Adverse events in surgical patients: incidence, characteristics and associated factors

Eventos adversos em pacientes cirúrgicos: incidência, características e fatores associados

Eventos adversos en pacientes quirúrgicos: incidencia, características y factores asociados

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ABSTRACT: Objective: To estimate the incidence of adverse events and identify the factors associated with their occurrence in surgical patients at a general reference hospital in the interior of Minas Gerais, Brazil. **Method:** Retrospective and documentary study carried out in 851 medical records of patients undergoing surgical procedures. To track and identify the adverse event, an adaptation of the Global Trigger Tool method was used, with double review of documents independently and data analysis using descriptive statistics, χ^2 test, Student's *t*-test and logistic regression. **Results:** 145 adverse events were identified in 108 medical records, more than half related to complications at the surgical site, such as bleeding and surgical site infections. Prolonged hospital stay, duration of surgery longer than four hours and surgical procedures classified as contaminated were associated with greater chances of adverse event occurrence ($p<0.001$). **Conclusion:** Adverse events in surgical care have a high frequency and impact of damage caused, reinforcing the importance of strategies aimed at the safety of surgical patients.

Keywords: Patient safety. Medical errors. Surgical procedures, operative. Perioperative nursing.

RESUMO: Objetivo: Estimar a incidência de eventos adversos e identificar os fatores associados à sua ocorrência em pacientes cirúrgicos de um hospital geral de referência do interior de Minas Gerais, Brasil. **Método:** Estudo retrospectivo e documental realizado em 851 prontuários de pacientes submetidos a procedimentos cirúrgicos. Para rastrear e identificar o evento adverso, utilizou-se uma adaptação do método *Global Trigger Tool*, adotou-se a dupla revisão dos documentos de forma independente e a análise de dados por estatística descritiva, teste χ^2, *t* de Student e regressão logística. **Resultados:** Foram identificados 145 eventos adversos em 108 prontuários, mais da metade relacionada a complicações no local da cirurgia, como sangramento e infecções de sítio cirúrgico. O tempo de internação prolongado, a duração da cirurgia superior a quatro horas e procedimentos cirúrgicos classificados como contaminados mostraram-se associados a maiores chances de ocorrência do evento adverso ($p<0,001$). **Conclusão:** Os eventos adversos na assistência cirúrgica possuem elevada frequência e impacto de danos causados, reforçando a importância das estratégias voltadas para a segurança do paciente cirúrgico.

Palavras-chave: Segurança do paciente. Erros médicos. Procedimentos cirúrgicos operatórios. Enfermagem perioperatória.

RESUMEN: Objetivo: Estimar la incidencia de eventos adversos e identificar los factores asociados a su ocurrencia en pacientes quirúrgicos en un hospital general de referencia en el interior de Minas Gerais, Brasil. **Método:** Estudio retrospectivo y documental realizado en 851 historias clínicas de pacientes sometidos a procedimientos quirúrgicos. Para el seguimiento e identificación del evento adverso se utilizó una adaptación del método *Global Trigger Tool*. Se adoptó el procedimiento de doble revisión de documentos de forma independiente y el análisis de datos se realizó mediante estadística descriptiva, prueba de chi-cuadrado, prueba t de *Student* y regresión logística. **Resultados:** Se identificaron 145 eventos adversos en 108 historias clínicas. Más de la mitad se relacionaron con complicaciones en el sitio quirúrgico, como sangrado e infecciones del sitio quirúrgico. La estancia hospitalaria prolongada, la duración de la cirugía mayor a cuatro horas y la realización de procedimientos quirúrgicos clasificados como contaminados se asociaron con mayores posibilidades de ocurrencia de eventos adversos ($p<0,001$). **Conclusión:** Los eventos adversos en la atención quirúrgica tienen una alta frecuencia e impacto del daño causado, reforzando la importancia de las estrategias dirigidas a la seguridad de los pacientes quirúrgicos.

Palabras clave: Seguridad del paciente. Errores médicos. Procedimientos quirúrgicos operativos. Enfermería perioperatoria.

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Received: 03/13/2023 – Approved: 07/12/2023
https://doi.org/10.5327/Z1414-4425202328890

INTRODUCTION

Interest in patient safety in healthcare organizations has grown exponentially around the world, driven by epidemiological studies that have revealed the frequency and impact of harm associated with healthcare. Patient safety, considered an essential dimension of quality of care, is conceptualized as the reduction of the risk of unnecessary damage associated with health care to an acceptable minimum[1].

