Guideline for Radiation Safety in Interventional Cardiology (JCS 2011)

– Digest Version –

JCS Joint Working Group

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Introduction of the Revised Guidelines

The Guideline for Radiation Safety in Interventional Cardiology were prepared in 2004 to 2005 and published in 2006[1] in response to the situation that the recent increase in use of cardiac interventions for the treatment of coronary artery disease and arrhythmias, which increased the number of cases of radiation injuries such as radiation-induced skin injuries in patients and cataract in healthcare professionals. In the preparation of the guidelines, we called on a wide range of healthcare professionals such as physicians, radiation technologists, nurses, and clinical laboratory technicians for questions about radiation safety, and specialists in radiology prepared answers to commonly asked questions. The guidelines are presented in Q-and-A style to provide basic scientific information and practical knowledge to ensure radiation safety. The first edition was widely supported by healthcare professionals, and its English translation has been used in other countries.[2]

Although the basic concepts of radiation safety remain the same, medical technology has advanced rapidly in the past five years since the release of the first edition, and the general public has become increasingly interested in radiation exposure in the healthcare setting. The earthquake and nuclear disaster in March 2011 ignited safety concerns over radiation exposure. Healthcare professionals involved in radiology have a responsibility to have adequate knowledge about radiation exposure and explain to patients. The 2006 revision of the guidelines was prepared to include new descriptions and update outdated descriptions.

The following revisions were made to the guidelines:
(1) Coronary computed tomography (CT): The use of coronary CT has increased substantially because of its low invasion. Although many new instruments have been developed to reduce radiation exposure, careful consideration

should be made to weigh the benefits of imaging against the risk of radiation exposure when it is used to screen for coronary artery disease, performed repeatedly during routine check-ups, or expected to be followed by coronary angiography (CAG). A question and answer section about coronary CT were added in this revision.

(2) A question and answer section about cardiac interventions in children was added to reflect the increase in the number of children treated with this technique.

(3) The descriptions and figures of flat panel detector (FPD) were updated to reflect the widespread use of the devices.

(4) A question and answer section about newly released patient skin dosimeters was included. Outdated products and software that are no longer available were described as such.

(5) A question and answer section about radiation exposure to technicians involved in thallium (Tl) myocardial scintigraphy was added.

(6) A question and answer section about radiation exposure during portable X-ray procedures in cardiac care unit (CCU) was added.

In addition to these topics, we updated the guidelines to include up-to-date information to make this revision more user-friendly. We hope the guidelines will help healthcare professionals involved in cardiovascular imaging.

I General Issues

1. In Formulating the Guidelines

As the prevalence of interventional procedures to treat cardiovascular diseases increases, cases of radiation-induced skin injury among patients who undergo cardiovascular intervention are increasing rapidly. Warnings concerning skin injuries associated with interventional cardiology have been issued by the Food and Drug Administration (FDA) and the Japan Radiological Society since the mid-1990s. However, cardiovascular physicians have generally not been well aware of radiation-induced skin injuries, possibly because of their interest mainly in life-threatening diseases such as ischemic heart disease and arrhythmias. Interventional cardiology has become increasingly sophisticated, and the indications for it have expanded. This trend has resulted in an increased number of radiation-induced skin injuries and other types of health hazards, such as cataract and hypothyroidism, in those who perform the procedures.

Since not all physicians engaged in interventional cardiology have basic knowledge of radiation, appropriate education and training programs are required. For nurses and medical technologists working in departments other than radiology as well, it is important to have a good understanding of exposure doses that can occur during work hours and their effects. In this situation, "the Guidelines for Prevention of Radiation-induced Skin Injuries Associated with Interventional Radiology (IVR)" were formulated in 2001 by the Japan Association on Radiological Protection in Medicine with the participation of 13 academic institutions. The Guidelines describe relevant issues in a readily understandable fashion, including Q-and-A lessons, and are quite useful for cardiovascular physicians as well. Unfortunately, however, cardiovascular physicians are not in general awareness of their availability. In addition, there has been a demand for more readily understandable guidelines including answers to common questions shared by cardiovascular physicians, procedures characteristics of cardiovascular medicine, such as percutaneous coronary intervention (PCI) and ablation, the best mode of informed consent, and other issues. In the USA, similar guidelines for cardiovascular physicians have been formulated and published.

Members of the Japan Association on Radiological Protection in Medicine made significant contributions to the formulation of the present guidelines. Featuring Q-and-A lessons with many straightforward tables and figures, the guidelines are believed to help educate and train cardiovascular physicians who are not specialized in radiology. We hope that the present guidelines will be used in the best way possible for the sake of the safety of patients and medical personnel.[3]

2. Basic Knowledge of Radiation Exposure Control: Stochastic and Deterministic Effects, Absorbed Dose, Effective Dose, and Dose Units (Gy/Sv)

1. Differences Between Patient Exposure and Exposure of Medical Personnel

Cardiac catheterization is a procedure performed for diagnostic and therapeutic purposes by means of images obtained by the delivery of X-irradiation to the patient. The X-rays from the X-ray system (X-ray tube focus) delivered directly to the patient during this procedure are termed primary X-rays. The X-rays that have entered the patient's body collide with the orbital electrons of atoms in the body and exhibit interactions, such as flipping of orbital electrons with loss of energy (photoelectric effect) and scattering in directions other than the direction of entrance (Compton scattering). The X-rays emitted from the body as a result of these interactions are termed secondary X-rays.

A fact requiring special attention is that while the X-ray tube is the source of primary radiation causing exposure to the patient, the secondary X-rays from the patient's body make a much larger contribution to exposure of the operator.

2. Stochastic Effects and Deterministic Effects

Most organs and tissues remain unaffected by the loss of a considerable number of cells. If the number reaches a critical level, however, impairment of tissue function results in an observable disorder. Although the probability of causing such a disorder is nearly zero at low doses of radiation, it rises to 100% rapidly after a given level of dose (threshold value) is exceeded. Above the threshold value, the severity of disorder increases with the dose. Effects of this type are termed deterministic effects. If biodefensive mechanisms fail to function well in the process of repair of radiation-irradiated cells that have survived, malignancy, i.e, cancer, can develop after a latent period. The probability of onset of cancer due to radiation probably rises in proportion to the increase in dose, without a threshold value, at least at doses sufficiently lower than the threshold value for deterministic effects. The severity of cancer is not influenced by dose. Effects of this type are also known as stochastic effects. In the event of such an injury to germ cells, the effects of radiation will be manifested in offspring of the person exposed. Stochastic effects of this type are termed genetic effects.

3. Measuring Radiation (Radiometry)

The ionizing radiation (hereinafter simply referred to as radiation) delivered to a patient is mostly absorbed in his or her body tissue, with only a very small portion permeating the body to contribute to the formation of images. In addition, the radiation delivered to the human body scatters in ambient space, reaching the bodies of medical personnel. The radiation delivered to human beings can have adverse effects. Because the amount of exposure can be markedly reduced by implementing appropriate management, however, dosimetry is of critical importance in quantifying the level of exposure of individuals in particular conditions and thus enabling control of exposure and ensuring safe procedures.

(1) Tissue-Absorbed Dose

The tissue-absorbed dose of radiation is defined as the energy per unit mass of human tissue or organ transmitted by the radiation. As such, the tissue-absorbed dose serves as the basis for calculations of equivalent dose and effective dose, and is also used to express doses that have caused acute radiation injuries and in other cases as well. The international system of units (SI) for tissue-absorbed doses is J/kg, with "gray" and "Gy" used as the special unit name and symbol, respectively.

(2) Equivalent Dose

Even when the mean tissue-absorbed dose for a tissue or organ is constant, the effects of radiation on living organisms vary depending on the type of radiation. For example, the likelihood of chromosomal abnormality differs between X-rays and neutron rays. Essentially, the equivalent dose of radiation is a modification of the mean absorbed dose for each tissue or organ taking into account the effects of the radiation, and has been defined as an index of the risk of carcinogenesis and genetic effects in tissues and organs resulting from low-dose exposure (risk of stochastic effect). In related laws, however, the equivalent dose is used as an index of the risk of deterministic effects on the skin, lens, and female abdomen (fetuses). The special unit name and symbol for equivalent dose are "sievert" and "Sv", respectively.

(3) Effective Dose

Susceptibility to radiation-induced cancers and genetic effects varies among tissues and organs. Hence, the equivalent dose may be averaged by weighing according to the radiosensitivity of each tissue or organ to obtain a numerical index known as the effective dose. The effective dose serves as an index of the risk for carcinogenesis and genetic effects resulting from low-dose exposure in individual persons. In related laws, the effective dose is used to specify not only the limits of exposure to persons engaged in medical practice, but also place related limitations, such as the boundaries of radiation-controlled areas. This is because these dose limits have been established as legal regulations on the doses to which persons entering a certain location may possibly be exposed. As with equivalent dose, the special unit name and symbol for effective dose are "sievert" and "Sv", respectively.[4,5]

3. Clinical Picture of Radiation-Induced Skin Injuries

1. Classification by Severity of Radiation-Induced Skin Injuries and Clinical Course

If the human body is affected by tissue damage resulting from radiation exposure, this condition is termed a radiation injury.

