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OCCURRENCE OF ADVERSE EVENTS IN THE HEMODYNAMIC UNIT

OCORRÊNCIA DE EVENTOS ADVERSOS EM UNIDADE DE HEMODINÂMICA

LA OCURRENCIA DE EVENTOS ADVERSOS EN LA UNIDAD DE HEMODINAMIA

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ABSTRACT

Objective: to analyze the adverse events occurred with patients during procedures performed at a hemodynamic unit. **Method:** this is a quantitative, documentary, retrospective and cross-sectional cohort study through the analysis of the records in the books of nursing notes. Data were analyzed in SPSS and descriptive statistical analysis was performed and presented in the form of tables. **Results:** there were 84 adverse events related to medical devices or equipment and clinical procedures or processes. The main causes are lack of material resources and failure in the service settings. The consequences identified were delay of diagnosis and treatment and the worsening of the clinical situation, which were not notified. **Conclusion:** the study showed that the occurrence of adverse events is multifactorial and reveals the importance of improving the management regarding the physical structure and materials. Furthermore, adverse events are considered an important indicator of the quality of assistance, since they allow an organizational diagnosis and changes in the structure and work processes to achieve a culture of institutional safety. **Descriptors:** Patient Harm; Hemodynamics; Patient Safety; Nursing; Patient-Centered Care; Quality of Health Care.

RESUMO

Objetivo: analisar os eventos adversos ocorridos com pacientes durante procedimentos efetuados em uma unidade de hemodinâmica. **Método:** trata-se de estudo quantitativo, documental, retrospectivo e de coorte transversal realizado por meio da análise dos registros nos livros de anotações de enfermagem. Estudaram-se os dados no SPSS e realizou-se a análise estatística descritiva apresentando em forma de tabelas. **Resultados:** identificaram-se 84 eventos adversos relacionados aos dispositivos ou equipamentos médicos e aos procedimentos ou processos clínicos. Verificou-se que as principais causas consistem na falta de recursos materiais e na falha na estrutura do serviço. Identificaram-se, como consequências, o atraso do diagnóstico e do tratamento e o agravamento da situação clínica. Destaca-se que esses agravos não foram notificados. **Conclusão:** verifica-se que a ocorrência dos eventos adversos é multifatorial e revela a importância da melhoria da gestão quanto à estrutura física e de materiais. Consideram-se, além disso, os eventos adversos como um importante indicador da qualidade da assistência, pois permitem um diagnóstico organizacional e as mudanças na estrutura e processos de trabalho para o alcance de uma cultura de segurança institucional. **Descritores:** Dano ao Paciente; Hemodinâmica; Segurança do Paciente; Enfermagem; Assistência Centrada no Paciente; Qualidade da Assistência à Saúde.

RESUMEN

Objetivo: analizar los eventos adversos ocurridos con pacientes durante procedimientos realizados en una unidad de hemodinamia. **Método:** se trata de un estudio cuantitativo, documental, de cohorte retrospectivo y de corte transversal a través del análisis de los registros en los libros de notas de enfermería. Los datos fueron analizados en SPSS y el análisis estadístico descriptivo se presenta en forma de tablas. **Resultados:** se identificaron 84 eventos adversos relacionados con dispositivos médicos o equipos y procedimientos o procesos clínicos. Se encontró que las principales causas son la falta de recursos materiales y el fracaso en la estructura del servicio. Se identificaron como consecuencias, el retraso del diagnóstico y tratamiento y el empeoramiento de la situación clínica, las cuales no fueron notificadas. **Conclusión:** parece que la ocurrencia de eventos adversos es multifactorial y revela la importancia de la mejora de la gestión en cuanto a la estructura física y material. Se consideran, además, eventos adversos como un indicador importante de la calidad de la asistencia, ya que permiten un diagnóstico organizacional y los cambios en la estructura y los procesos de trabajo, para lograr una cultura de seguridad institucional. **Descritores:** Daño del Paciente; Hemodinámica; Seguridad del Paciente; Enfermería; Atención Dirigida al Paciente; Calidad de la Atención de Salud.