The lack of safety in health services became a focus of attention especially in the 1990s, with the release of the report "To err is human: building a safer health system", presented by the Institute of Medicine, causing an impact throughout the world by estimating that 98,000 Americans die each year as a result of preventable failures and adverse events caused by healthcare[1,2].

In this context, it is noteworthy that adverse events (AE) are unintentional harm caused by care, resulting in temporary or permanent disability, prolonged hospitalization or death. Although AE may occur in any context and form of health care, data from the literature estimate that 10% of patients admitted to hospitals suffer some type of AE[2].

In the United States, it is estimated that in every ten hospitalized patients one suffers from some type of AE. Data from European countries show that AE occur in 8 to 12% of hospitalizations. In Brazil, information from a report released in 2018 by the Institute for Supplementary Health Studies, with data from 445,671 patients from 13 states, revealed that the prevalence of patients with AE was 6.4% in the Brazilian Unified Health System (SUS) and 7.1% in supplementary health, with mortality rates of 22 and 12%, respectively. The study also showed that the incidence of death of patients exposed to a severe AE exceeded 20%[3,4].

When it comes to surgical assistance, the growing technological advances allow for increasingly complex procedures, consequently increasing the potential for incidents. Studies indicate that surgical AE are frequent and contribute with half or three quarters of all harm associated with health care[5]. Compared with AE that occur in clinical patients, surgical ones produce more serious damage, translating into an increased length of hospital stay, the need for additional therapeutic procedures, permanent disabilities and deaths, in addition to considerably increasing treatment costs[1,5].

It is important to highlight that every surgical complication characterizes an AE as it is an unintentional consequence of the care provided. However, its occurrence does not necessarily mean an error in the care of the surgical patient, as there are surgical complications that cannot be avoided. Despite this, it is necessary to recognize that these complications contribute to high health care costs, as well as to patient morbidity and mortality[5].

As a result of the frequency and impact of AE for surgical patients and health organizations, knowing the incidence and factors associated with their occurrence is important to assess and measure the existing gaps in surgical care, supporting the planning of strategies to improve patient safety. In the national context, the available evidence on this topic is still limited, justifying the elaboration of this study.

OBJECTIVES

The objectives of the study were to estimate the incidence of adverse events in surgical patients at a reference general hospital located in the countryside of the state of Minas Gerais (Brazil) and to identify the factors associated with these AEs.

METHOD

This is a retrospective and documentary study guided by the review of medical records of patients undergoing surgical procedures in the years 2012 and 2015. The time frame was chosen to enable the evaluation of an intervention (implementation of the safe surgery checklist) carried out in 2013, whose outcome is published.

The description of the methodological stages of this research was guided by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[6].

The study scenario was a philanthropic general hospital of high complexity, which offers secondary and tertiary care in several clinical and surgical specialties. The institution has approximately 500 beds and its surgicenter (SC) has 17 operating rooms, where an average of 1,500 procedures are performed monthly.

The study population consisted of patients undergoing surgical procedures performed in 2012 and 2015. Exclusion criteria were: age under 18 years, hospitalization period of less than 24 hours, patients undergoing non-surgical invasive procedures, interventional cardiology and normal delivery. It should be noted that the last two types of procedure were performed in specific sectors, that is, hemodynamics and the obstetric center, respectively, and were directed

to the SC sporadically, when there was a technical or structural situation that made it impossible to use these sectors.

To calculate the sample, a total of 12,359 patients who underwent surgical procedures in the years 2012 and 2015 were considered. For a test power of 80%, considering the standardized difference between the proportions of patients with AE equal to 0.20 and the same size for each sample, with unknown but equal population variances, and independent samples, the sample size calculation for α=0.05 indicated the need to evaluate the medical records of at least 786 surgical patients, which represents 393 patients for each year studied[7]. The study accounted for 428 patients in 2012 and 423 in 2015, totaling 851.

Thus, the sample of medical records (n=851) was extracted using simple random sampling from a database made available by the institution containing the care records of all patients undergoing surgical procedures in the analyzed years. Sampling was also stratified monthly and proportional to the number of surgeries each month, seeking to approximate the criteria proposed by the Global Trigger Tool (GTT) method, which allows monitoring the incidence of AE over time.

Tracking and identification of AE were performed through a retrospective review of medical records guided by an adaptation of the GTT method proposed by the Institute for Healthcare Improvement (IHI), which presents objective criteria/clues (triggers) to track records with suspected AE. As a definition for AE, the one described by the GTT as an unintentional physical harm resulting directly or indirectly from health care, which requires additional monitoring, treatment or hospitalization, or which resulted in death was adopted[8].

