

Incidence of surgical adverse events at a day hospital

Incidência de eventos adversos cirúrgicos em hospital dia

ABSTRACT

Eliana Auxiliadora M. Costa^{1*}

Lícia Lígia Moreira^{II}

Maria Enoy Neves Gusmão^{II}

Surgical adverse events are especially relevant because of their impact on patients' health and because they are preventable events. Despite the growing number of publications in this area, there are still gaps in knowledge about these events in the ambulatory surgical care modality. This study aimed to estimate the incidence of surgical adverse events at a day hospital. It is a retrospective cohort study of 55,879 patients operated in a hospital between 2010 and 2014. The incidence of surgical adverse events was 0.51%. Of these, 0.31% were surgical site infections and 0.19% of other surgical adverse events proportionally distributed in surgical wound dehiscence (12.90%), hemorrhage (5.20%), phlebitis (5.20%) and lower limb thrombosis (4.90%). The results of this study confirm that the surgery performed at an outpatient day hospital is related to lower incidences of surgical adverse events; however, a follow-up of patients after discharge is indispensable in order to avoid under and subreporting, that can hide data and identify unrealistic rates.

KEYWORDS: Adverse reaction; Day Care; Patient safety; Sanitary Surveillance

RESUMO

Os eventos adversos cirúrgicos têm especial relevância pelo impacto sobre a saúde dos pacientes e por serem preveníveis. A despeito do crescente número de publicações nessa área, persistem lacunas de conhecimento acerca desses eventos na modalidade da assistência cirúrgica ambulatorial. Esta pesquisa objetivou estimar a incidência de eventos adversos cirúrgicos em hospital dia. Trata-se de um estudo de coorte retrospectiva de 55.879 pacientes operados num hospital dia entre os anos de 2010 e 2014. A incidência de eventos adversos cirúrgicos foi de 0,51%. Destes eventos, 0,31% foram de Infecções do sítio cirúrgico e 0,19% de outros eventos adversos cirúrgicos distribuídos proporcionalmente em: deiscência da ferida cirúrgica (12,90%), hemorragia (5,20%), flebite (5,20%) e trombose dos membros inferiores (4,90%). Os resultados deste estudo ratificam que a cirurgia realizada em regime ambulatorial de hospital dia está relacionada a menores incidências de eventos adversos cirúrgicos, entretanto, é indispensável um sistema de seguimento dos pacientes após alta, no sentido de evitar a subnotificação e sub-registros dos dados, que, na ausência desse, pode ocultar dados e identificar taxas irreais.

PALAVRAS-CHAVE: Reação adversa; Hospital dia; Segurança do paciente; Vigilância Sanitária

^I Universidade do Estado da Bahia (UNEB), Salvador, BA, Brasil

^{II} Universidade Federal da Bahia (UFBA), Salvador, BA, Brasil

* E-mail: costaeliana2003@hotmail.com



INTRODUCTION

Thousands of patients are harmed by diagnostic and therapeutic mistakes occurred during health care. The role of in-hospital assistance and its quality and safety have been widely discussed, as well as the contribution of the factors that affect the distribution of risk of incidents in health services, particularly in hospital services¹. However, in spite of their relevance, quality and safety are not easy topics to be addressed in health services.

Quality is an intricate concept that includes the relationship between the benefits, risks and costs of a health-related intervention. Health quality is “how health services increase the likelihood of desirable outcomes and reduce the possibility of undesirable outcomes”^{2,3,4,5}. This is a challenge in the daily practice of health care. In this sense, good quality health care is the one that provides the patient with maximum well-being, after having considered the balance between benefits (gains) and losses (harms) that accompany the care process throughout⁵.

The evaluation of the quality of health care services is a pressing matter, driven all over the world by studies on adverse events (AE) and safety, since patient safety is considered a priority in the quality of health care services.

Data published on errors, negligence and AE of unsafe health care are a major concern of international health agencies, state regulatory bodies, institutions, health care professionals and, in particular, patients who use these services and require answers from health care institutions and government agencies^{2,5,6}.

Although it is the subject of contemporary debate, health safety has been a matter of concern since antiquity. This is evidenced by a well-known saying by Hippocrates, in 429 BC: *Primum Non Nocere*. Patient safety is defined as the act of avoiding, preventing and improving adverse outcomes or injuries arising from the medical-hospital care process⁵. The World Health Organization (WHO) defines Safety as “no unnecessary, actual or potential harm associated with health care”^{2,4,6,7}.

In the study of health safety, several concepts are addressed as follows: *incident* - defined as any event or circumstance that may or may not result in harm to the patient; *adverse event (AE)* - the unintentional injury or harm resulting in temporary or permanent disability or impairment and/or longer hospitalization or death as a result of health care; *error* - the failure to carry out a plan as intended; *violations* - intentional errors/acts; *negligence* - an unjustifiable error caused by abandonment, indolence, apathy, insufficient study, lack of diligence, omission of precautions due to lack of care in the application of knowledge by a qualified professional^{7,8,9,10,11}.