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INTRODUCTION

Hemodynamic Units (HDU) are high-complexity health services that feature a highly technological apparatus for performing minimally invasive procedures. These units have a high-cost physical and functional structure, in addition to a care team duly qualified and trained to ensure the quality of medical and nursing care to patients with diseases of the cardiovascular system.¹⁻²

In these units, endovascular procedures are performed, percutaneously, most of the times, under local anesthesia and/or sedation, guided by fluoroscopy, a radiological procedure that allows viewing, in real time, the anatomical structures and planning the best strategy for intervention, requiring administration of contrast medium into the bloodstream. At the end of the procedure, the patient is referred to the post-anesthetic recovery room, where he/she remains under hemodynamic monitoring and on bed rest with the catheterized limb immobilized.²⁻⁴

These are high-complexity procedures, due to the handling of complex anatomical structures of the heart, with risks of complications and clinical conditions of greater risk, requiring medical and nursing staff qualified, efficient and responsive to act effectively and quickly, in the safe care of patients.⁵

Patient safety promotion consists of reducing the risk of unnecessary damage associated with health care to a minimum acceptable level, which refers to what is viable using current knowledge, available resources and the context in which the assistance is performed.⁶

The World Health Organization (WHO) defines adverse events as incidents arising from health care that result in some type of injury to the patient, with impairment of the structure or function of the body and/or any harmful effects, which can be physical, social or psychological, including diseases, injuries, pain, incapacity or death.⁶

Annually, the estimates show the occurrence of adverse events of around 4% through 16% in all hospital inpatients, and 50% are considered preventable.⁷ Data from the First Hospital Care Safety Yearbook in Brazil show that, every five minutes, three Brazilians die in the country from adverse events that occurred during the health assistance, totaling 829 deaths per day. These events result in a mortality rate higher than those associated with cancer, homicide, armed robbery and traffic accidents.⁸

The occurrence of adverse events is considered a serious problem related to patient safety and quality of care. These events result from deficiencies in health care, directly affecting patients' health and the economic repercussions on social and health expenditures. Adverse events are reflected in the quality of care and represent an instrument to assess the quality of care.⁶⁻⁹

A quality assistance, free of adverse events, represents a patient's right, and health services are responsible for providing an effective, efficient and safe assistance.⁶ There is, in addition to the intense technological advance in interventional cardiology, the emergence of the concern for improving, both structurally as organizationally, the laboratories of cardiovascular intervention to guarantee the effectiveness of work processes.^{3,9}

At health services of reference in cardiovascular high complexity, actions for promoting patient safety and improving quality are regulated by Decree 210/2004, of the Brazilian Ministry of Health,¹⁰ and by RDC 36/2013, of the National Health Surveillance Agency (ANVISA),¹¹ which recommends the interaction with the HDU Technical Surveillance Commission for notification of adverse events related to materials and equipment used in the service. It allows, therefore, health services to adopt measures with quality standards appropriate to their reality, in accordance with the laws in force.

In this way, this study allows knowing the profile of adverse events in the HDU, a service that involves an arsenal of high-tech and high operational cost and that is still little explored in this context. Moreover, there should be the elaboration of actions to determine a policy of prevention of adverse events, as well as the awakening of professionals for the complexity of work processes in this health sector and the importance of continuous surveillance for patient safety in the trans-operatory of percutaneous cardiovascular procedures.

OBJECTIVE

- To analyze the adverse events occurred with patients during procedures performed at a hemodynamic unit.

METHOD

This is a quantitative, documentary, retrospective and cross-sectional cohort study, conducted at a hemodynamic unit (HDU) of a teaching hospital in the Midwest region of Brazil. The institution is part of the

Sentinel Network of the National Sanitary Surveillance Agency (ANVISA), has a Patient Safety Core (PSC), and one of its actions is the active and qualified notification of adverse events and technical complaints related to health products, as well as the continuing education of professionals.