To review the medical records, a list containing 37 triggers divided into three modules was used. The search for the trigger was systematically carried out in the electronic medical record, in the following parts: discharge summary, hospitalization summary, laboratory tests, medication prescription, information regarding the surgical procedure (anesthesia report, surgery description, and SC nursing records), request for imaging exams and opinions and evolution of the health team.

The medical records were reviewed from January to December 2016 by a nurse with experience in caring for surgical patients and three undergraduate students, one from the nursing course and two from the medical course. The team of reviewers was previously trained by a nurse certified by the IHI to use the GTT method. The procedure of double review of the medical records was adopted independently, carried out by the nurse and at least one of the students. Two physicians with expertise in the use of the GTT method were added to the team of reviewers, who acted as authenticators of the occurrence of AE and the classification of the severity of the damage.

The medical records were scanned in search of triggers, avoiding a complete and exhaustive reading. AE identification and confirmation occurred in three steps:

1. Primary review of medical records to identify triggers and select those with potential AE;
2. Meeting of the primary reviewers to decide on the occurrence of AE, describe the event, and classify the severity of the damage; and
3. Consensus meeting with the participation of authenticating physicians to present and analyze the cases and confirm the occurrence of the event, as well as the severity of the damage. Differences that arose at this stage were resolved by the professionals' clinical judgment.

To support the clinical judgment regarding the occurrence of AE, questions used in a Brazilian study that evaluated the application of triggers proposed by the GTT to identify AE to medications[9] were adapted, as follows:

1. Is the event a natural consequence of the disease or could it be associated with health care?
2. Could the event be associated with the surgical procedure, considering the clinical conditions of the patient?
3. Could the event be associated with the surgical procedure, considering the clinical conditions of the patient?

Regarding the severity classification, IHI adapted the definition of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) originally developed to classify AE related to medication use. Categories E, F, G, H, and I were considered because they refer to AE, which were adapted as follows:

E. temporary damage to the patient that required intervention;
F. temporary damage to the patient that required additional intervention or prolonged hospitalization;
G. permanent damage to the patient;
H. damage that required immediate intervention to save the patient's life; and
I. death.

The events were described and classified according to their nature, place, and time of occurrence. Avoidability of

AE was not analyzed in the present study, as the GTT method waives this assessment, as it considers that adverse events can be avoidable as it involves unnecessary damage to the patient.

The occurrence of AE confirmed by the consensus of professionals was the primary outcome chosen for this study. To identify possible factors related to the outcome, the following variables were analyzed:

1. Patient characteristics: gender, age range, race, Charlson comorbidity index (CCI) corrected for age, anesthetic risk assessment according to the American Society of Anesthesiology (ASA);
2. Characteristics of hospitalization: type of care, type of hospitalization, length of stay in days, type of discharge;
3. Surgery characteristics: specialty, type of anesthesia, duration of surgery, surgery classification regarding the potential for contamination and urgency.

Initial analysis included a description of the study variables using descriptive statistics and exploratory data analysis. The bivariate analysis investigated the association of the outcome with the independent variables, using Pearson's x^2 test (categorical variables) and Student's *t*-test for independent samples (numerical variables), at a significance level of 5%.

The magnitude of the association between the outcome and the independent variables that showed potential statistical significance ($p<0.20$) in the bivariate analysis was verified by estimating the parameters of simple logistic regression models, with the variables inserted in three blocks (patient characteristics, hospitalization, and surgery) using the Backward feature of the statistical package Statistical Package for the Social Sciences (SPSS, version 20.0 for Windows).

This research project was approved by the Research Ethics Committee of Universidade Federal de Juiz de Fora, under opinion No. 2.046.497.

RESULTS

Of the sample of 851 surgical patients, 108 had at least one AE, determining the incidence of 12.7%. Some patients had more than one event, contributing to 145 AE, with an average of 1.3 AE per patient. The proportion of patients who had at least one AE related to the surgery site was 8.2%, that is, 74 events, showing that this type of complication contributed to more than half of all AE identified.

Considering the characteristics of the sample, it was observed that most patients were aged up to 59 years (65.3%), with a mean age of 49.6 (±19.4) and were females (61.7%). There was also a predominance of white patients (76.8%). Regarding the CCI, patients had a mean score of 1.85 (±2.1), ranging from zero to ten points. According to the ASA anesthetic risk classification, most patients (81.5%) were classified as P1 and P2, therefore being considered healthy or with some type of mild comorbidity.

