# Assessment of surgical adverse events in Rio de Janeiro hospitals

## *Avaliação de eventos adversos cirúrgicos em hospitais do Rio de Janeiro*


***Abstract***

A study on surgical adverse events (AE) is relevant because of the frequency of these events, because they are in part attributable to deficiencies in health care, because of their considerable impact on patient health and economic consequences on social and health expenditures, and because this study is an assessment tool for quality of care. We aimed to evaluate the incidence and the contributive factors of surgical AE in hospitals of Rio de Janeiro. This retrospective cohort study aimed to perform a descriptive analysis of secondary data obtained from the Adverse Events Computer Program, which was developed for collecting data for the assessment of AE in three teaching hospitals in the state of Rio de Janeiro. Incidence of patients with surgical AE was 3.5% (38 of 1,103 patients) (95% CI 2.4 – 4.4) and the proportion of patients submitted to surgery among patients with surgical AE was 5.9% (38 of 643) (95% CI 4.1 – 7.6). The proportion of avoidable surgical AE was 68.3% (28 of 41 events) and the proportion of patients with avoidable surgical AE was 65.8% (25 of 38 patients). One in five patients with surgical AE had a permanent disability or died. Over 60% of the cases were classified as not complex or of low complexity, and with low risk for care-related AE.



**Keywords:** Adverse events. Patient safety. Evaluation of health services. Surgical complications. Health care quality. Safe surgery.



**Maria de Lourdes de Oliveira Moura**[I]

**Walter Mendes**[II]

[I] Escola de Governo em Saúde da Escola Nacional de Saúde Pública Sérgio Arouca da Fundação Oswaldo Cruz.

[II] Departamento de Planejamento em Saúde da Escola Nacional de Saúde Pública Sérgio Arouca da Fundação Oswaldo Cruz

**Correspondencia:** Maria de Lourdes de Oliveira Moura. Escola Nacional de Saúde Pública. Rua Leopoldo Bulhões, 1480 Manguinhos - CEP 21041-210 Rio de Janeiro, RJ. E-mail: mlourdesmoura@gmail.com

## *Resumo*

O estudo dos eventos adversos (EAs) cirúrgicos tem especial relevância por sua frequência, porque em parte são atribuíveis a deficiências na atenção à saúde, pelo impacto considerável sobre a saúde dos pacientes, pela repercussão econômica no gasto social e sanitário e por constituir um instrumento de avaliação da qualidade da assistência. O objetivo deste estudo é avaliar a incidência de EAs cirúrgicos e os fatores contributivos em hospitais do Rio de Janeiro. Esta pesquisa é um estudo de coorte retrospectivo que buscou realizar análise descritiva de dados secundários do Programa Computacional Eventos Adversos, desenvolvido para a coleta de dados da pesquisa de avaliação da ocorrência de EAs em três hospitais de ensino localizados no Estado do Rio de Janeiro. A incidência de pacientes que desenvolveram EAs cirúrgicos foi de 3,5% (38 de 1.103 pacientes) (IC 95% 2,4 - 4,4) e a proporção de pacientes submetidos à cirurgia entre os pacientes com EAs cirúrgicos 5,9% (38 em 643) (IC 95% 4,1 - 7,6). A proporção de EAs cirúrgicos evitáveis foi de 68,3% (28 de 41 eventos) e a proporção de pacientes com EAs cirúrgicos evitáveis 65,8% (25 de 38 pacientes). Cerca de 1 em 5 pacientes com EA cirúrgico tiveram incapacidade permanente ou morreram. Mais de 60% dos casos foram classificados como pouco ou nada complexo e de baixo risco de ocorrer um EA relacionado ao cuidado.



**Palavras-chave:** Eventos adversos. Segurança do paciente. Avaliação de serviços de saúde. Complicações cirúrgicas. Qualidade em saúde. Cirurgia segura.


## Introduction

In 2004, expressing a growing global concern with the safety of patients, the WHO (World Health Organization) created the World Alliance for Patient Safety. The WHO sought, amongst other orientations, to organize the taxonomy aspects related to the theme of patient safety[1], defining incident as an event or circumstance that could have resulted, or did result, in unnecessary harm to the patient. The incident can be with or without harm. Incidents with harm are called adverse events (AEs).

Another intervention by the WHO was the creation of programs that minimize patient harm through the Global Patient Safety Challenge, which covers risk themes related to health care, considered relevant to WHO member countries. The first theme selected was healthcare – associated infection, followed by safety in surgical care, aimed at preventing errors, avoiding damage and save lives[2,3].

AEs are estimated to occur in 4 to 16% of all hospitalized patients, with over half that taking place in surgical care[2]. In industrialized countries complications occur in 3 - 16% of the surgical procedures made in patients in hospital care, with mortality rate of 0.4 - 0.8%[2]. Studies made in developing countries estimate a mortality rate of 5 to 10% in patients who undergo major surgery[4].

The study of surgical AEs has special relevance due to its frequency, as often they are attributable to deficiencies in health care, for their considerable impact on the health of patients, for the economic repercussions and for their being an instrument to assess care quality[5]. The AEs of greater interest to public health are the preventable ones, susceptible to interventions directed at their prevention[6].