Studies on the incidence of AE in the world began in the 1980s with a study conducted at Harvard University, aimed at developing an up-to-date and reliable estimate of the incidence of AE and negligence in hospitalized patients in New York City in 1984⁸. A total of 31,429 records of patients hospitalized in acute and non-psychiatric hospitals were analyzed. The incidence rate of AE was 3.7%, with 27.6% of the AE attributed to negligence. The

majority of the AE (56.8%) was considered as small harm with complete reversal in one month⁸.

Further studies warn that 10% of all hospitalized patients suffer some type of adverse event. In Europe, it is estimated that one out of every 10 inpatients is victim of AE and 50% to 60% of these events are classified as preventable^{2,5,7}.

There is little data on AE in developing countries. A cross-sectional study identified the occasional prevalence of AE in 58 hospitals in Argentina, Colombia, Costa Rica, Mexico and Peru. A total of 11,379 hospitalized patients were analyzed and an occasional prevalence rate of AE of 10.5% was identified. Of these, 28% caused disability to the harmed patients, 6% caused their death and 60% of these AEs were classified as avoidable¹⁰.

In Brazil, the pioneer evaluation of the incidence of AE was conducted in 2003 in three public and teaching hospitals in Rio de Janeiro. The study evaluated 1,103 patients and identified 56 avoidable AEs (5.1%), with a 66.7% ratio of avoidable AEs between avoidable and non-avoidable events. These events were related to surgery (32.3%), health care-associated infections (24.6%), non-surgical medical procedures (29.2%) and diagnostic errors (15.3%) as the most frequent. HCAI were the AEs with the strongest impact and resulted in an additional 226 days of hospitalization for the patients⁷.

As a recognition of how important the patient safety problem is worldwide, WHO established the World Patient Safety Alliance in 2004 to identify and establish priorities in this area in various parts of the world, as well as to contribute to a global research agenda⁶.

To this end, this alliance launched two global challenges. The first, in 2005, focused on prevention and reduction of HCAI. The second challenge, launched in 2007, was called “Safe Surgery Saves Lives” and aimed at preventing surgical site infections, promoting safe anesthesia, safe surgical teams and indicators of surgical care⁶.

The study of surgical AEs is particularly relevant because of their substantial impact on patients’ health and health care-related costs. It is also an instrument to increase the quality of care, since these events are often preventable^{6,11,12,13}.

Among the AEs that may occur in surgical patients, WHO cites: infection of the surgical site (the most frequent); surgeries performed in the wrong place; anesthetic complications; foreign body left in the patient’s body during the procedure; operative wound dehiscence; metabolic and physiological disorders; pulmonary embolism; deep vein thrombosis, hemorrhages, bruising, burns, among others⁶.

Despite the growing number of published studies on AEs in the surgical field, knowledge gaps and several questions remain. For example, what is the risk of surgical AEs for a patient undergoing day hospital procedures? Which surgical specialty is involved



with higher rates of AEs? To what extent does the implementation of the surgical safety protocol contribute to the reduction of these events? These are questions that give rise to more studies in this area.

In this sense, this study seeks to answer the following key question: What are the most frequent surgical AEs in day hospital settings? Our goal is to estimate the incidence of surgical AEs in such day hospital conditions.

METHOD

This is a retrospective cohort study that allowed us to estimate the incidence of major surgical AEs in a day hospital. The concept of day hospital was defined as the “intermediate care between hospitalization and outpatient care for the performance of clinical or surgical procedures that require the patient to stay in the unit for a maximum period of 12 hours”, defined by the GM/MS Ordinance n. 44, of January 10, 2011¹⁴.

The day hospital we studied is a private organization located in Salvador, Bahia, Brazil. It only performs surgical procedures on a day hospital basis, with approximately 1,000 surgeries/month and a total of 12,000 surgical procedures/year.

In view of the particularity of the hospital under study, where the patients are discharged on the same day of the surgical procedure, we used the patient database of the Hospital Infection Control Service (HICS). This service has a monitoring file for each patient operated on and a follow-up system after discharge through telephone contacts (maximum of three contacts per patient), 28-30 days after surgery, to identify the postoperative evolution and the AEs that might have appeared after discharge.

Thus, this cohort study included the individual monitoring files of patients operated on from 2010 to 2014, totaling 55,879 patient files.

Data survey was performed between March and May, 2015. Data collection on the files of the operated patients was performed in two stages.

