

Follow-up protocol for patients with delayed skin reactions due to interventional cardiology procedures: follow-up of patients with skin reactions due to radiation

Protocolo de seguimento de pacientes com reações de pele tardias devido a procedimentos cardiológicos intervencionistas: seguimento de pacientes com reações de pele devido à radiação

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ABSTRACT – Interventional cardiology procedures can generate high doses of ionizing radiation and delayed skin reactions in patients undergoing complex procedures with a substantial radiation dose level. Since 2014, we have implemented, in the cath lab, the monitoring of patients undergoing procedures with a substantial radiation dose level, to identify these patients and provide patient care support. We present two case reports of such patients, who are undergoing dermatological treatment. The implemented protocol provided specialized treatment for the patients and awareness of radiation safety among health workers.

Keywords: Percutaneous coronary intervention; Radiation, ionizing; Radiation protection; Patient-centered care; Integral healthcare practice

RESUMO – Os procedimentos cardiológicos intervencionistas podem gerar doses altas de radiação ionizante e reações tardias na pele de pacientes submetidos a procedimentos complexos, classificados como nível de dose substancial. Implementamos desde 2014, no laboratório de hemodinâmica, o monitoramento de pacientes submetidos a procedimentos com nível de dose substancial, para identificá-los e oferecer suporte assistencial. Apresentamos dois relatos de caso desses pacientes, que se encontram em tratamento dermatológico. O protocolo implementado proporcionou tratamento especializado aos pacientes e conscientização dos profissionais quanto à radioproteção.

Descritores: Intervenção coronária percutânea; Radiação ionizante; Proteção radiológica; Assistência centrada no paciente; Prática integral de cuidados de saúde

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INTRODUCTION

Interventional cardiology procedures can generate high doses of radiation for patients and, occasionally, cause skin reactions in the irradiated region. Skin exposed to radiation may present with erythema, scaling, ulceration, and even necrosis. These generally late manifestations can occur after a radiation dose threshold, and the effect may or may not be reversible. The radiation dose responsible for severity of the injury depends mainly on the complexity of the procedure, which includes the patient's biometric characteristics and clinical status, as well as the techniques employed.^{1,2}

Given the importance of patient care for complex procedures, with prolonged radiation exposure time, we implemented the monitoring of patients undergoing

diagnostic and intervention procedures at the Cardiac Catheterization Laboratory of *Hospital São Paulo da Escola Paulista de Medicina da Universidade Federal de São Paulo* (Unifesp), in 2014.³

We follow the recommendations of the NCRP Report No. 168, Radiation Dose Management for Fluoroscopically-guided Interventional Medical Procedures, of the National Council on Radiation Protection and Measurements (NCRPM),⁴ which suggests two levels of action:

- Notification Level (NL): >300 Gy cm² (kerma-area product); 3 Gy (air kerma as cumulative radiation dose at the reference point), and/or 30 minutes of fluoroscopy time.
- Substantial Radiation Dose Level (SRDL): >500 Gy cm² (kerma-area product); 5 Gy (air kerma as cumulative radiation dose at the reference point), and/or 60 minutes of fluoroscopy.

In the case of patients identified with NL or SRDL doses, the values of radiation dose-area product (air kerma x area), cumulative radiation dose (air kerma), and exposure time were documented in the medical record, and the cardiologist responsible for the procedure was aware of this fact. A multiprofessional radiology safety committee was established to discuss SRDL cases and provide patient care, given the possibility of potential skin lesions related to high doses of radiation.

The Brazilian health regulations require the interventional radiology services to establish a Risk Management Committee to ensure quality and safety of the procedures.⁵ Patient follow-up actions are not explicit in the aforementioned regulations; however, these practices must be adopted by the cath labs for continuous improvement in risk management. Nonetheless, in Brazil, they are still not much disseminated among the services. Patients must be informed about risks, and the health workers must be prepared to minimize them by optimizing radiation doses.

Our proposal was to identify procedures that generate greater risk and to provide care support to patients, in the medium- and long-run, for treatment of potential skin lesions.

The complexity of the procedure may contribute to an increase in radiation dose to the patient's skin. The degree of complexity of coronary lesions was estimated

considering the number of vessels, lesions and occlusions, severe tortuosity, and bifurcations, based on the publication Safety Report 59, of the International Atomic Energy Agency (IAEA).⁶ They were classified as complexity index (CI) namely, CI=1 (simple); 1<CI<2 (medium); and CI>2 (complex). The SYNTAX score values were also shown⁷ to evaluate complexity of coronary lesions in terms of medical management, in stratification of patients for prognosis and therapeutic options.