When the definition put forward by the WHO for incident included the term "unnecessary damage to the patient" it eliminated the term preventable, so that every EA would be preventable. However, most of the studies on AEs are prior to the WHO

definition and use the term preventable. An EA can be preventable or not. A non-preventable AE would be a consequence of an injury resulting from a therapy employed, where the benefit outweighs an already-known risk.

A study to evaluate AEs was done in three public school hospitals in the state of Rio de Janeiro[7]. The study had a method based on a retrospective review of medical records and used in its first stage an explicit assessment made by nursing staff based on a list with 19 screening criteria and in a second stage by an implicit assessment made by a physician reviewer[7]. The method was adapted to assess the occurrence of AEs in Brazilian hospitals[8] from the Canadian Adverse Event Study (CAES)[9]. The incidence of AEs was of 7.6%, with 66.7% being deemed as preventable[7]. The most frequent source of AEs - 36.2% of the total cases - was the surgical procedure. The operating room was the second greatest frequency place for AEs where 34.7% of the cases took place[7].

The goal of this study was to assess the incidence of surgical AEs in Rio de Janeiro hospitals and to compare the results with studies on surgical AEs made in other countries.

## Method

The project for this research was approved by the Commission for Ethics in Research of the Brazilian Public Health School at FIOCRUZ. The authors represent that there is no conflict of interests.

It is a retrospective cohort study with a descriptive analysis of secondary data from the database generated by the Adverse Event Software, developed to collect data of the assessment survey on the occurrence of adverse events in Brazilian hospitals, conducted by Mendes et al. (2009)[7]. The original research was accomplished by a retrospective review of medical records of 27,350 patients admitted in 2003 in three general, teaching and public hospitals in the state of Rio de Janeiro. These hospitals have over 200 beds; emergency services and two of them have obstetric service. A simple random sample was selected of inpatients. The patients under 18 years old, patients who had been in hospital for less than 24 hours and patients with a main diagnosis for psychiatric disease were excluded from the sample. The size final of the sample was 1,103 patients eligible for the study. The last hospital admission occurred in 2003 was considered for the study[7].

The method of the study and the electronic form used in the original study were based on the Canadian Adverse Events Study (CAES)[9]. The definition of AEs used and also based on the CAES was "an unintended injury or complication that results in incapacity or disability, temporary or permanent, death or prolonged hospital stay as a result of the healthcare provided"[7]. A preventable EA was defined as "an error in the care provided to the patient due to a failure, individual or of the system, non compliant with good medical practice"[7].

The assessment of AEs involved two stages[7]. The first one was based on tracking potential AEs using explicit criteria, carried out by nursing staff. When the nurse found the presence of at least 1 criterion the medical records were set aside to be evaluated by a physician in the second stage. The second stage, done by physician was based on implicit criteria to the assessment of the AEs. The physician identified the occurrence of non-intentional harm and temporary or permanent incapacity, and/or with the prolonging of hospital stay or death. After that, using a six-point scale the physician judged whether the harm was caused by the care provided to the patient[7]. An injury or harm was deemed as EA when it reached a rating in the scale of 4 or more points. Once an EA was ascertained the physician would go on to define its characteristics, such as the moment in which it occurred and where it had been detected; the location (operating room, ward, intensive care unit, etc.); source (surgical, drug-related event , etc.); contributing factors and other characteristics. The preventability of the AEs was also judged according to a six-point scale, with

an EA being deemed as preventable when it reached 4 points or more. The nursing staff and physician who did the reviewing were trained with the use of medical records selected to this end. All the physician and nursing staff had over 20 years' experience[7].

The description of all the cases with AEs was studied, to identify patients who underwent surgery, whose AEs had not been previously rated as surgical AEs, to check the pertinence of their inclusion in the research sample, according to the definition of surgical AEs of Bruce et al.[5].

Four databases were generated by the Adverse Event Software for this research: a database with patients who had surgical and obstetric AEs; a database with surgical and obstetric AEs; a database of patients who underwent procedures, and a database for the 1,103 patients of the sample.

Procedures performed in all patients in the sample were analyzed to identify the number of patients who underwent surgery. Patients who underwent a non-invasive procedure and/or non-surgical invasive procedure were excluded. The invasive procedures were analyzed using as reference the Table for Procedures, Drugs and OPMs of the Brazilian Health System – SUS of 11/07/2004, group 04 – SURGICAL PROCEDURES and the description of major surgery adopted by the World Health Organization (WHO)[2] as 'any procedure done in operating room involving incision, excision, manipulation, or tissue suture that usually requires general or local anesthesia or deep sedation to control pain'.

Were also analyzed: the demographic characteristics of patients; the positive tracking criteria in medical records of patients with surgical AEs; the character of hospital admission; the condition for the discharge from patients; the proportion of surgical AEs; the factors that contributed to surgical AE; the average length of stay ; the portion of length of stay due to surgical AE; the degree of physical harm; the location of the occurrence; the confidence on the evidence that the care provided caused the harm; the moment of detection and occurrence in relation to the index hospital admission; the contributing factors; the classification of the complexity of the case; the surgical procedure made; the degree of risk of occurrence of a surgical AE related to care; the confidence in the evidence of possible preventability; the reason for the lack of prevention; the areas identified for efforts to avoid recurrence; the type of error – by omission or action . The pre-operation risk not was collected in the medical records.