Table 1. Threshold Skin Entrance Doses for Different Skin Injuries

Effect	Approximate threshold dose (Gy)	Time of onset
Skin		
Early transient erythema	2	2 to 24 hours
Main erythema reaction	6	Within 1.5 weeks
Temporary epilation	3	Within 3 weeks
Permanent epilation	7	Within 3 weeks
Dry desquamation	14	Within 4 weeks
Moist desquamation	18	Within 4 weeks
Secondary ulceration	24	>6 weeks
Late erythema	15	8 to 10 weeks
Ischaemic dermal necrosis	18	>10 weeks
Dermal atrophy (1st phase)	10	>52 weeks
Induration (invasive fibrosis)	10	
Telangiectasis	10	>52 weeks
Dermal necrosis (delayed)	>12	>52 weeks
Skin cancer	None known	>15 years
Eye		
Lens opacity (detectable)	>1 to 2	>5 years
Lens/cataract (debilitating)	>5	>5 years

Adapted from ICRP Publication 85: Avoidance of Radiation Injuries from Medical Interventional Procedures, 85, Annals of the ICRP, Vol. 30 No. 2, 2000, with permission from Elsevier Inc.

Some types of radiation injuries have no clinical symptoms, and are hence undetectable without appropriate examination. Biologic effects resulting from radiation exposure are classified into stochastic effects and deterministic effects based on the difference between the dose-response relationships. It has been shown that threshold doses exist for deterministic effects, such as skin and lens injuries, under which such effects are not observed. The doses irradiated in ordinary imaging procedures such as chest X-ray radiography are much smaller than the threshold doses and will never cause skin injury. However, in PCI, catheter ablation, and other procedures that can involve the delivery of large amounts of radiation, skin injuries can occur, making confirmation of radiation dose of paramount importance. A list of effects of radiation on the skin and lens, threshold doses, and times of onset is given in **Table 1**.

The threshold dose is a numerical value that must always be borne in mind by the individual responsible for radiation delivery in the context of protection against radiation injuries. In performing PCI or catheter ablation, it is important that the patient's skin-absorbed dose be kept below the threshold value for serious injuries, in order to prevent serious deterministic effects. It should be noted, however, that in actual cases of skin or lens injury, the course is widely variable; the numerical value is thus not applicable to all cases. Prior to performing PCI or similar procedures, the upper limit of the skin dose should be specified as a numerical target for radiation management at the institution. Since there are cases in which priority is given to completion of the treatment over control of minor deterministic effects, as in emergency medical services, it is necessary to determine in advance the procedural steps to be taken in order to obtain the best outcome for the patient; this includes determination of the individual making judgments regarding continued delivery of irradiation at levels exceeding the management target value.

The earliest change after acute delivery of radiation is tran-

Figure 1.   (**A**) Skin reactions of second degree. (**B**) Skin reactions of third degree. (**C**) Skin reactions of fourth degree.

sient erythema, which develops in several hours. This is due to capillary dilation upon release of a histamine-like substance from damaged epithelial cells, and is only rarely observable clinically. The skin damage that follows (acute skin reaction) is classified into four grades of severity, from degree 1 to degree 4, as shown below.

(1) Skin Reactions of First Degree
After irradiation, the proliferation of epithelial basal cells is first inhibited, followed by keratinized layer desquamation, resulting in thinning of the epithelium. This reaction emerges about 3 weeks after irradiation of 3 to 4 Gy dose. The skin becomes dry, and epilation occurs. Almost no other symptoms develop.

(2) Skin Reactions of Second Degree [Dry Dermatitis]
(Figure 1A)
The major symptom is main skin erythema, in which arterioles become partially stenosed, with increased blood flow, resulting in dry dermatitis. The skin congests and swells, but does not erode, then desquamation begins. Erythema becomes evident about 2 weeks after irradiation of 6 to 19 Gy, and it persists for about 3 to 4 weeks.

(3) Skin Reactions of Third Degree [Moist Dermatitis]
(Figure 1B)
Irradiation of a single dose of 20 to 25 Gy produces bullae in

the epithelium. At higher doses, bullae also appear in subcutaneous tissue, and fuse together. Upon breakage of the bullae, subcutaneous tissue becomes bare. Moist dermatitis develops about 1 week after irradiation and persists for 4 to 5 weeks. Fibrin deposits in the wounds. Affected regions are susceptible to infection. After about 1 to 2 weeks regeneration of the epithelium begins.

(4) Skin Reactions of Fourth Degree [Ulceration]
(Figure 1C)
These reactions occur within 1 week after irradiation of a dose of 30 Gy or more. Deep-red erythema develops, followed by formation of bullae, which in turn erode to form ulcers, and the epithelium necrotizes and sloughs off. At higher doses, sharply indented radiation ulcers typically develop. The epithelium loses its basal membrane, leaving the thin layer of epithelium directly in contact with subcutaneous tissue; the affected skin is now vulnerable to mechanical stress.

It is important that the dose received by the patient in PCI be accurately determined with the above facts in mind, and that the dose and time of onset of its effects be confirmed. Whenever possible, the patient should be followed for an appropriate period, considering the time course of the adverse reactions to radiation described above.[6–11]

II Specific Issues (Qs and As)

1. Basic Knowledge of Radiation-Induced Skin Injuries

1. Radiation-Induced Skin Injuries in PCI
Q1: I've heard that in PCI the patient receives higher doses than in other radiological procedures. Is this true?
A: **Figure 2** shows mean cumulative doses per exam in 62 patients undergoing PCI and diagnostic contrast-enhanced CAG at the National Cerebral and Cardiovascular Center. It is evident that PCI involves greater doses than diagnostic contrast-enhanced CAG. In PCI, the transillumination time is extended because a catheter must be inserted into the target coronary artery, and a thin guidewire, balloon, and stent are inserted into the coronary artery and dilated or left deployed. Imaging

must be repeatedly performed to check the positions and degrees of patency of the balloon and stent. As a result, the dose received by the patient increases.[11]

Q2: I've heard that in PCI greater exposure occurs during transillumination than during imaging. Is this true?
A: In diagnostic contrast-enhanced angiography, catheter insertion in the target coronary artery is followed only by repeated positioning and imaging in various directions. Since PCI, on the other hand, involves not only catheter insertion into the target coronary artery but also the delivery of a thin guide wire, balloon, and stent to the inside of a coronary artery and dilation and positioning of the stent at deployment, transillumination time must be extended. In addition imaging is repeatedly performed to check the positions and degrees of dilation of the
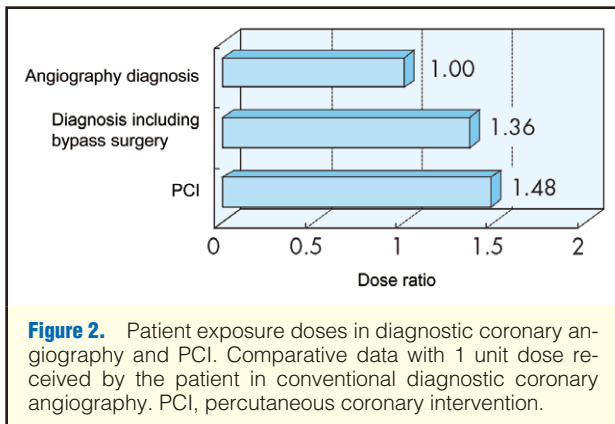
Figure 2. Patient exposure doses in diagnostic coronary angiography and PCI. Comparative data with 1 unit dose received by the patient in conventional diagnostic coronary angiography. PCI, percutaneous coronary intervention.
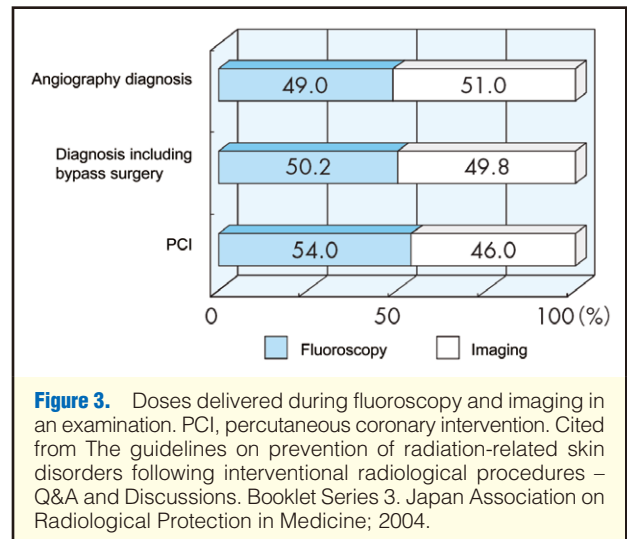
Figure 3. Doses delivered during fluoroscopy and imaging in an examination. PCI, percutaneous coronary intervention. Cited from The guidelines on prevention of radiation-related skin disorders following interventional radiological procedures – Q&A and Discussions. Booklet Series 3. Japan Association on Radiological Protection in Medicine; 2004.

