesthetics (2 cases each), local anesthetics, vasodilators, parasympathetic blocking agents (1 case each), and others (2 cases) (Fig. 2). The administration of both the correct and incorrect drug, both being opioids was most frequent (6 cases). In 9 cases where stimulants/vasopressors were mistakenly administered, the drugs that should have been administered were intravenous anesthetics (1 case), opioids (2 cases), local anesthetics (1 case), muscle relaxants (1 case), electrolyte-correcting drugs (1 case), and other drugs (2 cases).

Syringe swap was the most common cause of wrong medication (10 cases), followed by drug ampoule swap (8 cases), and the wrong choice of drug (misunderstanding or preconception, 4 cases) and others (2 cases) (Fig. 3). In 8 of the 10 cases of syringe swap, a marked similarity between the sizes of the drug-containing syringes that should have been and actually were used was noted.

The error frequency of wrong medication did not decrease over the 15-year period. All 6 cases in which opioids were mistakenly administered were associated with ampoule swap, and the responsible anesthesiologists were those without qualifications in anesthesiology by the Ministry of Health, Labour and Welfare, first-year interns, or trainees from other specialties. In 9 cases where cardiac stimulants/vasopressors were mistakenly administered, syringe swap was the most common cause (6 cases), ampoule swap was the second (2 cases), and 1 case of misunderstanding or preconception was reported. Six of the 10 cases of syringe swap, 4 of the 8 cases of ampoule swap, and 2 of the 4 cases of misconception, that is, more than half of all incidents were associated with miscommunication between the responsible anesthesiologist and other medical staffs.

The drugs involved in 19 cases of overdose were as follows: stimulants/vasopressors (5 cases), opioids (4 cases), muscle relaxants (3 cases), insulin (3 cases), vasodilators (2 cases),

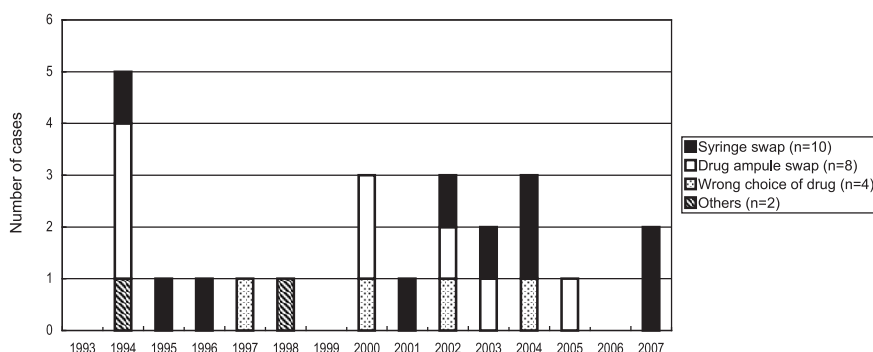


Fig. 3 Number of cases of the wrong medication, divided by the cause of the incident

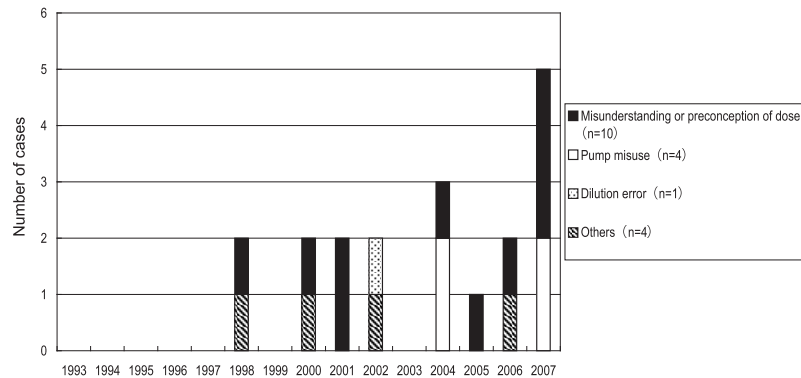


Fig. 4 Number of cases of overdose, divided by the cause of the incident

inhalation anesthetics (1 case), and antibiotics (1 case). In one case each, the drugs involved in underdose were an opioid and a local anesthetic.

