ADVERSE EVENTS TO IODINE CONTRAST MEDIUMS IN CORONARY ANGIOPLASTIES EVENTOS ADVERSOS A MEIOS DE CONTRASTE IODADOS EM ANGIOPLASTIAS CORONÁRIAS EVENTOS ADVERSOS A MEDIOS DE CONTRASTE YODADOS EN ANGIOPLASTIAS CORONARIAS

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ABSTRACT

Objective: to identify the incidence of adverse events to iodinated contrast media in patients submitted to Coronary Angioplasty. **Method:** this is a quantitative, descriptive, exploratory, prospective and observational study carried out with records from the Hemodynamics sector. A total of 104 subjects were interviewed, 36 were excluded after chart analysis, and 68 were included. Data were compiled with Microsoft Excel and descriptive statistical analysis was performed, presenting the results in tables. **Results:** three adverse events related to contrast media were identified in three different participants: two males and one female, where 120, 130 and 450 milliliters of contrast volume were used, respectively. **Conclusion:** it was observed that the prevalence of 4.4% of events is in line with the literature. It was observed that the main causal factor was not related and it was verified that the adverse events are important indicators of the quality of the assistance, being pertinent its prevention. **Descriptors:** Drug-Related Side Effects and Adverse Reactions; Contrast Media; Radiology, Interventional; Clinical Nursing Research; Patient Safety.

RESUMO:

Objetivo: identificar a incidência de eventos adversos a meios de contraste iodados em pacientes submetidos à angioplastia coronária. **Método:** trata-se de um estudo quantitativo, descritivo, exploratório, prospectivo e observacional realizado com registros de um setor de Hemodinâmica. Entrevistaram-se 104 indivíduos, excluíram-se 36 após a análise de prontuários e incluíram-se 68. Compilaram-se os dados com *Microsoft Excel* e realizou-se a análise estatística descritiva, apresentando os resultados em tabelas. **Resultados:** identificaram-se três eventos adversos relacionados aos meios de contraste em três diferentes participantes, sendo dois do sexo masculino e um do sexo feminino, onde se utilizaram, respectivamente, 120, 130 e 450 mililitros de volume de contraste. **Conclusão:** constatou-se que a prevalência de 4,4% de eventos está em consonância com a literatura. Observou-se que não se relacionou fator causal principal e verificou-se que os eventos adversos constituem importantes indicadores da qualidade da assistência, sendo pertinente a sua prevenção. **Descritores:** Efeitos Colaterais e Reações Adversas Relacionadas a Medicamentos; Meios de Contraste; Radiologia Intervencionista; Enfermagem; Pesquisa em Enfermagem Clínica; Segurança do Paciente.

RESUMEN

Objetivo: identificar la incidencia de eventos adversos a medios de contraste yodados en pacientes sometidos a la angioplastia coronaria. **Método:** se trata de un estudio cuantitativo, descriptivo, exploratorio, prospectivo y observacional realizado con registros de un sector de Hemodinámica. Se entrevistaron 104 individuos, excluidos 36 después del análisis de prontuario y se incluyeron 68. Los datos fueron seleccionados con Microsoft Excel y se realizó el análisis estadístico descriptivo presentando los resultados en tablas. **Resultados:** se identificaron tres eventos adversos relacionados con los medios de contraste en tres diferentes participantes, siendo dos del sexo masculino y un del sexo femenino donde se utilizó, respectivamente, 120, 130 y 450 mililitros de volumen de contraste. **Conclusión:** se constató que la prevalencia del 4,4% de eventos está en consonancia con la literatura. Se observó que no se relacionó factor causal principal y se verificó que los eventos adversos constituyen importantes indicadores de la calidad de la asistencia, siendo pertinente su prevención. **Descriptor:** Efectos Colaterales y Reacciones Adversas Relacionados con Medicamentos; Medios de Contraste; Radiología Intervencional; Investigación en Enfermería Clínica; Seguridad del Paciente.