In the HDU, percutaneous procedures are performed in morning and afternoon shifts and in the endovascular, neurological and cardiological specialties. The health team includes interventional doctors, anesthesiologists, Radiology technicians and the nursing team. The nurse acts in the management of the unit and of the provided assistance, and the technicians are responsible for aiding in the procedures.

The data source used were books of nursing records used by the unit staff with the purpose of socializing the complications of their duty to the following shift and for the management. The study was delineated by the adverse events occurred and recorded in these books, in the period from January 2014 through November 2015.

Data collection occurred between August and November 2015, from the systematic reading of the annotations, extracting the records that showed the occurrence of adverse events. The study used a structured and validated¹² instrument containing questions such as date, time, categories of types of adverse events, the consequences for the patient and the professional conduct regarding the occurrence.

The types of adverse events were classified according to the definitions of the WHO:

clinical administration; clinical process/procedure; documentation involved; hospital infection; intravenous medication/fluids; blood transfusion; nutrition; gas/oxygen; medical equipment; behavior - professionals and patients; accidents with the patient; structure and management of organizational resources.⁶

The data were analyzed in the software Statistical Package for Social Sciences (SPSS), version 20.0, and the descriptive statistical analysis was performed showing absolute and relative frequencies.

The Research Ethics Committee of the Clinical Hospital of the Federal University of Goiás approved the study (Protocol 064/2008), linked to the matrix survey entitled “Analysis of occurrences of adverse events at a hospital of the Sentinel Network of the Midwest Region”.

The study followed all ethical aspects, in accordance with national and international standards of ethics in research involving human beings.

RESULTS

There were 84 adverse events described in the books of nursing records of the unit, during the period of 23 months. In the HDU, an average of 55 procedures are performed per month, and the most frequent are arteriography, cardiac catheterization and angioplasty.

There were 1,269 procedures performed during the study period, which indicates the prevalence of 6.6% of adverse events. Table 1 shows the characteristics of the visits.

Table 1. Characteristics of the visits to patients of the hemodynamic unit of a teaching hospital in the Midwest region. Goiânia (GO), Brazil, 2014-2015.

Characteristics	n	%
Medical specialty		
Endovascular	42	50.0
Neurology	09	10.0
Cardiology	12	14.3
Uninformed	21	25.0
Type of intervention		
Diagnostic	48	57.1
Therapeutic	36	42.9
Examination/procedure performed		
Arteriography	25	29.8
Angioplasty	17	20.2
Cardiac catheterization	11	13.1
Chemoembolization/embolization	09	10.7
Endoprosthesis	02	2.4
Implant of vena cava filter	01	1.2
Pulmonary function test	01	1.2
Uninformed	18	21.4
Total	84	100

Most adverse events related to medical equipment (n=38; 45.2%), highlighting situations such as loss of connections,

unavailability and malfunction of equipment, according to the reports below.

During the procedure of the patient S., there was the rupture of the hard MSB catheter guidewire. (R66)

The catheterization of the patient D. was not performed because of a defect in the polygraph, which was solved by the clinical engineering. (R49)

The examination of the patient J. was rescheduled due to lack of 5F introducer (R36)

The adverse events related to Clinical Procedures/Processes (n=26; 31.0%) refer to complications during interventions and inadequate procedures.

During arteriography and embolization of cerebral aneurysm, the patient had a thrombus at the end of the procedure. Request of two bottles of specific medicines. At 18:50h, the patient was referred to surgical ICU intubated. (R30)

Patient remained under observation because of the bleeding and hematoma in the inguinal region, on the puncture site. Specific medication (protamine) was required to contain the bleeding. (R50)

Patient started the arteriography in the arm, but without success. After removing the catheter, a brachial artery obstruction was observed, and the patient was referred to the surgical center for clearance. (R54)

The adverse events related to Resource Management/Organizational Management (n=7; 8.3%) referred to the lack of human resources and organization of teams, as explained below.