Misunderstanding or preconception was the most common cause of overdose (10 cases), followed by pump misuse (4 cases), dilution error (1 case), and others (4 cases) (Figure 4). The error frequency of overdose did not decrease over the 15-year period. Six of 10 cases of misunderstanding or preconception were associated with miscommunication. Instructions on drug administration by an anesthesiologist were misunderstood by other anesthesiologists or nurses, which led to overdose of the medication. Two cases were due to dosage-miscalculation of vecuronium to children, and the other 2 involved an incorrect dosage of ketamine or remifentanyl via continuous intravenous infusion using a syringe pump. Two of 4 cases of pump-misuse resulted from setting the unit of velocity to 'mg/kg/hr' instead of ' μ g/kg/min'. All 3 cases of insulin overdose were caused by responsible anesthesiologists' (the trainees from other specialties) lack of knowledge regarding the insulin concentration.

Concerning the incorrect administration route (4 cases), propofol and tranexamic acid, which should be administered intravenously, were administered intraarterially (1 case each), and, in 2 cases, a dye which should be injected via a stomach tube was administered intravenously.

In the context of measures taken against the adverse effects and outcomes of errors, 26 of the 50 cases did not require any rescue procedures or

action other than close observation, 21 cases required simple procedures or treatment, one case had a prolonged operation room stay, and 2 cases required artificial ventilation lasting more than several hours. None of the incidents led to serious sequelae. The responsible anesthesiologists were most likely to be anesthesiologists without qualifications in anesthesiology by the Ministry of Health, Labour and Welfare (24 cases), followed by interns and trainees from other specialties (15 cases). However, 8 cases were reportedly caused by professional anesthesiologists and 3 cases by anesthesiology specialists.

Discussion

This study revealed an anesthesia-related medication error rate of 0.078% over a 15-year period. The investigation of anesthesia-related mortality and morbidity from 1999 to 2002 by the Japanese Society of Anesthesiologists reported an anesthesia-related medication error rate of 0.018%¹⁾. The latter only registered the critical incidents, and it is speculated that studies which did not register such incidents, such as the present one, show greater error rate. Other data from overseas have shown varied error rates ranging from 0.012% to 0.75%^{5)~8)}. The definition of errors and the way that investigation was conducted differ with each study, which may have resulted in the differing error rates.

None of the anesthesia-related medication errors (50 incidents) had more than a transient effect on the patients, and including the cases

where some procedures were required, no incidents led to serious sequelae. This is probably because errors were recognized in the early stage and were managed promptly and appropriately. The investigation of anesthesia-related mortality and morbidity from 1999 to 2002 by the Japanese Society of Anesthesiologists also suggests that the outcome of anesthesia-related medication errors is less serious compared to those related to other causes⁹. The incident due to medication errors represented 44% of the cases leading to cardiac arrest, while it comprised only 22% of all cases resulting in patient's death. The incidents related to ventilation and respiratory tract failure represented 24% and 49%, respectively, indicating that they are more likely to cause severe outcomes compared to incidents related to medication errors.

Syringe swap was the leading cause of wrong medication (10 cases). In 8 cases, syringe swap occurred between syringes of the same size. No cases in which syringe labeling was unclear were reported and incidents reportedly occurred due to the wrong syringe being picked up, and the drug applied in it being administered without its label being read. It has been pointed out that syringe swap is more likely to occur between syringes of the same size⁶. To prevent such errors, it is essential to educate anesthesiologists to read the label prior to taking the syringe and administering the drug within it.

According to a report by the Australian Incident Monitoring Study, muscle relaxants and opioids are the most frequently administered drugs in cases of wrong medication¹⁰. However, in this study, opioids and cardiostimulants/vasopressors were the most common. The system and environment in operation rooms differ among institutions, which may result in varied error-prone conditions.

