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Fatal Surgical or Procedure-Related Complications: A Finnish Registry-Based Study

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Abstract

Introduction In Finland, all healthcare personnel must be insured against causing patient injury. The Patient Insurance Centre (PIC) pays compensation in all cases of malpractice and in some cases of infection or other surgical complications. This study aimed to analyze all complaints relating to fatal surgical or other procedure-related errors in Finland during 2006–2010.

Materials and methods In total, 126 patients fulfilled the inclusion criteria. Details of patient care and decisions made by the PIC were reviewed, and the total national number of surgical procedures for the study period was obtained from the National Hospital Discharge Registry.

Results Of the 94 patients who underwent surgery, most fatal surgical complications involved orthopedic or gastrointestinal surgery. Non-surgical procedures with fatal complications included deliveries ($N = 10$), upper gastrointestinal endoscopy or nasogastric tube insertion ($N = 8$), suprapubic catheter insertion ($N = 4$), lower intestinal endoscopy ($N = 5$), coronary angiogram ($N = 1$), pacemaker fitting ($N = 1$), percutaneous drainage of a hepatic abscess ($N = 1$), and chest tube insertion ($N = 2$). In 42 (33.3 %) cases, patient injury resulted from errors made during the procedure, including 24 technical errors and 15 errors of judgment. There were 19 (15.2 %) cases of inappropriate pre-operative assessment, 28 (22.4 %) errors made in postoperative follow-up, 23 (18.4 %) cases of fatal infection, and 11 (8.8 %) fatal complications not linked to treatment errors.

Conclusion Fatal surgical and procedure-related complications are rare in Finland. Complications are usually the result of errors of judgment, technical errors, and infections.

Introduction

Patient death following surgery can be a consequence of an error in patient care, an inevitable surgical complication (for example, fatal multi-organ failure after operative treatment of diffuse peritonitis), or a failure to cure the patient because of the nature of the disease [1, 2].

In April 2011, an international prospective cohort study was conducted to assess in-hospital mortality after non-cardiac surgery in 28 European nations. Of the 46,539 patients included, 4 % died before hospital discharge. Mortality rates varied widely between countries. However, after adjusting for confounding variables, Finland was found to have the lowest odds ratio for postoperative in-hospital death, and Poland the highest [3]. Adverse events are estimated to occur in 3.8–17.0 % of all hospital admissions, of which almost half are preventable. In addition, it is estimated that 7 % of adverse events result in patient death [4].The Patient Insurance Act came into force in Finland in 1987. According to law, all medical institutions, hospitals, and private healthcare personnel now have to be insured against causing patient injury. The non-profit national Patient Insurance Centre (PIC) pays financial

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compensation to patients in cases of malpractice and, under certain circumstances, following infection or other serious consequences of a complication. All major surgical and other complications related to patient care are reported to the center. The Patient Insurance Act ensures that compensation is paid for patient injury resulting from inadequate examination or treatment, or from a failure to treat [5].

In the case of injury, the prerequisite for paying compensation is that another experienced healthcare professional would have acted differently under the same circumstances, and thus the injury should have been avoided. This evaluation is made by specialists at the National Patient Injury Insurance Centre. An injury may also be classified as unreasonable, and thus compensable, if there is a significant imbalance between the outcome and the illness or injury originally treated, and whether it could have been avoided by taking other action. Financial compensation for unreasonable injury is considered only if it results in a permanent treatment-related illness, injury, or death. In addition, complications involving infection may be compensated without a requirement that the infection could have been avoided by acting differently; instead, the normal risk of infection from the procedure, the patients' health status, and the consequences of the infection are taken into account. Infection may be considered an acceptable risk if the disease/injury is severe or if the procedure is usually associated with a high infection rate [5].

All major surgical complications are reported to the PIC. As a consequence of its comprehensive database, the National Patient Insurance Association registry is a reliable source of information for the analysis of major surgical adverse effects.

The goal of this study was to analyze the incidence and causes of fatal surgical or procedure-related errors in Finland during 2006–2010.

Materials and methods

The study included all patients who experienced fatal surgical or other procedure-related complications and were paid financial compensation by the PIC between 1 January 2006 and 31 December 2010. A total of 126 patients fulfilled the inclusion criteria. The medical records of these patients were reviewed, and demographic data and all details of the procedures were recorded. For each case, the decision of the PIC was reviewed and the reason for making the decision was recorded. For many patients, there was more than one reason for providing financial compensation; for example, a technical error in surgery followed by a postoperative infection. The reviews were performed by a multi-specialty medical group consisting of a general surgeon, an orthopedic surgeon, a gastrointestinal surgeon, a cardiothoracic surgeon, a vascular surgeon, and an anesthesiologist.