The study was approved by the Research Ethics Committee of the *Escola Paulista de Medicina* (Unifesp), under number 6.188.460, CAAE 63037922.8.0000.5505. In the period from 2014 to 2021, a total of 19,091 interventional procedures were performed at the Cath Lab of *Hospital São Paulo* – in that, 67% were diagnostic catheterizations and 33% were percutaneous coronary interventions, with an annual average of 2,386 cases. During this period, 65 patients were called for medical and/or dermatological follow-up and 40 returned to visit. Out of 40 patients, we identified eight with skin lesions supposedly caused by radiation.

Patients with SRDL doses were evaluated every 2 to 3 months. During the follow-up of these reported patients, observations were made and photographs were taken of the radiation-exposed skin. A biopsy of the skin lesion was performed, with fragments of skin removed using a 5-mm punch and placed in 10%-formaldehyde vials. The materials were sent to the Pathology Department of *Hospital São Paulo*, where macroscopic and microscopic examinations of specimens and hematoxylin-eosin staining were carried out. The analysis and images of the slides were obtained with an Olympus BX40[®] microscope.

Patients underwent one or two SRDL procedures in a short interval. They accepted clinical follow-up and dermatological treatment. Both patients did not report pain or any discomfort.

CASE REPORTS

Case 1

A 60-year-old female patient, body mass index (BMI) of 33.2 kg/m² (grade I obesity). The declared risk factors were hypertension (HTN) and smoking. She underwent two procedures, as shown in table 1.

Table 1. Dosimetry records of cardiological procedures carried out in 2020 on case 1 patient and lesion complexity classifications

Date	Procedure	Air-area kerma product (Gy cm ²)	Cumulative air kerma (Gy)	Exposure time (minutes)	Lesion complexity index	SYNTAX score
May 11, 2020	CX <i>ad hoc</i> PCI	551.03	12.68	86.22	4.29	19
May 18, 2020	LAD elective PCI	193.35	3.48	22.42	3.09	09
Total		744.38	16.16	108.64	NA	NA

PCI: Percutaneous coronary intervention; CX: circumflex artery; LAD: left anterior descending artery; NA: not applicable.

A skin lesion was observed in the left scapular region, characterized by a hyperchromic spot with a lacy pattern, quadrangular in shape, four months after the procedure, as shown in figure 1A. In January 2021, a skin biopsy was performed for pathological examination, which revealed a hyperplastic lesion in epidermis, a slight increase in melanin pigmentation in the basal layer, and a slight pigment discharge in the papillary dermis (melanoderma). The dermis had preserved collagen fibers, as shown in figure 1B. The skin lesions had a post-inflammatory residual appearance. The patient is under specialized clinical follow-up.

Case 2

A 66-year-old male patient, BMI of 30.7 kg/m² (grade I obesity). The declared risk factors were smoking and familial hypercholesterolemia (FH). He underwent two procedures, as shown in table 2.

A skin lesion was observed in the left scapular region, characterized by a hypochromic spot and hyperchromic border, as shown in figure 2. In June 2021, a skin biopsy was performed for pathological examination, which revealed discrete focal spongiosis in the epidermis with exocytosis of lymphocytes. In the dermis, there was a slight superficial perivascular lymphocytic infiltrate, blood vascular ectasia, and mild solar elastosis in the superficial dermis. Collagen fibers are preserved in the deep dermis (Figure 2). The skin lesions had a post-inflammatory residual appearance. The patient was undergoing specialized clinical monitoring.

DISCUSSION

As from the 1990's, several guidelines on radiation dose management have been published, highlighting the