balloon and patency of the stent. **Figure 3** shows mean transillumination-imaging dose ratios per exam in 62 patients undergoing CAG at the National Cerebral and Cardiovascular Center. Although PCI involves longer transillumination times than diagnostic contrast-enhanced angiography, the number of times imaging is performed increases proportionately, so the ratio of doses required for transillumination and imaging does not differ much between PCI and CAG performed for diagnostic purposes.[6]

Q3: How many grays of exposure are needed to induce complications such as skin erythema and skin ulcers on a patient? How many minutes can a patient undergo CAG without radiation-induced skin injuries?
A: The human body is influenced by radiation in various ways. If the skin-absorbed dose is 2 Gy or more, transient erythema of the skin can occur relatively early (within several hours), while irradiation of 24 Gy or more can cause skin ulcers. Since the patient radiation dose delivered during CAG may differ substantially depending on the type of instrument used and the skill of the physician, it is impossible to estimate the number

of minutes a patient may undergo CAG without experiencing radiation-induced skin injuries. It is recommended that each institution develops a protocol for CAG on the basis of the reference doses used in the institution and monitor radiation dose with dosimetry.[6,11]

2. Areas Where Radiation-Induced Skin Injuries Are Most Likely to Occur
Q4: Why are skin injuries more prevalent on the right part of the back in PCI?
A: As shown in **Figure 4**, the distance between the X-ray tube focus and the patient's skin surface is shorter in the left anterior oblique (LAO) position than in right anterior oblique (RAO) position because the heart is located on the patient's left side. Even with delivery of X-irradiation of the same intensity for the same length of time, a greater dose enters the patient's body in LAO than in RAO. When the direction of X-ray entrance is
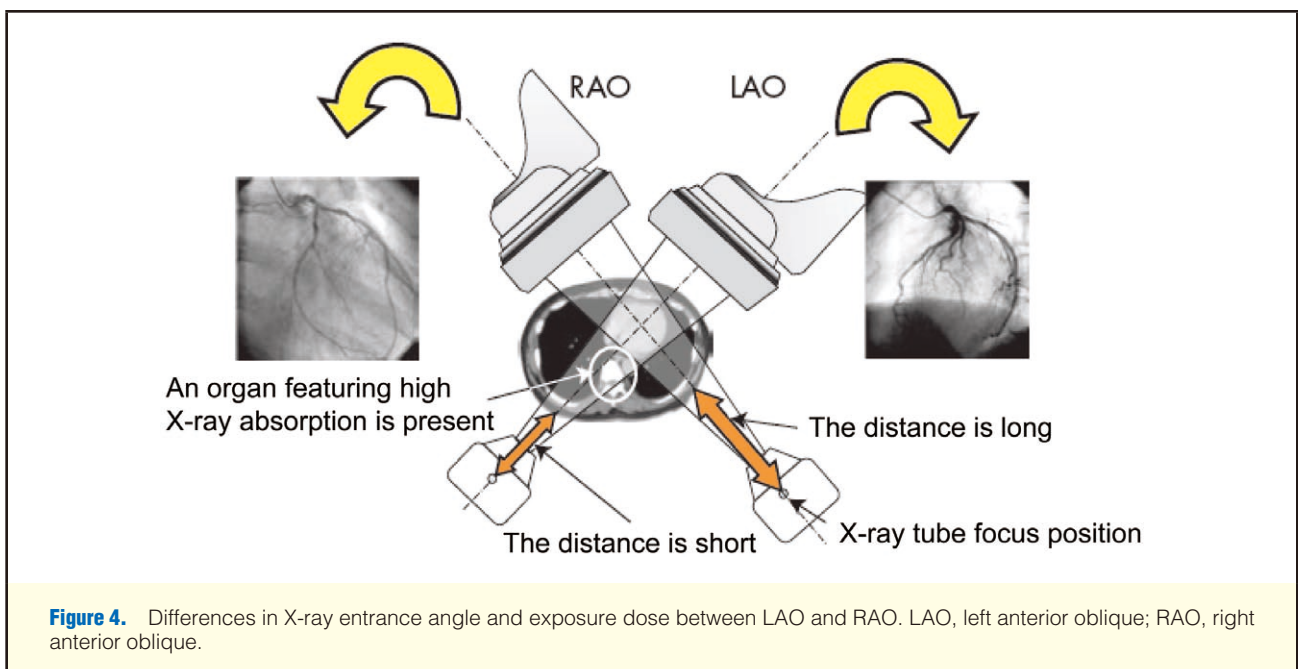
Figure 4. Differences in X-ray entrance angle and exposure dose between LAO and RAO. LAO, left anterior oblique; RAO, right anterior oblique.

RAO, the heart is observed through the left lung from the patient's left back. In contrast, in the case of LAO, the heart is observed through the vertebral column and mediastinum from the patient's right back. The lungs are easily permeated by X-rays because they contain much air, while the vertebral column and mediastinum are much less permeable to X-rays because of their high densities, and thus requiring higher doses. For this reason, skin injuries are more prevalent on the right part of the patient's back than elsewhere when the patient is visualized in the LAO projection for a long period of time.[11]

2. Informed Consent and Countermeasures in Case of Excess Exposure and Onset of Radiation-Induced Skin Injuries

1. Matters to Be Included in the Explanation of Radiation Injuries

Q5: In obtaining informed consent prior to CAG or PCI, what should be explained regarding radiation injuries? I am concerned that explanation of such injuries may increase patient anxiety.

A: Although the PCI procedure is less invasive than ordinary surgical operations, it involves the use of radiation, so prolonged treatment can result in radiation-induced skin injuries. It is therefore necessary that prior to performing PCI an explanation of radiation-induced skin injuries be provided, in addition to information on the method used in the procedure and possible complications. Since inconsistency in content of explanations among those providing them makes the patient more anxious, it is important that an explanatory manual or the like be produced to ensure that the contents of explanation are unified across the institution. Although expert knowledge is required to explain the effects of radiation, it is important that the provider of the explanation bear in mind the reason for the patient's anxiety, rather than merely using jargon and presenting numerical data, so as to put him or her at ease. Since a specific explanation helps ease the patient, the operator should endeavor to be able to explain the following:

(1) There are threshold values for radiation-induced skin injury.
(2) The dose can exceed the threshold value for radiation-induced skin injury depending on the course of treatment. In such cases, consent to continue or discontinue the examination is to be obtained from the patient.
(3) The system used for delivery of radiation is appropriately controlled to ensure that the examination is always performed at the optimal dose.
(4) The operator will endeavor to check skin entrance doses by monitoring the conditions of irradiation and implementing other protective measures.
(5) Countermeasures against radiation-induced skin injury are available.

Explanation of the above is required even in emergency examinations.[11,12]

2. Explanation and Consent During PCI Procedure and Subsequent Measures

Q6: If transillumination time is prolonged during PCI to the extent that the patient exposure dose approaches levels that can cause skin injuries, how can I determine whether to continue or discontinue the procedure?

A: The threshold dose for possible onset of early transient erythema is 2 Gy (**Table 1**). The exposure dose per unit time varies widely among different institutions, and also depends on imaging conditions (e.g., the patient's body type, angle of imaging, frame rate). Therefore, each institution should establish a reference level of transillumination and imaging times corresponding to 2 Gy. When it is found that the sum of transillumination and imaging times is likely to reach this level, the operator should determine whether to continue or discontinue the procedure. If the operator judges that the benefits to the patient of continuing the examination or treatment will outweigh the risk of radiation injuries, the examination or treatment may be continued. It is desirable, however, that even when prior consent has been obtained with a full explanation of the risk of radiation-induced skin injury, the patient's intent be reconfirmed at the time when this judgment is made. If it is difficult to confirm the patient's consent, consent may be obtained from his or her family. In situations in which the patient's life is threatened by acute myocardial infarction, shock, or other severe conditions, priority should be placed on life-saving rather than on avoiding the onset of radiation-induced skin injuries.

If the procedure is continued even after the threshold dose is judged to have been reached, still greater caution should be exercised in reducing the exposure dose. Possible measures include:

(1) Lowering the fluoroscopy pulse rate and/or imaging frame rate,
(2) Changing the fluoroscopy and/or imaging angle to shift the skin irradiation field to other positions (see **Q22** and **Figure 15**).

3. Explanation of and Measures Taken After Exposure to Excessive Doses

Q7: If it is found after the performance of catheter intervention that the patient exposure dose may have exceeded the threshold dose for the onset of skin injury, what measures should be taken?

A: The person in charge of radiation safety management should inform the attending physician of the predicted dose and severity of skin injury, and request subsequent countermeasures.

