

ADVERSE EVENTS IDENTIFIED AMONG PATIENTS UNDERGOING CORONARY ANGIOGRAPHY AND/OR TRANSLUMINAL CORONARY ANGIOPLASTY

Eventos adversos identificados em pacientes submetidos à coronariografia e angioplastia

Eventos adversos identificados en pacientes sujetos a coronariografía y angioplastia

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ABSTRACT

Objectives: To identify the adverse events that occurred in patients submitted to coronariography and / or coronary transluminal angioplasty and to propose an instrument that would allow the implementation of the nursing process. **Methods:** Exploratory, prospective, quantitative approach. Data were collected from June to September 2017, at the Cardio-Intensive Unit of a Hospital in *Rio de Janeiro*. **Results:** The most frequent adverse events related to cardiac catheterization involved vascular manifestations (13.3%), pain (50%) and skin lesions (40%). **Conclusion:** Although catheterization is the most eligible for the diagnosis and treatment of coronary diseases, it still presents adverse events that cause great discomfort to the patient and increase the time and costs of hospital admission.

Descriptors: Cardiovascular diseases, Cardiac catheterization, Patient safety.

RESUMO

Objetivos: Identificar os eventos adversos ocorridos em pacientes submetidos à coronariografia e/ou angioplastia transluminal coronária e propor um instrumento que viabilize a implementação do processo de enfermagem. **Métodos:** Pesquisa de caráter exploratório, prospectivo, com abordagem quantitativa. Os dados foram coletados de junho a setembro de 2017, na Unidade Cardio-Intensiva de um Hospital do Rio de Janeiro. **Resultados:** Os eventos adversos mais frequentes relacionados ao cateterismo cardíaco envolveram manifestações vasculares (13,3%), dor (50%) e lesões de pele (40%). **Conclusão:** Apesar de o cateterismo ser o mais elegível para o

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diagnóstico e tratamento das coronariopatias, ainda apresenta eventos adversos que causam grande desconforto ao paciente e que aumentam o tempo e os custos da internação hospitalar.

Descritores: Doenças cardiovasculares, Cateterismo cardíaco, Segurança do paciente.

RESUMEN

Objetivos: Identificar los eventos adversos ocurridos en pacientes sometidos a la coronariografía y / o angioplastia transluminal coronaria y proponer un instrumento que viabilice la implementación del proceso de enfermería. **Métodos:** Investigación de carácter exploratorio, prospectivo, con abordaje cuantitativo. Los datos fueron recolectados de junio a septiembre de 2017, en la Unidad Cardio-Intensiva de un Hospital de Río de Janeiro. **Resultados:** Los eventos adversos más frecuentes relacionados con el cateterismo cardíaco involucraron manifestaciones vasculares (13,3%), dolor (50%) y lesiones de piel (40%). **Conclusión:** A pesar de que el cateterismo es el más elegible para el diagnóstico y tratamiento de las coronariopatías, todavía presenta eventos adversos que causan gran incomodidad al paciente y que aumentan el tiempo y los costos de la hospitalización.

Descriptores: Enfermedades cardiovasculares, Cateterismo cardíaco, Seguridad del paciente.

INTRODUCTION

According to the Ministry of Health (Brazil),¹ coronary diseases of ischemic origin is the most predominant type of cardiovascular disease. In 2010, its specific mortality rate (deaths per 100,000 inhabitants) was 52.4%. Ischemic heart disease is more frequent among elderly people, but it is not a natural consequence of aging (senescence). This disease also affects women after menopause probably due to protection by female hormones.

PINHEIRO (2010)² states that ischemic heart disease is caused by an obstruction of the coronary arteries and is the result of the formation of atherosclerotic plaques. Atherosclerotic plaques are made of fibrous tissue and cholesterol that grow and accumulate in the vessel walls, hindering or preventing the passage of blood. Consequently, necrosis of myocardium can occur due to ischemia, which characterizes myocardial infarction. Because of the narrowing of the artery lumen, the necessary treatment is to clear it and resume its normal blood flow in order to reduce complications.