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INTRODUCTION

The coronary transluminal angioplasty (CTA) was idealized by Andreas Gruentzig, and in 1977 the first percutaneous coronary dilation was performed with a contrast-enhanced image in humans, in which a balloon catheter was used for the treatment of coronary stenosis at order to restore normal flow, eradicate myocardial ischemia and its symptoms and prevent its occlusion.¹⁻³

The coronary stent in humans, developed by Julio Palmaz and Richard Schatz, was implanted after a decade in 1987, for the first time, through percutaneous coronary intervention (PCI), by Jose Eduardo Morais Rego de Sousa.^{2,4}

It is explained that the coronary stent acts by a mechanism of remodeling, causing fractures and fissures in the atherosclerotic plaque, redistributing it uniformly against the vascular wall, restoring more adequately the light of the vessel¹. With the introduction of drug-eluting stents in 1999 by Jose Eduardo M.R. de Sousa, and after its proven effectiveness in reducing restenosis rates, PCI has been shown to be more complex in procedures such as multi-vessel lesions, bifurcations, total arterial occlusions and in diabetic patients, always being performed in a room of Hemodynamics with scopia (x-ray) along with the use of contrast media.²

It is known that the contrast media are compounds used in the body that allow to increase the definition of the radiographic images, due to the increase of the contrast between the different tissues caused by them, allowing a greater precision in the diagnostic exams. It is estimated that more than 80 million per year of diagnostic or therapeutic interventions using iodinated contrast media.⁵⁻⁷

It is shown that ICM, by increasing the visibility of all surfaces of organs and tissues to be studied, may help the interventional cardiologist to determine the presence and extent of coronary artery disease or injury during the procedure of cardiac catheterization and during PCI.

Barium Sulphate, Fluorescein, Gadolinium and iodinated contrast media (ICM) are included in the contrast media available on the market, the latter being the focus of the work.⁵⁻⁷

The ICMs are classified according to their basic properties, which are: osmolality in relation to plasma (number of free particles), so called high-ICM(600 to 2100 mOsm/kg H₂O), low osmolality (290 and 860mOsm/Kg H₂O) or isosmolar (290mOsm/kg H₂O) and according to their ionicity, chemical structure and viscosity.^{2,4}

It is reported that osmolality is the number of free particles in relation to one Kg of H₂O, with the mean osmolality of the solutions and organic cells being about 290 mOsm/kg H₂O, ie the closer

the osmolality of the medium of iodinated contrast of the osmolality of the organic solutions, the better will be its tolerance in the human organism.⁴

The osmotic pressure is influenced by the ionicity of the ICMs and, consequently, the viscosity of the solutions. It is added that nonionic monomers do not ionize in solution because they do not have the carboxyl group, so for every three iodine atoms, there is only one particle in solution (3:1), and, at a certain concentration of iodine, the nonionic monomers have approximately half the osmolality of the ionic monomers in solution. It is described that the ionic dimers are the junction of two ionic monomers, with the substitution of a carboxyl group for an amide, which decreases the osmotic pressure, in contrast, increases its viscosity in solution; nonionic dimers are the junction of two non-ionic monomers, containing six iodine atoms for each particle in solution (6:1), being isosmolar with respect to human plasma.⁴

The viscosity of the iodinated contrast medium is related to the force required to inject it by means of a needle or catheter, limiting the rate at which it can be injected, also preventing rapid mixing in the blood, which slows down of the contrast inside the small vessels. However, this feature may be beneficial in terms of vascular intervention by allowing longer duration of contrast on cardiac catheterization and PCI. It is possible to reduce the viscosity by heating it, but has the drawback that it can only be used to its maximum effect immediately after being heated.^{4,9}

The opacifying power of the solution is elevated, as the iodine concentration of the contrast medium increases, in the same way that it increases to osmolality and viscosity, decreasing its tolerance in the human organism⁴. Thus, adverse events to ICM are common, which can be divided into three different types: toxic reactions; allergic and non-allergic hypersensitivity reactions, which may occur less than one hour after the infusion of ICM (immediate reactions), triggered by unknown mechanism or immunoglobulin E (IgE) mediated as anaphylactic symptoms, or one to ten days after the infusion of ICM (non-immediate reactions), triggered by unknown mechanism or by cells, such as the appearance of erythematous rashes, in addition to unrelated events that may appear as nonspecific symptoms.⁵⁻⁷

Adverse events that may be related to the use of ICMs due to their severity are differentiated between: mild (signs and symptoms are self-limiting, with no evidence of progression); signs and symptoms are more pronounced and commonly require medical treatment, where some of these events have the potential to become

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serious if left untreated) and severe (signs and symptoms are often life-threatening and may result in permanent morbidity and death if not properly managed).^{4,11,12}

Immediate hypersensitivity reactions are reported to occur in 0.7% to 3% of the population exposed to iodinated (nonionic) contrast medium and, from these reactions, 0.02% to 0.04% are

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severe and 0.00001 % to 0.00003% are fatal; in non-immediate reactions, the incidence is 0.5% to 3%, being more associated with the use of non-ionic dimer contrast. The events, also, according to their etiology, can be classified as allergic and physiological,^{4,11-2} which are described in the following figure.