The measures used in this research were: incidence of surgical AE amongst inpatients ((number of patients with at least one surgical AE / total number of patients) x 100); proportion of preventable surgical AEs ((number of preventable surgical AEs / total number of surgical AEs) x 100); proportion of patients with preventable surgical AEs [(number of patients with preventable surgical AEs / total number of patients with surgical AEs) x 100]; proportion of surgical AE amongst surgical patients [(number of surgeries with at least one surgical AE / total number of surgeries) x 100], and incidence density of surgical AEs [(number of surgical AEs / summation of the days of hospital stay for all patients who underwent surgery) x 100].

The statistical analyses were made with the use of the STATA 10.0 statistical package. Another analysis was done to compare the results of the research with results from the studies on surgical adverse events selected in bibliographical review.

## Results

Three patients submitted to caesarean delivery with AEs rated as obstetric were identified. Based on the definition of Bruce et al.[5] for surgical AEs and used in this study, the AEs occurred in patients who underwent caesarean delivery, rated in the original research as obstetric, were considered as surgical AEs.

The Adverse Event Software also generated a list of the procedures made in patients, totaling 855 procedures. Two hundred and

twelve procedures were excluded, considered non-invasive or invasive but non-surgical, and a new surgical procedure variable was created in a third database. All non-invasive procedures were excluded.

A total of 38 patients from the original study, of a 1,103 patient population, had surgical AEs. Some had more than 1 surgical AE, totaling 41 surgical AEs. The incidence of patients with surgical AEs in the total population of inpatients was 3.5% (38 of 1,103 patients) (95% CI 2,4 - 4,4). The proportion of patients who underwent surgery with surgical AEs was 5.9% (38 in 643) (95% CI 4,1 – 7,6). Amongst patients with surgical AE, 3 (7.9%) had over one EA, an average 1.1 events by patient. The incidence density of surgical AE in patients who undergo surgery was 0.5 in 100 patients-day (41 surgical AEs in 7.597 patients-day).

The most frequent surgical procedures were: caesarean delivery 6% (68/643); cholecystectomy 6.2% (40/643); surgical hernia correction 5.8% (38/643); curettage 3.6% (24/643); hysterectomy 2,2% (14/643) and cataract surgery 2.9% (19/643). The proportion of patients who underwent these procedures with surgical AE was 7.4% to (5/68) caesarean delivery; 5.0% (2/40) to cholecystectomy; 2.5% (1/38) to surgical hernia correction; 21.4% (3/14) to hysterectomy and 5.3% (1/19) to cataract surgery.

As to gender, among patients who underwent surgical procedure 387 (60.2%) were women and 256 (39.8%) men and excluding patients who did not have surgical AE, 367 (60.4%) were women and 241 (39.6%) men. Of the 38 patients who had surgical AE, 23 (60.4%) were women and 15 (39.5%) men. The non-obstetric cases were 33 (86.7%) and 5 were obstetric (13.2%). The mean age of patients who underwent surgical procedure was 47, excluding patients who did not have surgical AE, at 46 years of age and patients who had surgical AE at approximately 55 years of age (95% CI 49.9 – 60.5), where 26 years was the smallest age and 82 the oldest and 52 years the average. Nearly 60% (23/38) of the patients who had surgical AE were aged 18-60 years t. Of the total of these patients, 22 (57.9%) had an elective admission to hospital and 16 (42.1) emergency admission.

The most frequent tracking criteria were: criterion 3 in 42.1% (16/38); criterion 9 in 36.7% (14/38); criterion 15 in 36.7% (14/38), and criterion 7 in 28.9% (11/38) (Table 1).

The mean length of hospital stay of patients with surgical AEs was 30.1 days (standard deviation 4.6, 95% CI 20.4 to 39.5), with minimum length of hospital stay of 2 days and maximum 130 days. An evaluation was made by the reviewers as to whether part of the length of hospital stay was due to surgical AEs, based on the judgment of the physician reviewer who took in consideration the time that the patient needed to remain hospitalized due to the EA, being positive in 25 events (60.9%). The number of extra days that the patient was hospitalized due to a surgical AE was evaluated in 19 events (46.2%), with the average being calculated at 14.1 days (standard deviation 3.3, 95% CI 7.2 to 21.0), with an increase of 1 day at least and 64 days maximum. The most frequent place of occurrence for surgical AEs was the operating room, where 32 events (78.1%) occurred. As for the moment of detection of the surgical AE in relation to the index hospital admission, 36 events (87.8 %) were detected in the index hospital admission. In relation to the moment of occurrence of the surgical AE, 32 (78.0 %) occurred during the index hospital admission.

An evaluation was made as to whether the patient has suffered unintentional damage or complication, being considered that in 100% of the events the injury or damage were not intentional. The evidence that the care provided caused injury or damage was considered practically certain in 32 surgical AEs (78.1%).

The proportion of preventable surgical AEs was estimated at 68.3% (28/41 events) with standard deviation 7.3% and 95% CI 53.3% to 83.2% and the proportion of patients with preventable surgical AEs was calculated at 65.8% (25/38 patients) with standard deviation 7.8% and 95% CI 50.0% to 81.6%.