Regarding the type of care, it was observed that most patients (52.9%) were attended by SUS. Considering the nature of the care, there was a predominance of emergency admissions (52.7%). Average length of stay was 8.9 (±18.2), with 94.6% of patients being discharged from hospital and 5.4% of deaths. The most prevalent surgical specialties were: gynecology and obstetrics (23.6%), general surgery (22.7%), and orthopedics and traumatology (21.3%). Regarding the characteristics related to the surgical procedure, most of them used regional anesthesia (53%), had an average duration of 103 minutes (±86), and were classified as elective (74%). It should be noted that part of SUS hospitalizations, through the Vacancy Center, are requested on an emergency basis, even for elective surgical procedures when patients are hospitalized in Emergency Care Units.

Table 1 describes the characterization of the sample according to the characteristics of the patient, hospitalization and surgery, considering the occurrence or not of AE.

In the primary review of the charts, 497 triggers were identified in 191 documents, with an average of 2.6 triggers per chart. The average review time was 19 minutes (±2.02), ranging from 4 to 59 minutes. Most frequent triggers were:

1. Care module: transfusion of blood or blood products (18.2%), healthcare-associated infections (12.9%), readmission within 30 days (9.4%), and reduction in hemoglobin or hematocrit of 25% or more (8.4%);
2. Surgical module: intra or postoperative death (6.9%) and unplanned return for surgery (5.4%);
3. Medication module: urea or serum creatinine twice the normal values (6.8%). The description of the 37 triggers used to guide the review of the medical records, as well as their observed frequencies, can be found in Table 2.

Of the 191 records with the presence of triggers, 113 were considered to be suspected of AE by the primary reviewers at the consensus meeting in step 2. After presenting the cases at this meeting, which had the participation of the

Table 1. Characterization of the sample regarding the characteristics of patients, hospitalization and surgery, according to the occurrence of adverse events. Juiz de Fora (MG), Brazil.

Characteristics	With AE (n=743)		Without AE (n=108)		p-value
	n	%	n	%	
Patient characteristics					
Mean age [years (SD)]	47.9 (19.2)	-	61.0 (15.9)	-	0.000*
Age range (years)					
Up to 59	506	68.1	50	46.3	0.000*
60+	237	31.9	58	53.7	
Gender					
Male	281	37.8	45	41.7	0.442
Female	462	62.2	63	58.3	
Race					
White	574	77.3	79	73.2	0.488
Black	61	8.3	8	7.4	
Brown or Indigenous	106	14.4	21	19.4	
CCI					
0	354	47.7	11	10.2	0.000*
1	88	11.8	13	12.0	
2 and 3	166	22.3	33	30.6	
4+	135	18.2	51	47.2	
Mean CCI square (SD)	2.5 (2.9)	-	4.9 (4.6)	-	0.000*
Anesthetic risk					
P1	324	43.6	8	7.4	0.000*
P2	313	42.2	49	45.4	
P3	97	13.0	40	37.0	
P4	9	1.2	11	10.2	
Hospitalization characteristics					
Type of service					
SUS	383	51.5	67	62.0	0.041
Insurance or private	360	48.5	41	38.0	
Character of hospitalization					
Elective	366	49.3	36	33.4	0.002
Emergency	377	50.7	72	66.6	
Average days of hospitalization (SD)	7.4 (15.5)	-	24.3 (25.9)	-	0.000*
Length of stay in days					
<2	346	46.6	8	7.4	0.000*
3	98	13.2	3	2.8	
4–10	167	22.4	23	21.3	
11+	132	17.8	74	68.5	
Type of discharge					
Medical discharge	734	98.7	73	67.6	0.000*
Death	11	1.3	35	32.4	

Continue...

Table 1. Continuation.

Characteristics	With AE (n=743)		Without AE (n=108)		p-value
	n	%	n	%	
Surgery characteristics					
Specialty					
General surgery	173	23.3	20	18.5	0.000*
Gynecology and Obstetrics	196	26.4	5	4.7	
Orthopedics and traumatology	158	21.3	23	21.3	
Cardiothoracic and vascular surgery	82	11.0	33	30.5	
Others	134	18.0	27	25.0	
Type of anesthesia					
Sedation/local	44	6.0	7	6.5	0.000*
Local	419	56.4	32	29.6	
General	280	37.6	69	63.9	
Surgery time in minutes					
Up to 30	77	10.4	4	3.7	0.000*
31–60	266	35.8	18	16.8	
61–120	241	32.4	29	26.8	
121–140	131	17.7	29	26.8	
241+	27	3.7	28	25.9	
Classification according to the potential for contamination					
Clean	334	45.0	61	56.5	0.000*
Potentially contaminated	327	44.0	20	18.5	
Contaminated	48	6.5	13	12.0	
Infected	34	4.5	14	13.0	
Classification according to urgency					
Elective	540	72.7	89	82.4	0.031
Emergency	203	27.3	19	17.6	