The angiographies could not be performed in the morning period due to lack of an anesthesiologist. (R04)

Patient was prepared for angioplasty; however, the responsible physician did not attend it. The exam was suspended and rescheduled. Patient was discharged home. (R43)

In relation to Clinical Administration, there are failures in the scheduling of procedures and an inadequate response to the emergency in five (6%) adverse events, according to the reports below.

Patient came to the unit at 10 AM to undergo the examination, but without any companion and medical chart. (R29)

Angioplasty was performed in patient T., the 2nd procedure was not successful, CRA at 6 PM with reversion, 2nd CRA without success, death at 6:15 PM. (R54)

In adverse events related to Documentation (n=4; 4.8%), the requisitions of materials required to procedures lack authorization.

The patient J.M.'s chemoembolization was not performed due to lack of authorization of the list of materials. The patient was informed regarding the occurrence and the procedure was rescheduled. (R32)

The adverse events related to Intravenous drugs/fluids correspond to problems since supply to administration. These events occurred less frequently in this study (n=2; 2.4%) and are highlighted in the following report.

Two cerebral arteriographies were performed. The procedures took too long because of the poor quality of the provided guidewire (hard), a fact that exposed patients to a greater amount of contrast/radiation, as well as professionals in the room. (R72)

There were problems in the supply of energy in relation to the adverse events identified in the category Structure (n=2; 2.4%).

During the realization of the endoprosthesis, the energy went off, and generator kept the equipment on. The patient was intubated and the procedure was interrupted due to lack of foresight of restoration of the general energy. Patient referred to the surgical ICU. (R38)

Table 2 shows the characteristics of the adverse events occurred.

Table 2. Characteristics of adverse events occurring in patients submitted to procedures in the hemodynamic unit of a teaching hospital in the Midwest region. Goiânia (GO), Brazil, 2014-2015.

Characteristic of the adverse event	n	%
Time of the occurrence		
Morning	47	56.0
Afternoon	35	42.0
Uninformed	2	2.0
Causes		
Lack of material resources	30	35.7
Flaws in the service settings	12	14.3
Endogenous factors of the patient	11	13.1
Flaws in human management/dimensioning	08	9.5
Wrong procedure	05	6.0
Flaws in the communication process	02	2.4
No records	16	19.0
Involved professional		
Doctor	36	42.9
Nursing and medical teams	32	32.1
Nurse	09	10.7
Nursing technicians	04	4.8
Doctor and the clinical management/engineering sector	03	3.6
Consequences for the patient		
Delay in diagnosis/treatment	40	47.6
Worsening of the clinical Picture	13	15.5
Need for additional procedure	07	8.3
Hemorrhage/bleeding/hematoma	04	4.8
Death	02	2.3
No records	18	21.4
Total	84	100.0

DISCUSSION

This study showed the occurrence of 84 adverse events in the HDU, with a prevalence of 6.6%, a low value considering the number of procedures performed during the same period. Similar studies, performed at a surgical center and at an emergency room, showed that the prevalence of adverse events was low, compared to the high demand and turnover of patients in these units. The authors of these studies concluded that this result relates to the lack of notification or underreporting of adverse events.¹³⁻⁴

The notification of complications during health assistance is an effective strategy for managing, reducing and controlling the occurrence of adverse events.¹⁴ In the studied HDU, the only records of adverse events were in books of Nursing Records; thus, in the absence of a notification system, these records, performed with as much information as possible, are fundamental to identify and manage the incidents in order to ensure communication between team members and legal support for the nursing professional.¹⁵⁻⁶

This study showed that the most frequent adverse events related to vascular specialty and arteriography; these are high-complexity procedures and involve several pathologies and technically qualified personnel. Its success requires a careful evaluation of the

work process in order to identify the failures during the assistance and propose effective strategies for the reduction of incidents.¹⁷

There were no studies about adverse events at HDU.

The most frequent type of adverse event, with a recorded percentage of 45.2%, relates to medical equipment, which shows the importance of managing the material, the need to develop actions for the continuous and systematic evaluation of the resources required for health procedures, prior to any procedure, and to maintain effective communication with the sector of material resources, responsible for the maintenance of the structure for the proper functioning of the equipment of the unit.