The specific actions to be taken are as follows:

(1) Reconfirm informed consent of the patient and his/her family for such actions (see **Q8**).
(2) Prepare a patient skin-absorbed dose report and inform all persons concerned of the delivery of a dose exceeding the threshold as documentation for follow-up examination (see **Q9**).
(3) Detection of initial injuries: Early transient erythema appears soon after the examination. The physician should monitor the site of irradiation or ask a ward physician or nurse to monitor the site.
(4) Notification to dermatologist and request for cooperation (if required because of severity of predicted injury): Notify the dermatologist of the site of irradiation, exposure dose, and predicted severity of skin injury. It is desirable that the skin-absorbed dose report be submitted with attachment of an examination status report (examination records) and reference documents concerning radiation-induced skin injuries.

With these contents included, a manual should be prepared for the institution in order to deal with skin injuries. In all cases, it is important that all staff members endeavor to develop and maintain good communication with each other in order to work together as a team.[11,12]

Q8: If a dose that can cause radiation-induced skin injuries has been delivered, what explanation should the
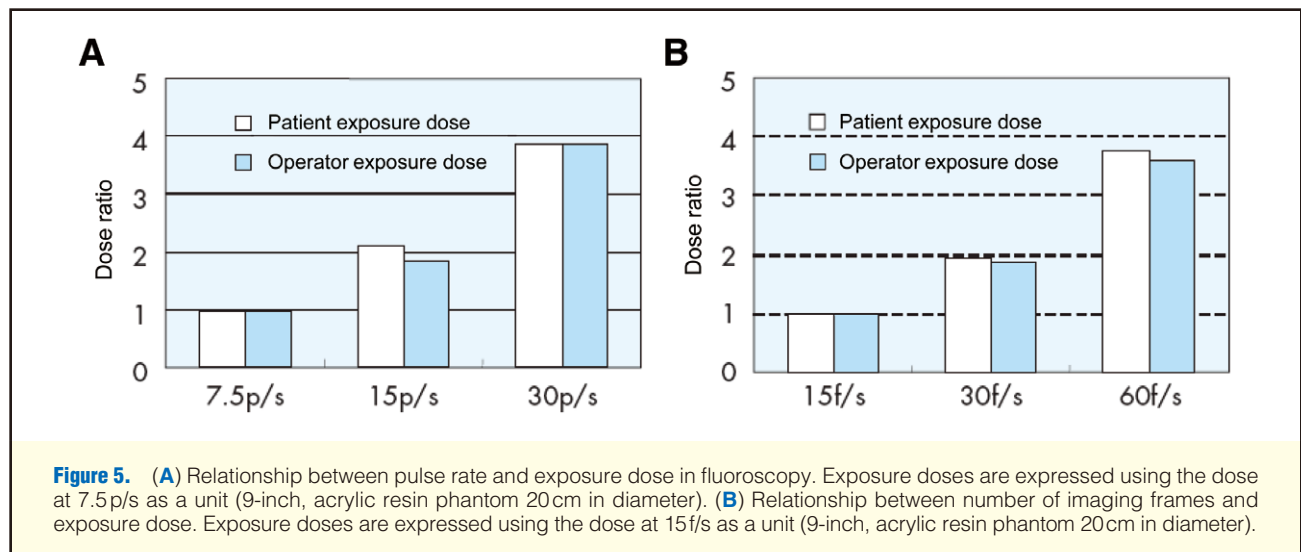
Figure 5. (**A**) Relationship between pulse rate and exposure dose in fluoroscopy. Exposure doses are expressed using the dose at 7.5 p/s as a unit (9-inch, acrylic resin phantom 20 cm in diameter). (**B**) Relationship between number of imaging frames and exposure dose. Exposure doses are expressed using the dose at 15 f/s as a unit (9-inch, acrylic resin phantom 20 cm in diameter).

patient receive?

A: Irrespective of whether prior informed consent has been obtained, the physician should inform the patient that a dose that can cause radiation-induced skin injuries has been delivered and that the diagnosis/treatment were necessary, and provide an explanation of your institution's policy on the treatment of skin injuries. Even when prior informed consent has been obtained, an explanation should be provided again for the sake of confirmation.

The physician should tell the parts of the skin where injury may occur, and give the following advice and suggestions regarding measures to be taken for the parts of the skin:
(1) Periodic medical follow-up examination is necessary.
(2) Instruct the patient not to scratch them, to avoid the use of highly irritating bathing agents and soaps during bathing, and not to apply any drugs other than those prescribed by the physician.
(3) Instruct the patient to visit the clinic when skin symptoms develop since the effects of radiation usually appear after a time lag.

Q9: If a dose that can cause skin injury has been delivered, is it necessary to record the fact? If so, please show how this is done and which form is used.

A: Among catheter intervention techniques, PCI may particularly be performed repeatedly depending on the condition of the heart. Since radiation skin injuries may be caused by at doses lower than the threshold value when radiation to the same area is repeated during a relatively short duration of time, the site of irradiation and dose should be recorded, and the operator should strive to prevent excessive irradiation. In the International Commission on Radiological Protection (ICRP) Publ.85, it is recommended that if the skin exposure dose can be estimated to be 3 Gy (1 Gy for cases of repeated irradiation) or more, the estimated dose and the site of irradiation be indicated on an appropriate body surface map.[6]

4. Measures Taken in Case of Onset of Radiation-Induced Skin Injuries

Q10: In case of slight acute dermatitis that has remitted quickly, is it necessary for the patient to be treated with medication or to undergo ambulatory treatment at an out-
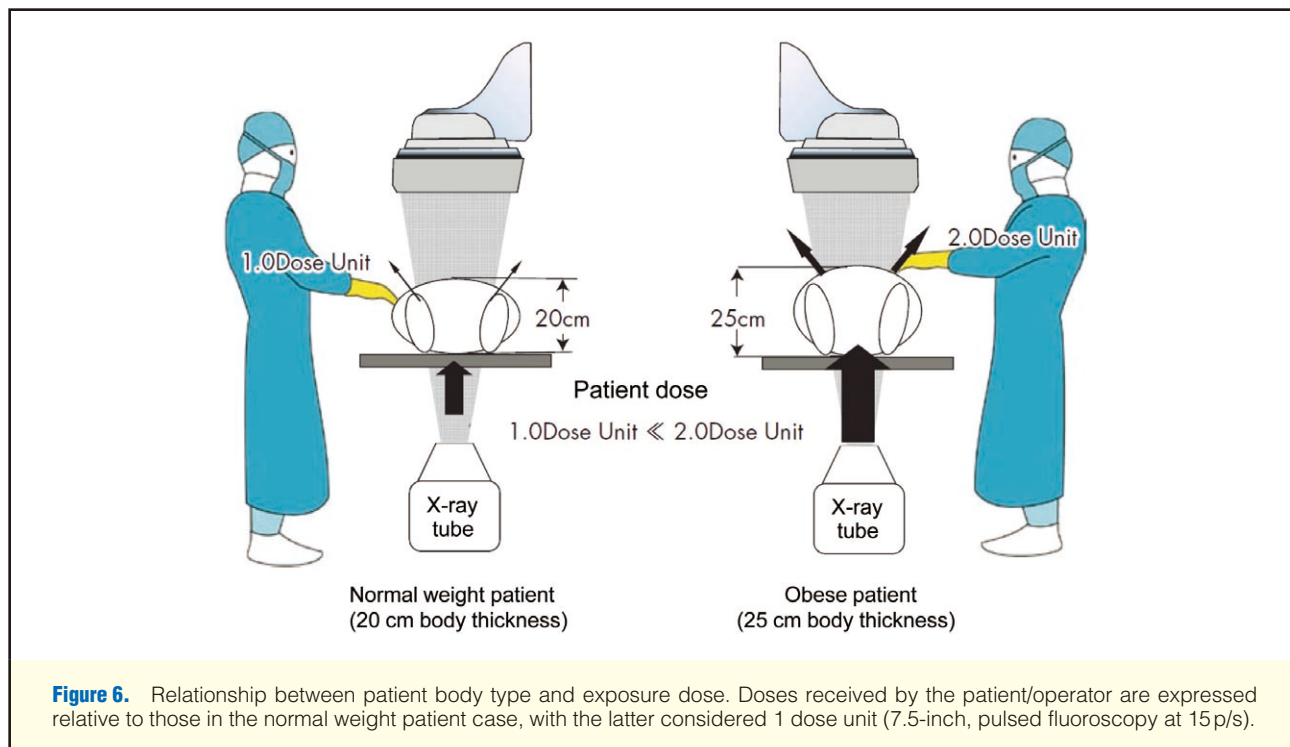
patient dermatology clinic?