Coronarography is an invasive, effective and widely used procedure to identify the ischemic artery. It is performed to define the extent and severity of the heart disease, helping to decide whether or not to approach the injury.⁹

BUZATTO and ZANEI (2010)³ define cardiac catheterization as the introduction of a catheter until reaching the aorta and left ventricle through a radial, brachial or femoral puncture of the artery. The image formation of the coronary arteries occurs through the injection of a contrast material by the catheter, and this procedure is indicated for diagnostic evaluation when there is need for confirming or determining the extension of the coronary disease, as well as for the definition of its severity and decision on how to approach the lesion (angioplasty).

Cardiac catheterization is the most suitable procedure for the diagnosis and treatment of coronary diseases. Studies show that, despite the growing technological advance and the use of contemporary techniques of cardiac catheterization, adverse events related to these procedures are still observed.

In one of the first publications on adverse events that arise during cardiac catheterization, BRAUNWALD and GORLINÓ (1968)⁴ analyzed 12,367 studies carried out in 16 different laboratories over two years. They reported that major adverse events (death, severe arrhythmia, deep hypotension, arterial perforation, catheter problems, severe allergic reaction, embolism, heart complications, severe bleeding, and pneumothorax) occurred in 3.4% of patients.

WYRNAN et al. (1988)⁵ define the adverse events arising during cardiac catheterization as any intercurrent occurring within 24 hours after the procedure. These adverse events cause great discomfort to the patient, increasing hospitalization time and intervention costs. According to BRITO JÚNIOR et al. (2007),⁶ the most frequent events related to cardiac catheterization are: vascular, ischemic, arrhythmic, and vasovagal manifestations; reactions resulted from the use of contrast material; skin lesions; pain; and incorrect medication administration.

The quality of care and patient safety in health care institutions are global concerns. Data showed that among the 33.6 million hospitalizations, approximately 44,000 to 98,000 patients died as a result of adverse events (CASSIANI, 2010).⁷ Such events are viewed by the Brazilian Ministry of Health⁸ as an incident that results in harm to the patient. This damage is serious enough to increase the hospitalization time, leading to dysfunction or temporary/permanent disability at the time of discharge. In some cases, both situations can occur.

The nursing staff, as the largest group of professionals that delivers direct and uninterrupted care to patients, needs to be alert to adverse events, aiming to provide safe and quality care in order to prevent damage to patients. According to the World Health Organization (WHO),⁹ safety is to reduce the risk of unnecessary harm associated with health care to an acceptable minimum.

Patient safety is one of the great challenges of health care today. Recognizing the occurrence of adverse events has been leading health care managers to seek alternatives to reduce risk situations within institutions. It is essential that nurses, as professionals that provide care uninterruptedly, be alert to measures relevant to patient safety.

Bearing in mind the adverse events related to the performance of cardiac catheterization procedures and the growing concern with the patient's safety, a study needs to be carried out in order to analyze the occurrence of these complications for reducing their incidence.

Given the great relevance of these procedures for investigating and treating coronary diseases and the need to provide safe and targeted care for these patients affected by them, it is evident the importance of creating an instrument

capable of evaluating and systematizing nursing in front of events related to nursing care for clients undergoing these procedures.

Hence, the following research question was developed: "What adverse events occur in patients undergoing coronary angiography (CA) and/or transluminal coronary angioplasty (TCA) admitted to the cardiac intensive care unit (CICU) of a university hospital?" This study aims at identifying the adverse events among patients undergoing CA or TCA so that they could be prevented and proposing an instrument for implementing the nursing process.

METHODS

This exploratory, descriptive, prospective research with a quantitative approach was carried out from June to September 2017 at the CICU of a university hospital in the Rio de Janeiro State, Brazil. This CICU had nine hospital beds with 31 hospitalizations/month on average from January to September 2016. Furthermore, 23% of the patients admitted to this CICU were submitted to CA and/or TCA.

The inclusion criteria were: (1) being able to answer the questions, (2) and hospitalization time ≥ 48 h in the CICU, being 24 h before and 24 h after the CA and/or TCA.

