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Comparison of radiological exposure of patients undergoing coronary angiography and staged or ad hoc percutaneous coronary intervention by radial access

Comparação da exposição radiológica de pacientes submetidos à coronariografia e à intervenção coronária percutânea estadiada ou *ad hoc* pelo acesso radial

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ABSTRACT – **Background:** Ad hoc percutaneous coronary intervention via radial access has become frequent in interventional cardiology services, with reduced bleeding rates, vascular complications and costs. There are few reports in the medical literature on radiological exposure rates (kerma area product – K_{ap}, and incident air kerma – I_{ak}) in these procedures, when they are performed via radial access. The objective of the study was to compare radiological variables in staged percutaneous coronary interventions with ad hoc interventions via radial access. **Methods:** A total of 120 patients were studied, divided into two groups of 60: Group A, patients undergoing diagnostic coronary angiography and staged percutaneous coronary intervention, versus Group B, patients undergoing ad hoc percutaneous coronary intervention via radial access, from August 2014 to September 2015. The values of radiological exposure rates were measured. **Results:** When comparing Groups A and B, we observed body mass index of 27.83±4.20kg/m^2 vs. 26.88±4.14kg/m^2 (p=0.3); total K_{ap} of 16,222.5±10,613.5μGym^2 vs. 12,029.2±7,360.6μGym^2 (p=0.01); total I_{ak} of 3,886.8±2,946.7mGy vs. 2,940.3±1,841.0mGy (p=0.04); total fluoroscopy time of 23.2±13.17 minutes vs. 17.1±9.68 minutes (p=0.0009); SYNTAX score 14.7±8.3 vs. 13.7±8.9 (p=0.54). **Conclusion:** Radiological exposure rates in ad hoc percutaneous coronary interventions were lower than in staged percutaneous coronary interventions, when the procedures are performed via radial access.

Keywords: Radiology information systems; Radiation dosage; Percutaneous coronary intervention; Radiation, ionizing; Radial artery

RESUMO – **Introdução:** A intervenção coronária percutânea *ad hoc* pelo acesso radial tem se tornado frequente nos serviços de cardiologia intervencionista, com redução das taxas de sangramento, complicações vasculares e diminuição dos custos. São escassas, na literatura médica, informações sobre as taxas de exposição radiológica (produto kerma área – P_{ka} – e kerma incidente no ar – K_{ai}), nesses procedimentos por tal via. O objetivo do estudo foi comparar as variáveis radiológicas das intervenções coronárias percutâneas estadiadas com as intervenções *ad hoc* pelo acesso radial. **Métodos:** Foram estudados 120 pacientes, divididos em dois grupos de 60 cada, submetidos à coronariografia diagnóstica e intervenção coronária percutânea estadiada (Grupo A) vs. *ad hoc* (Grupo B), pelo acesso radial, no período de agosto de 2014 a setembro de 2015. Foram mensurados os valores das taxas radiológicas. **Resultados:** Quando comparados os Grupos A e B, observamos índice de massa corporal de 27,83±4,20kg/m^2 vs. 26,88±4,14kg/m^2 (p=0,3); P_{ka} total de 16.222,5±10.613,5μGym^2 vs. 12.029,2±7.360,6μGym^2 (p=0,01); K_{ai} total de 3.886,8±2.946,7mGy vs. 2.940,3±1.841,0mGy (p=0,04); tempo de escopia total de 23,2±13,17 minutos vs. 17,1±9,68 minutos (p=0,0009), escore SYNTAX de 14,7±8,3 vs. 13,7±8,9 (p=0,54). **Conclusão:** As taxas radiológicas das intervenções coronárias percutâneas *ad hoc* foram menores do que nas estadiadas pelo acesso radial.

Descritores: Sistemas de informação em radiologia; Dosagem de radiação; Intervenção coronária percutânea; Radiação ionizante; Artéria radial

INTRODUCTION

Technological evolution and the advent of new tools have made ad hoc percutaneous coronary intervention (PCI) a safe procedure with low rates of early complications. In ad hoc PCI, patients are subjected to higher radiation exposure in the same procedure, greater contrast volume, and, consequently, greater chance of developing contrast-induced nephropathy, longer procedure duration, difficulty in obtaining informed consent for the procedure, and a faster decision-making process, compromising the heart team concept.[1-5]

Almost all data available in the literature on ad hoc PCI are from real-world registries, showing a reduction in puncture site-related vascular complications, no increase in the incidence of procedure-related complications, including mortality, and no significant changes in the immediate success rate of the procedure.[1]