Alergic reaction	Physiological Reaction
Light	Light
Itching/burning	Nause/vomiting
Skin edema	Transient flow/heat/chills
Scratchy throat	Headache/dizziness/anxiety/taste changed
Nasal congestion	Mild hypertension
Sneezing/conjunctivitis/rhinorrhea	A spontaneously resolved vasovagal reaction
Moderate	Moderate
Difuse itching/burning	Prolonged nausea/vomiting
Diffuse erythema with stable vital signs	Hypertensive urgency
Facial edema without dyspnea	Isolated chest pain
Throat tightness or hoarseness without dyspnoea	Vagal vase reaction that requires treatment and is responsive to it
Wheezing/bronchospasm with or without mild hypoxia	
Severe	Severe
Diffuse edema or facial edema with dyspnoea	Treatment-resistant vagal vase reaction
Diffuse erythema with hypotension	Arrhythmias
Laryngeal edema with stridor and/or hypoxia	Convulsions
Wheezing/bronchospasm with significant hypoxia	Hypertensive emergency
Anaphylactic shock (hypotension + tachycardia)	

Figure 1. Adverse events resulting from the use of iodinated contrast media. Adapted from ELLIS, JH, et al. 2018.

Thus, it is important that the Nursing team carry out the collection of a suitable history that considers the risks and benefits of using or avoiding the use of ICM, which should include the identification of factors that may evidence a contraindication to its use or a higher likelihood of an adverse event, in order to direct the patient's preparation appropriately for the cardiac catheterization procedure and PCI, having equipment and medications available to treat possible reactions resulting from the ICM and to guarantee training in the to provide effective patient care in a timely manner..¹³

It is generally understood that female sex is considered a risk factor for the development of adverse events, however, there is no solid evidence to prove and/or relate such a claim.^{7;14-15} This study is justified by the paucity of comparative studies of iodinated contrast media used in the Hemodynamic sector by nurses to perform coronary ther- apies and the incidence of adverse events related to the sexes, evidencing the need to develop studies about the same.

This study was developed to test the following hypothesis: “Does the sex of the patient directly influence the incidence of adverse events related to the use of ICM?”.

OBJECTIVES

- To identify the incidence of adverse events related to the use of iodinated contrast in patients submitted to elective coronary angioplasty;

- To compare the incidence of adverse events related to the volume of iodinated contrast media used;
- To compare the incidence of adverse events related to patients' sex.

METHOD

This is a quantitative, descriptive, exploratory, prospective and observational study in which the data collection was performed in the Hemodynamic and Angioplasty Infirmary sectors at a public institution in the State of São Paulo, Brazil, with patients submitted to elective coronary angioplasty.

The significance level of 5% and a power of 80% were set for the sample calculation using the Fisher's exact test and the assumption that 50% of the female patients would have some adverse event and that 30% of the male patients would have some adverse event, totaling a sample size of 216 patients, being 72 men and 144 women.

Patients aged 18 years or older, male and female, admitted to the Hemodynamic area (pre-catheterization room) or who were hospitalized (Angioplasty Ward) for the procedure were included in the study of percutaneous coronary angioplasty. Patients who did not meet the criteria described above and/or who reported a previous history of adverse events to the use of ICMs were excluded from the study.

Data collection was performed with patients who met the criteria for inclusion in the study,

who were invited to participate in the study by the researcher in the pre-catheterization room in the Hemodynamic sector or in the Angioplasty Infirmary bed, who were explained in this study and delivered the Free and Informed Consent Term (FICT) to be signed.

Data was collected on the patient's medical record on the day after the procedure by means of an instrument that showed the adverse events occurring during and after the procedure that could be related to the ICM used and other pertinent data, such as patient identification, gender, age, weight, height, previous allergies, values of laboratory tests of admission and the day following the procedure (serum creatinine and creatinine clearance), comorbidities and/or risk factors and ICM volume used in the procedure.