As Reason's¹¹ "Swiss cheese" model of human error has stated, there are many steps in the process where errors can occur. The causes of errors can often not be simply explained by the

error prone actions anesthesiologists tend to make. In all wrong medication-cases that involve opioids in our hospital, opioid was accidentally switched to another opioid on administration. They were caused by anesthesiologists with inadequate experience who took a wrong ampoule out from the drug tray. To prevent these errors, it is important to follow the basic rule of confirming the labels on ampoules 3 times, just before taking the ampoule out from the tray, aspirating the drug into the syringe, and discarding the ampoule out. Furthermore, first year interns should be instructed not to administer drugs by themselves, and the dispensation system of opioids should be improved. In our hospital, fentanyl, morphine, and pethidine have been delivered in separate boxes since 2002. No switches between these ampoules have been reported since. However, buprenorphine and pentazocine are still placed in the same tray with other drugs. They are stored in a specific compartment of the tray, but further measures should be taken to distinguish them more clearly.

In our hospital, cases of wrong medication with cardiac stimulants and vasopressors were distinctively common compared to other institutions. More cases of taking wrong pre-filled syringes (6 cases) were reported than ampoule mix-ups (2 cases). Syringe mix-ups were likely to occur at the stage of induction and maintenance, when different kinds of cardiac stimulants and vasopressors were placed on the same tray. Half of such incidents happened when an anesthesiologists gave oral instructions to a nurse or another anesthesiologists, and they picked up a wrong syringe. The basic principle of preventing such errors is to read the label prior to taking the syringe or the ampoule and administering the drug in it, even when administration must be done urgently. Furthermore, we have implemented that vasopressors administered via bolus injection such as etilefrine, ephedrine and phenylephrine are diluted and administered using red 10-ml syringes, since 2007. "A universal standard

color-coded drug labeling system”, for color-coded labels on syringes may help to distinguish drugs but further investigations should be conducted to determine if they are effective in reducing medication errors⁶⁾¹⁰⁾¹²⁾. Placing anesthetic agents, cardiac stimulants and vasopressors used emergently, in different trays may be useful in enhancing the redundancy (error-awareness)¹³⁾.

Of 19 cases of overdose, the leading cause was misunderstanding or preconception of the dosage. They were more likely to be caused by miscommunication than the anesthesiologists' lack of knowledge, where nurses or another anesthesiologist who received anesthesiologists' instruction incorrectly administered wrong amount of drug. The measures taken against such errors were standardizing oral instructions (for an instance, “Inject 1.5 cc, 6 mg of vecuronium out of ampoules containing 4 mg/cc”), and making it a rule to repeat the given instructions. Even after taking these measures, errors still occurred and additional measures were taken, that is, the anesthesiologist who gave an instruction should watch those who administer drugs in order to double-check.

To prevent errors by misunderstanding or preconception of the dose, the most important thing is to improve the quality of anesthesiologists by providing them a good education system¹⁾. Furthermore, having another person double check dispensation and administration of drugs improves patient safety. In our hospital, first-year interns do not dispense or administer drugs by themselves. Errors are more likely to occur when drugs with which they have insufficient familiarity with are administered, and closer attention should be taken at such times. There were 2 cases in which vecuronium was administered to children 10-fold the appropriate dosage. Mistakes often occur when calculating dilution and the actual dosage using dosage per weight, and so it is important to unify the dilution-concentration of vecuronium, and to check the dosage on designing anesthesia plans with several people.

Important measures that should be taken against errors caused by unfamiliarity with syringe pumps are to train the beginners in proper use and to check its use with several people. On the other hand, it should be noted that the flow set system of syringe pumps are error-prone in some ways. Before weight and drug dilution concentration input, the unit of velocity should be set. If the button to set the unit of velocity by mistake when an attempt was made to set weight and drug dilution concentration (buttons are next to each other), unit of velocity changes. Manufactures should develop systems of pumps which would reduce such errors, and a standardized system of medical devices including anesthetic machines and monitoring devices is required.

