

Importance of a Patient Dosimetry and Clinical Follow-up Program in the Detection of Radiodermatitis After Long Percutaneous Coronary Interventions

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Abstract

Purpose Complex percutaneous interventions often require high radiation doses likely to produce skin radiation injuries. We assessed the methodology used to select patients with potential skin injuries in cardiac procedures and in need of clinical follow-up. We evaluated peak skin dose and clinical follow-up in a case of radiodermatitis produced during a total occlusion recanalization.

Materials and Methods This prospective study followed CIRSE and ACC/AHA/SCAI recommendations for patient radiation dose management in interventional procedures carried out in a university hospital with a workload of 4200 interventional cardiac procedures per year. Patient dose reports were automatically transferred to a central database. Patients exceeding trigger levels for air kerma area product (500 Gy cm^2) and cumulative skin dose (5 Gy) were counseled and underwent follow-up for early detection of skin injuries, with dermatologic support. The

Ethical Committee and the Quality Assurance and Radiation Safety Committee approved the program.

Results During 2010, a total of 13 patients (3.0/1,000 that year) received dose values exceeding trigger levels in the cardiovascular institute. Only one patient, who had undergone two consecutive procedures resulting in 970 Gy cm^2 and 13.0 Gy as cumulative skin dose, showed signs of serious radiodermatitis that resolved in 3.7 months. The remaining patients did not manifest skin lesions during follow-up, and whenever patient examination was not feasible as part of the follow-up, neither patients nor families reported any skin injuries.

Conclusions Peak skin dose calculation and close clinical follow-up were feasible and appropriate, with a moderate additional workload for the staff and satisfaction for the patient.

Keywords Interventional cardiology · Peak skin dose · Radiodermatitis · Skin radiation injury

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Introduction

Radiation dose is a matter of concern for patients and clinical staff in the context of the growing complexity of invasive interventional procedures. Radiation skin injuries in patients may occur, and this risk should be contemplated in the informed consent to patients [1–6]. In addition, systematic evaluation of patient radiation doses should be performed as part of quality programs to allow the selection of patients who require longitudinal clinical follow-up on the grounds of presenting a higher risk of radiation injuries [2–6].

In 2000, the International Commission on Radiological Protection published a set of recommendations to avoid

radiation injuries during interventional procedures [1]. These recommendations have been expanded in several guidelines adopted by interventional radiology and cardiology societies [2–6].

Despite all these recommendations, many patients treated with complex percutaneous interventions are still neither counseled on the risks associated with radiation exposure nor followed up after receiving radiation doses that exceed the threshold for deterministic effects. Radiation-induced skin injuries frequently result from deficiencies in radiation dose management. However, they may also occur when complex procedures are performed on patients with a high body mass index [1, 5].

Practical actions to control dose to the patient are unfortunately still not part of the quality programs in some interventional radiology and cardiology services. The absorbed dose to the patient in skin areas receiving the maximum dose is a priority, but unfortunately, these values are still not available in most modern X-ray systems used for interventional procedures. The current standard for the X-ray systems used in interventional radiology requires to supply information on the air kerma area product (KAP) (also known as dose area product, DAP) displayed in different units for different manufacturers but usually reported in Gy cm^2 and cumulative air kerma (or dose) usually displayed in mGy at the patient entrance reference point (previously called “interventional reference point”) and also used as cumulative skin dose after the appropriate calibration factor is applied [7]. It must be noted that cumulative skin dose does not equal “peak skin dose” at the most irradiated skin area during the procedure because the X-ray beam incidence varies with C-arm angulations. A more detailed information about dosimetric quantities and units used for patient dosimetry in interventional procedures can be found elsewhere [2, 3, 5].

Because the estimation of the peak skin dose requires additional calculations, it is only performed in some catheterization laboratories, mainly on a selection of patients who have been exposed to high doses during complex procedures and who are likely to develop potential radiation-induced injuries.

In 2005, the American College of Cardiology and the American Heart Association (ACC/AHA) published a “clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures” [5]. Dose monitoring quantities and units are described together with a table of factors affecting patient dose. The benchmarking for KAP values is discussed, and 100 Gy cm^2 is mentioned as the reference value used in Europe. The substantial influence of the complexity of the procedure as well as of patient characteristics on the dose values is highlighted, and it is also mentioned that radiation injury should be

included in the informed consent of patients at increased risk.