*p-value rounded to three decimal places.
NOTE: AE: adverse events; SD: standard deviation; CCI: Charlson comorbidity index; SUS: Unified Health System (*Sistema Único de Saúde*); anesthetic risk: classification of the patient's physical status according to the American Society of Anesthesiology (P1: healthy person; P2: presence of mild systemic disease(s) and absence of significant functional limitation; P3: presence of moderate to severe systemic disease(s) with functional limitation; P4: presence of severe systemic disease with constant risk of death; P5: moribund patient with no hope of survival without surgery; P6: patient with declared brain death, organ donor). Note: In the study sample, no patient was classified as P5 or P6.

authenticating physicians, 108 records were confirmed with the presence of AE (step 3). In only five cases was there disagreement between the primary reviewers and the authenticating physicians; disagreements were resolved by consensus.

AE identified by the consensus of professionals occurred mainly in the surgical inpatient unit (33.8%) and in the intensive care unit (33.1%). Regarding the time of occurrence, most of these events were still detected during the researched hospitalization (73.8%). Some patients (20.7%) had AE at home after discharge; in these cases, the AE were detected due to the need for readmission to treat the damage that had occurred.

As for the severity of damage produced by AE, it was observed that among surgical patients, AE mainly caused temporary damage, which required intervention or prolonged hospitalization (54.4%) and deaths (24.2%). The occurrence showed a significant association with the patient's evolution to death ($p<0.001$), mainly caused by pulmonary sepsis. Most deaths occurred in cardiothoracic surgery patients. Table 3 presents an extract of the causes of deaths that occurred in the sample of patients with AE.

x^2 showed significant associations ($p<0.05$) with the occurrence of AE in the following variables: age range, CCI,

Table 2. Frequencies of positive triggers for adverse events in the sample of medical records of surgical patients from the years 2012 and 2015. Juiz de Fora (MG), Brazil.

Nº	Trigger	n	%
Care module			
1	Transfusion of blood or blood products	93	18.2
2	Emergency service (on call or rapid response time)	34	6.9
3	Acute hemodialysis	8	1.6
4	Positive blood culture	13	2.7
5	X-ray or Doppler for diagnosis of pulmonary embolism or deep vein thrombosis	2	0.4
6	Reduction in hemoglobin or hematocrit of 25% or more	41	8.4
7	Patient fall	1	0.2
8	Pressure injury	8	1.6
9	Readmission within 30 days	46	9.4
10	Use of mechanical restraint	2	0.4
11	Health care related infection	64	12.9
12	Stroke during hospitalization	2	0.4
13	Transfer to a more complex care unit	21	4.3
14	Any complication of procedure	3	0.6
15	Other	1	0.2
Surgical module			
16	Unplanned return to surgery	26	5.4
17	Change of procedure	7	1.4
18	Unplanned admission to the intensive care unit postoperatively	9	1.9
19	Intubation or reintubation in post-anesthesia recovery	2	0.4
20	Intraoperative X-ray or post-anesthesia recovery	1	0.2
21	Intraoperative or postoperative death	35	6.9
22	Mechanical ventilation for more than 24 hours postoperatively	5	1.0
23	Intraoperative administration of epinephrine, norepinephrine, naloxone, or flumazenil	2	0.4
24	Increased troponin level >1.5 ng/ml postoperatively	4	0.8
25	Organ injury, repair, or removal during surgery	5	1.0
26	Other	12	2.4
Medication module			
27	Feces positive for *Clostridium difficile*	-	-
28	Partial thromboplastin time >100 seconds	2	0.4
29	International normalized ratio (INR)>6	1	0.2
30	Glycemia <50 mg/dl	-	-
31	Serum urea or creatinine 2x > normal values	33	6.8
32	Vitamin K administration	5	1.0
33	Use of diphenhydramine or other antiallergic	2	0.4
34	Use of antiemetic	4	0.8
35	Excessive sedation/hypotension	1	0.2
36	Sudden discontinuation of medication	-	-
37	Other	2	0.2
	Total	497	100

Table 3. Causes of death in the sample of medical records of surgical patients in the years 2012 and 2015. Juiz de Fora (MG), Brazil.