The data collected on a Microsoft Excel worksheet was recorded and analyzed by statistical software. In categorical variables, the Fisher exact test was used to examine the significance of the association (contingency) between these variables. In the continuous variable, the Cox-Stuart test was used to detect if there is a tendency in the set of observations raised in the research. The Pearson correlation coefficient was used to correlate the contrast volume used in the procedure with other variables, which measured the degree of linear correlation between the two quantitative variables. Adverse effects were analyzed by logistic regression and normal regression, according to the ICM groups used (group 1: ionicity and group 2: osmolality), sexes (female and male) and the contrast volume used in the procedure in milliliters (ml).

The results obtained in the form of tables and graphs were subsequently organized in the form of results. The following hypothesis was then tested: "Does the sex of the patient directly influence the incidence of adverse events related to the use of ICM?".

The study was approved by the Ethics and Research Committee of the Dante Pazzanese Institute of Cardiology, obeying the criteria established in Resolution 466, of 2012, on February 6, 2018, with the Certificate of Ethics Presentation Certificate (CAAE) number 80479317.2.0000.5462.

RESULTS

It is noteworthy that 104 patients were interviewed, out of the 216 patients suggested by the sample calculation, from March to September 2018, who met the inclusion criteria of the study, to whom the Free and Informed Consent Term was given and explained Enlightened. This number was given due to the time limitation for data collection during the Residency Program in Cardiovascular Nursing.

Thirty-six patients were excluded during the second stage of data collection, of which seven (19.4%) were excluded due to unavailability of the medical record for data collection; eight (22.2%) due to catheterization/re-evaluation followed by angioplasty; six (16.7%) because they presented evidence on allergy prior to iodine; five (13.9%) due to a change in medical conduct in relation to angioplasty, being referred to coronary artery bypass graft surgery or clinical treatment; four (11.1%) because they underwent FFR or OCT or intravascular ultrasound (IVUS) followed by angioplasty; two (5.6%) because they underwent catheterization followed by Optical Coherence Tomography (OCT) or Intravascular Ultrasound (IVUS) only; one (2.8%) because of cardiac catheterization; one (2.8%) for carrying out bridges studies; one (2.8%) because of presenting thrombocytopenia in a previous laboratory examination without authorization of the hematologist and one (2.8%) because of the intercurrent during the attempt of angioplasty (coronary artery dissection during guidewire passage). exam. Thus, 68 participants were included and the data were analyzed according to table 1, below.

Table 1. Profile of the participants submitted to elective coronary angioplasty at the Hemodynamic Unit of a cardiological hospital in the Southeast region. São Paulo (SP), Brazil, 2018.

Participant's profile	n	%
Sex		
Male	48	70.7
Female	20	29.3
Age		
≤ 50 years	5	7.4
51 to 60 years	17	25
61 to 70 years	33	48.5
≥ 71 years	13	19.1
Race		
White	51	74.7
Black	12	17.3
Brown	4	6.7
Yellow	1	1.3
Risk Factors/Comorbidities		
Systemic Arterial Hypertension	60	88
Dyslipidemia	59	86.7
Acute Myocardial Infarction (AMI)	42	61.3
Smoking (ex. and current)	38; 8	56; 12
Diabetes Melittus	37	54.7
Coronary Angioplasty	24	36
Others	18	26.7
Myocardial Revascularization (MR)	13	18.7
Renal insufficiency (Clea. of Creat. <60mL/min/1,73 m ²)	9	12.5
Peripheral Vascular Disease	8	12
Chronic Obstructive Pulmonary Disease (COPD)	2	2.7
Asthma	1	1.3
Total	68	100

Ionic and non-ionic contrast mediums of low and high osmolality were used, which were divided into groups according to their properties for later analysis, being the first group related to ICM ionicity, of which there were 16 (23.5%), with a mean volume of 90 ml, and 52 (76.5%) nonionic, of which a mean volume of 128.3 ml was used. The second group was classified according to the osmolality of the ICM, of which 47 (69.1%) were of low osmolality, where a mean volume of 112.8 ml was used, and 21 (30.9%) , of high osmolality, of which a mean volume of 134.2 ml.

The occurrence of three (4.4%) adverse events in the sample of 68 participants, described in the unit's Nursing records, during the six-month collection period was verified. An average of 208

procedures/month of coronary angioplasty were performed in the Hemodynamic Unit during the same period.