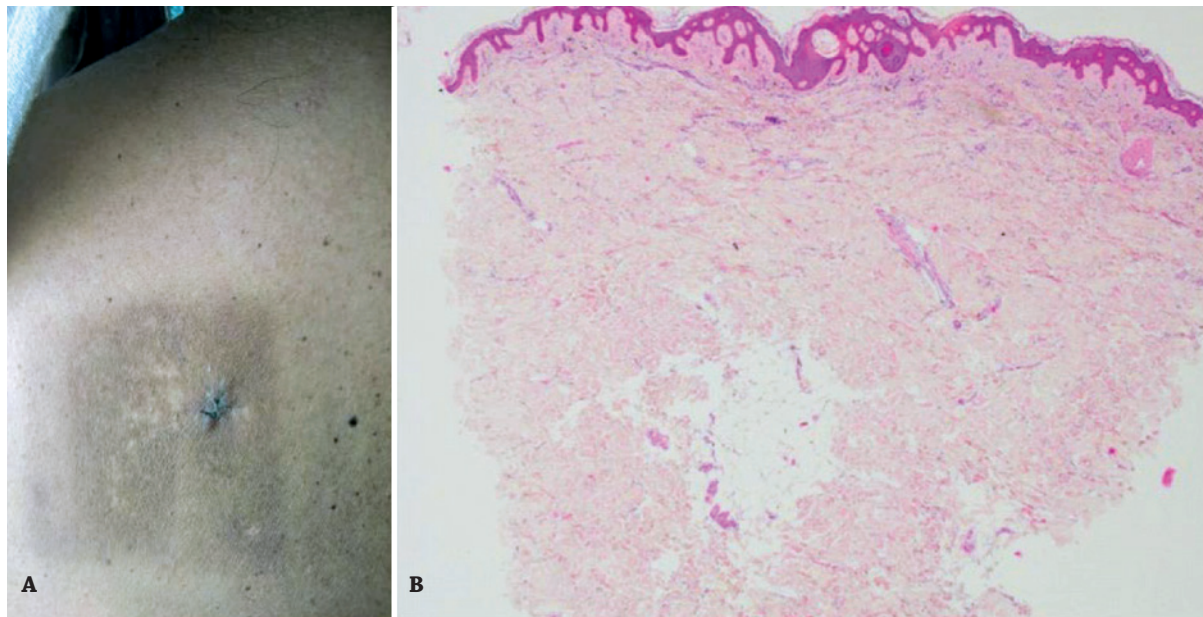


Figure 1. Photographs of the skin in the left scapular region of case 1 patient after 4 (A) and 8 (B) months of percutaneous coronary intervention, in September 2020 and January 2021, respectively. Cumulative kerma of 16.2 Gy in two procedures with one-week interval. A hyperplastic lesion can be seen in the epidermis (B), with a slight increase in melanin pigmentation in the basal layer and a slight pigment discharge in the papillary dermis (melanoderma). The dermis has preserved collagen fibers (hematoxylin-eosin 20x).

Table 2. Dosimetry records of the cardiological procedures carried out in 2020 on case 2 patient and lesion complexity classification

Date	Procedure	Air-area kerma product (Gycm ²)	Cumulative air kerma (Gy)	Exposure time (minutes)	Lesion complexity index	SYNTAX score
June 16, 2020	CX <i>ad hoc</i> PCI	892.1	12.4	86.2	3.7	19
June 30, 2020	Elective PCI in LAD	429.7	7.2	59.5	2.1	17
Total		1,321.8	19.6	145.7	NA	NA

PCI: percutaneous coronary intervention; CX: circumflex artery; LAD: left anterior descending artery; NA: not applicable.