The use of radial access for coronary angiography and PCI has increased significantly in recent years. The advantages of this approach include lower bleeding and vascular complication rates, and greater patient comfort, with a significant reduction in hospital costs and length of stay.[6,7] The higher radiological exposure via radial access compared with femoral access is related to the operator's experience.[8,9] Combining ad hoc PCI with the radial technique, compared with the femoral technique, provides more comfort for the patient, and reduces hemorrhagic complications and costs.[7,10-12]

The potential harmful effects of ionizing radiation are classified as deterministic effects, which occur when the exposure threshold is exceeded, increasing the probability of cell damage, and stochastic effects, which are threshold-independent, linked to the cell sensitivity of the exposed individual, and may cause somatic DNA damage, even in chronic low doses. The risk is cumulative for patients and professionals, and the greater the number of procedures performed, the greater the doses and the potential risks.[13-16]

There are few reports in the medical literature on radiation doses for patients and health professionals in ad hoc PCI using the radial technique.[15,17] The objective of this study was to compare the radiological variables of staged PCI with ad hoc interventions, using radial access.

METHODS

This is an observational, sequential, prospective, comparative study of radiological variables related to radiation exposure obtained in an AXIOM Artis (Siemens Healthcare GmbH, Erlangen, DE, Germany) equipment. The study was conducted from August 2014 to September 2015, in 120 patients divided into two equal groups of patients undergoing coronary angiography and staged (Group A) or ad hoc (Group B) PCI, at the *Hospital do Servidor Público Estadual "Francisco Morato de Oliveira"* (HSPE-FMO) *do Instituto de Assistência Médica do Servidor Público Estadual* (IAMSPE).

The study was approved by the Research Ethics Committee of the IAMSPE, under CAAE number 868,337. The use of an Informed Consent Form was not required, because this was an equipment protocol and data collection, and the procedures occurred regardless of the research.

Population

The inclusion criteria included patients undergoing coronary angiography and staged or ad hoc PCI via radial access, and excluded patients who underwent other procedures (intracoronary ultrasound or fractional flow reserve) and procedures performed using the femoral technique.

The cases were sequentially selected based on the variables radial access approach and type of procedure (staged or ad hoc). They were all performed at the IAMSPE/HSPE, and included radiological exposure data. For all patients selected for the study, the SYNTAX score was calculated by the operators. As to staged PCI, we included patients referred to only one procedure after diagnostic coronary angiography. We used two forms for the staged procedures, since they were performed on different days, and the radiological doses and the other parameters were added for purposes of comparison with the ad hoc procedures.

Study procedures

The procedures were performed according to the local practice of the hospital and operators, who were experienced in the radial technique and blind as to the inclusion of patients in the protocol. The ad hoc PCI followed the usual protocol at the hospital, based on the agreement of the patient and the attending physician, on previous renal function, on radiological exposure, and on the amount of contrast used in the diagnostic procedure. Renal function was analyzed by comparing serum creatinine at 24 hours before elective and ad hoc PCI, and at 48 hours after the procedures.

The term dose in our study refers to the amount of radiation delivered to the patient (primary radiation) and to the environment, as well as the scattered radiation (secondary radiation), during the procedures. Doses were measured using an ionization chamber, Diamentor© PTW DALI (Freiburg), attached to the primary collimator output end (Figure 1). The response of the equipment was related to the dose delivered to the patient.[18] Doses related to kerma area product (K_{ap}) and incident air kerma (I_{ak}) were measured on the procedure room monitors and in the technical control room, and recorded in the protocol of the study. The radiological data were collected and added to the protocol only after the examination was completed.