Thirty patients participated in this study. They were evaluated for 48 hours (24 hours before and 24 hours after the procedure) in order to identify the occurrence of adverse events.

The study was approved by the Research Ethics Committee from the Hospital Universitário Pedro Ernesto under the *Certificado de Apresentação para Apreciação Ética* (CAAE) [Certificate of Presentation for Ethical Appreciation] No. 66724617.6.0000.5259 and complied with the Resolution No. 510/2016 from the Brazilian National Health Council, which defines the ethical standards of research involving human participants. The participants agreed to participate in the research by signing an informed consent form.

Data were collected by applying a form for identifying the subjects' profile and the adverse events from which they suffered while undergoing CA and/or TCA. The form consists of 24 items divided into 4 steps: (1) identification, (2) pre-procedure evaluation, (3) intra-procedure data, and (4) post-procedure evaluation.

The first step is to obtain identification data from the participants, preserving anonymity. At this stage information about the participant such as initials of his/her name, gender, age, weight, and height are omitted.

An evaluation was performed during the second stage in order to identify risk factors in the subject, in addition to evaluating the correct preparation before the procedure, including fasting, avoiding hypoglycemic agents and oral anticoagulants, allergic desensitization (if necessary), hydration for renal protection, among others. At this stage it was also evaluated whether the patient knew the procedure

that he/she would undergo, enabling the nurse to guide him/her before the procedure.

Intra-procedural data were collected during the third step. At this stage, the performed procedure was evaluated, the gauge of the introducer needle, access route, intercurrents, and need for sedation during the procedure.

In the fourth stage, the occurrence of possible adverse events was observed through physical examination and verbal reports, among them hematomas, bleeding, pseudoaneurysm, arrhythmia, skin lesion and pain.

The collected data were inserted into Microsoft Excel spreadsheets and analyzed by means of descriptive statistics. Absolute and relative frequencies were evaluated and discussed based on the literature.

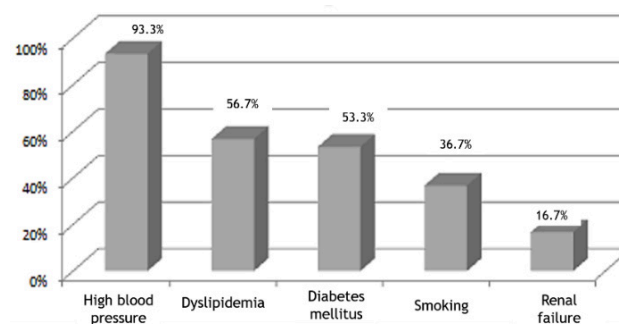
RESULTS

Considering the 30 participants, 18 (60%) were male and 12 (40%) were female. It is necessary to pay attention to the numbers regarding the procedures that women underwent. There are studies on their underutilization with regard to women and on the difficulty in diagnosing women with acute coronary syndrome, since the symptoms presented are atypical, increasing the occurrence of more serious complications (FINATO, NAKAZONE, and FRANCE, 2005).¹⁰

Concerning the participants' age group, 73.3% were elderly people. The youngest participant aged 41 years old and the oldest one aged 82 years old. The average age was 65 years old for men and 62.5 years old for women.

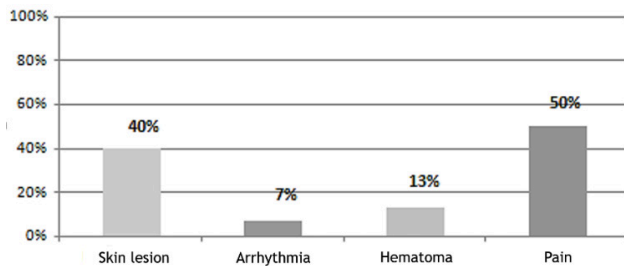
Risk factors for coronary artery disease were observed in the participants (**Figure 1**). The most frequent risk factors were high blood pressure (93.3%), diabetes mellitus (53.3%), dyslipidemia (56.7%) and smoking (36.7%). Of these, 86.7% had two or more risk factors. Studies showed that these risk factors worked in a synergic way to increase the likelihood of occurring cardiovascular events.¹¹

Figure 1 - Risk factors for coronary artery disease.