A: If slight skin injury develops early after performing PCI and then disappears spontaneously, the condition is deemed early transient erythema (threshold dose=2 Gy) or main erythema (threshold dose=6 Gy). Main erythema often leaves pigmentation (or depigmentation) after healing. If it has healed without pigmentation, it is quite unlikely that delayed skin injury will develop later, so no dermatological treatment is necessary, nor is there any need for periodic follow-up examination. Visits to a dermatologist are needed only after the patient or his or her family has noted a change in the patient's skin. If an dyschromia remains in a part of the skin where rash has healed, the risk of subsequent development of delayed skin injury cannot be ruled out even if the change is initially very mild, so periodic follow-up examination by a dermatologist is required. Regarding the duration and frequency of ambulatory medical checkups, it is desirable that the patient visit the institution every 3 months for about 1 year. Even if the dyschromia remains, however, macroscopic observation alone is sufficient, with no special treatment required. It is important that the site of irradiation and dose be recorded at the time of irradiation.[11]

3. Variables Affecting Exposure Doses

1. Effects of Irradiation Pulse Rate

Q11: To what extent can I reduce the exposure dose by lowering the pulse rate or image acquisition rate during fluoroscopy?

A: Pulsed fluoroscopy is effective as a method of reducing exposure in PCI. As shown in **Figure 5A**, exposure dose decreases as the pulse rate falls from 30 p/s to 15 p/s and then to 7.5 p/s. It should be noted, however, that the doses irradiated at high pulse rates are similar to those with continuous fluoroscopy, so if pulsed fluoroscopy is used in an attempt to reduce patient exposure, a low pulse rate must be used. In the system shown in **Figure 5A**, there is a proportional relationship between pulse rate and dose. In other type of systems as shown in the figure, however, even when a low pulse rate is chosen to examine a patient with a thick body, the system automatically expands the pulse width, increases the tube current, or takes other measures to ensure that doses comparable

Figure 6. Relationship between patient body type and exposure dose. Doses received by the patient/operator are expressed relative to those in the normal weight patient case, with the latter considered 1 dose unit (7.5-inch, pulsed fluoroscopy at 15 p/s).

to those with high pulse rate fluoroscopy are delivered. In such cases, choosing a low pulse rate does not always lead to a reduced exposure dose. Prior to using the system, it is necessary to become familiar with the its performance by taking actual measurements using it, or asking the manufacturer to provide detailed specifications for the instrument in different operating conditions. In addition, since it is difficult to confirm the position of catheters and other devices in blood vessels under low pulse rate fluoroscopy if performed by an unskilled operator, it is important that this technique be utilized only after a full discussion with the operator.

The image acquisition rate during imaging also influences patient exposure dose. **Figure 5B** shows the doses received by the patient at image acquisition rates of 15 f/s, 30 f/s, and 60 f/s. Because the dose received by the patient increases as the image acquisition rate rises, emphasis should be placed on choosing an image acquisition rate suitable for the patient's heart rate and pathologic condition, and minimizing the dose received by the patient, rather than on increasing the image acquisition rate merely to improve visibility.[13]

2. Effects of Patient Body Type

Q12: To what extent does exposure dose differ depending on the body type of the patient?

A: Generally, obese patients receive greater doses per unit time than thin patients. **Figure 6** shows the difference in entrance surface dose for two patients 20 cm and 25 cm in body thickness; as the subject of imaging thickens by 5 cm, the entrance surface dose nearly doubles. Therefore, when the subject is an obese patient, the cumulative dose administered during examination must be carefully monitored in order not to administer excessive doses of radiation. Of note, the operator is also subject to greater exposure when examining an obese patient.
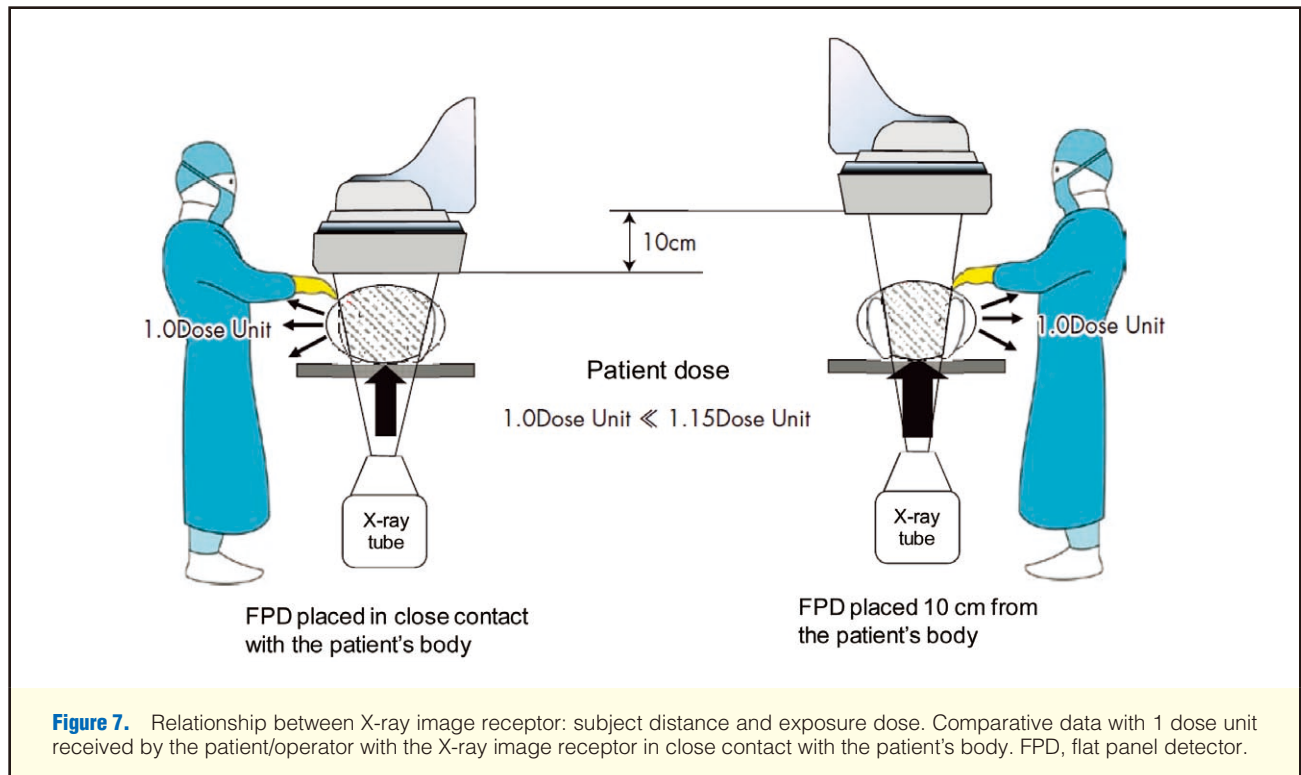
3. Distance Between X-Ray Image Receptor (FPD or Image Intensifier [I.I.]) and Patient

Q13: Why does the exposure dose increase as the FPD or I.I. becomes more distant from the patient? What is the operator exposure dose under such conditions?

A: If the distance between the X-ray tube and patient is constant, the distance between the X-ray tube and FPD or I.I. increases as the FPD or I.I. becomes more distant from the patient, so automated adjustment by the system ensures delivery of a larger amount of X-rays. As a result, the patient exposure dose increases. **Figure 7** shows the change in entrance surface dose where radiation enters when the FPD is distanced from the patient while keeping the catheter table height constant. With increase in distance of the FPD of only 10 cm, the entrance dose increases by about 15%. In routine examination, the FPD and patient are often separated by about 10 cm. However, since even small changes will lead to major differences in dose if they accumulate, the distance between the FPD and the patient must be kept as close as possible in order to avoid excessive irradiation of the patient. Since the operator should concentrate on PCI procedures, his/her supporting members such as radiologic technologist should control irradiation conditions carefully.

The dose received by the operator changes relatively little when the FPD or I.I. is placed more distant from the patient. Theoretically, the scattered dose increases as the exposure dose increases when the FPD or I.I. is placed more distant from the patient, but the beam limiting device equipped with current X-ray units uses the positive beam limitation (PBL) mechanism [Note: PBL mechanism is automatic focus function to adjust the irradiation field according to the distance between X-ray tube focus and the image reception plane as well as the size of the image reception area.] that automatically narrows the irradiation field to avoid radiation to the outside of the effective radiation field when the PPD or I.I. is placed distant from the

Figure 7. Relationship between X-ray image receptor: subject distance and exposure dose. Comparative data with 1 dose unit received by the patient/operator with the X-ray image receptor in close contact with the patient's body. FPD, flat panel detector.

patient as **Figure 7** shows. The scattered dose to the operator does not increase even when the distance increases by 10cm.[11]

4. Distance Between X-Ray Tube and Patient

Q14: Tips for reducing radiation exposure include the statement "distance the patient from the X-ray tube as much as possible." Why? And what is the operator exposure dose when the examination table is at low position?
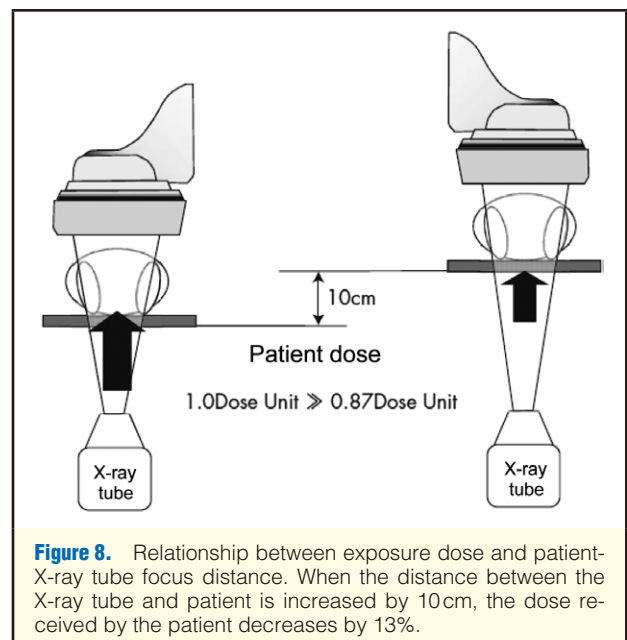
A: As the distance of the patient from the X-ray tube is increased, the distance between the X-ray tube focus and X-ray image receptor increases, so the X-ray output increases. At the same time, however, the amount of low-energy X-rays reaching the patient, which do not contribute to images but do have a major impact on patient exposure, decreases, so skin dose decreases. This is exemplified in **Figure 8**. As the patient is brought about 10cm closer to the X-ray tube, the dose increases by about 15%, so it is necessary to heighten the catheter table to distance the patient from the X-ray tube, as long as this does not interfere with procedures by the operator.