**Table 1 -** Distribution of positive triggers for surgical adverse events.
***Tabela 1 -*** *Distribuição de critérios de rastreamento positivos para eventos adversos cirúrgicos.*

| Nº | Tracking criterion | Frequency N (%) |
|---|---|---|
| 1 | Unplanned hospital admission (including re-admission) as a result of any health care provided for one year prior to the index hospital admission | 8/38 (21.1) |
| 2 | Unplanned hospital admission in any hospital for one year after the discharge of the index hospital admission | 2/38 (5.3) |
| 3 | Occurrence of injury to patient during hospital admission (including any damage, injury or trauma occurred during the index hospital admission) | 16/38 (42.1) |
| 4 | Drug adverse reaction | 2/38 (5.3) |
| 5 | Unplanned transfer to intensive or semi-intensive care unit | 7/38 (18.3) |
| 6 | Unplanned transfer to another acute care hospital (excluding transfers for tests, procedures, or specialist care that is unavailable at the source hospital) | 2/38 (5.3) |
| 7 | Unplanned return to the operating room | 11/38 (28.9) |
| 8 | Unplanned removal, injury or correction of organ or structure during surgery, invasive procedure or vaginal labor | 2/38 (5.3) |
| 9 | Other unexpected complications occurred during hospital admission that are not a normal development of patient disease or an expected treatment result | 14/38 (36.7) |
| 10 | Development of neurological change that was absent at admission, but found at the time of discharge from index hospital admission (includes neurological alterations related to the procedures, treatments or investigations) | 2/38 (5.3) |
| 11 | Death | 7/38 (18.3) |
| 12 | Inappropriate hospital discharge/inadequate discharge plan from index hospital admission (excludes patient's decision to leave hospital) | 2/38 (5.3) |
| 13 | Cardiopulmonary arrest reversed | 2/38 (5.3) |
| 14 | Injury related to abortion or labor delivery or labor | 2/38 (5.3) |
| 15 | Hospital infection/septicemia (excludes infections/ septicemia occurred less than 72hs after admission) | 14/38 (36.7) |
| 16 | Dissatisfaction with care received, documented in medical records or evidence of complaint produced | 1/38 (2.5) |
| 17 | Documentation or correspondence indicating litigation, whether merely intended or after effective action | - |
| 18 | From normal creatinine at hospital admission, there has been a doubling of its value during hospital stay? | 2/38 (5.3) |
| 19 | Any other undesired events not mentioned above | 10/38 (26.2) |

The adequacy and response to the measures adopted to treat the EA during the index hospital admission was considered adequate in 39 events (95.0%) and the response to injury or damage from the measures adopted was calculated as positive in 34 (83.0%).

The mortality rate for patients with surgical AEs was estimated at 18.4 % (95% CI 5.5 to 31.3) (7 of 38 patients). The proportion of surgical AEs that led to death was calculated at 17.1% (95%CI 5.0 to 29.1) (7 of 41 surgical AEs) and the proportion of preventable surgical AEs that led to death, 17.9% (5 of 28 preventable surgical AEs). No case of maternal death was recorded.

The physician reviewers assessed the degree of evidence for preventability of surgical AEs at: 16 (39.0%) probable, little over 50%; 5 (12.2%) moderate to strong and 3 (7.3%) practically certain.

The degree of physical damage of the surgical AE at the time of hospital discharge was judged by the physician reviewers,

based on the data from the medical records of patient: no damage or physical incapacity in 23 (56.1%); minimum damage and /or with recovery in one month in 5 (12.2%), and permanent damage in 9 (21.9%), of which 7 (17.1%) were deaths.

In relation to the complexity of the case, 10 surgical AEs (24.4%) occurred in cases rated as of little complexity and 15 (36.6%) in cases rated as not complex, that is, nearly 60% of the events occurred in cases of low complexity. The risk of occurrence of a surgical AE related to care was considered as low in 27 events (65.8%). The reason for non-prevention of surgical AEs was assessed in 95.1% (39/41) of the surgical AEs, with the most frequent being the failure to take precautions to avoid accidental injury, in 27 (69.2%) events.

The most frequent surgical AEs were those related to the surgical wound, which occurred in 46.3% (19/41) of the events, with 19.5% (8/41) due to infection of the surgical wound and 26.8% (11/41) due to another problem with the surgical wound. Infection not related to the surgical wound occurred in 14.6 % (6/41) and hemorrhages in 12.2% (5/41) of the events, with 9.8 % (4/41) being severe (Table 2).

For a better understanding of the cases of patients with surgical AEs a summary of the cases was prepared (Table 3).

An evaluation was made of the factors that contributed to the surgical AEs, being non-determined in 33.3% (14/41). The norm factor - did not verify or did not follow the protocol, contributed to 31.0% of the events (13/ 41) and skill - errors or lapses in 14.3% (6/ 41), therefore in 45.3% (20/41) of the surgical AEs the contributing factors were preventable. The proportion of the errors due to omission was of 12.2% (5/41) and as a result of action 87.8% (36/41). The main areas of attention to avoid the recurrence of surgical AEs were education in 63.4% (26/41) of the events and quality assurance / peer revision in 53.7% (22/41). It should be pointed that more than one area of attention can be indicated by the reviewers for each event.