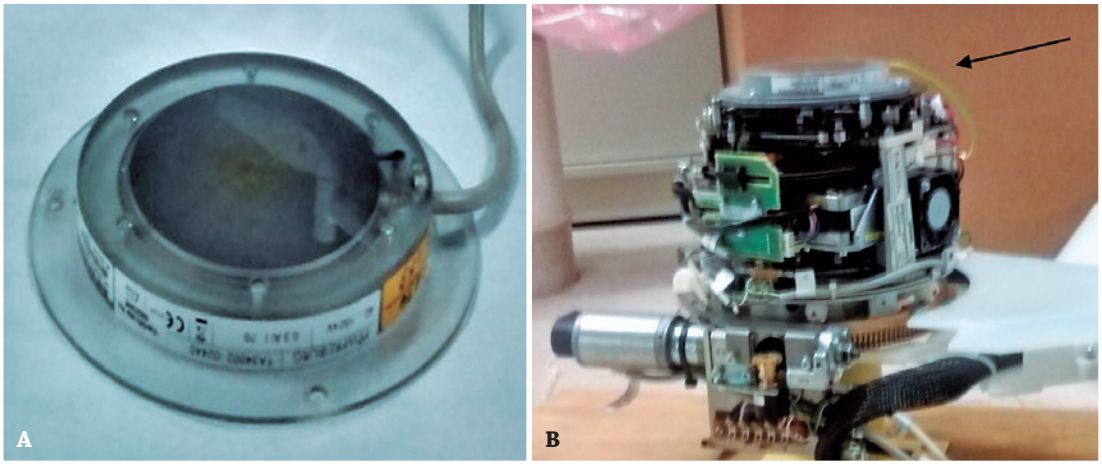

Figure 1. (A) Diamentor © PTW DALI (Freiburg). (B) Diamentor (arrow) positioned at the primary collimator output end, without the protective enclosure, in order to be installed in the C-arc.

Clinical and procedural data were compiled in a specific form, and a comparative analysis of the variables in the two groups was performed. In the radiological rate form, we compiled data regarding the images in cine mode and the total sum of doses. The variables that we compiled and analyzed were: number of cine projections (projections); amount of 15f/s and 30f/s cine frames; total fluoroscopy time (FT); cine scoping time (CST); kilovolt (kV) – ampoule tension; milliampere (mA) – ampoule current; millisecond (ms) – pulse width; frame rate (F) – frame rate μGym² – K_{ap}; mGy – I_{ak} (dose in patient's skin), presented, respectively, in total dose, fluoro, total cine, 15 f/s cine, and 30 f/s cine.

Statistical analysis

The software Sample Size Calculations Online (SISA) was used to calculate the sample size, considering the FT for ad hoc interventions as 16±10 minutes, and for staged interventions, 22±14 minutes. Epi Info™ (version 7.2 software for Windows), and an Excel (Microsoft Office 2010) database were used for statistical analysis. Categorical variables were described as frequencies and percentages, and compared with the Chi-square test or Fisher's exact test, when appropriate. Continuous variables were described as mean and standard deviation, and compared with the Kruskal-Wallis test and paired Student's t test for both groups. Data were expressed as median and interquartile range in nonhomogeneous groups. The level of significance was set at $p<0.05$.

RESULTS

From August 2014 to September 2015, a total of 1,936 procedures were performed in 1,460 patients, of whom 368 underwent coronary angiography and PCI, of which 203 were elective procedures, and 165 were emergency procedures. Of the 368 patients, 248 were excluded for not meeting inclusion criteria. The remaining 120 patients who underwent both procedures via radial access were divided into two equal groups: staged (Group A), and ad hoc (Group B).

When comparing the clinical characteristics of Groups A and B, there was no statistically significant difference between the variables (Table 1). A predominance of lesions in the left anterior descending and right coronary arteries was observed. When comparing the lesion classification and the SYNTAX score of the treated vessels, there was no difference between the groups. However, we observed a greater number of stent implants in Group A when compared with Group B (Table 2).

Table 1. Clinical characteristics

Variables	Group A (n=60)	Group B (n=60)	p-value
Age, years	70±8	66±11	0.99
Male sex	36	35	0.85
Body mass index	27.8±4.2	26.8±4.1	0.28
Current smoking	14	12	0.66
Hypercholesterolemia	39	30	0.09
Hypertension	47	51	0.34
Insulin-dependent diabetes mellitus	6	4	0.50
Non-insulin-dependent diabetes mellitus	18	16	0.68
Prior acute MI	17	14	0.53
Coronary artery bypass graft	9	1	0.008
Stable angina	28	6	0.0001
Silent ischemia	13	7	0.24
Non ST-segment elevation ACS	17	38	0.0001
ST-segment elevation MI	3	9	0.06

Results expressed as mean ± standard deviation, or n. MI: myocardial infarction; ACS: acute coronary syndrome.

Table 2. Angiographic characteristics

Variables	Group A (n=60)	Group B (n=60)	p-value
Treated artery			
Left main coronary artery	0	1	NS
Left anterior descending artery	29	29	NS
Left circumflex artery	15	15	NS
Right coronary artery	16	15	NS
Stent implantation	97	80	0,02
Classification of lesions			
B1	13	17	NS
B2	18	21	NS
C	29	22	NS
SYNTAX score	14,7±8,3	13,7±8,9	NS

Results expressed as n or mean ± standard deviation. NS: non-significant.