It should be noted that two (2.9%) adverse events were of moderate allergic origin and one (1.5%) of severe physiological origin, evidencing situations such as lip edema, throat tightening with hoarseness and bradycardia with nausea. The characteristics of the adverse events occurring in Table 2 were identified.

Table 2. Adverse events occurring with participants submitted to Elective Coronary Angioplasty in the Hemodynamic Unit of a cardiological hospital in the Southeast region. São Paulo (SP), Brazil, 2018.

Adverse event characteristic	n; %	Sex	Age (years)	ICM (ionicity; osmolality)	Volume (ml)	Place/time of occurrence
Allergic reaction						
Lip Edema	1; (1.5)	Male. ¹	58	Ionic (Low osmolality)	120	Infirmary
Throat tightness and hoarseness	1; (1.5)	Fem. ²	66	Non-ionic (Low osmolality)	130	Procedure room
Physiological Reaction						
Bradycardia with nausea	1; (1.5)	Male. ¹	66	Non-ionic (High osmolality)	450	Procedure room
TOTAL	3; (4.4)					

To read: ¹Male. (Male); ²Fem. (Female).

DISCUSSION

Three adverse events were observed in Elective Coronary Angioplasty in the Hemodynamic Unit, with an incidence of three (4.4%), a value considered in agreement with the literature, in view of the quantitative of procedures studied in the same period (n = 68).

In studies conducted in hemodynamic units and in a teaching hospital in Goiânia, it was demonstrated that the prevalence of adverse events was low when compared to the high demand and turnover of patients in those units.¹³⁻¹⁶

It is understood that it is well known that ICM doses should be tailored to the examination and regions to be tested, as well as body weight and renal function of the individual, especially in children.¹⁷⁻¹⁹

In a study of immediate complications related to cardiac catheterization, it has been shown that these may be local or systemic, with vascular, vasovagal, ischemic and allergic complications being more frequent. Allergic complications occurred in only 2.9% of the cases and there were no significant complications in this category, which is similar to the results of previous studies.²⁰

It was found that only one (1.5%) patient presented a physiological adverse reaction during the coronary angioplasty procedure, in which an ICM volume was higher than the recommended one, according to the patient's weight (86 kg), with ICM non-ionic high osmolality reference and of which 450 ml (recommended maximum volume of 5 ml/kg) was used. It is also recommended by the manufacturer that the total dose used for procedures in general should not exceed 250 ml, further suggesting that, when large volumes are administered, the hemodynamicist should wait a period of minutes between each injection to allow the decrease of intensity of any hemodynamic disorder.¹⁷

It is emphasized that in the other two individuals that presented adverse reactions, the volume of the ICM infused was within the parameters recommended by the manufacturer, 65-270 ml (infused 130 ml) and for the ICM ionic low osmolality 75-400 ml (infused 120 ml).¹⁸⁻¹⁹

In this study, it was shown that labial edema and tightening of the throat with hoarseness were the most frequent adverse events related to moderate allergic reaction, with a recorded percentage of 2.9%, which shows the importance of the management of reactions of hypersensitivity. It is worth noting, given the complexity of these processes, that the occurrence of some complications is inevitable, requiring an agile and capable team to prevent and control such interurrences. Thus, it is essential the training of the Nursing team and

medical team to deal with this type of situation, performing Nursing history and medical consultation with emphasis on the identification of risk factors for the occurrence of adverse events.¹⁴⁻¹⁵

It has been shown in other studies that the previous history of adverse reaction to iodinated contrast is the main risk factor for the development of a new reaction, and also that if the previous reaction is to non-ionic contrast, the individual has a risk five times greater to develop a new reaction, compared to those who never received this contrast or who received it and had no reaction.^{11,14-15} In this way, the patient's history must be investigated before the beginning of any procedure, as well as the development of continuous and systematic evaluation of the necessary resources, such as the risk management of patients most susceptible before, during and after the procedures.¹⁴⁻¹⁵

In the same studies, it has been shown that there is no evidence that female is a major predictor of adverse events, complementing the hypothesis of this study, that sex should not be considered a risk factor, since only 1/3 of the events occurred in female subjects.¹⁴⁻¹⁵

It has been shown in a similar study that the adverse event related to excessive exposure to contrast can increase the length of hospital stay, create the need for additional procedures and also cause irreversible consequences for the patient, such as the incidence of 10 to 30 % of contrast-induced nephropathy (CIN).²¹⁻²² In addition, patients should be hydrated before and after administration of ICMs, according to creatinine clearance. It is noted that failure to perform hydration during client preparation may contribute to the development of acute renal failure in patients with advanced vascular disease, diabetics, and in susceptible non-diabetic patients (often elderly with pre-existing renal disease),¹⁷ however, in this study, the occurrence of CIN in individuals.