Three cases of insulin overdose had been reported but they have not been reported since 2002. In that year, manuals for handling insulin were established, which stated that insulin should be diluted to 1 unit/ml, and dispensation must be done by 2 people. The handling procedures of insulin were noted in residency manuals, and they were explained in orientations, which led to no incidents after 2002.

The prevention measures against medication errors have been taken but the number of incidents has not decreased. This may be associated with the interns and trainees from other specialties who take anesthesiology residency course for a short time, which emphasizes the importance of orientation and education of procedures. In this study, the responsible anesthesiologists were most likely to be doctors with a little experience. On the other hand, it is suggested that particular anesthesiologists are more likely to cause incidents repeatedly, and education as a prevention measure has its limit. Although “To error is human”¹⁴⁾, it is important to establish systems that encourage every procedure to be checked by several people. The use of a bar-code reader to scan the drug to facilitate checking of the drug's identity may be effective in

helping anesthesiologists manage patient safety¹³⁾. Confirming the drug by cross-check and displaying the cautions on it at the same time should provide anesthesiologists with information needed for making proper judgments. Having pharmacists in the operation rooms may be effective in preventing medication related errors. If they manage drug dispensation, and usage in the operation room, and have daily discussion with other paramedics, drugs would be delivered more safely and effectively.

Many more strategies for anesthesiologists to take against medication errors have been suggested¹³⁾¹²⁾¹⁵⁾¹⁶⁾. The Japanese Society of Anesthesiologists will collect the data from the national investigation and analyze the data on error rates and factors related to them, and propose a standardized error prevention measures; however, it is also important to take factors peculiar to each institution into consideration, such as personnel-, environment- and system-factors. A crisis managing cycle for safer anesthesia¹⁷⁾, which promotes improvement in systems, and education based on an analysis of incidents are needed. An environment that discourages errors can be created by medical staff in the operation rooms to improve the standard procedures.

In conclusion, we conducted an analysis of anesthesia-related incidents over a 15-year period, and revealed an error rate of 0.078% ; the leading causes were wrong medication and overdose, and opioids, and cardiac stimulants, and vasopressors were the most commonly involved drugs. The error-rate did not decrease, which suggested the importance of the improvement of procedures and the education system, based on incident analysis.

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(和文抄録)

九州大学病院 15 年間の麻酔関連薬剤投与に関するインシデントの分析

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九州大学病院における麻酔関連薬剤投与のインシデントの実態を明らかにすることを目的に、日本麻酔科学会「麻酔関連薬剤の投与に関するインシデント調査」に基づき、1993年から2007年までの麻酔関連偶発症例を後ろ向きに調査した。麻酔科管理 64,285 症例のうち、薬剤投与関連のインシデントは 50 症例 (0.078%) に認められた。全例、後遺症なく転帰良好であった。発生事象の種類の内訳は誤薬が 48%、過量投与が 38%、過少投与 4%、投与すべき薬剤を投与しなかった症例 2%、投与経路の誤り 8%であった。投与薬剤の種類ではオピオイド、強心薬・昇圧薬が多かった。誤薬が発生した段階の分類では、シリンジを選別する段階での誤り 42%、アンプルを選別する段階での誤り 33%、勘違い 17%であった。過量投与が発生した段階の分類では、投与量に関する誤解や思い込み 53%、シリンジポンプの操作の誤り 21%、希釈の誤り 5%であった。15年間の推移上、発生件数の減少傾向は認められなかった。麻酔担当医の資格別にみると、麻酔科標榜医を有さない麻酔科医が 48%と最も多く、ローテータ (30%) が続いた。薬剤投与に関するインシデントを予防するためには、薬剤取り扱いおよび指示に関する業務手順の改善と麻酔科研修医に対する教育・オリエンテーションの徹底が求められる。