A comparative analysis of the procedures' impact on renal function in the two groups showed that, although Group B received a higher volume of iodinated contrast (p=0.03), there was no statistically significant difference in creatinine dosages at 48 hours after the procedure (Table 3). Two patients with dialytic chronic renal failure (CRF) were excluded from the analysis due to the customary hospital practice of dialyzing CRF patients after the procedures.

Table 3. Characteristics of procedures

Variables per group	Median (minimum – maximum)	Mean ± SD	Interquartil range		p-value
			Q1	Q3	
Duration of the procedure, minutes					0.03
Group A	60 (7-135)	61.23±26.20	45	75	
Group B	50 (10-130)	53.35±29.54	30	65	
Contrast media volume, mL					0.32
Group A	170 (60-420)	178±78	135	230	
Group B	160 (20-340)	165±75	110	220	
Baseline creatinine, mg/dL					0.28
Group A	1.0 (0.5-2.4)	1.04±0.38	0.8	1.2	
Group B	1.1 (0.7-4.7)	1.10±0.43	0.9	1.2	
Creatinine 48 hours, mg/dL					0.28
Group A	1.0 (0.6-2.5)	1.07±0.40	0.8	1.3	
Group B	1.05 (0.6-5.6)	1.16±0.67	0.8	1.3	

SD: standard deviation; Q1: lower quartile; Q3: upper quartile.

When we analyzed the radiological exposure rates and the technical parameters of the groups, we observed statistically higher values in Group A when compared with Group B in K_{ap} total dose, K_{ap} fluoro, K_{ap} cine, I_{ak} total dose, I_{ak} fluoro, I_{ak} cine, total scoping time, CST, and number of projections (Table 4). In a more detailed analysis of cine images, we observed higher values, with statistical significance, in Group A when compared with Group B in the radiological rates of K_{ap} 15f/s cine (6,240.5±3,016.5μGym^2 vs. 4,860.2±2,786.2μGym^2; p=0.004); I_{ak} 15f/s cine (1,526.8±749.2mGy vs. 1,233.9±889.6mGy; p=0.004); and 15f/s images (2,135.8±672.2 frames vs. 1,694.7±549.3 frames; p=0.0001). However, we did not observe a statistically significant difference in K_{ap} – 30f/s cine (1,630.8±2,080.1μGym^2 vs. 1,524.4±2,423.3μGym^2; p=0.33) in K_{ai} – cine 30f/s (434.2±552.4mGy vs. 420.6±676.7mGy; p=0.37); and 30f/s images (709.8±1,120.7 frames vs. 593.1±907.1 frames; p=0.28).

To evaluate the impact of the number of stent implants in one artery on radiological rates and technical parameters, a comparative sub analysis was performed in the two groups, with one or two stent implanted in one artery. In patients undergoing one stent implantation, there was a statistically significant difference in Group A (n=30) compared with Group B (n=39) in fluoroscopy time (18.4 minutes vs. 12.8 minutes; p=0.03), total 15f/s frames (1,775 frames vs. 1,521 frames, p=0.01), and total projections (33 projections vs. 27 projections, p=0.001). In patients with two stents in one artery, there was a statistically significant difference in Group A (n=19) as compared to Group B (n=16) in fluoroscopy time (24.6 minutes vs. 20.9 minutes; p=0.02), and in total projections (49 projections vs. 35 projections, p=0.004) (Table 5). The radiological exposure rates did not show a statistically significant difference.

DISCUSSION

Differing from other publications our study compared all radiological variables collected from the records of patients undergoing coronary angiography and staged or ad hoc PCI performed via radial access. All first operators were physicians and highly experienced radial operators. The data showed that patients undergoing ad hoc PCI were less exposed to radiation than those undergoing staged PCI, in agreement with the study by Truffa et al., who also observed lower radiological exposure rates in the ad hoc approach.[17]