**Table 2 -** Proportion of surgical adverse events.
***Tabela 2 –*** *Proporção de Eventos adversos cirúrgicos.*

| Surgical Adverse Event * | Total N (%) |
|---|---|
| Surgical wound | |
| Infection of surgical wound | 8 (19.5) |
| Other problems with surgical wound | 11 (26.8) |
| **Sub-total** | 19 (46.3) |
| Hemorrhage | |
| Severe hemorrhage | 4 (9.8) |
| Mild hemorrhage | 1 (2.4) |
| **Subtotal** | 5 (12.2) |
| Infection not related to surgical wound | 6 (14.6) |
| Technical problem | 3 (7.3) |
| Perforation | 2 (4.9) |
| Related to the prosthetics placement | 1 (2.4) |
| Stroke | 1 (2.4) |
| Other events | 4 (9.8) |
| **Total** | 41 (100.0) |

Nota: *Nenhum paciente sofreu os seguintes EAs cirúrgicos: ruptura de anastomose; dificuldade na definição anatômica; insuficiência cardíaca congestiva; infarto do miocárdio; trombose venosa profunda; pneumonia, e embolia pulmonar.
*Note: *None of the patients had the following surgical adverse events: anastomotic rupture, difficulty in defining anatomy, congestive heart failure, myocardial infarction, deep vein thrombosis, pneumonia, or pulmonary embolism.*

**Table 3** – Description of the cases presenting surgical adverse events.
***Tabela 3*** *– Descrição dos casos com eventos adversos cirúrgicos.*

| | Description of the cases |
|---|---|
| 1 | ♀, 82 years, colecystitis, underwent cholecystectomywith rupture of gall bladder with leakage of bile fluid in abdomen cavity. |
| 2 | ♂, 60 years, with intestine sub-occlusion due to rectum adenocarcinoma, underwent rectum abdominalperineal resection, with intestinal obstruction, exploratory laparotomy was performed. |
| 3 | ♂, 70 years, diabetic, underwent radical prostatectomy, evolved with urethral stenosis, being performed endoscopic urethrotomy . |
| 4 | ♀, 49 years, with uterine fibroid and ovarian follicular cyst, underwent full abdominal hysterectomy and left oophorectomy. Developed abdominal wall abscess. |
| 5 | ♀, 75 years, hypertensive, underwent surgery to correct urinary incontinency, had an injury of the artery uterina that led to surgery suspension. Evolved with bladder-vaginal fistula. |
| 6 | ♀, 26 years, hypertensive, with liver cirrhosis, underwent liver transplant. Evolved with large sub-capsular liver hematoma and severe bleeding, liver dysfunction and death. |
| 7 | ♀, 82 years, hypertensive, with broken femoral neck, underwent femur transtrochanteric osteosynthesis. Evolved with surgical site infection |
| 8 | ♂, 66 years, hypertensive, chronic obstructive pulmonary disease and chronic renal failure, underwent kidney transplant. Had a fall equivalent to his own height. Evolved with perinephric abscess, septic shock, digestive hemorrhage and death. |
| 9 | ♀, 59 years underwent cornea transplant; evolved with sub-conjunctive hemorrhage and suture dehiscence. |
| 10 | ♀, 40 years with lumbar disc hernia, underwent laminectomy and discectomy. Evolved with neuropraxia in L5 root post-laminectomy. |
| 11 | ♂, 71 years with pulmonary nodule in right upper lobe, underwent pulmonary segmentectomy. Evolved with empyema, pressure ulcer, subcutaneous emphysema, pulmonary drain with air flight and death. |
| 12 | ♀, 43 years with bilateral ovary tumor, underwent hysterectomy and bilateral adnexectomy bilateral. Developed laceration of the sigmoid loop and suture dehiscence of the abdominal wall. |
| 13 | ♂, 74 years with acute myocardial infarction, underwent heart catheterism and revascularization of the myocardium. Developed surgical site and respiratory infection , going to sepsis and death. |
| 14 | ♀, 81 years, hypertensive, duodenal tumor, underwent cholecystectomy and Kerr drainage. Evolved to dehiscence of suture, intraperitoneal abscess, urinary infection, sepsis and death. |
| 15 | ♀, 69 years with splenic angle malignant tubular adenoma, underwent left hemicolectomy with transversal-sigmoid anastomosis. Evolved to colonic fistula. |
| 16 | ♂, 47 years with tendon injury underwent tenorrhaphy right Achilles tendon with organic insert. Evolved with insert infection. |
| 17 | ♂, 64 years with abdomen trauma and exposed left lower limb fracture, underwent exploratory laparotomy and to reduction of fracture . Evolved with respiratory infection. |
| 18 | ♀, 31 years in labor with cephalic-pelvic disproportion, underwent Caesarean delivery, with laceration of lower edge of the myometrium, hysterorraphy made. |
| 19 | ♂, 43 years with sub-liver retrocecal appendix, underwent appendectomy. Evolved with abdominal wall abscess. |
| 20 | ♀, 76 years with deslocad lens of RE, underwent pars plana vitrectomy and removal of the RE core. Evolved with retinal detachment, and performed total pars plana vitrectomy |
| 21 | ♂, 49 years, diabetic, with pleural empyema, underwent toracocentesis, had intense bleeding and hypovolemic shock. Exploratory thoracotomy and pleurectomy performed. |
| 22 | ♀, 58 years, hypertensive, with thyroid nodules, underwent total thyroidectomy . Evolved with cardiac arrhythmia and hypocalcaemia. |
| 23 | ♀, 48 years, hypertensive, with colon adenocarcinoma, underwent hemicolectomy. Evolved with dehiscence of suture, peritonitis, subphrenic abscess, lung infection and death. |