When a short operator performs the examination, he or she is apt to lower the catheter table to facilitate the operation. However, lowering the table makes the patient and X-ray tube approach each other, which in turn increases the patient exposure dose; caution thus needs to be exercised in this regard. The dose received by the operator remains unchanged with this alteration.[11]

5. Size of Transillumination Field

Q15: In PCI, magnified views are often used to obtain clear images of the guidewire and stent. What is the extent of change in dose received by the patient associated with this? Does the change of the dose when using an FPD differ from that using an I.I.?

A: When the I.I. size is reduced and the screen is expanded,

Figure 8. Relationship between exposure dose and patient-X-ray tube focus distance. When the distance between the X-ray tube and patient is increased by 10cm, the dose received by the patient decreases by 13%.

the dose received by the patient increases, as shown in **Figures 9A** and **9B**. By contrast, when the I.I. size is increased and the field is widened, the dose decreases. Traditionally, this has not commonly been performed since magnified views with smaller I.I. sizes lead to a lack of dose, which hampers obtaining clear images. However, recent technical innovations, including the expanded capacity of X-ray tubes and the introduction of new technologies such as digital image processing have,
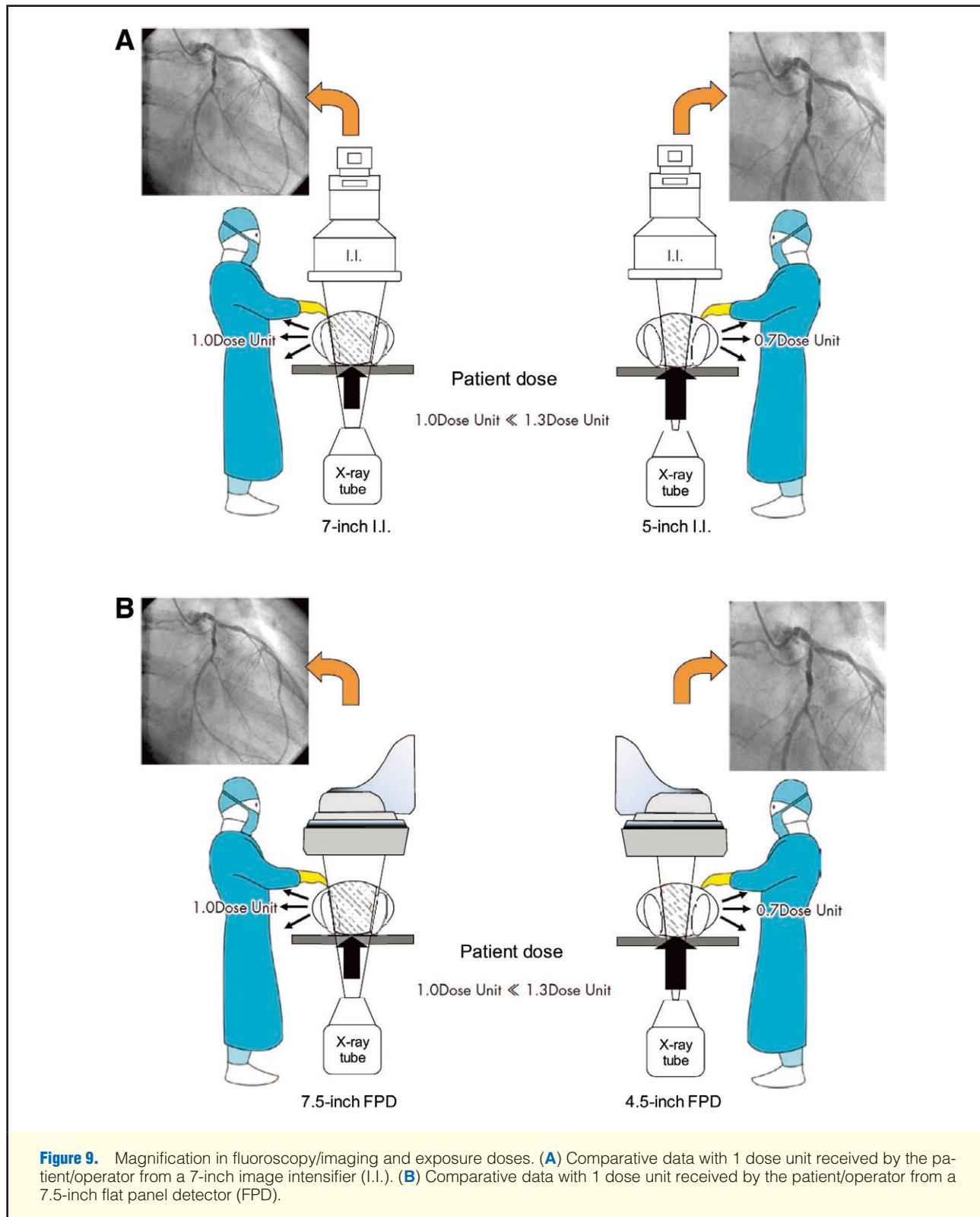
Figure 9. Magnification in fluoroscopy/imaging and exposure doses. (**A**) Comparative data with 1 dose unit received by the patient/operator from a 7-inch image intensifier (I.I.). (**B**) Comparative data with 1 dose unit received by the patient/operator from a 7.5-inch flat panel detector (FPD).

along with the spread of PCI, led to the current wide use of magnified views at many institutions.

Recently FPD systems are becoming common. Since the luminance of the output phosphor screen depend on the size of the input phosphor screen in I.I., a decrease in the size of

input visual field leads to a dark output phosphor screen. In order to keep the luminance of the output phosphor screen, the entrance dose must be increased (**Figure 9A**). On the other hand, FPD systems do not use focus electrodes to intensify the luminance as the I.I. does, the luminance of the output phos-