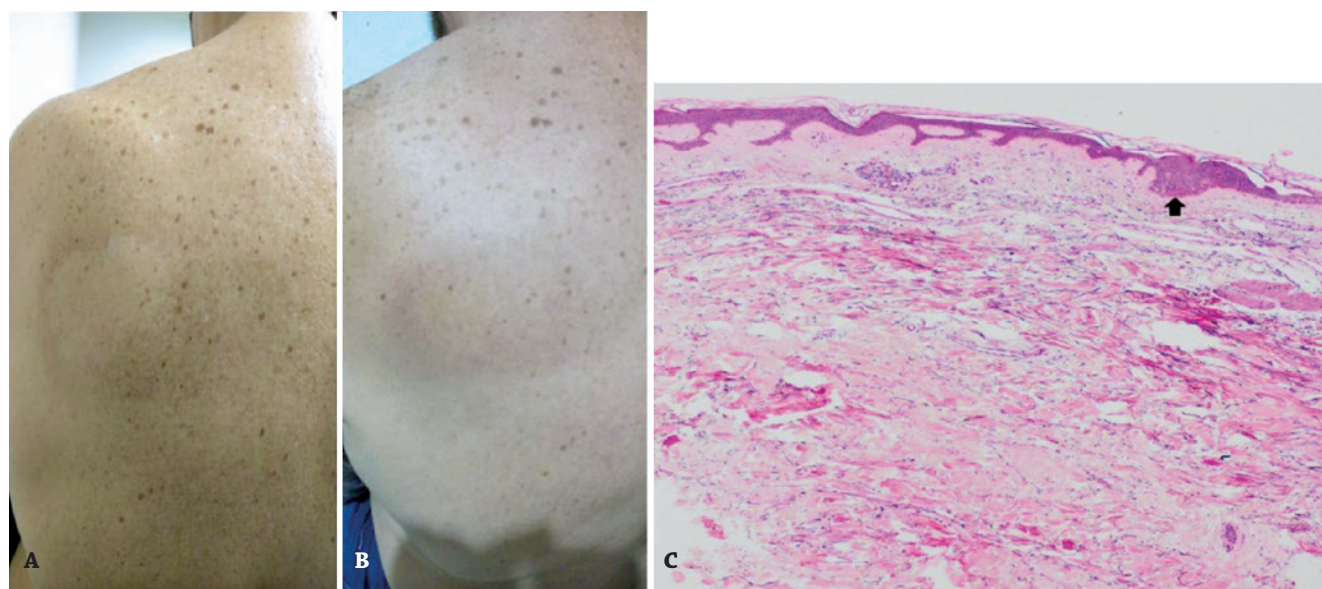


Figure 2. Photographs of the left scapular region of case 2 patient after 3 (A) and 7 months (B) of angioplasty, in September 2020 and January 2021, respectively. Total cumulative kerma of 19 Gy, in two procedures with interval of 14 days. In the epidermis (C), in June 2021, there was mild focal spongiosis with exocytosis of lymphocytes (arrow). In the dermis, there was a slight superficial perivascular lymphocytic infiltrate, blood vascular ectasia, and slight solar elastosis in the superficial dermis. Collagen fibers were preserved in the deep dermis (hematoxylin-eosin, 40x).

importance of recording radiation doses and of monitoring patients.¹ Since 2009, the Society of Interventional Radiology (SIR)⁸ and the Cardiovascular and Interventional Radiological Society of Europe (Cirse)⁹ published guides on the subject, drawing attention to interventional procedures, with the potential to generate adverse effects (radiological risk).

Potential deterministic effects after skin radiation dose thresholds are well described in the literature, by international regulatory bodies. The radiation doses during procedures depend on numerous technical-operational variables, managed by the operating physician, and on the clinical conditions of patients.

Awareness of the importance of optimizing radiation doses in the cath lab routine is essential, whatever the patient's situation, and, especially, in obese patients with comorbidities. Special protocols should be considered for these patients and for those with previous procedures (like the patients herein reported) to minimize radiation doses and risks.

Vano et al.¹¹ described that patient follow-up is feasible and appropriate after complex procedures when there is a risk of skin injuries, and this follow-up should be part of a quality improvement program in radiology and interventional cardiology services. Therefore, it is important that services establish a multidisciplinary team to evaluate cases, monitor patients, and raise awareness

among health workers of the importance of radiology safety in the laboratory routine. We suggest the team comprises interventional cardiologists, nurses, radiation technicians, medical physicists, and dermatologists. This is fully justifiable due to the expansion of activities at cath labs, where currently coronary, valvular, congenital and aortic diseases are treated, besides the development of new resources for angiographers.¹² This accounts for an important increase in interventional cardiology procedures, highlighting the percutaneous coronary intervention for complex lesions in the specialty's therapeutic armamentarium.³

Procedures with significant radiation doses and monitoring of the cases by the services have been a recurring topic presented in specialized scientific literature. Some studies have demonstrated interventional procedures deliver higher doses of radiation, both to health workers and patients, increasing the risk of biological effects.³ Hence, radiation dose management can lead a reduction in the number of procedures with high radiation doses over time.¹³

Dosimetry indicators, clinical data, and complexity indexes must be considered when planning a second procedure, to minimize radiation doses. Procedure planning, associated with best practices, can help to optimize radiation doses and minimize risks, for both patients and team.

In the reported cases, percutaneous coronary intervention was justified by the cardiovascular risk, and the radiation doses in the skin region were justified by degree of complexity of the clinical cases.

Although the SYNTAX score values did not corroborate the high radiological risk values,⁷ the fact that patients underwent two procedures within a short interval stands out. This certainly contributed to the onset of skin lesions observed. New studies involving a larger number of patients are warranted to gather more information on the real impact of ionizing radiation on skin lesions in patients undergoing complex coronary intervention.

Action level classification (notification level and substantial radiation dose level) based on routine recording of dosimetry data at the end of procedures was crucial to identify patients at greater risk of tissue reactions, allowing them to receive the required specialized treatment.

Establishing a multidisciplinary team, formed by interventional cardiologists, nurses, radiation technicians, medical physicists and dermatologists, contributed to raising awareness among health workers on relevant aspects of radiation safety.

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CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: PLB, RBM and AHPB; data collection: PLB; data interpretation: PLB, AHPB, PMR, HEBD, MCF and RBM; text writing: PLB, AHPB and RBM; approval of the final version to be published: PLB, AHPB and RBM.

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