**Table 3** – Description of the cases presenting surgical adverse events. (cont.)
***Tabela 3*** *– Descrição dos casos com eventos adversos cirúrgicos. (cont.)*

| | Description of the cases |
|---|---|
| 24 | ♂, 69 years, hypertensive, chronic obstructive pulmonary disease, with pulmonary abscess, underwent bronchoscopy, implant of vena cava filter and vein dissection. Evolved with obstruction of the vein and cellulites in left upper limb. |
| 25 | ♀, 47 years, diabetic, with chronic renal failure, myoma, anemia, bone tuberculosis and cachexia, with rejection of kidney transplant. Made transplantectomy and evolved with lymphocele. |
| 26 | ♀, 53 years, hypertensive, with extra-systole, urinary incontinency and hiperlipemia with main diagnosis of incisional hernia. A herniography with mesh was made. |
| 27 | ♀, 41 years, chronic renal failure, hydronephrosis and schizophrenia, with specific hypertensive illness of gestation. Had two falls, causing a fracture of the radius and jaw fracture. Cesarean section was performed, evolving with wound dehiscence. |
| 28 | ♀, 40 years, hypertensive, with congestive heart failure, bronchitis, hydatidiform mole, underwent hysterectomy and bilateral salpingo-oophorectomy. Evolved to dehiscence of suture, peritonitis and abdominal wall infection. |
| 29 | ♂, 64 years, hypertensive, with acute appendicitis, underwent appendectomy. Evolved with dehiscence of aponevrosis in the surgical wound and post-surgery paralytic ileum. |
| 30 | ♀, 49 years, hypertensive, with uterus fibroid, underwent myomectomy and bilateral adnexectomy, evolved with parietal blood collection. |
| 31 | ♂, 38 years with double mitral and aorta lesion and rheumatic fever, underwent double mechanical mitral-aortic substitution. Evolved with bleeding in surgical incision and retro-sternum hematoma. |
| 32 | ♀, 33 years, HIV positive, admitted with specific hypertensive illness of gestation, underwent Caesarean section. Evolved with intra-abdominal abscess. |
| 33 | ♀, 28 years, hypertensive, with specific hypertensive illness of gestation, underwent Caesarean section. Evolved with severe bleeding and surgical site infection. |
| 34 | ♂, 51 years with acute respiratory distress and acute pancreatitis, re-admitted with pancreatic adenoma; underwent pancreaticoduodenectomy. Evolved with peritonitis, perforation of intestine loop and sepsis. |
| 35 | ♀, 29 years with premature amniorrhexis, underwent Caesarean section. Developed hyperemia and vesicles in sacrum region and in surgical wound. |
| 36 | ♂, 65 years, hypertensive, with larynx cancer, underwent partial horizontal laryngectomy with cervical emptying. Evolved with surgical site infection. |
| 37 | ♀, 65 years with LE senile cataract, underwent facetectomy and LE LIO. Evolved with suture loosening in 11 hours, with re-suture following facetectomy. |
| 38 | ♂, 38 years with rectum tumor, purulent peritonitis and metastatic liver, underwent exploratory laparotomy. Evolved with dehiscence of surgical wound and death. |

## Discussion

The proportion of surgical AEs in patients undergo surgery found in this study was of 5.9%, and in selected studies on Surgical AEs[10-18] ranged from 3.0% to 35.8%. The studies had different design, EA identification technique and definitions. Consistently with other studies[10,11], over 60% of the surgical AEs were preventable and nearly 1 in 5 led to permanent incapacity or death.

In the study by Gawandee et al. (1999)[10] the proportion of surgical AEs that led to death was estimated at 5.6% (95% CI 3.7% to 8.3%), including the confidence interval for the proportion found in this study, which ranged from 5.0% to 29.1%. The proportion of preventable surgical AEs in the study mentioned above[10] that led to death was calculated at 15% (95% CI 11.8% to 18.9%), similarly to the result of this study at 17.9%.

The most frequent place of occurrence for surgical AEs was the operating

room, where 78.1% of the events occurred, similarly to that found by Gawandee et al. (1999)[10], who identified that 74.1% of the surgical AEs (CI 69.6% to 78.1%) took place in the operating room or in the delivery room. This finding shows the importance of adopting patient safety and monitoring measures in the surgery center.