1.0Dose Unit

The entrance dose per unit area is the same

0.75Dose Unit

Beam limiting device

X-ray tube

X-ray tube

Fully open irradiation field

Limited irradiation field

Figure 10. Beam limiting device and exposure dose. Comparative data with 1 dose unit received by the operator when the field of irradiation is fully open (7.5-inch flat panel detector [FPD]).
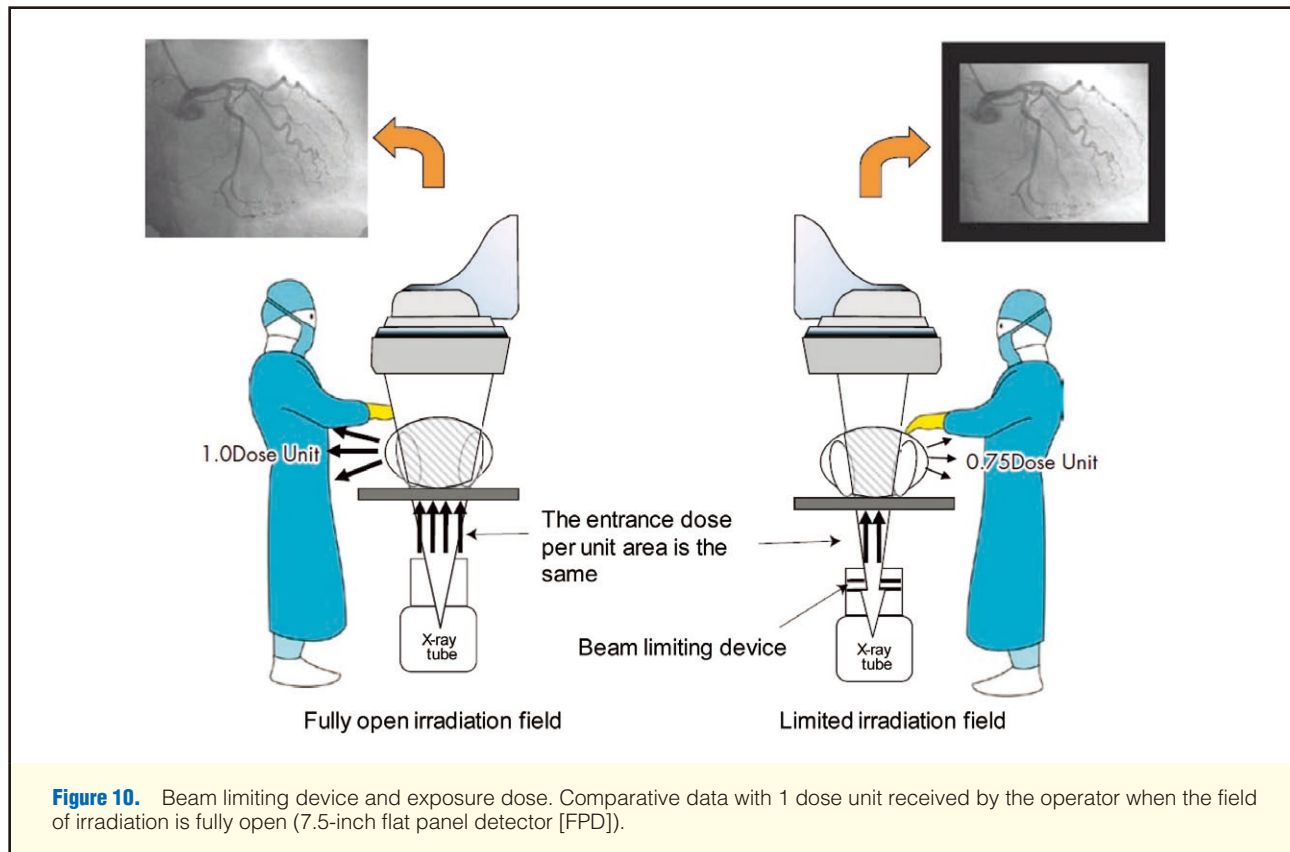
phor screen is maintained even when the visual filed is enlarged. However, since the resultant images are contaminated with noise, the entrance dose is increased according to the size of the expanded visual field to avoid noises (**Figure 9B**). Although magnified views are essential for ensuring safe performance of PCI, it results in greater patient doses, so use should be limited to the minimum required frequency to prevent skin injuries.

As the FPD or I.I. size is reduced, the field of irradiation is automatically narrowed, and the operator's dose therefore decreases. As the FPD or I.I. size is increased, the field of irradiation widens, with increase in scattered dose and a tendency for operator exposure dose to increase.[11]

6. Effects of Beam Limiting

Q16: As the field of irradiation is narrowed, does patient exposure dose actually decrease?

A: Figure 10 compares patient exposure doses produced with a fully open field of irradiation and a narrowed field of irradiation with 70% of the initial area. Even when the field of irradiation is narrowed, the dose per unit area received by the patient remains unchanged. However, as the field of irradiation increases, the area of skin at risk for skin reactions to radiation will increase, so effort is always needed to avoid irradiation of sites where it is unnecessary, in order to prevent radiation injury. Additionally, by narrowing the field of irradiation, the area of skin irradiated repeatedly during fluoroscopy or imaging at different angles can be narrowed. In **Q22** a method is described for avoiding skin injuries by changing the angle of X-ray entrance. When the field of irradiation is limited to a small area in advance, the operator may change the entrance angle only slightly to avoid irradiating the same
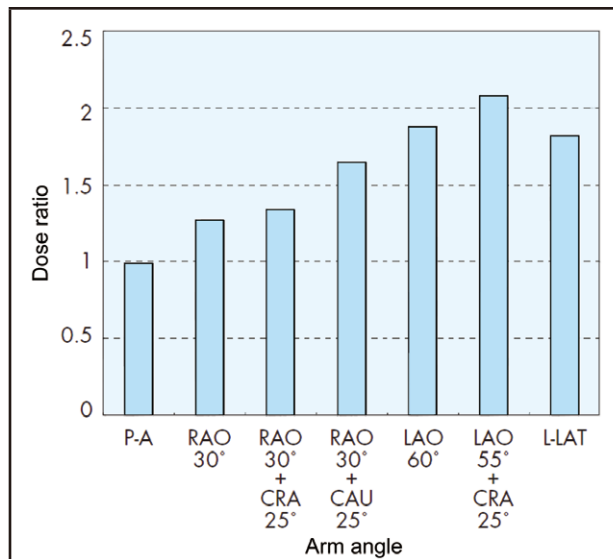
Figure 11. Fluoroscopic angle and exposure dose. Comparison of exposure doses during pulsed fluoroscopy at 15 p/s at different angles. The dose in a 7.5-inch P-A view was set as 1 dose unit. P-A, posterior-anterior; RAO, right anterior oblique; CRA, cranial; CAU, caudal; LAO, left anterior oblique; L-LAT, left lateral position.

region of the skin. The operator's dose also decreases as the field of irradiation is narrowed.[11]

Figure 12.   Schemes of flat panel detector (FPD) type imaging systems. Comparison of different types of devices. CsI, cesium iodide; TFT, thin-film transistor.
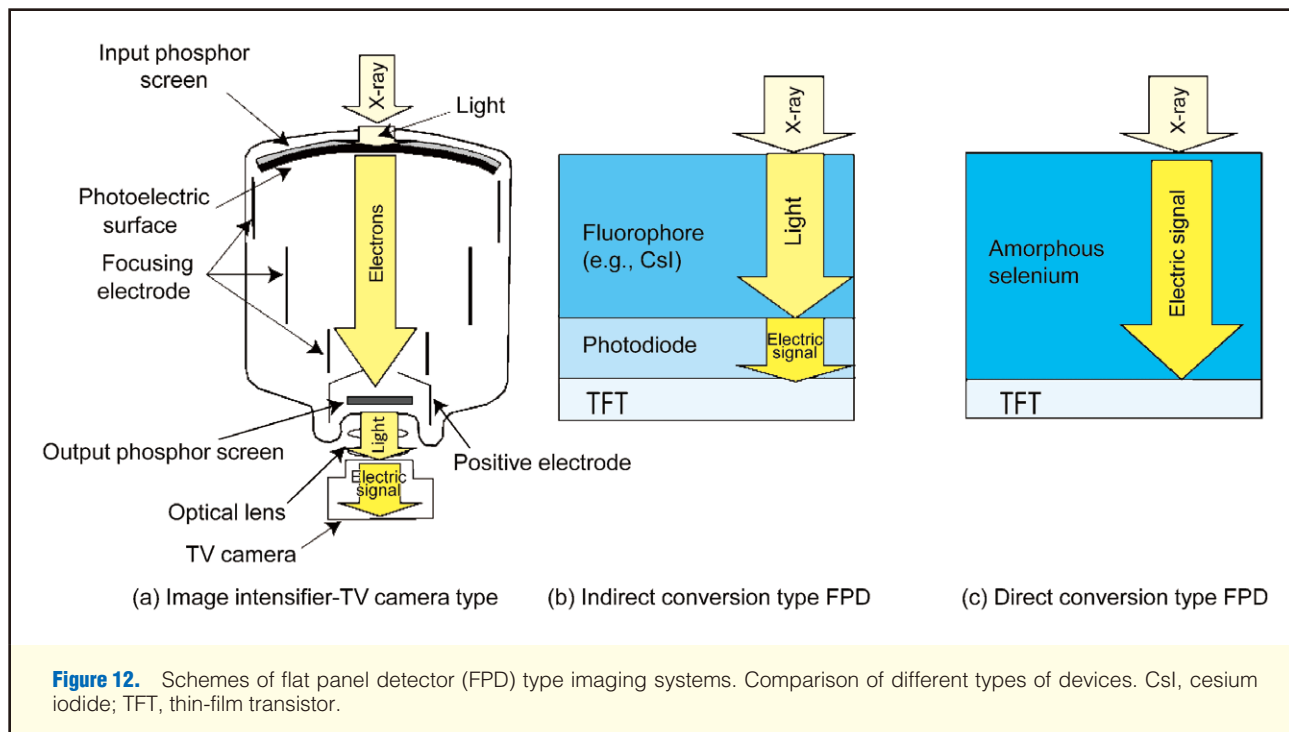
7. Effects of Fluoroscopic/Imaging Angle

Q17: I've heard that in LAO cranial views and LAO caudal views, the patient skin-absorbed dose is high. Why? And how can I reduce this dose?

A: In order to maintain uniform image quality even when viewed from different angles, the X-ray fluoroscopic/imaging device is controlled to keep the dose entering the FPD or I.I. constant. As the direction of X-ray entrance is changed, the thickness of the subject imaged changes as well, and the dose is adjusted according to the thickness irradiated. This is why the patient entrance dose differs depending on the X-ray entrance angle. **Figure 11** compares doses with various entrance angles using phantoms; there is an approximately two-fold difference in dose among the different entrance angles evaluated. In the LAO projection, the heart is examined through the vertebral column and mediastinum from the patient's right back, so greater doses are delivered (see **Figure 4**). In the cranial or caudal projection, body thickness increases still more, so greater doses are delivered. This is the reason why the dose increases in the LAO cranial and LAO caudal projections. When the examination is performed using these X-ray entrance angles, the operator should endeavor to reduce the dose by, for example, lowering the pulse rate or avoiding the use of magnification during fluoroscopy and imaging.