In the first stage, called screening, all patient files were analyzed by two interns from the 6th semester of the undergraduate nursing course. The interns were trained by the researchers and transcribed the data from the HICS records into a tool used in this study. The following pieces of information were surveyed: patient identification, age, telephone, basic diagnosis, type of surgery, name and number of regional surgeon's council, surgical time, clinical classification system [*American Society of Anesthesiologists (ASA)*], use of prophylactic antibiotics, complications during the intraoperative period, and data reported by patients during telephone contact after discharge performed by HICS and recorded in the monitoring files. The records of the patients who had complications during the surgical period and the files of the patients who reported complaints during telephone contact after discharge by the HICS of the hospital were selected.

In the second stage, called analysis, the files of the patients selected in the 1st stage were evaluated by the researchers in

order to identify suspect cases and confirm or not the existence of AEs related to the surgical procedures.

We used the diagnostic criteria of surgical site infection adopted by the National Agency of Health Surveillance (Anvisa)¹⁶ and the definition of AE adopted by WHO⁷. Whenever a question came up, the researchers contacted the surgeons responsible for the surgery to try to find a consensus about the AEs identified in their patients. The data was stored and analyzed in the Epiinfo program.

We contacted the hospital's board of directors to present the research objectives and obtain their permission for its conduction. We guaranteed the confidentiality of the collected data and the request was approved by the Institution's Ethics Committee under number 2/2015.

RESULTS

The distribution of the surgical procedures of the studied day hospital is shown in Table 1.

We observed that, between 2010 and 2014, 63,655 patients were operated on at the hospital under study. A total of 55,879 of these patients were monitored after discharge through phone calls made by HICS. The ratio of monitored patients ranged from 84.50% (2014) to 90.50% (2012), with a total of 87.70% patients followed up after discharge.

We observed that of the 55,879 patients operated on and monitored at the day hospital, 285 (0.51%) presented surgical AEs. Some AEs were excluded because although they were diagnosed in the collection of data after discharge, they were defined as inherent parts of the recovery process after the surgical procedure, such as: pain, edema, inflammation and serous secretion at the operated site. Therefore, these signs and symptoms were not considered AEs in this study. Between the years 2010 and 2013, the AEs presented a non-significant variation in the absolute number (47 to 52), with an average of 51 events per year. In 2014, there were 83 AEs, an increase of 62.7% in comparison with previous years (Table 2).

The incidence of AE by type and per year is shown in Table 3. Surgical AEs were divided into two groups: the surgical site infection group (SSI) and the group of other events. Of the 285 (0.51%)

Table 1. Proportional distribution of monitored patients among those who underwent surgical procedures, according to the year, in the day hospital. Salvador (2010-2014).

Period	N. operated patients	N. monitored patients	
		n	%
2010	12,103	10,932	90.30
2011	12,284	10,470	85.20
2012	12,708	11,506	90.50
2013	13,648	12,054	88.30
2014	12,912	10,917	84.50
Total	63,655	55,879	87.70



events, we identified 175 (0.31%) SSI and 110 (0.19%) other AEs. A nearly even distribution of both SSI and other surgical AEs in the years studied was observed. The rates for SSI ranged from 0.24% in 2013 (lower rate) to 0.37% in 2014. For the AEs other than surgical infection, the lowest rate was 0.12% in 2010 to 0.38% in 2014.

We observed that SSI were the most frequent AEs (61.4%). Then, operative wound dehiscence (12.90%), hemorrhage at the operated site and phlebitis (5.20%) and thrombosis in the lower limbs with a percentage of 4.9% (Table 4).

DISCUSSION

The cohort of 55,879 surgical patients operated on in the outpatient setting of this study identified a percentage of AEs of 0.51%, of which 0.31% were of SSI and 0.19% of other surgical AEs, most frequently distributed among surgical wound dehiscence (12.9%), hemorrhage (5.20%), phlebitis (5.20%) and thrombosis of the lower limbs (4.90%).

A Spanish study conducted in 24 hospitals with 5,908 patients revealed 525 (8.8%) AEs and a mortality rate of 4.4%². A Dutch study, which reviewed 7,926 records in 21 hospitals, found that surgical AEs occurred in 3.6% of hospital admissions and accounted for 65% of all AEs. Nearly 40% of these events were infections, 23% were bleeding and 22% were injuries due to mechanical, physical or chemical causes¹³.

Another study on surgical AEs in pediatric hospitals in Canada identified a percentage of 37.2%¹⁶.

In Brazil, a study carried out in hospitals in Rio de Janeiro with 1,103 patients revealed an incidence of 3.5% of AEs. The ratio of patients who underwent surgical surgeries was 5.9%, with a mortality rate of 18.4%. The most frequent surgical AEs were those related to SSI (19.5%)¹¹.