Causes	n	%
Related to the surgical site		
Bleeding with hemodynamic repercussions	3	8.7
Surgical site infection	2	5.7
Non-surgical wound infections		
Pulmonary focus sepsis	18	51.5
Urinary focus sepsis	1	2.8
Abdominal focus sepsis	1	2.8
Sepsis of undetermined focus	4	11.4
Cardiovascular complications		
Acute lung edema	1	2.8
Pulmonary thromboembolism	1	2.8
Cardiogenic shock	3	8.7
Neurological complications		
Stroke	1	2.8
Total	35	100

anesthetic risk, type of care, discharge, specialty and anesthesia, length of surgery and hospitalization, type of hospitalization and classification of the surgery regarding the potential for contamination and urgency (Table 1). Most of these variables lost significance when analyzing their joint influences.

Mean age and CCI scores were significantly associated with the occurrence of AE ($p<0.001$). Patients with AE had a higher mean age (61.03; ±15.9) than patients without AE (47.9; ±19.3). Considering the CCI, it was found that patients with AE also had a mean score higher (4.9; ±4.6) than that observed in patients without AE (2.5; ±2.9). Average length of stay for surgical patients who did not have AE was 7.4 days (±15.2), shorter than for those with AE: 24.3 days (25.9), ranging from 1 to 242 days (Table 1).

In the multivariate analysis, variables that were potentially associated with the outcome in the bivariate analysis were included, considering a p-value of up to 0.20. The logistic regression model showed that some of them maintained a significant association with the outcome. Patients classified as P2, according to the ASA, were approximately twice as likely to have AE (OR: 2.98; 95%CI 1.1–7.9) when compared to healthy patients classified as P1.

The analysis also showed that the longer the hospital stay, the greater the chance of a person having AE. Considering the variables related to the surgical procedure, it was found that surgeries lasting more than four hours have a chance of having an AE equivalent to nine times the chance of surgeries with a shorter duration (OR: 9.1; 95%CI 2.1–38.3). In addition to surgery time, the variable classification of the procedure regarding the potential for contamination showed that in surgeries classified as contaminated, the chance of a person having AE is almost three times (OR: 2.9; 95%CI 1.1–7, 9) greater than the odds for surgeries classified as clean. The multivariate analysis is shown in Table 4.

Considering death as an event of interest, another multivariable analysis was performed to verify the effect of the association between the presence of AE and the occurrence of death. In this analysis, the patient's risk adjustment variables (gender, age group, and CCI) were included along with the occurrence of AE. The variables age range and gender did not show a significant association with the occurrence of death. Patients with a score equal to or greater than 4, according to the CCI, were almost 30 times more likely to die (OR: 29.59; 95%CI 3.85–227.60) compared to the chances of patients with a score equal to or greater than zero (no comorbidities). Surgical patients who suffered at least one AE were 25 times more likely to die than those without AE (OR: 25.2; 95%CI 11.29–56.27).

DISCUSSION

The incidence of AE found in this study is in line with estimates already shown in international research, despite the different definitions and methods used to track and identify AE, which makes comparisons difficult. In international surveys, the incidence of AE in surgical patients from 5 to 14% was reported, with a mean prevalence of 14.4%[10,11].

Researchers who analyzed adverse events in clinical care showed that patients who underwent a surgical procedure were more likely to have AE (OR: 7.93; 95%CI 3.90–16.2) compared to those who did not undergo surgery[12].

The method for tracking and identifying AE proposed by the IHI used in this study has been considered suitable for application both in research and in monitoring the incidence of AE in health organizations[13,14]. In studies on the performance of the triggers proposed by the GTT, it was found that the tool is more sensitive than spontaneous notification of AE, despite the subjective component present at the moment of decision regarding the occurrence of the event[14,15].

According to the GTT method, the primary review of medical records in search of triggers should be practical and

Table 4. Multivariable analysis of the outcome occurrence of adverse events among surgical patients. Juiz de Fora (MG), Brazil.

Characteristics	β	p-value	OR	95%CI
Anesthetic risk				
P1	-	-	1.00	-
P2	1.09	0.029	2.98	1.12 – 7.90
P3	0.60	0.298	0.28	0.59 – 5.74
P4	0.87	0.267	0.25	0.52 – 11.06
Length of stay (days)				
Up to 2	-	-	1.00	-
3	0.24	0.740	1.27	0.32 – 5.07
4 to 11	1.10	0.021	3.01	1.19 – 7.61
11+	2.01	0.000*	7.43	2.90 – 19.05
Classification of the surgery according to the potential for contamination				
Clean	-	-	1.00	
Potentially contaminated	0.32	0.708	0.88	0.44 – 1.76
Contaminated	1.04	0.030	2.82	1.11 – 7.20
Infected	0.78	0.113	2.18	0.84 – 5.67
Surgery time (minutes)				
Up to 30	-	-	1.00	-
31 to 60	0.30	0.661	1.34	0.37 – 4.92
61 to 120	0.82	0.214	2.27	0.63 – 8.24
121 to 240	1.08	0.112	2.94	0.78 – 11.10
240+	2.21	0.003	9.10	2.16 – 38.33