Skin injuries pose the specific problems of a difficult diagnosis and a complex management. Because skin lesions seldom become evident before 2–3 weeks after the causative exposure, the patient and the consulting physician frequently fail to link dermatitis to radiation exposure. The lesion is normally located on the patient’s back because the C arm is below the table X-ray tube system and may interfere with sleep. Some skin ulcerations require skin grafting [5]. The ACC/AHA document states that patients should be warned of possible radiation-induced injuries whenever the procedure uses more than 50 min of fluoroscopy time or delivers more than 4 Gy to the patient entrance reference point [7]. The threshold for such a warning should be reduced to 30 min if the patient is obese or if the procedure was done with an X-ray unit that was more than 5 years old. In such circumstances, arrangements should be made for appropriate follow-up 1–3 months after procedure to ascertain whether there is no evidence of a radiation-induced injury [5].

In 2009, the society of interventional radiology (SIR) in North America and the cardiovascular and interventional radiology society of Europe (CIRSE) both published and adopted common “guidelines for patient radiation dose management” [6]. The document introduced the term “significant radiation dose” as a selected threshold value used to trigger additional dose management actions.

The National Council on Radiation Protection and Measurements (NCRP) has recently published a report on “radiation dose management for fluoroscopically guided interventional medical procedures” [2], also using a similar term as the one in the SIR/CIRSE guidelines, “substantial radiation dose level” (SRDL), defined as an appropriately selected reference value used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically relevant injury in an average patient. The SRDL is proposed for 3 Gy for peak skin dose, 5 Gy for cumulative air kerma, 500 Gy cm^2 for KAP, and 60 min for fluoroscopy time.

The society of cardiovascular angiography and interventions (SCAI) has also recently published a “radiation safety program for the cardiac catheterization laboratory,” including preprocedure, procedure, and postprocedure best practice recommendations [3] and recommended levels of dose quantities for postprocedure follow-up equal to those included in the NCRP report [2].

The 2011 ACC/AHA/SCAI “guideline for percutaneous coronary intervention” [3] includes a section on radiation safety recommendations stating that cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data and should define

thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose.

In our hospital, we adopted a follow-up procedure and trigger levels in line with the postprocedural care included in most of these guidelines, especially in terms of dose documentation and patient follow-up.

Several articles have been published on radiation skin injuries in cardiology and interventional procedures [8–13], but few elaborate on peak skin dose evaluation and clinical follow-up of the injuries.

We sought to present our experience following the ACC/AHA/SCAI recommendations and the SIR/CIRSE guidelines for patient radiation dose management in post-procedural care, first to select patients in need of clinical follow-up after complex interventional procedures, then to report the percentage of patients requiring follow-up in cardiology, and finally to describe the methodology used to estimate the peak skin radiation dose in a case of a complex chronic total occlusion procedure resulting in a radiodermatitis and the corresponding clinical follow-up.

Materials and Methods

The cardiovascular institute of the hospital where the study was carried out performed around 4,200 procedures in 2010 (43 % therapeutic) with four catheterization laboratories. All the X-ray systems are equipped with flat detectors. A central medical physics service is in charge of quality control, calibrations, patient and staff radiation protection, and dosimetry management. All the operators (interventional cardiologists) have, in compliance with national regulation and European guidelines [14], successfully completed a 20-h training course on radiation safety certified by the health authority. During this training, operators are educated on the interpretation of the patient dose quantities shown in the catheterization laboratory and on the thresholds for potential skin injuries. Radiation risk is included in the patient informed consent form. A quality assurance program including radiation safety aspects is running at the hospital, accepted by the local health authority, and patient dose values are measured and recorded for all the interventional procedures according to the national regulations. The program requires the introduction of corrective actions if patient doses are consistently higher than the diagnostic reference levels as part of the optimization process.