It is recalled that other risk factors for the occurrence of adverse events present in the study did not have solid evidence that related to the events occurred, therefore, they were not discussed.

It is noted that all modern contrast media in use today are based on organic iodine which, because of its high atomic number and chemical versatility, proved to be of excellent applicability for intravascular opacification.²³

Notification of these events is an important source of information to improve patient care as these records assist in the detection of causes, in the evaluation of adverse events, in the reduction of occurrences, and in the management of risks. At the institution studied, the Nursing records of adverse events were recorded in the patient's

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chart, in a procedure room form and in an Excel spreadsheet. Therefore, it can be stated that the presence of these reporting instruments is fundamental for the identification and management of events, in order to guarantee communication and legal support for Nursing professionals.^{15-16,21,23-25}

It is known that the professionals involved in the occurrence of adverse events are, mainly, doctors and the Nursing team, because they are the professionals who provide the direct assistance to the patient during the procedures in the Hemodynamics Unit. It is thus defined as the responsibility of the team: ensuring patient well-being and conducting the procedure free of adverse events.²⁶⁻²⁷

The Ministry of Health of Brazil, Order No. 210, of June 15, 2004, regulates the services of high cardiovascular complexity, stating that the units must have a properly qualified and qualified care team, assuring the quality of patient care and making the coordinating nurse responsible for the management of these resources.²⁶

It is also extremely important to establish the conduct of an adverse event for the proper management and correction of failures, since in this study and in a similar study, the prevalence of administrative and clinical behaviors was determinant for the adequate management of the adverse event.¹³

In another Administrative Rule, No. 529 of April 1, 2013, which instituted the National Patient Safety Program, on a set of measures to prevent the occurrence of adverse events in health services, including the implantation of the Patient Safety Center and the creation of an Adverse Event Notification System,²⁹ items that are already included in the institutional culture where the study was performed.

It is believed that notification is an important tool for the identification of adverse events since, from it, it is possible to verify the quality indicator of care and to develop practices of continuous improvement focused on the patient.^{20,29-30}

The hemodynamics unit was searched for its own instrument for reporting adverse events, and data collection was performed through a spreadsheet in the sector and in Nursing records in printed medical records. It is observed that these records are performed by the Nursing team and that, in many cases, are not very comprehensive in their reports.

It is understood that the development and promotion of a safety culture, the practice of nursing records, the discussion of the circumstances in which adverse events occurred, as well as professional and organizational conduct in the face of the damages caused are the way to be followed for the transformation of reality in health institutions. In addition, adverse events

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should be treated as an opportunity to improve health care through risk management.^{20,30}

This study was limited by the time taken to collect data concomitant with the routines of the Residency Program in Cardiovascular Nursing. Another limiting factor was the unavailability of some of the printed medical records for the collection of data. It is also worth noting that only three studies on adverse events were found in Hemodynamics Unit.

CONCLUSION

It was verified the occurrence of only three adverse events in the hemodynamic unit, being the majority related to physiological reactions, however, it was not possible to relate the female sex and the volume of contrast used directly with the events, once the sample harvested was limited.

The value of continuous and continuing education on the subject for patients and professionals is remarkable. It is believed that it is important to perform a detailed nursing history, focusing on the risk factors for developing adverse events, and the notification for the implementation of measures to prevent the occurrence of adverse events, in order to develop a safety policy of the Patient focused on nursing care.

It was concluded that adverse events are important indicators of the quality of care and should be reported in order to allow changes in the structure of the service and work processes and thus ensure a culture of safety at the institutional level.

It is noteworthy that it is necessary to develop studies related to the subject, with a larger number of individuals, in order to verify if there are actually a significant number of occurrences of these events, in order to strengthen, with scientific evidence, the practice of professionals of health.