*p-value rounded to three decimal places.
Note: Anesthetic risk: classification of the patient's physical status according to the American Society of Anesthesiology (P1: healthy person; P2: presence of mild systemic disease(s) and absence of significant functional limitation; P3: presence of moderate to severe systemic disease(s) with functional limitation; P4: presence of severe systemic disease with constant risk of death; P5: moribund patient with no hope of survival without surgery; P6: patient with declared brain death, organ donor). Note: In the study sample, no patient was classified as P5 or P6.

objective, with an average duration of 20 minutes. In the present study, the average time for reviewing the medical records was close to the recommended one. However, in some cases, it was necessary to exceed the time limit, especially when dealing with medical records with suspected AE, so that sufficient information could be collected. In addition, the double review of the medical records provided more comprehensive information to support the professionals' clinical judgment regarding the AE and the classification of the severity of the damage.

In the primary review stage of the medical records, many cases of triggers with no corresponding AE were found in addition to others in which several triggers were related to the same event. Of the total number of medical records with triggers, a little more than half (56.6%) had AE confirmed by the consensus meeting. As this is a sample of surgical patients from a highly complex hospital, some of the triggers identified situations expected for the intra and postoperative period, for example, the need for transfusion of blood components and admission to an intensive care unit in large-sized surgeries. Despite this, the most frequent triggers in the analyzed medical records (transfusion of blood or blood products and infection related to health care) corresponded to the two most frequent types of AE (bleeding and SSI, respectively).

Five consensus meetings were held with the participation of authenticating physicians to present the 113 cases with suspected AE, which were presented considering the temporality of the events that led to changes in the clinical conditions of the patients. In the five cases in which there was disagreement about the occurrence of AE, it was believed that the reported situation was a complication of the underlying disease, that is, unrelated to the care provided.

Regarding the description of AE in terms of its nature, it was found that the most common causes were complications at the surgical site, followed by infections related to care. Other studies on the occurrence of AE in surgical care

also indicated complications at the surgical site as the most frequent event[10-16]. The incidence of surgical complications is considered as a marker for assessing the quality of surgical care[17].

In the present study, in addition to SSI and bleeding with hemodynamic repercussions already reported as the most frequent, cases of iatrogenic injury to organs and tissues during surgery and of fistulas and suture dehiscence, complications directly related to the surgical technique, were identified. It is important to emphasize that surgical complications are potentially controllable factors, which contribute to the high costs of care, as well as to the morbidity and mortality of patients. Prophylactic interventions for infections and hemorrhages, based on therapeutic protocols, can contribute to the reduction of these complications[2,18].

After the surgical complications, infections related to health care (excluding SSI) were also frequent, especially those with a pulmonary focus, which may be related to the endotracheal intubation procedures and mechanical ventilation required in surgeries using general anesthesia. It is important to emphasize that, due to the lack of a reference to classify the nature of the damage, it was considered that all events were related to surgical assistance, being a direct or indirect consequence of the procedure performed.

AE occurred more frequently during the analyzed hospitalization (73.8%), being identified mainly in the surgical (33.8%) and intensive care (33.1%) inpatient units. It is important to highlight that many surgical complications manifest themselves after the patient's discharge and are not captured if there is no readmission.

As for the severity of the damage, it was observed that most of the events under study were included in category F (54.4%), that is, damage that resulted in temporary damage to the patient. A study carried out in 63 hospitals in Sweden with surgical patients also found that more than half of the AE were included in category F[2,10]. Even temporarily, these damages were responsible for additional interventions such as reoperations, increased length of stay or required readmissions for treatment related to the damage.

The increase in length of stay due to an AE has been constantly reported in studies on this topic[10,13]. A smaller portion of AE, included in category G (4.1%), caused permanent damage to patients, with important consequences on quality of life, translating into peripheral nerve injuries that caused physical limitations, need for permanent colostomy due to rectovaginal fistula, lower limb amputation due to acute arterial occlusion in a revascularization procedure, vocal cord paralysis associated with endotracheal intubation and hemiparesis due to stroke after carotid endarterectomy procedure.

Considering the total number of AE identified, 24.2% of them led patients to death. Several works have shown the association between AE and death[19,20]. Results found in this study reinforce the evidence of this association, indicating that surgical patients who suffered at least one AE had a chance of dying equivalent to 25 times greater than those who did not suffer an AE.