The total number of surgical operations carried out during the study period was obtained from the Finnish Hospital Discharge Register, which is maintained by the National Board of Health. The purpose of this register is to provide information for research development, administration, and planning. Every hospital in Finland submits data from all surgical operations to the register [6]. Data obtained from the register were used to calculate the incidence of fatal complications during the study period.

IBM SPSS for Windows, Release 20.0 (SPSS, Chicago, IL, USA) was used for statistical analysis.

Results

During 2006–2010, a total of 1,425,000 surgical procedures and 295,000 deliveries were performed in Finland (population 5.4 million). The patient distribution for the different surgical subspecialties is presented in Table 1, along with the total number of surgical procedures performed in Finland during the study period. Of the 94 deaths following surgery, the majority involved gastrointestinal surgery, followed by orthopedics, traumatology, and cardiothoracic surgery. A total of 126 patients were included in the study (Table 2), including nine newborn babies. There were no significant differences in basic characteristics between genders. Most patients were not obese. More than half of patients had cardiopulmonary co-morbidity and 75 % were classified as American Society of Anesthesiology class 3 or 4. Two-thirds of patients were treated in secondary or tertiary referral hospitals. Of the procedures, 70 % were elective and 30 % were urgent or emergency cases. In 72 % of cases, the physician/surgeon

Table 1 Percentage of surgical patients ($N = 94$) with fatal outcome during 2006–2010, by surgical specialty

Surgical specialty	Number of patients	Total number of operations	Percentage (%)
Gastrointestinal and general surgery	36	275,991	0.013
Orthopedics and traumatology	29	645,518	0.004
Cardiothoracic surgery	14	64,844	0.022
Urology	6	103,204	0.006
Neurosurgery	5	60,341	0.008
Gynecology	3	172,641	0.002
ENT surgery	1	102,945	0.001

ENT ear, nose, and throat

Table 2 Demographics and characteristics of patients included in the study ($N = 126$), including nine newborn babies

Characteristics	Mean (SD) or number (%) of patients
Age in years (SD), excluding perinatal deaths	66 (18.05)
Body mass index (SD), excluding perinatal deaths	28 (6.60)
Gender	
Male	70 (56.0)
Female	55 (44.0)
ASA patient classification	
Class 1	3 (3.1)
Class 2	20 (21.3)
Class 3	50 (53.2)
Class 4	21 (22.3)
Co-morbidity	
No co-morbidity	15 (12.0)
Diabetes mellitus	14 (11.2)
Rheumatoid arthritis	5 (4.0)
Cardiac disease	46 (36.8)
Peripheral vascular disease	5 (4.0)
Stroke/TIA	13 (10.4)
Asthma or COPD	21 (16.8)
Other	53 (42.4)
Type of hospital	
Tertiary referral hospital	43 (34.4)
Secondary referral hospital	54 (43.2)
Primary referral hospital	23 (18.4)
Private hospital	5 (4.0)
Urgency category	
Elective	88 (70.4)
Urgent between 8am and 4 pm	25 (20.0)
Urgent between 4 pm and 10 pm	5 (4.0)
Urgent between 10 pm and 8 am	7 (5.6)
Physician in charge	
Specialist in the particular specialty	91 (72.8)
Another type of specialist	5 (4.0)
Registrar	25 (20.0)
Unknown	4 (3.2)
Time from operation/procedure until death	
During the operation	9 (7.2)
Within 24 h	14 (11.2)
Within 1–7 days	24 (19.2)
Within 1–4 weeks	26 (20.8)
More than 4 weeks	52 (41.6)

ASA American Society of Anesthesiology, *COPD* chronic obstructive pulmonary disease, *SD* standard deviation, *TIA* transient ischemic attack