An automatic system called dose on line for interventional radiology (DOLIR) has been implemented at the hospital [15]. All the X-ray systems used for interventional cardiology and radiology have the capability to export a patient dose report including fluoroscopy time, KAP, and cumulative air kerma at the patient entrance reference

point, at the end of the procedure, and via e-mail to a central database. A detail of the radiographic and geometric parameters (including angulations) for all the cine and recorded fluoroscopy series is also included, along with the name of the procedure and patient demographic information.

Trigger levels have been adjusted to alert the medical physics service when kerma area product or cumulative skin dose exceeds the trigger levels recommended by SIR/CIRSE, NCRP, and SCAI (500 Gy cm² and 5 Gy [2, 3, 6]). Procedures with patient doses over the trigger levels generate alerts that are reviewed daily by a senior medical physicist who decides on the need for a more detailed analysis of the individual dose reports. When appropriate, a meeting with the cardiologist in charge of the procedure is scheduled within 24 h in order to determine whether additional information on potential radiation skin injuries should be given to the patient or to his or her family, and whether a clinical follow-up is required. The hospital quality assurance and radiation safety committee has approved the clinical follow-up procedure. The ethical committee approved this study under the title “radiological risks in fluoroscopy-guided procedures” (code B-09/20). The patients involved in this survey have accepted the clinical follow-up.

The rate of alerts in our hospital resulted in an average of one per month during the year 2010. It is worth noting that our cardiovascular institute has launched several chronic total occlusion and valvular programs in the year 2010: some of the most complex pathologies are more likely to be addressed to our center rather than at other, similar hospitals that consequently have a lower rate of high doses.

Compared to nonocclusive stenoses, percutaneous coronary interventions of chronic total occlusions represent a greater challenge for interventionalists because of a procedural complexity and a high radiation dose. The European registry of chronic total occlusion (ERCTO, operational since January 2008) currently contains data from 16 centers across Europe. In 2 years, a total of 1914 patients with 1983 chronic occlusion lesions were entered into the registry [16].

One of the alerts produced during 2010 and requiring close follow-up was a 50-year-old man weighing 90 kg and measuring 1.70 m (body mass index of 31.1 kg/m²) with a total chronic cardiac occlusion in the mid segment of the right coronary artery and stable angina. The vessel supplied blood to a large area of viable myocardium. The vessel presented good collateral support from the left circumflex coronary artery through CC2 epicardial collaterals. Two catheterization procedures were carried out. The first was a diagnostic coronary angiogram, with 159 Gy cm² and 2.5 Gy as cumulative air kerma at the patient entrance

reference point. The second, a more irradiating procedure, was carried out on October 8, 2010, in an attempt to perform percutaneous revascularization from the antegrade and retrograde approach, and resulted in 811 Gy cm^2 and 19.4 Gy as cumulative air kerma.

The cumulative dose (i.e., the air kerma without backscatter) at the patient entrance reference point is similar to the skin-absorbed dose (with an accuracy of $\pm 5 \%$) if we consider the attenuation of the X-ray beam in the table and mattress and the increase due to the backscatter. Values transferred to the patient dose database are corrected by the corresponding calibration factors.

Given the radiation dose received during the second intervention, the patient was immediately included in the clinical follow-up program, and a detailed dosimetry evaluation of the peak skin dose was performed. The patient and his family were informed about the possible skin injury and scheduled for periodic revisions, initially at the interventional cardiology service and later in a specialized dermatology unit.

Results

During 2010, a total of 13 patients (i.e., 3/1,000) presented dose quantities over the trigger levels (500 Gy cm^2 or 5 Gy as cumulative skin dose) (Fig. 1). Twenty-five percent of the cases were chronic total occlusion procedures. All the catheterization laboratories in our hospital use the same X-ray system model (Philips Allura DF-10) with similar dose settings for fluoroscopy and cine acquisition. In most cases, initial follow-up revealed no signs of lesions. In cases where the clinical follow-up was not possible, patients or families reported no skin injuries. The only patient with skin injuries after complete follow-up was patient 12 (Fig. 1). The follow-up and additional peak skin dose evaluation for this patient is described in the next section.