It should be pointed that over 60% of the cases were rated as of little or no complexity and with a low risk for the occurrence of an EA related to care. In nearly 70% of the surgical AEs the reason for non-prevention as identified were "a failure to take precautions to avoid accidental injuries", that was much above that identified by Kable et al.[11], who found the same reason in 29% of the events. Furthermore, 46% of the complications were related to the surgical wound. Prophylactic interventions to infections and hemorrhages, based on therapeutic guideline can contribute to the reduction in the occurrence of surgical AEs[11].

Surgical AEs contributed to an increase in hospital care costs, as in over 60% of the events, part of the length of hospital stay was attributed to surgical AEs and in nearly 45% of the surgical AEs, there was an increase on average of 14 days of hospitalization.

Eleven tracking criteria contributed very little in identifying surgical AEs (criteria 2, 4, 6, 8, 10, 12, 13, 14, 16, 17 and 18), whilst five had a more expressive frequency in the positive tracking of patients medical records (criteria 1, 3, 7, 9 and 15). Of the five criteria considered by Kable et al.[11] as related to surgical procedures (unplanned return to the operating room; hospital infection or sepsis; other complications (severe heart attack, stroke, pulmonary embolism); unplanned removal of, damage or repair to organ during surgery, and a development of neurological deficit), three had a frequency above 25% as positive EA tracking criteria. The tracking criteria considered as related to surgery can be an important tool to identify patients with a greater potential risk of undergoing surgical AE.

Amongst the factors that contributed to the surgical AEs "norm - the protocol was neither verified nor followed" occurred in nearly 30% of the events, which shows the importance of monitoring the implementation of a quality assurance policy related to the compliance with clinical protocols.

The main areas of attention to prevent the recurrence of the surgical AE identified were education and quality assurance, both highlighted by Kable et al.[11] and are consistent with the failure to comply with the protocol in 1/3 of the events and with 14.3% of the surgical AEs having as a contributing factor "skill – errors and lapses".

The results of the study are limited, due to its being based on data from a retrospective review of medical records and due to the lack of some information in the medical records, especially that related to surgical AEs, with the AEs captured being only those that were documented in the medical records, which allows an underestimating of the rates of incidence[10,11]. Another limitation is that certain complications appear after the discharge of patient and, if they do not cause another hospital admission, they are not recorded; in other occasions a death occurs at the home of the patient and is not detected as an EA; moreover, readmissions can occur in another hospital[12].

The retrospective review of medical records has methodological limitations related to the impracticality of its routine use by the health services, to the difficulty in identifying less severe AEs, and to the reliability of the results from medical and no medical reviewers. In spite of the limitations, this has been the methodology employed in most of the studies focused on the wide diagnoses on the occurrence of AEs in hospitals that were the basis for the development of management strategies for patient safety in several countries. Although there are questions made about the validity of the methods used in measuring AEs, retrospective methods continue to be the most used ones in the diagnosis stage or in the measurement of AE frequency[8].

These retrospective studies have used two stages to assess the frequency of the AEs. The first stage in tracking was done by

nursing staff, which set aside the medical records with possible AEs, using explicit criteria. The second stage was made by physician s, who defined the existence of an EA and its characteristics, including whether the EA was preventable or not. This method is based on the judgment of the physician and, therefore carries a degree of subjectivity. In some foreign studies one physician reviewer was used whilst other two physician in search of consensus. The studies that used 2 physician reviewers had, in general, low reliability. A study[19] on the reliability of medical auditing in the assessment of quality of medical care found an agreement corrected by chance (Kapa) of the items considered more relevant in the process and of the result of the medical care that ranged from low to moderate (0.2 to 0.6). A recent Swedish study[20] using the methodology of retrospective review of medical records created a medical instance as it validated the results found by the physician reviewers.

The availability of physician with clinical experience to take part in surveys is not great, however the importance of measuring the damage and understanding its causes is a central issue to get the attention of decision-makers to create policies to prevent the occurrence of AEs, or even mitigate the risks.

The absence of well-established classification taxonomy for surgical AEs and the subjective nature to determine an EA and error, apart from the absence of a consistent standard[21] and methods to track, recognize, judge and report are limitations of the study[16].Complications are admitted in the surgery literature[14] as an important measure of result and are used as quality indicators in surgical care, being the basis to improve it Inconsistent methods of recording complications[18] make its use as a measure of quality unreliable , due to the wide variation of definitions[10,13,14,16-18] and classification systems[10-18,21,22], where the fragility of using complications with this purpose lies in the reliability of the recording process.

The incidence of recorded complications depends on the validity of the definitions and of the recording system used[18]. Complications can be rated according to different classification systems. An optimal classification system ought to be clear and allow uniformity in the classification of surgical complications[18].

The comparison of incidences is made difficult, especially of complications in different institutions, due to an absence of uniform definitions and populations of patients[14]. No surgery is exempt of risk, and thus a surgical complication is not necessarily from an error. The uniform character of the classification systems for surgical complications is necessary, to allow the comparison of the results between different institutions. The difficulties to attain uniformity in the recording and in the classification are many, due to the differences amongst patients, difficulties in the diagnosis of complications and a lack of consensus and clarity in the definitions of the complications[19] and surgical AEs.