Table 3 Cause of operation-related injury in 94 patients

Cause of patient injury ($N = 94$)	Number of patients (%)
Error in pre-operative assessment	13 (13.8)
Wrong pre-operative diagnosis	6 (6.4)
Operation should have been conducted in tertiary referral hospital	4 (4.3)
Error made during surgery	42 (44.7)
Technical error	21 (22.3)
Overlooked intra-operative bleeding	4 (4.3)
Error in judgment	15 (15.9)
Patient fell from operating table	1 (1.1)
Complication related to epidural analgesia	1 (1.1)
Postoperative bleeding	16 (17.0)
Incorrect postoperative follow-up	12 (12.8)
Insufficient postoperative antithrombotic medication	2 (2.1)
Excessive postoperative antithrombotic medication	1 (1.1)
Infection complication without treatment error	23 (24.5)
Unreasonable injury without treatment error	11 (11.7)

Some patients experienced more than one type of complication

performing the procedure that led to a complication was a specialist in that particular medical/surgical specialty.

The causes of all injuries in surgical patients are presented in Table 3. The main pre-operative reasons for patient injury were inappropriate pre-operative examination and incorrect pre-operative diagnosis. In four cases, the PIC and our expert team stated that the operation should have been done in a tertiary referral hospital instead of a primary or secondary referral hospital.

For intraoperative injuries, the cause was surgical error in 42 cases; most commonly, this was a technical error, for example, a common bile duct lesion during cholecystectomy. In addition, four patients died from peri-operative bleeding; for these, the PIC stated that the hemorrhage could have been controlled using proper surgical techniques. For example, one patient who underwent a biopsy of a pulmonary hilar lymph node died from a hemorrhage from a pulmonary artery. In 15 patients, errors in judgment

during surgery led to wrong decisions being made that led to the patient's death. In one patient, a pathological fracture was suspected radiologically. However, during an open operative fixation of the fracture, no biopsy was taken of the lesion, which led to a diagnostic delay of sarcoma for several years. This led to the death of the patient from lung metastases. In addition, one patient fell onto the floor from the operating table and died, and another patient died from a complication because of subsequent and incorrectly applied epidural analgesia.

The most common postoperative complication leading to patient injury was postoperative bleeding. Negligence during postoperative follow-up leading to patient death was the second most common cause of patient injury: two patients died following inefficient postoperative antithrombotic medication and one patient died from bleeding caused by excessive antithrombotic medication.

Perinatal complications caused nine fetal or perinatal deaths. Furthermore, one mother died from bleeding after a delivery followed by an emergency hysterectomy. In this case, patient injury was caused by inappropriate fluid resuscitation and delayed surgical intervention after delivery. Of the fetal or perinatal deaths, three cases involved cesarean section, three involved vacuum extraction, and three were normal deliveries. In all nine cases, patient death resulted from errors in judgment about how to perform the delivery.

Twelve patients had fatal complications following endoscopy. Seven deaths following upper gastrointestinal endoscopy were caused by technical errors leading to esophageal perforation. Five patients experienced colon perforation after lower intestinal endoscopy that led to peritonitis and death. Furthermore, in one patient, a nasogastric tube was mistakenly inserted into the bronchus and the patient's death was caused by attempted enteral feeding.

Insertion of a suprapubic urinary catheter caused the death of four patients, either because of bleeding or bowel lesion and peritonitis. In addition, follow-up after a chest tube insertion was deemed to be inadequate for two patients who died of bleeding. Of the two cardiac patients included in the study, one died of a ruptured coronary artery during percutaneous coronary intervention and the other died 1 day after having a pacemaker fitted. In the latter case, autopsy revealed that the pacemaker wire had not been correctly attached to the wall of the right ventricle. Further, one patient underwent percutaneous drainage of a hepatic abscess and died of postoperative bleeding after the procedure because of inappropriate follow-up.

A further 23 cases of complications involving fatal infections and 11 cases of fatal complications were not associated with errors in treatment. In 42 % of all patients, complications led to death after a prolonged period (over 4 weeks) in which there were many attempts to correct the situation.

Discussion

The percentage of postoperative or post-procedural deaths that are compensated by the Finnish Patient Injury Association due to errors in treatment or due to infection or unreasonable injury is low: there is one financially compensated death per 15,000 surgical operations. Peri-operative and anesthesia-related mortality has declined significantly worldwide over the past 50 years despite an increasing baseline risk for patients resulting from patients being older with more co-morbidities, and this decline is greatest in the developed world [7]. Postoperative mortality in Finland is among the lowest in Europe: a cohort study performed in 2011 found in-hospital mortality in Finland to be 2.0 % [3]. Based on these studies, and the results of the present study, we conclude that surgical treatment in Finland is relatively safe.