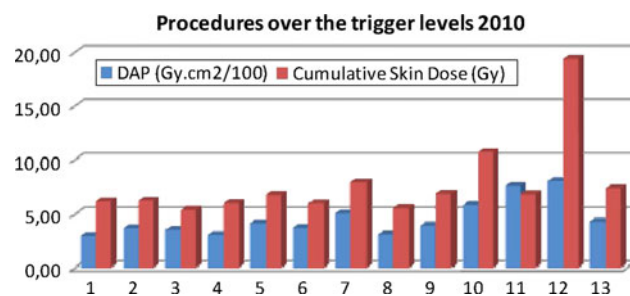


Fig. 1 Dosimetric values of the 13 procedures resulting in dose quantities (KAP presented as $\text{Gy cm}^2/100$ to fit in a similar scale) and cumulative skin dose (Gy) higher than the trigger levels. The radiodermatitis resulting from procedure 12 corresponds to the case we present here

Peak Skin Dose Evaluation for Patient with Skin Injuries

The patient dose report of the main procedure indicates a total of 134 min of fluoroscopy, 66 cine series with 5,170 frames, with a total KAP of 811 Gy cm^2 (33 % due to cine acquisitions and 67 % due to fluoroscopy).

The details of the cine series in the dose report indicate the radiographic parameters (mA, kVp, and ms of the radiation pulses), the C-arm angulations, the distance focus to the flat detector, and the number of frames per series. For this procedure, only one fluoroscopy series was recorded and fluoroscopy was set at 15 frames/s. All the cine series were acquired at 15 frames/s.

With these data, and from the output of the X-ray tube (measured during the acceptance test and later during the periodic quality controls), the skin dose per cine frame and per cine series were calculated for the different projections. Skin dose per cine frame resulted between 0.74 and 1.48 mGy. The number of frames per series was 78 ± 45 , and the skin dose per series was $94 \pm 61 \text{ mGy}$. The fluoroscopy contribution was assumed to be proportional to the cine dose for the different angulations of the C arm. A total of 37 cine series were acquired with left anterior oblique at $41\text{--}45^\circ$ and cranial between 16 and 23° . The skin dose of all these cine series (and the corresponding part of fluoroscopy) resulted in a total of 12.1 Gy in a single area of the skin (the most irradiated area).

In an attempt to verify the accuracy of the calculation made while using the X-ray tube output and the radiographic and geometric parameters included in the patient dose report, we compared the total cumulative dose calculated (18.7 Gy) with the dose measured by the ionization chamber built in the X-ray system (19.4 Gy) and transferred to the patient dose report. The difference between the two cumulative doses (calculated and measured by the X-ray system) was only 4 %. A similar calculation was made with the first catheterization (159 Gy cm^2 and 2.4 Gy). The contribution to the irradiated area of the skin corresponded to the same range of angulations in this procedure (left anterior oblique $41\text{--}45^\circ$ and cranial between 16 and 23°) was 0.9 Gy .

The accuracy for the calculation of the total absorbed dose in the most irradiated area of the skin (13.0 Gy) can be estimated in $\pm 15 \%$.

Figure 2 presents a graph of the skin dose distribution from the C-arm angulations corresponding to the procedure carried out on October 8, 2010. The area of the circles is proportional to the skin dose for the different series in these angulations.

Figure 3 presents both a selection of the angulations having contributed in the procedure of October 8, 2010, to the irradiation of the skin area where the radiodermatitis

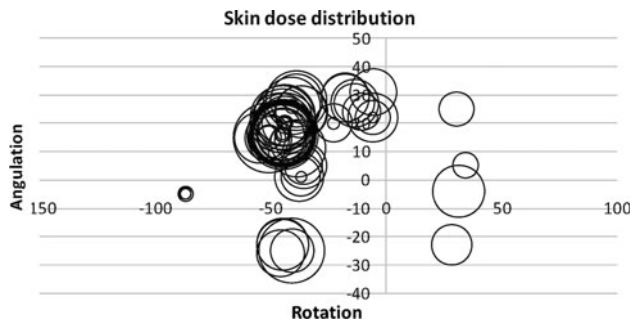


Fig. 2 Skin dose distribution from the C-arm angulations corresponding to the procedure carried out on October 8, 2010. The area of the circles is proportional to the skin dose for the different series in these angulations

appeared and a graph adapted to the anatomic position of the skin injury. When the contribution of the first procedure (September 20) to this area of the skin (0.9 Gy) was considered, the final skin dose in the area was 13.0 Gy.