REFERENCES

1. Oliveira O, Morgado P. De coração e alma: 40 anos de história da SBHCl. São Paulo: SBHCl; 2015.
2. Quilici AP; Bento AM, Ferreira FG; Cardoso LF; Moreira RSL; Silva SC. Enfermagem em Cardiologia. 2nd ed. São Paulo: Ed. Atheneu; 2014.
3. Feres F, Costa RA, Siqueira D, Costa Jr JR, Chamié D, Staico R, *et al.* Diretriz da Sociedade Brasileira de Cardiologia e da Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista sobre Intervenção Coronária Percutânea. Arq Bras Cardiol. 2017 July;109(1). Available from : <http://www.scielo.br/pdf/abc/v109n1s1/0066-782X-abc-109-01-s1-0001.pdf>
4. Santos AP, Gaivão, AM, Tavares A, Ferreira S. Produtos de contraste iodados. Acta Med. Porta.

Flaibam MJ, Silva EV da, Almeida MH de, Oki FH.

2009 Jan; 22:261-74. Available from: <https://core.ac.uk/download/pdf/62712779.pdf>

5. Felix MMR, Malaman MF, Ensina LFC. Diagnóstico das reações imediatas aos meios de contraste iodados: revisão da literatura. *Braz J Allergy Immunol.* 2013;1(6):305-12. Doi: [10.5935/2318-5015.20130045](https://doi.org/10.5935/2318-5015.20130045)

6. Pinho KEP, Gewehr PM, Silva CWP, Barison A, Tilly Jr. JG, et al. Avaliação de meios de contraste submetidos à radiação ionizante. *Radiol. Bras.* 2009 Set/Out;42(5):309-313. Doi: [10.1590/S0100-39842009000500010](https://doi.org/10.1590/S0100-39842009000500010)

7. Brockow K, Christiansen C, Kanny G, Clément O, Barbaud A, Bircher A, et al. Management of hypersensitivity reactions to iodinated contrast media. *European J of Allergy and Clin Immunol.* 2005 Feb;60(2):150-158. Doi: [10.1111 / j.1398-9995.2005.00745.x](https://doi.org/10.1111/j.1398-9995.2005.00745.x)

8. Eduardo JCC, Macedo HW, Caldas MLR, Silva LE. Nefropatia induzida por contraste: avaliação da proteção pela n-acetilcisteína e allopurinol em rato uninefrectomizados. *Radiol. Bras.* 2008 Mai/Jun;41(3):177-181. Available from : <https://www.lume.ufrgs.br/bitstream/handle/10183/164509/001019989.pdf?sequence=1>

9. Associação Brasileira de Alergia e Imunologia. Statement ASBAI: Posicionamento da ASBAI Sobre Contrastes em Radiologia. ASBAI. 2016. Available from: http://www.asbai.org.br/imagebank/2016-09-26-USO-DE-CONTRASTY-DE-ODADO_Sem-Papel-Carta.pdf

10. Davenport MS, McDonald CRJ, Asch D, Mervak B, Cavallo J, Mody R, et al. ACR Manual on Contrast Media. American College of Radiology. 2018;10.3:1-127. Available from: https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

11. Rosado IA, Doña DI, Cabañas MR, Moya QMC, Garcia AC, Garcia NI, et al. Clinical Practice Guidelines for Diagnosis and Management of Hypersensitivity Reactions to Contrast Media. *J Investig Allergol Clin Immunol.* 2016;26(3):144-155. Doi: [10.18176/jiaci.0058](https://doi.org/10.18176/jiaci.0058)

12. Seignemartin BA, Jesus LR, Vergílio MSTG, Silva EM. Evaluation of the quality of nursing records in the emergency department of a teaching hospital. *Rev RENE.* 2013;14(6):1123- 32. Doi: [10.15253/rev%20rene.v14i6.3724](https://doi.org/10.15253/rev%20rene.v14i6.3724).

13. Juchem, BC; Almeida, MA. Risco de reação adversa ao meio de contraste iodado: um estudo de validação. *Rev Gaúcha Enferm.* 2017;38(2):e68449. Doi: [10.1590/1983-1447.2017.02.68449](https://doi.org/10.1590/1983-1447.2017.02.68449).

14. Rodrigues TP, Bezerra ALQ, Boaventura RP, Teixeira CC, Paranaguá TTB. Ocorrência de eventos adversos em unidade de hemodinâmica. *Rev Enferm UFPE online.* 2019 Jan;13(1):86-95. Doi: [10.5205/1981-8963-v13i01a235853p86-95-2019](https://doi.org/10.5205/1981-8963-v13i01a235853p86-95-2019).

Adverse events to iodine contrast mediums...