The lower exposure to radiation in ad hoc interventions, compared with staged interventions, can be explained by the use of the same access for the diagnostic procedure, thus eliminating the need for another fluoroscopy for catheter placement, since the guidewire is already positioned in the aorta, and only a catheter replacement is performed; by the lower frequency of left ventriculography; by the awareness of the best projection to properly visualize the lesion, avoiding unnecessary image acquisitions; by the lower incidence of revascularized patients; by the fact that the same operator performs the procedure and controls the amount of contrast and radiation used.[2,17,19] We emphasize that, in staged procedures, there are more cine projections, greater number of frames, and longer FT, and these factors contribute greatly to a higher amount of radiation delivered to the patient. However, FT alone does not ensure that a lower dose is delivered to the patient, for it does not include the sum of cine and fluoroscopic modes, which is very variable among procedures and operators.[20,21]

Table 4. Radiological exposure rates, fluoroscopy time and amount of cine projections

Variables per group	Median (minimum – maximum)	Mean ± SD	Interquartile range		p value
			Q1	Q3	
K_{ap} total dose, µGym²					0.01
Group A	13,751.1 (3,054.8-63,522.2)	16,222.5±10,613.5	9,374.8	20,245.4	
Group B	12,009.9 (2,002.4-35,663.5)	12,029.2±7,360.6	6,375.9	35,663.5	
K_{ap} fluoro, µGym²					0.04
Group A	7,338.4 (117.1-53,589.6)	9,936.4±8,381.6	3,744.6	13,262.3	
Group B	5,976.2 (788.4-24,434.1)	7,169.0±5,303.8	2,660.4	10,396.9	
K_{ap} cine, µGym²					0.02
Group A	7,002.8 (1,877.7-26,215.6)	7,871.4±4,319.6	4,612.0	10,334.0	
Group B	5,169.2 (1,230.8-18,580.3)	6,384.6±3,911.5	3,719.2	8,319.7	
I_{ak}, total dose					0.04
Group A	3,198 (648-19,284)	3,886.8±2,943.7	2,015	4,766	
Group B	2,780 (507-9,268)	2,940.3±1,841.0	1,488	3,774	
I_{ak} fluoro, mGy					0.10
Group A	1,682 (209-16,629)	2,347.7±2,423.1	898	2,989	
Group B	1,346 (156-5,706)	1,703.0±1,286.6	640	2,476	
I_{ak} cine, mGy					0.03
Group A	1,723 (420-5,967)	1,961.1±1,079.6	1,213	2,507	
Group B	1,388 (337-8,308)	1,654.6±1,230.9	839	2,259	
Total fluoroscopy time					0.0009
Group A	21.5 (7.9-96.2)	23.2±13.17	14.5	27.9	
Group B	14.4 (4.7-53.3)	17.1±9.68	10.7	21.1	
Cine fluoroscopy time					0.0001
Group A	2.7 (1.5-4.9)	2.7±0.78	2.1	3.2	
Group B	2.0 (1.1-3.9)	2.2±0.68	1.7	2.7	
Cine projections					0.0001
Group A	44 (20-79)	44.9±14.9	33	51	
Group B	28 (11-77)	32.7±17.9	22	77	

SD: standard deviation; Q1: lower quartile; Q3: upper quartile; K_{ap}: kerma area product; I_{ak}: incident air kerma.

Table 5. Impact of implant of one or two stents in one artery

Variables per group	Implant of one stent in one artery Group A=30 staged; Group B=39 ad hoc				Implant of two stents in one artery Group A=24 staged; Group B=17 ad hoc			
	Median (minimum – maximum)	Interquartile range		p value	Median (minimum – maximum)	Interquartile range		p value
		Q1	Q3			Q1	Q3	
Scoping time				0.03				0.02
Group A	18.4 (7.9-37.4)	12.2	24.1		24.6 (11.1-43.9)	19.3	32.5	
Group B	12.8 (4.7-53.3)	8.3	19.4		20.9 (8.6-35.0)	14.2	23.5	
K_{ap} total, µGym²				0.25				0.77
Group A	10,436.9 (4,031.0-29,264.3)	6,796.5	15,566.3		19,551.4 (3,054.8-49,107.6)	13,751.1	26,780.6	
Group B	8,299.9 (2,002.4-32,968.5)	5,990.8	13,442.4		14,961.2 (4,738.0-35,663.5)	12,159.8	18,635.3	
K_{ap} fluoro. µGym²				0.36				0.18
Group A	5,486.5 (1,888.0-19,065.9)	3,197.7	9,188.2		11,378.8 (1,177.1-30,217.5)	7,552.9	16,688.1	
Group B	4,348.8 (788.4-24,434.1)	2,273.5	9,239.8		8,444.7 (2,069.0-22,440.6)	5,651.5	11,840.2	
I_{ak} total. mGy				0.29				0.30
Group A	2,366.0 (1,039.0-6,433.0)	1,644.0	3,801.0		4,370.0 (648.0-11,819.0)	3,450.0	6,130.5	
Group B	2,052.0 (507.0-6,262.0)	1,188.5	3,591.5		3,920.0 (1,000.0-9,268.0)	2,465.0	9,268.0	
I_{ak} fluoro. mGy				0.43				0.33
Group A	1,071.7 (389.4-4,349.8)	761.1	2,262.5		2,699.9 (227.2-7,152.0)	1,828.2	3,646.4	
Group B	989.8 (156.6-4,300.3)	497.9	2,417.8		2,286.3 (336.8-5,706.5)	1,187.8	3,001.3	
Cine 15 frames				0.01				0.08
Group A	1,775 (800-3,039)	1,541	2,219		2,346 (71-3,336)	1,889	2,687	
Group B	1,521 (365-2,993)	1,282	1,785		2,055 (477-2,679)	1,597	2,399	
Projections				0.004				0.01
Group A	33 (20-62)	28	43		49 (29-79)	44	57	
Group B	27 (11-75)	22	33		35 (19-77)	28	46	