Clinical Follow-up

After the procedure carried out on October 8, 2010, to solve the total occlusion and considering the estimated total peak skin dose of 13.0 Gy in the right subscapular area, we decided to include the patient in the clinical follow-up protocol for radiation injuries. The patient and his family were informed about the injury, the sequence of revisions, and the medical support to solve the skin lesion. Patient and family were instructed to be in contact with the

cardiologist (or the doctor assigned for the follow-up) if any symptom (such as a redness in the back) should appear before the scheduled revisions.

The first medical visits were scheduled 3 and 20 days after the most irradiating procedure. During these revisions, no sign of any redness was reported. The patient reported some redness in the back 46 days after the procedure (November 23, 2010) and was called to the hospital for a third visit. A significant radiodermatitis (5×4.5 cm) was observed in the subscapular right region (Fig. 4). Note that the shape of the lesion is not rectangular as a result of the use of the wedge filter during the procedure. Physical examination revealed an erythematous, indurated, and exudative red plaque, with well-defined borders and areas of denuded epidermis. No signs of necrosis were detected. No other lesions were observed in other locations. The patient was referred to the dermatology service. That day, the first images of the skin were obtained with a reflectance confocal microscope (RCM) (Fig. 5) so as to follow the evolution of the injury.

RCM images of the lesional skin showed inflammatory cells together with a morphologic alteration of dermal papillae. Clinical, dermatoscopic, and RCM evaluation of the skin revealed a skin injury concordant with an acute exudative radiodermatitis, but no signs of necrosis. Treatment with 0.05 % Betamethasone cream twice daily was initiated.

On December 3 (56 days after the procedure), the skin lesions improved after treatment with topical steroids.

Fig. 3 Selection of the angulations (from the procedure of October 8, 2010) contributing to the irradiation of the skin area and the subsequent radiodermatitis. The anatomic position of the skin injury is presented