15. OPTIRAY. [Bula]. Estados Unidos: Mallinckrodt do Brasil Ltda; 2014 June.

16. HENETIX. [Bula]. Brasil: Guerbet Produtos Radiológicos Ltda; 2013 Sept.

17. HEXABRIX. [Bula]. Brasil: Guerbet Produtos Radiológicos Ltda; 2015 Oct.

18. Rossato G, Quadros AS, Sarmento-Leite R, Gottschall CAM. Analysis of in-hospital complications related to cardiac catheterization. *Rev Bras Cardiol Invas.* 2007 Jan/Mar;15(1):44-51. Doi: [10.1590/S2179-83972007000100010](https://doi.org/10.1590/S2179-83972007000100010)

19. Paranaguá TTB, Bezerra ALQ, Santos ALM, Silva AEBC. Prevalência e fatores associados a incidentes relacionados à medicação em pacientes cirúrgicos. *Rev Esc Enferm USP.* 2014 Feb;48(1):41-7. Doi: [10.1590/S0080-623420140000100005](https://doi.org/10.1590/S0080-623420140000100005).

20. Maccariello E. Nefropatia induzida por contraste. *J Bras Nefrol.* 2016;38(4):388-389. Doi: [10.5935/0101-2800.20160062](https://doi.org/10.5935/0101-2800.20160062)

21. Saad JA, Garcia JCF, Guimarães JI. Diretriz para realização de exames diagnósticos e terapêuticos em hemodinâmica. *Arq. Bras. Cardiol.* 2004;82(1):1-6. Available from : http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0066-782X2004000700001&lng=en.

22. Paranaguá TTB, Braga QP, Bezerra ALQ, Silva AEBC, Azevedo Filho FM, Souza MRG. Incidents: instrument management assistance for patient safety in emergency room. *Enferm Glob.* 2014; 34(2):219-31. Available from: http://scielo.isciii.es/pdf/eg/v13n34/pt_administracion1.pdf

23. Siman AG, Cunha SGS, Brito MJM. The practice of reporting adverse events in a teaching hospital. *Rev Esc Enferm USP.* 2017 Oct;51:e03243. Doi: [10.1590/s1980-220x2016045503243](https://doi.org/10.1590/s1980-220x2016045503243).

24. Larizgoitia I, Bouesseau MC, Kelley E. WHO Efforts to promote reporting of adverse events and global learning. *J Public Health Res.* 2013 Dec;2(3):e29. Doi: [10.4081/jphr.2013.e29](https://doi.org/10.4081/jphr.2013.e29).

25. Sousa P, Uva AS, Serranheira F, Nunes C, Leite ES. Estimating the incidence of adverse events in Portuguese hospitals: a contribution to improving quality and patient safety. *BMC Health Serv Res.* 2014 July;14:311. Doi: [10.1186/1472-6963-14-311](https://doi.org/10.1186/1472-6963-14-311).

26. Conselho Federal de Enfermagem. Código de ética enfermagem: Resolução COFEN nº 311 de 08 de fevereiro de 2007. Brasília: COFEN; 2012. Available from: http://www.cofen.gov.br/resoluco-cofen-3112007_4345.html

27. Conselho Federal de Medicina. Código de ética médica: Resolução CFM nº 1931, de 17 de setembro de 2009. Brasília: CFM; 2010. Available from: <https://portal.cfm.org.br/images/stories/biblioteca/codigo%20de%20etica%20medica.pdf>.

28. Ministério da Saúde (BR), Gabinete do Ministro. Portaria nº 529, de 1º de abril de 2013.

Flaibam MJ, Silva EV da, Almeida MH de, Oki FH.

Adverse events to iodine contrast mediums...

Institui o Programa Nacional de Segurança do Paciente. Brasília: Ministério da Saúde. Available from:

http://bvsmis.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html

29. Carneiro FS, Bezerra ALQ, Silva AEBC, Souza LP, Paranaguá TTB, Branquinho NCSS. Adverse events in the surgical clinic of a university hospital: a tool for assessing quality. Rev Enferm UERJ. 2011 Apr/June;19(2):204-11. Available from:

<http://www.facenf.uerj.br/v19n2/v19n2a06.pdf>

30. The National Quality Forum. Safe practices for better healthcare 2010 update. Washington: The National Quality Forum;2010. Available from:

https://www.qualityforum.org/Publications/2010/04/Safe_Practices_for_Better_Healthcare_%E2%80%93_93_2010_Update.aspx

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