Q1: lower quartile; Q3: upper quartile; K_{ap}: kerma area product; I_{ak}: incident air kerma.

In our study, no statistically significant difference between the two groups was observed in lesion classification, but the number of stent implants and the number of revascularized patients were higher in staged PCI when compared with ad hoc PCI. This could also have influenced the results obtained, explaining the greater amount of radiation delivered to the patients in staged procedures. A sub analysis was performed separating the groups according to the number of stents implanted per artery. In staged PCI with one or two stent implants per vessel, when compared with ad hoc PCI, a statistically significant difference was observed only in the variables fluoroscopy time, total 15f/s frames, and total projections. The fact that no change was observed in K_{ap} and I_{ak} can be explained by the small size of the sample.

According to the recommendations of the International Atomic Energy Agency (IAEA), Report 59, the following reference levels for the dose delivered to the patient should be observed based on K_{ap} values: 50 $Gycm^2$ for coronary angiography, and 125 $Gycm^2$ for PCI.[18] Doses above these levels increase the risk of deterministic effects, such as skin lesions.[19] However, for the operator and for team members, I_{ak} is an indicator of stochastic effects, and it is not an ideal parameter for determining deterministic risks.[17] It is important to note whether the unit of measurement supplied by the equipment is compatible or requires a conversion to the reference level, i.e., 1 $\mu Gym^2=10^{-2}\,Gycm^2$. We observed that 60% of staged procedures and 45% of ad hoc procedures were above K_{ap} reference levels. This highlights the need for greater control of radiological exposure rates among patients and professionals.

In 2006, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) added a recommendation that a 15 Gy fluoroscopy skin dose (I_{ak}) is a sentinel event. Doses above 2 Gy should be included in the patients' medical records, and doses above 5 Gy require the patient to be followed-up.[15] Blankenship et al. recommended the dose did not exceed 4 to 6 Gy a day, and that the possibility of staging the procedure should be considered if the radiological rate reference levels are exceeded.[19] In our study, 13.3% of staged procedures and 5% of ad hoc procedures exceeded the recommended level of 6 Gy. This highlights the need for managing the doses delivered to patients and professionals, and for developing specific protocols for staged and ad hoc procedures, taking into account the recommended limits.

The decision-making process regarding whether to intervene immediately or to stage the procedure should also be based on renal function, avoiding exceeding safe limits for the patient.[1,2,19] In this study, although the ad hoc PCI group received higher volume of radiological contrast, there was no decline in renal function, according to creatinine levels at 48 hours after the procedure, when compared with Group A. We emphasize the importance of developing quality control protocols, planning the optimization of radiological exposure doses, and following-up cases in which the reference levels have been exceeded.

Limitations of the study

This was an observational, sequential, non-randomized study. The procedures were performed in a single center, with a reduced number of patients. A higher prevalence of individuals with a history of coronary artery bypass grafting and stable angina was observed in Group A. The procedures were performed by more than one operator, although all operators had extensive experience in the radial technique.

CONCLUSION

Radiological rates in ad hoc percutaneous coronary interventions are lower than in staged percutaneous coronary interventions, when the procedures are performed via radial access. The results suggest that lower doses of radiation may be interpreted as a potential benefit of the ad hoc approach.

SOURCE OF FINANCING

None.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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