In the bivariate analysis, patient-related characteristics, such as mean age, CCI score and anesthetic risk, were significantly associated ($p<0.05$) with the occurrence of AE. Results showed that more vulnerable patients, because they were aged and had a higher mean CCI score due to many comorbidities, were more affected by AE. Other studies have also identified that characteristics such as advanced age and the presence of comorbidities are directly related to the risk of AE occurrence[20]. However, in the analysis of their joint influences, it was found that only the length of stay variable remained associated with the outcome.

Thus, some characteristics related to the surgical procedure, such as specialty, type of anesthesia, duration of surgery and classification of the surgery in terms of urgency and degree of contamination, analyzed separately, also showed a significant association with the outcome. However, only the surgery classification variables regarding contamination potential and duration remained significant at the final adjusted time.

Multivariate analysis showed that surgical patients with mild comorbidities and without expressive functional limitations (P2), according to the ASA classification, were more likely to have AE compared to healthy patients (P1). Those with moderate or severe comorbidities (P3 and P4) were not likely to have AE. This paradox seems to be related to the low frequency of patients classified as having a higher risk for complications (P3 and P4) in the analyzed sample[14,16-20].

Regarding the length of stay, it was observed that after a period of three days, the chance of AE occurrence practically doubled in the analyzed categories. Patients who remained hospitalized for 11 days or more had a chance of having AE equivalent to seven times the chance of patients who remained hospitalized for up to two days.

A similar situation was verified with the variable length of surgery, as it was verified that patients undergoing

longer surgical procedures had a ninefold chance of AE in relation to the chance of those undergoing surgeries of shorter duration. Another variable that remained in the final model was the classification of the surgery regarding the potential for contamination, revealing that in cases in which the surgical procedure was classified as contaminated, the chance of patients suffering AE was almost three times greater.

This study has limitations inherent to the AE identification method based on the retrospective review of medical records, since the results directly depend on the quality of the records, which may contribute to the underestimation of cases. As the present study used the electronic medical record, the limitation regarding the illegibility of the records was circumvented. In addition, the use of electronic medical records favored the analysis of changes in the patient's clinical conditions in chronological order, an essential condition for establishing the temporality that allows the decision regarding the occurrence of AE. Regarding the quality of information, the use of electronic medical records also minimizes the absence of records, since the system requires the daily input of patient data, even if this information is minimal.

Despite the limitations, the primary reviewers and the authenticating physicians considered that the quality of the information present in the analyzed medical records was adequate and sufficient to track, identify, and describe the AE. Another limitation that should be mentioned refers to the event identification method proposed by the GTT, based on the clinical judgment of the authenticating physicians in relation to the cases presented, and there may be identification and classification errors related to the subjectivity of the professionals and those involved.

In addition to the limitations inherent to the method used in the research, the time frame also stands out, since the analyzed medical records refer to 2012 and 2015. Despite the changes over time, the results presented here bring great contributions, since national studies regarding the occurrence and description of AE are still scarce.

CONCLUSION

The study made it possible to know the incidence of AE in surgical patients in a general reference hospital in high complexity, a subject still little explored in the national context. The results found provide a valuable overview to support strategies aimed at patient safety in surgical care, since they allowed mapping and describing AE considering their nature, location and time, classification of damage severity and factors associated with it.

The information presented confirms the magnitude of the occurrence of AE in surgical care, due to its high frequency, impact of harm caused to patients, in addition to the increase in hospitalization time and mortality. The evidence produced points to the understanding that the characteristics related to hospitalization and the surgical procedure are the most important factors associated with the occurrence of AE, and should, therefore, be targets of strategies for the prevention and/or reduction of these injuries.

Future investigations should be carried out with the aim of systematically monitoring the incidence of AE in surgical care, providing useful information to assess the impact of implemented strategies to improve surgical patient safety in health organizations.

FUNDING

None.

CONFLICT OF INTERESTS

The authors declare there is no conflict of interests.

AUTHORS' CONTRIBUTION

LRF: Project administration, Formal analysis, Conceptualization, Data curation, Methodology, Writing – original draft, Writing – review & editing, Validation. ALSA: Writing – review & editing, Visualization, Validation. HSD: Writing – review & editing, Visualization, Validation. FCC: Writing – review & editing, Visualization, Validation. CFS: Writing – review & editing, Visualization, Validation. RRB: Project administration, Formal analysis, Conceptualization, Data curation, Methodology, Writing – original draft, Writing – review & editing, Validation.

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