In a prospective study conducted in the Netherlands, Bosma et al. [8] analyzed the incidence, nature, and impact of errors in surgery in 12,121 surgical patients during 2005–2007. During the study period, 16.8 % of patients experienced a complication, and there was a documented error in 6.1 % of cases. Five patients (0.6 %) died as a result of error. The most common type of error was found to be an error in surgical technique, followed by an error in judgment and a delay in the operating theater [8]. The results of the present study are consistent with this report. We found the cause of patient injury in 45 % of the 94 patients who underwent surgery to be an error made during surgery, most commonly an error in surgical technique, followed by an error in judgment. When taking pre- and postoperative care into consideration, the most common cause of injury was an error in judgment: incorrect decisions were made both in preoperative evaluation and in postoperative care.

There were 23 deaths directly linked to infections. In addition, there were 11 cases where death was classified as unreasonable. In these 34 cases, no treatment error was seen as a factor by the panel of experts. The remaining 92 cases were all seen by the experts as potentially preventable.

As a consequence of decisions often being made in demanding circumstances, it is unrealistic to believe that human error can be completely eliminated in clinical practice. However, every effort should be made to minimize the risk of error during surgery. In 2009, Haynes et al. [9] reported that a surgical checklist is useful for reducing mortality and morbidity during surgery. Since this report, the surgical checklist has been widely taken into clinical use in Finland. Due to the retrospective nature of this study,

we were unable to estimate the extent to which fatal errors may have been preventable using a surgical checklist. In addition to the use of checklists, the quality of surgical performance should be monitored to reduce the risk of associated complications and errors. It has been suggested that each surgical unit should keep a registry of complications [2, 10]. Limiting discussions about errors and complications to closed discussion among peers can fail to address systematic problems. The training of surgeons should reflect the constant need for feedback between experienced colleagues and their trainees. Therefore, open and transparent discussions about errors, complications, and deaths should be not only mandatory but also easy. In our opinion, the training of a surgeon ideally happens between two individuals, with transfer of not only technical skills but also perspective. Nevertheless, as most serious errors and complications are caused by failures of the system, rather than of an individual, an open analysis is important to reduce the risk of procedural errors [11].

Even minor surgical procedures can sometimes lead to patient death. One patient in our cohort died after intrapulmonary insertion of a nasogastric tube. A similar complication has previously been reported [12]. In our study, a few patients died from complications related to gastrointestinal endoscopy, suprapubic catheter insertion, or insertion of a chest tube. We were unable to calculate the incidence of these fatal complications because the total number of these types of outpatient procedures performed during the study period is unavailable. However, in a study of over 217,000 patients undergoing upper gastrointestinal endoscopy, the incidence of perforation was 0.033 %, of which 17 % were fatal [13]. The risk of perforation in colonoscopies is reported to be 0.06 % [14]. Rates of complication related to chest tube insertion vary between 2 and 25 %, with intercostal bleeding requiring operative treatment being the major complication related to inappropriate chest tube insertion [15]. Suprapubic catheter insertion is a common urologic procedure, which is often stated to be safe and simple even in inexperienced hands. However, a retrospective analysis of 219 suprapubic catheter insertions showed a 30-day complication rate of 19 %, and a mortality rate of 1.8 % [16].

The reported incidence of medication errors and adverse drug reactions are much higher than the incidence of errors and complications associated with surgery. It is estimated that 3–5 % of the total number of deaths in Finland and Sweden are caused by adverse drug reactions [17, 18]. In a prospective Japanese cohort study of 3,459 adult hospital patients to assess the incidence and preventability of adverse drug events and medication errors, 1,010 adverse drug reactions and 514 medication errors were identified. Among the adverse drug reactions, 1.6 % were fatal [19].

When considering the limitations of the present study, we should state that in some cases it is difficult to decide whether or not an error has been made. Some cases were judged to be unreasonable owing to the occurrence of an unexpected death in the absence of a specific contributory cause or error. In accordance with current legislation, these cases were compensated and were therefore included in the study. Another limitation is the lack of data on the actual incidence of fatal errors related to endoscopy and to the insertion of suprapubic catheters and chest tubes. However, it is reasonable to conclude that the incidence of fatal surgical and procedure-related complications compensated by the Finnish PIC is low. The most common causes of the most serious adverse effect of surgery, i.e., patient death, are errors in judgment, technical errors, and infections.

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