There is little data published on surgical AEs in day hospital settings, perhaps due to the specificity of this type of care. Most of the times, contact with these patients occurs only at the time of the preanesthetic interview and essentially on the day of the surgery. This contributes to increasing the difficulties in the longitudinal monitoring of these patients after surgical procedures.

A study conducted in California (USA) with patients undergoing general surgical procedures combined with cosmetic surgery at outpatient level between 2005 and 2010 identified a percentage of venous thromboembolism of 0.57% in patients undergoing abdominoplasty, 0.20% in patients submitted to liposuction, 0.12% of venous thromboembolism in patients submitted to breast reduction and 0.28% in patients with facial surgery¹⁷.

Another study that aimed to quantify AEs in surgeries for surgical removal of basal cell carcinoma identified 149 (0.72%) AEs in a total of 20,281 procedures. The most frequent AEs were infection (61.1%), dehiscence and partial or total necrosis (20.1%) and hematomas and hemorrhages (15.4%)¹⁸.

Research done on dermatological surgeries to characterize AEs revealed that among 2,418 patients submitted to these procedures, there was a 2.0% rate of AEs. The most frequent were infection (64.0%), postoperative hemorrhage (20.0%) and dehiscence of the surgical wound (8.0%)¹⁹.

Table 2. Incidence of surgical adverse events in patients monitored according to the year of study in the day hospital. Salvador (2010-2014).

Period	N. monitored patients	Adverse events	
		n	(%)
2010	10,932	52	0.47
2011	10,470	51	0.48
2012	11,506	52	0.45
2013	12,054	47	0.38
2014	10,917	83	0.76
Total	55,879	285	0.51

Table 3. Incidence of surgical adverse events by type and per year.

Period	Monitored patients	Surgical site infection	Other adverse events	Total adverse events
Anos	n	n (%)	n (%)	n (%)
2010	10,932	38 (0.34%)	14 (0.12)	52 (0.47)
2011	10,470	30 (0.28%)	21 (0.20)	51 (0.48)
2012	11,506	37 (0.32%)	15 (0.13)	52 (0.45)
2013	12,054	29 (0.24%)	18 (0.14)	47 (0.38)
2014	10,917	41 (0.37%)	42 (0.38)	83 (0.76)
Total	55,879	175 (0.31%)	110 (0.19)	285 (0.51)

Table 4. Percentage distribution of surgical adverse events versus years studied. Salvador (2010-2014).

Eventos adversos 2010-2014 %	n	%
Surgical site infection	175	61.4
Thrombosis of lower limbs	14	4.9
Hematoma	7	2.4
Hemorrhage	15	5.2
Burn	2	0.7
Allergy on the operated area	5	1.7
Retinal detachment	3	1
Dehiscence	37	12.9
Prolene mesh rejection	2	0.7
Phlebitis	15	5.2
Catheter tip rupture	1	0.3
Abdominal distension	1	0.3
Fibrosis	5	1.7
Lymphocele	1	0.3
Pulmonary thromboembolism	1	0.3
Intestinal perforation	1	0.3
Total	100	285



A prospective study with 1,174 patients conducted at eight day hospitals over a three-year period aimed at assessing the relationship between surgeries and secondary contacts identified a rate of return to the day hospital of 1.21%, resulting in a wide variety of diagnoses. Among these, hemorrhage and hematoma (0.5%), infection (0.4%) and thromboembolic events (0.03%). The procedure with the highest complication rate was tonsillectomy (11.4%), surgically induced abortions (3.1%), and correction of inguinal hernias (1.2%)²⁰.

Based on the data described above, especially reported day hospital data^{18,19,20,21}, we understand that the incidence of AEs of 0.51% found in our study is lower than the rates reported in the cited studies (0.72%¹⁸, 2%²⁰ and 1.21%²⁰).

The most frequent AEs identified in our study, such as SSI (61.40%), dehiscence (12.90%), hemorrhage and phlebitis (5.20%) and thromboembolism (4.90%) are compatible with reported AEs in the described studies, but at much lower percentages than those reported for the cited day hospitals. This may be explained by the absence or difficulty of follow-up of these patients after

the procedure, unlike our study, which has a systematic follow-up of patients after discharge from the day hospital.

CONCLUSIONS

This study succeeded in achieving the proposed goal and answering its guiding question, insofar as it identified the incidence of surgical AEs at a day hospital, thus contributing to the advancement of knowledge of these disorders in outpatient surgical health care.

Because of limitations in data collection, we were unable to identify which surgical specialty was most involved in the occurrence of these AEs, nor to consider the significant increase in AEs occurred in 2014 when compared to the previous years (2010 to 2013).

The results of this study confirm that surgeries performed in day hospital regime are related to lower rates of surgical AEs. Nevertheless, follow-up of patients after discharge is fundamental to avoid underreporting and sub-registration of the data. Its absence might hide data and suggest unrealistic rates.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.



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