As can be seen in **Figure 2**, pain was the most predominant adverse event that occurred among the participants after undergoing CA and/or TCA, followed by skin lesion, hematoma, and arrhythmia.

Figure 2 - Adverse events that occurred after the procedure.



DISCUSSION

Vascular manifestations

According to the study results, 13.3% of the subjects had a hematoma. In contrast to other studies, no difference between procedure route and gauge of the introducer needle was found that could bring about adverse vascular events. A 6 French introducer and a radial route were used in 50% of the patients who had these complications, whereas a 7-French introducer and a femoral route were used in the rest of them.

With regard to the difference between the participants' gender, all participants were female, corroborating what was observed by DUMONT et al.¹² when they reported that being female is a predictor for adverse vascular events.

The main adverse vascular events reported in the literature are bleeding at the access sites, thrombosis, arteriovenous fistulas and the formation of pseudoaneurysms. These events are often related to lumen catheters, prolonged procedures, advanced age and use of anticoagulants.⁶

Adverse events of vascular origin are more frequent when the puncture was performed using the femoral route or when an introducer with a large-gauge needle was used. Radial puncture was performed in 80% of the participants and a 6 French introducer was used in 90% of them. In addition to reducing the incidence of vascular complications, using the radial route and introducers with a small-gauge needle facilitate early walking of the patient and reduce the discomfort generated by the procedure. However, it requires greater ability from hemodynamicists.¹²

There has been a strong trend since 1989, when LUCIAN CAMPEAU¹³ introduced arterial access through the radial artery to perform cardiac catheterization by using this route, due to the reduced risk of complications associated with the access site. Radial arteries are easily compressible, superficial vessels, which allows reducing the risk of bleeding, and blood flow through the hand is ensured by the ulnar artery in cases of radial occlusion.¹²

According to the Directive on Percutaneous Coronary Intervention of the Brazilian Society of Cardiology and the Brazilian Society of Cardiac Hemodynamics and Intervention,¹⁴ advanced age, female gender, low body weight, chronic kidney failure, and anemia are also predictors for vascular complications.

Ischemia

Acute myocardial infarction related to CA or TCA was not reported in this study, which is corroborated by the literature. A study showed that the occurrence of acute myocardial infarction related to these procedures is not high.¹⁵ Classified by the Brazilian Society of Cardiology¹⁴ as a major complication, acute myocardial infarction is considered¹⁶ a pseudo-complication, that is, it could occur even if the patient was not submitted to the procedure. This happens because severe cardiac pathologies, including acute myocardial infarction, worsen over time in several ways.

Left coronary trunk lesions, diagnosis of ischemic heart disease and systemic high blood pressure contribute to the incidence of an ischemic adverse event. Acute myocardial infarction may occur at a very variable frequency, associated with cardiac catheterization. The occurrence of this adverse event increases in patients with unstable angina and in those undergoing coronary angioplasty.¹⁴

Arrhythmia

Reports on the occurrence of arrhythmias were observed in 6.6% of the participants. Only atrial fibrillation (AF) affected these participants. However, AF was already present in these patients' prior electrocardiograms. Thus, it was not possible to consider AF as an adverse event, as there was no report on arrhythmia known to be related to CA or TCA.

The intracoronary or intracardiac injection with iodinated contrast agent can cause arrhythmia, reducing the depolarization frequency of the sinus node which causes transient bradycardia and even sinus arrest, slowing the conduction at the atrioventricular node, increase in the PR interval. Furthermore, it is possible the occurrence of advanced atrioventricular blocks and changes in the T-wave configuration of unknown significance.^{15,16}

Vasovagal reactions

According to the study findings, there were no vasovagal reactions. One possible explanation for this fact is that 53.3% of the research subjects knew the procedure which they would undergo and denied any type of anxiety or discomfort related to it.