In relation to clinical procedures/processes, the reports evidence complications for the patient during procedures. Considering the complexity of these processes, the occurrence of complications is inevitable, requiring an agile and qualified team for preventing and controlling such complications.⁹

The literature also report complications related to the same procedures.¹⁸⁻⁹ A study on immediate complications related to cardiac catheterization identified that they may be local or systemic, and the most frequent were vascular, vasovagal, ischemic and allergic complications.¹⁸ Another study pointed out

vascular complications after a transfemoral cardiac catheterization procedure.¹⁹ The presence of comorbidities and other factors, such as diabetes mellitus, ischemic heart disease and smoking, as well as the puncture site and the time of the procedure, was decisive for the occurrence of complications.¹⁸⁻²⁰

The other adverse events highlighted in the reports reveal the lack of management of human resources, the flaws in the communication process, the lack of planning for the acquisition and use of material resources and infrastructure, such as the interruption in the energy supply during the procedure. To circumvent these contingencies, the hospital should have an own generator to avoid damage to patients during complex procedures. Studies conducted in other hospital units show that the occurrence of failures in the organization of the service and the care process are recurrent.^{13-4,20}

Other adverse events occurred with the patients, such as persistent bleeding and hematomas, obstruction of the brachial artery, excessive exposure to contrast and death, which can increase the time of hospitalization, creating the need for additional procedures, and can also cause irreversible consequences for the patient.^{12,21}

During the care practice, the occurrence of an adverse event is not equally distributed among patients, and the same individual can suffer from multiple events during the period of hospitalization.²² The literature shows that the occurrence of these events is multifactorial.^{20,23} Therefore, the characteristics of adverse events and the organizational context should be investigated for a systemic and appropriate approach of these occurrences.

This study highlighted that the types of adverse events that occurred in the HDU are mainly related to the organizational management, a similar result found in other studies^{13-4,18}, as well as to lack of foresight and provision of material and lack of equipment maintenance, which led to the suspension of surgeries, even though the patient was already anesthetized.¹³

Decree 210 of 15 June 2004, of the Ministry of Health of Brazil, regulates high-complexity cardiovascular services and establishes that the units must have all materials and equipment required, in perfect state of conservation and functioning, in addition to a care team duly qualified and skilled, assuring the quality of assistance to patients. The

coordinating nurse is responsible for managing these resources.¹⁰

The professionals involved in the occurrence of adverse events are mainly doctors and nursing staff, since they are professionals who provide direct care to patients during procedures in the HDU. There were no records of adverse events related to Radiology technicians.

The team is responsible for guaranteeing the patient's well-being and conducting the procedure free of adverse events. In case of proven harm to the patient, due to incompetence, recklessness or negligence, these professionals may respond to civil, criminal and ethical proceedings.²⁴⁻⁵

The delay in diagnosis or treatment, the worsening of the clinical situation and the need for additional procedures are considered the main consequences observed in this study. Situations related to delay negatively affect the patient and lead to unnecessary spending of resources, bearing in mind that some procedures were suspended with an anesthetized patient in the room.^{12,20}

The worsening of the clinical situation and the need for additional procedures are the most relevant consequences in the HDU context. The risks related to the procedures, added to the failures of the team, can result in avoidable serious consequences.

Some less frequent consequences related to complications in the puncture site, ranging from a discreet hematoma to an active bleeding, requiring, in some cases, surgical interventions and/or blood transfusions.²⁶⁻⁸

A study on the complications related to the puncture site in patients undergoing percutaneous transluminal coronary angioplasty found the occurrence of ecchymosis, hematoma and loss of vessel permeability.¹⁹

The team is also responsible for the proper management of the puncture site after the procedure, with the removal of the catheter, compressive dressing, monitoring for signs of bleeding and the immobilization of the limb for about four hours, in case of radial artery puncture, and six hours, in case of femoral puncture.²⁶⁻⁷

Adverse events can cause the loss or uselessness of limbs, temporary weakness, problems in the consciousness and damage to physical, mental or moral development.¹⁷ A study about the adverse events in the surgical clinic of a hospital in midwestern Brazil showed that most of these events resulted in temporary damage or in no apparent damage, requiring monitoring. A serious consequence of these events was the death.¹²

The survey of these two aspects is compromised by the lack of records in relation to causes and consequences of adverse events, which represent a significant value in the study sample. There is need for compromise with the nursing records and for a specific system for the notification of these incidents.