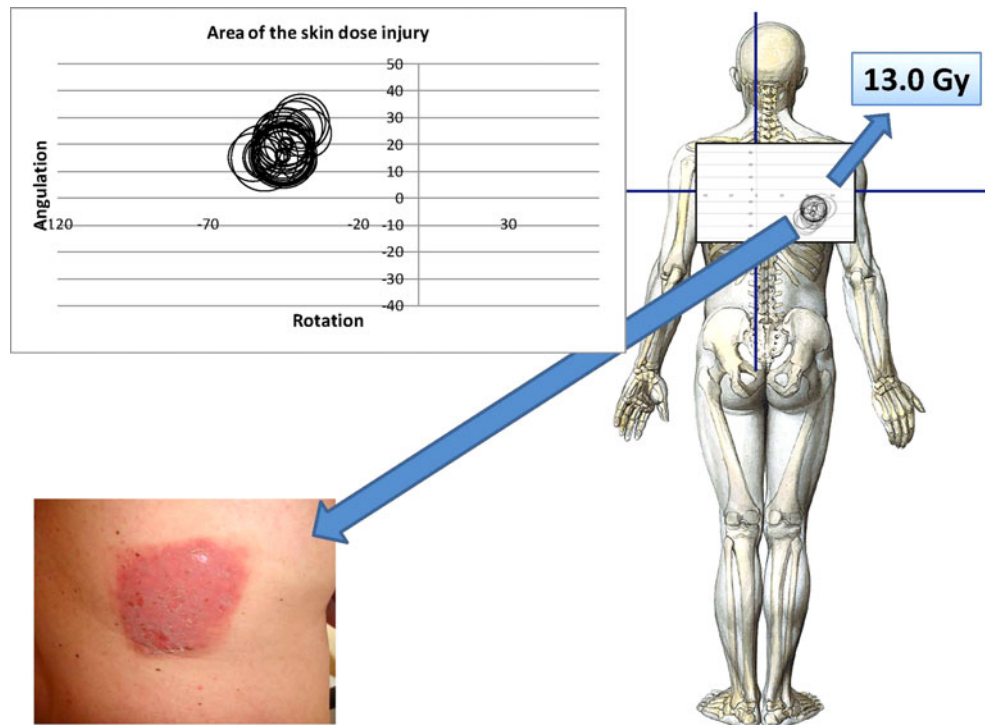




Fig. 4 Clinical images of the patient showing the evolution of the radiodermatitis. **A** Skin injury 45 days after the procedure (November 11, 2010). Erythematous, indurated, and exudative red plaque were evident on the subscapular region, with well-defined borders and areas of denudated epidermis, without signs of necrosis. **B** Skin injury 56 days after the procedure (December 3, 2010). The skin lesions improved after treatment with topical steroids. A denudated central

area was still present. There was no pain on palpation. **C** Skin injury 75 days after the procedure (December 22, 2010). Almost complete improvement of the lesion was evident, showing minimal erythema confined to the area of radiation, without ulcerative or necrotic lesions. **D** Skin injury 112 days after the procedure (January 28, 2011). The patient presented complete healing with minimal postinflammatory hyperpigmentation at the site of the radiodermatitis

There was no pain on palpation. RCM images showed lower grade inflammation, but the structure of dermal papillae was still altered.

On December 22 (75 days after the procedure), almost complete clearance of the lesion was evident, with minimal erythema confined to the area of radiation and without ulcerative or necrotic lesions. RCM images showed a geographic structure of dermal papillae without inflammation (Fig. 4).

On January 2011 (112 days—approximately 3.7 months—after the procedure), the patient presented minimal healing postinflammatory hyperpigmentation at the site of the radiodermatitis (Fig. 4). RCM images showed complete recuperation of the dermoepidermal junction, with dermal papillae of normal morphology and basal cell hyperpigmentation (Fig. 5).

Discussion

Skin radiation injuries are due to radiation damage to cells and are considered a deterministic effect, characterized by a threshold dose and an increase in the severity of the reaction as the dose is increased further. Radiation-induced

skin injuries may manifest themselves months after the radiation dose was administered. The diagnosis of radiation-induced skin injuries is often delayed as a result of their relatively rare occurrence and the difficulty of recognizing their cause [8].

It is essential to emphasize the importance of preprocedure planning for high-risk patients, of dose management during the case, of follow-up as part of best practice in radiation safety, and of dose management as recommended in national and international guidelines [2–6].

Launching a program of clinical follow-up offers the major advantages of alerting the patient and his or her family at an early stage and of preparing the postprocedural care with a specialized dermatology unit.

These injuries could be treated surgically. However, avoiding biopsy procedures is a way of increasing patient comfort, as biopsies sometimes lead to alterations in scarring and increase the risk of reinfection. RCM allows noninvasive assessment of skin histologic features and provides noninvasive evaluation of the dynamic changes of the skin during radiodermatitis [17, 18].

Calculating peak skin dose is critical to decide on an appropriate clinical follow-up. Interventional cardiology