Vagal reactions triggered by anxiety or pain occurred in fewer recent cases, possibly due to the wide dissemination of the test, which reduces tension, makes sedation more effective and increases the staff's experience.

There was a female nurse responsible for performing prior nursing consultation in the institution in which the study was carried out. This nurse provided information about cardiac catheterization and delivered care after it was executed. On the day of the procedure, she made another appointment to evaluate the correct patient's preparation for the procedure, such as fasting time, avoidance of consuming oral hypoglycemic and anticoagulant agents. Furthermore, she provided information about the procedure and removed any remaining doubts.

The initial contact with the staff and the possibility of knowing the procedure and removing doubts made the participants feel safer. This may explain why only two participants (6.6%) were sedated during cardiac catheterization.

Reactions to iodinated contrast agents

The use of iodinated contrast agents can cause adverse events, including allergies and contrast-induced nephropathy.

Little research has been done on allergic reactions due to contrast agents probably because of the detailed investigation of the patient, which allows knowledge of previous allergies, and medications used for allergic desensitization, which caused the use of contrast agents to be safer.

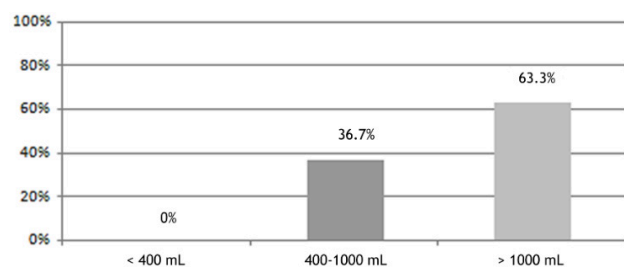
Iodinated contrast material-induced nephropathy is the condition in which renal function impairment occurs after intravenous use of contrast material in the absence of any other alternative etiology.¹⁷ This condition has also not been much observed because hydrated patients can undergo the procedure, which provides renal protection, helps in the elimination of the contrast agent and suspends the administration of nephrotoxic drugs. Moreover, due to their harmful effects, the lowest possible dose of contrast agents has been used. On the other hand, remaining in dorsal decubitus for prolonged periods of time, especially if the femoral access route was used, leads to physiological elimination with difficulty, consequently keeping the contrast agent inside the body.

According to GATTAZ (2002),¹⁷ prior renal failure is the most important risk factor for contrast material-induced nephropathy. The more severe the renal failure, the greater the risk.

The study results showed that 16.6% of the participants had renal failure, but 63.3% of them performed effective hydration before the procedure. It is worth mentioning that it was considered effective hydration when it was performed with 0.9% sodium chloride, acetylcysteine or sodium bicarbonate solution at least 12 hours before the procedure.

With regard to urinary output within 24 hours after CA or TCA (Figure 3), none of the participants had oliguria, which is classically defined as the reduction of urinary volume to below 400 mL within 24 hours (DA COSTA AND YU, 2009).¹⁸ Consequently, elimination of contrast agent through diuresis occurred as no reduction in the volume of diuresis related to the contrast agent was observed. However, it is possible that kidney complications may occur if the contrast agent remains inside the human body after 24 hours.

Figure 3 - Volume during diuresis within 24 hours after the procedure.



In order to better evaluate the contrast material-induced nephropathy, a creatinine clearance test should be performed. However, patients stay in CICUs for a short period of time after the procedure, making this test difficult to perform. The health care staff should provide guidance on possible adverse events so that the individual is aware of these changes.

Skin lesions

In contrast to the literature, there was an incidence of 40% of skin lesions due to the use of compressive dressing after the procedure. This high incidence may be related to the lack of homeostatic dressings, requiring manual compression and 24-hour maintenance of compressive dressings.

It is observed that there is a significant occurrence of skin lesions due to the use of compressive dressings after diagnostic or therapeutic cardiac catheterization.

Skin lesions may contribute to the increase of hospitalization time which, in turn, increases costs and makes patients uncomfortable. Thus, if there are no homeostatic dressings, the nursing staff should be aware of discomfort due to compressive dressings, as well as evaluate the perfusion of the limb, replacing it with a non-compressive dressing as soon as possible.