The conducts in case of an adverse event are determinants for the proper management and correction of flaws. The present study showed the prevalence of administrative and clinical behaviors, which were determinant for the proper management of the adverse event. Nevertheless, the occurrence of delays and interruptions in the completion of the procedures may aggravate the patient's clinical picture, and, consequently, create the need for additional procedures.^{13,17}

In 31% of the cases, corrective conducts were adopted, which constitute a proactive action to avoid other adverse events of the same order. The planning of necessary resources and the implementation of preventive maintenance of the equipment are necessary. The HDU team, along with support services of the institution, should implement these actions.

There was no evidence on the notification of adverse events to the sector of Sanitary Surveillance or to the Patient Safety Core. The notification is an important tool to identify adverse events, once it allows assessing the indicator of quality of care and developing policies for continuous improvement focusing on the patient.²⁰ In this way, all adverse events occurring at health services should be notified.^{12,20,28}

Despite the emergence of initiatives and policies to improve the engagement of the patient, the lack of information about adverse events and their causes are the main determinants found for new occurrences, in addition to damaging the action of managers for the quality of care focused on safe care.²⁹

Decree 529, April 1, 2013, which instituted the National Program for Patient Safety, establishes a set of measures to prevent the occurrence of adverse events at health care services, including the deployment of the Patient Safety Core and the creation of a System for Notification of Adverse Events.²⁸

This study identified that these measures were in the process of implantation in the studied hospital. If they are followed, they will be able to contribute to the production, systematization and dissemination of knowledge about adverse events, as well as

for the creation of a safety culture in the UHD and at the hospital.

It is important to promote a safety culture in all areas of health services, building a structural component related to values, attitudes, skills and behaviors that determine the commitment with the management of the health and safety of the patient. Furthermore, adverse events should be understood not simply as problems, avoiding blaming the professionals who commit unintentional errors and treating the issue as an opportunity to improve health care.³⁰

Moreover, the development of a safety culture, the practice of records, discussion of the circumstances when the adverse events occurred, as well as the organizational and professional conduct in case of damages is the right path to follow for the transformation of reality at health care institutions.²⁰

CONCLUSION

Adverse events are important indicators of the quality of assistance, and must be notified in order to allow the organizational diagnosis and changes in the structure of service and work processes, to achieve a culture of institutional safety.

There was the occurrence of 84 adverse events in the HDU, and the majority was caused by failures of medical equipment and clinical procedures and processes.

The occurrence of adverse events may have led to the delay in the disease diagnosis, the worsening of the clinical picture, the need for additional procedures, bleeding and/or bruising and death. Nonetheless, this study found no evidence on the notification of adverse events to the sector of Sanitary Surveillance or to the Patient Safety Core.

The HDU does not own a proper instrument of notification of adverse events and data collection was limited to nursing records, which may not reflect the exact number of occurrences. These records are performed by the nursing staff and, in many cases, are little comprehensive in their reports, possibly because of transcripts of medical reports.

There is a need to raise awareness and stimulate the professionals about the importance of notification for the institutional diagnosis and implementation of measures to prevent the occurrence of adverse events, as well as the implementation of the permanent continuing education with a view to professional training and development of a safety policy on assistance to these patients.

Furthermore, new studies should be developed regarding, specifically, preventive

strategies of adverse events that occurred during diagnostic and treatment procedures in the HDU with the incorporation of scientific evidence in the practice of health professionals.

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