Surgery[2] is one of the most complex and costly services provided by the health systems. In developing countries[2], the poor infrastructure and equipment conditions; the problems in supply and in the quality of drugs and surgical materials for medical use; the failures in organizational management and in infection control; the unsatisfactory performance of professionals due to low motivation or to a deficiency in technical qualifications; the failures in the correct preoperative diagnosis; the deficiencies in pre-anesthetic consultation, and the underfinancing of the operating costs of the health services, make the likelihood of the occurrence of adverse events much greater than that of developed countries.

The relevance of the surgery safety issue in Brazil can be evidenced if we consider the volume of hospital admissions related to surgery occurred in the country in 2003[23], nearly three million, reference-year for this study.

The high incidence rate for surgical AEs points to the need to monitor and for intervention strategies[11]. Surgery complications are potentially controllable factors[14] that contribute to the high costs of health care,

as well as to patient morbidity and mortality. Although complications may reflect the risks associated with modern health care, errors are preventable, this being an important task in improving the quality of patient care through the identification, monitoring and recording of the incidence and nature of the complications and the development of methods for its prevention[14,21].

The scientific literature[22] describes a wide range of factors organizational and human that contribute to unfavorable surgical results, including a lack of experience of the surgeon, small volume hospital surgeries, excessive work load, fatigue, unfavorable technology, insufficient supervision of interns, inadequate hospital systems, unfavorable communication amongst the professionals, time of day and administrative and bureaucratic failures. The identification of which of these factors are most frequently involved in surgical errors should be the object of intervention and of clinical, administrative and regulatory policies[22].

## References


1. World Health Organization: World Alliance for Patient Safety, Taxonomy. *The Conceptual Framework for the International Classification for Patient Safety. Final Technical Report*. January 2009, version 1,1.

2. World Health Organization. World Alliance for patient safety. *The Second Global Patient Safety Challenge: Safe Surgery Saves Lives.* Genebra; 2008.

3. World Health Organization. *World Alliance for Patient Safety: Forward Programme*. Genebra, 2005

4 . World Health Organization. *Guidelines for Safe Surgery*. Genebra; 2008.

5. Bruce J, Russell EM, Mollison J, Krukowski ZH. The measurement and monitoring of surgical adverse events. *Health Technol Assess* 2001; 5(22): 1-194.

6. Mendes W, Travassos C, Martins M, Noronha JC. Revisão dos estudos de avaliação da ocorrência de eventos adversos em hospitais. *Rev Bras Epidemiol* 2005; 8(4): 393-406.

7. Mendes W, Martins M, Rozenfeld S, Travassos C. The assessment of adverse events in Brazilian hospitals. *Int J Qual Health Care* 2009; 21(4): 279-284.

8. Mendes W, Travassos C, Martins M, Marques P. Adaptação dos instrumentos de avaliação de eventos adversos para uso em hospitais brasileiros. *Rev Bras Epidemiol* 2008; 11: 55-66.

9. Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canadá. *CMAJ* 2004; 170: 1678-86.

10. Gawandee AA, Thomas EJ, Zinner MJ, Brennan TA. The incidence and nature of surgical adverse events in Colorado and Utah en 1992. *Surgery* 1999; 126: 66-75.

11. Kable AK, Gibberd RW, Spigelman AD. Adverse event in surgical patients in Australia. *Int J Qual Heath Care* 2002; 14 (4): 269-76.

12. Aguiló J, Peiró S, Caño JG, Muñoz C, Garay M, Viciano V. Experiência em El estúdio de efectos adversos em um servicio de cirurgia general. *Rev Calidad Assistencial* 2005; 20(4): 185-92.

13. Veen MR, Lardenoye JWHP, Kastelein GW, Breslau PJ. Recording and classification of complications in a surgical practice. *Eur J Surg* 1999; 165: 421-4.

14. Wanzel KR, Jamieson CG, Bohnen JMA. Complications on a general surgery service: incidence and reporting. *Can J Surg* 2000; 43: 113-17

15. Bellomo R, Goldsmith D, Russell S, Uchino S. Postoperative serious adverse events in a teaching hospital: a prospective study. *MJA* 2002; 176: 216-8.

16. Healey MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients. *Arch Surg* 2002; 137: 611-7.

17. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 2004; 240: 205-213.

18. Veen EJ, Steenbruggen J, Roukema JA. Classifying surgical complications: a critical appraisal. *Arch Surg* 2005; 140: 1078-83.

19. Camacho LAB, Rubin HR. Reliability of medical audit in quality assessment of medical care. *Cad Saude Publica* 1996; 12: 85-93.

20. Soop M, Fryksmark U, Köster M, Haglund B. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care* 2009; 21: 285-91.

21. Calland JF, Adams RB, Benjamin DK, O'Connor MJ, Chandrasekhara V, Guerlain S et al. Thirty-day postoperative death rate at an academic medical center. *Ann Surg* 2002; 235: 690-8.

22. Gawande AA, Zinner MJ, Studdert DM, Brennan TA. Analysis of errors reported by surgeons at three teaching hospitals. *Surgery* 2003; 133: 614-21.

23. Porto SM, Santos IS, Ugá MAD. *A utilização de serviços de saúde por sistema de financiamento*. *Ciênc Saúde Coletiva* 2006; 11(4): 895-910.

Received: 06/02/11
Final version: 01/02/12
Approved: 02/05/12