Pain

Pain after cardiac catheterization was reported by 50% of the participants. Of the total number of women, 66.6% reported having some type of pain and 50% reported having intense pain. On the other hand, 38.8% of men reported having pain and 57% of them reported having moderate pain.

Lumbar pain was not observed in this study. Reducing the gauge of the introducer needle and the number of femoral procedures has contributed to early walking, which resulted in a lower occurrence of low back pain due to lack of movement. In contrast, pain at the puncture site was present in 64% of pain reports and this may be related to the amount of time applying compressive dressings.

According to the International Association for the Study of Pain (IASP), pain is defined as an unpleasant sensory and emotional experience associated with potential or current tissue damage. Thus, it was described by the American Pain Society as the 5th vital sign in 1996.¹⁹

Pain was one of the most reported events by patients after they underwent CA or TCA. The use of catheters and introducers causes discomfort after the procedure. Pain at the puncture site and lumbar pain were reported. Lumbar pain may be associated with procedure time and resting after it was performed, especially when the femoral route was used.

In order to evaluate pain, we used the visual/verbal analog scale, which aims at measuring pain intensity by using numeric values. Patients should be aware of their thoughts and actions and refer to their pain as a number from zero to ten (zero means "no pain" and ten means "maximum pain").

When pain is not controlled, hemodynamic, metabolic and respiratory changes can occur, increasing the probability of having cardiovascular instability, increased energy expenditure, and difficulty in walking which favors the onset of deep vein thrombosis.²⁰

Nurses are reference professionals; therefore, they should ensure that proper care focused on pain management is delivered. Shift work should help these professionals in identifying changes in patients and carry out correct interventions. To accomplish this, they should be well trained in order to know how to apply and interpret the pain scales. Thus, not only this type of instrument must spot changes, but also systematize actions, always aiming at improving the patient's condition.

It is important to emphasize that pain among women is greatly minimized and is often attributed to emotional issues.¹⁰ Health professionals are responsible for eliminating these behavior stereotypes and value judgments, as well as investigating the possible causes of pain and treating them so that the patient's well-being could be improved.

CONCLUSIONS

Cardiovascular diseases have been bearing great relevance all over the world, and it is up to health care professionals to know how to meet the patients' demands. Furthermore, these professionals should know the procedures that will be carried out and possible risks to patients.

The study findings pointed out that the percentages of male and female patients who underwent CA and TCA were not significantly different from those reported in the literature. Moreover, the adverse events affecting the participants (pain, skin lesion, vascular manifestation, and arrhythmia) were corroborated by previous studies, focusing more on minor complications.

It is worth mentioning that no studies were found in the literature reporting the presence of skin lesions and pain at the puncture site after these procedures. Thus, it is suggested that the occurrence of these adverse events may be related to the absence of homeostatic dressings.

The nursing care delivered to the study participants improved their safety, making it possible for them to receive guidance on CA and TCA. Delivering this care ease the identification of situations that may result in complications during or after the procedure, for example, allowing the use of oral hypoglycemic and anticoagulant agents and fasting for 6 hours or less. Additionally, the frequency of occurring these events may be reduced.

The results of this research allow nurses to systematize the care for dealing with adverse events occurring in patients undergoing CA and TCA.

Knowing the clinical history is essential for quality management. The instrument developed in this study allowed the monitoring of patients undergoing CA and TCA

and data collection (anamnesis and physical examination) by nurses, which is the first phase of the nursing process.

Furthermore, this study made it possible to know the adverse events and their risks in order to promote specific changes and allow the Nursing Care Systematization (NCS) to be implemented. NCS helps to intervene in adverse events and increase the safety of the assistance provided.

The financial crisis affecting Brazil, especially the *Rio de Janeiro* State, was considered as a major limitation of this study. The low number of hospital beds and lack of material limited the number of CAs and TCAs performed. Moreover, testing for non-visible hematuria and creatinine clearance was not possible due to the lack of routine laboratory tests for the patients who underwent TA and TCA.

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