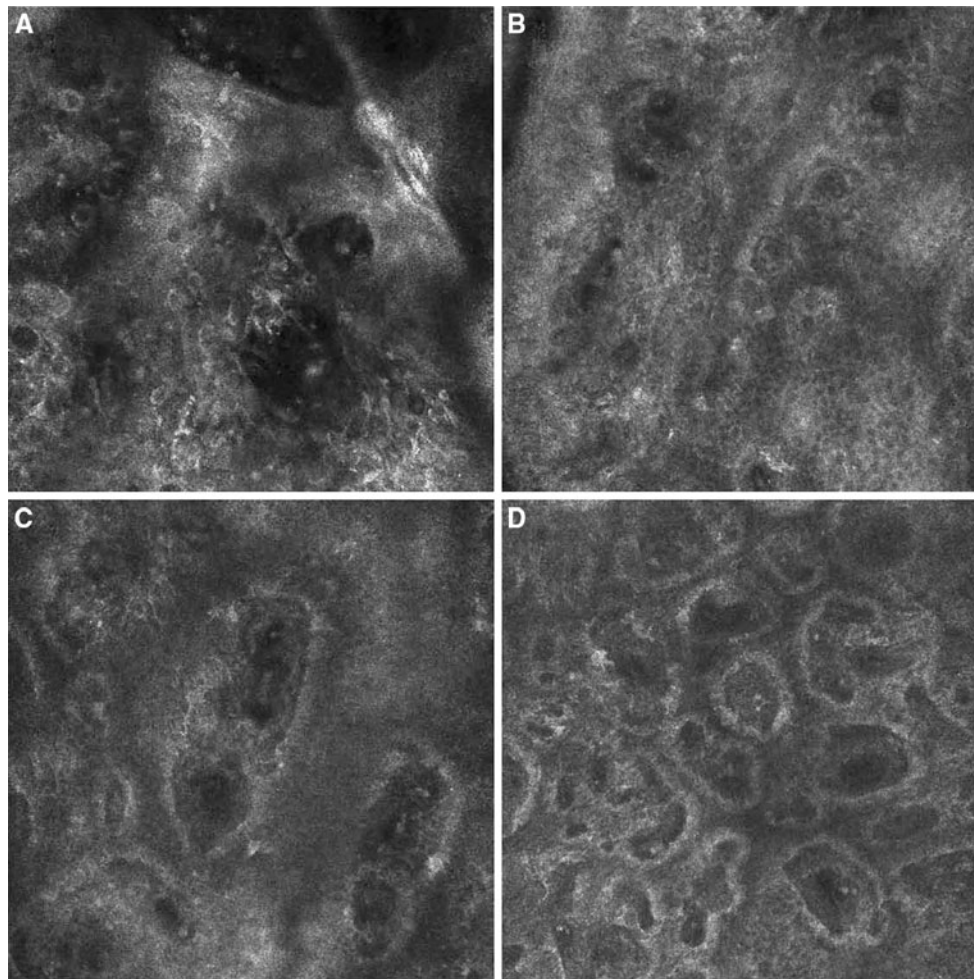


Fig. 5 Reflectance confocal microscopy images of the patient at the level of the dermoepidermal junction showing the histologic evolution of the radiodermatitis. **A** At 45 days after the procedure (November 23, 2010), RCM images of the lesional skin showed inflammatory cells together with a morphologic alteration of dermal papillae. **B** At 56 days after the procedure (December 3, 2010), RCM images showed a lower grade of inflammation, but the structure of

dermal papillae was still altered. **C** At 75 days after the procedure (December 22, 2010), RCM images showed a geographic structure of dermal papillae without inflammation. **D** At 112 days after the procedure (January 28, 2011), RCM images showed complete recuperation of the dermoepidermal junction, with dermal papillae of normal morphology and basal cell hyperpigmentation

services are usually busy units receiving a significant number of patients from remote areas and any additional postprocedural care requires additional resources, which is not always easy to organize. In addition, the follow-up of potential skin injuries adds to the patients' and families' anxiety. Therefore, follow-up should only be decided on after a careful analysis of the patient dose reports and after checking whether any previous procedures were performed on this patient at any other hospital.

Limitations

Calculations of peak skin dose are subject to inaccuracies because of the distribution of radiation dose arising from the fluoroscopy runs that is estimated to be proportional to the dose related to the cine runs in the specific angulations.

Another critical point would arise if some of the other 12 patients in our center with dose parameters over trigger levels had developed some late effects on the skin. The doses, as can be seen in Fig. 1, were much lower, and the initial follow-up has revealed no symptoms in the skin, but the fact that some of these patients may have developed injuries that they have not been reported to the cardiovascular institute of our hospital cannot be ruled out.

Conclusions

Peak skin dose calculation, detailed information provided to patients, and close clinical follow-up are feasible and appropriate after complex interventional procedures when there is a risk of skin injury. They should form part of the quality improvement programs in all interventional

radiology and cardiology services. The additional workload for the staff was moderate because the patients to be included in clinical follow-up were chosen wisely according to the most accurate dose calculations. Patients felt confident with the cardiology service during the follow-up.

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Conflict of interest The authors declare that they have no conflict of interest.

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