Since PCI involves repeated cycles of fluoroscopy and imaging with a constant X-ray entrance angle for a prolonged period of time, it is important to understand the relationship between the entrance angle and dose for the system used, and to prevent the patient from receiving excessive doses.[14]

8. FPD Type Imaging System

Q18: The FPD type imaging system reportedly generally enables reduction of exposure dose, although I've heard that the exposure dose in fact increases in some cases. In which cases does the exposure dose rise? And what are the points of note in using the system?

A: Currently, there are two modes of imaging by FPD: direct conversion and indirect conversion (**Figure 12**). The direct conversion type employs amorphous selenium (a-Se) as the X-ray imaging medium. The electric charge generated by X-rays in the a-Se medium is directly read out using a thin-film transistor (TFT). The direct conversion type involves only slight loss of energy during energy conversion, and has excellent spatial resolution. In the indirect conversion type, X-rays entering the imaging system are converted to visible light through a fluorophore such as cesium iodide (CsI) as the X-ray imaging medium, using a photodiode or the like, which is then converted to electric signals. Although some loss of image quality due to light scattering is unavoidable, this type is now commonly used for cardiovascular imaging because it is easy to perform.

Advantages of FPD include the following:
(1) The FPD undergoes less time-related deterioration, ensuring image quality that is stable over a long period of time;
(2) Lack of distortion;
(3) High contrast.

Since FPD has higher efficiency in X-ray detection than I. I., it theoretically enables reduction of dose. In fact, in imaging at a high dose rate, which is not influenced by X-ray quantum noise (noise caused by random fluctuation of quantum flow), some extent of dose reduction is possible. On the other hand, in low-dose fluoroscopy, which is influenced by X-ray quantum noise, FPD contributes less to dose reduction than I.I., so the cumulative dose per examination is the same as with I.I. Since an increase in the dose is not necessary for FPD even when the field is expanded, the dose is actually increased to maintain the quality of images as in the case of I.I. Conventional dose-reduction approaches developed for I.I. are also necessary for FPD.

Since FPD has advantages including little time-related deterioration, low running cost, freedom from image distortion, absence of halation even without use of a compensating filter
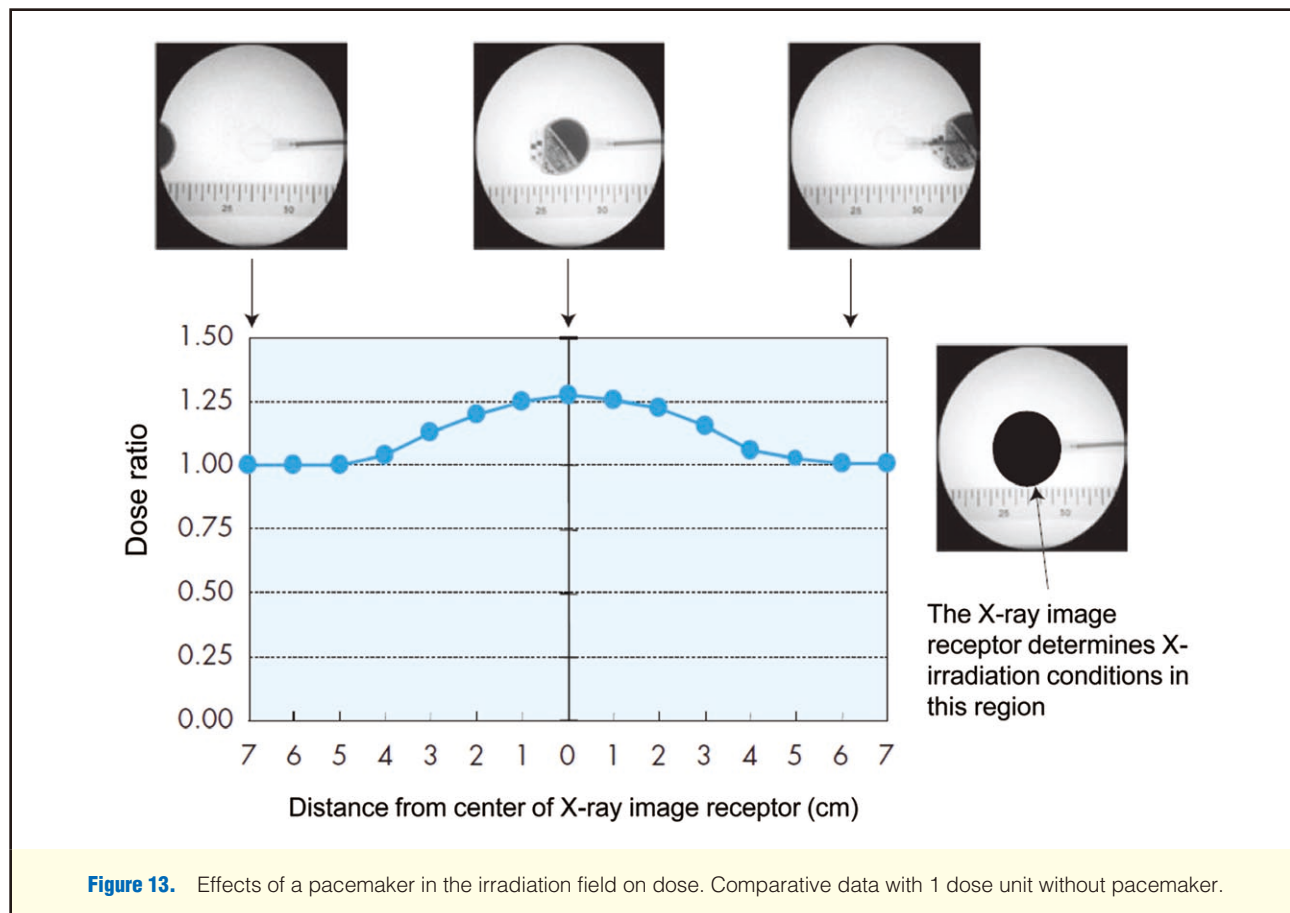
Figure 13. Effects of a pacemaker in the irradiation field on dose. Comparative data with 1 dose unit without pacemaker.

due to its broad dynamic range, it is expected that FPD will replace I.I. in the future.[15–18]

9. Effects of Pacemakers and Leads

Q19: Why does the exposure dose increase when the body of a pacemaker or a lead enters the field of irradiation?

A: X-irradiation conditions during fluoroscopy and imaging depend on the dose received by the photoreceptor in the center of the X-ray image receptor such as FPD or I.I. **Figure 13** shows the relationship between the position of the pacemaker in the field of irradiation and the corresponding dose ratio. When a pacemaker is present in the peripheral portion of the field, where determination of X-irradiation conditions is not affected, the conditions remain unchanged, so the dose received by the patient does not change. However, when the pacemaker is present in the center of the X-ray image receptor, X-irradiation occurs in amounts that depend on the material of the pacemaker. Generally, since the pacemaker is made of metal, larger amounts of X-rays are required than for a human body of the same thickness. Therefore, when the pacemaker is present in the center of the field of irradiation, the dose received by the patient increases, and at the same time an excessive dose is delivered to the surrounding tissue where the pacemaker is absent, which can result in deterioration of image quality due to halation or other factors. For these reasons, it is important not to locate the pacemaker in the center of the X-ray image receptor whenever possible.

10. Effects of the Upper Arm in the Irradiation Field on Fluoroscopy/Imaging

Q20: In case of entry of the patient's arm (upper arm) into the irradiation field, does the dose received by the patient change? What are the points to note in protection against skin injury in this case?

A: When X-rays are delivered to a patient for diagnostic or therapeutic purposes, a basic rule of X-ray imaging is to remove objects that interfere with imaging from the irradiation field in order to obtain clear images. For this reason, the patient is asked to raise his or her arm if it enters the irradiation field during coronary imaging. Recently, however, CAG has often been performed with approach from the cubital artery or radial artery, and the number of cases of inability to raise the arm has correspondingly increased.

Additionally, catheter ablation is sometimes performed while neither arm is raised, for various reasons, including the great burden placed on the patient by the long period of examination; the use of an electrode catheter, which features relatively high X-ray visibility, ensuring that the presence of interfering shadows of arms in the field of irradiation does not markedly interfere with examination; and recently the increased capacity of X-ray tube systems allowing fluoroscopy even with both arms located in the irradiation field.

Figure 14 shows the positional relationship between the irradiation field and the patient's arm as it enters, and corresponding dose ratios. Even if an arm is positioned in the vicinity of the irradiation field and the presence of the arm does not affect X-ray irradiation conditions because the arm itself will
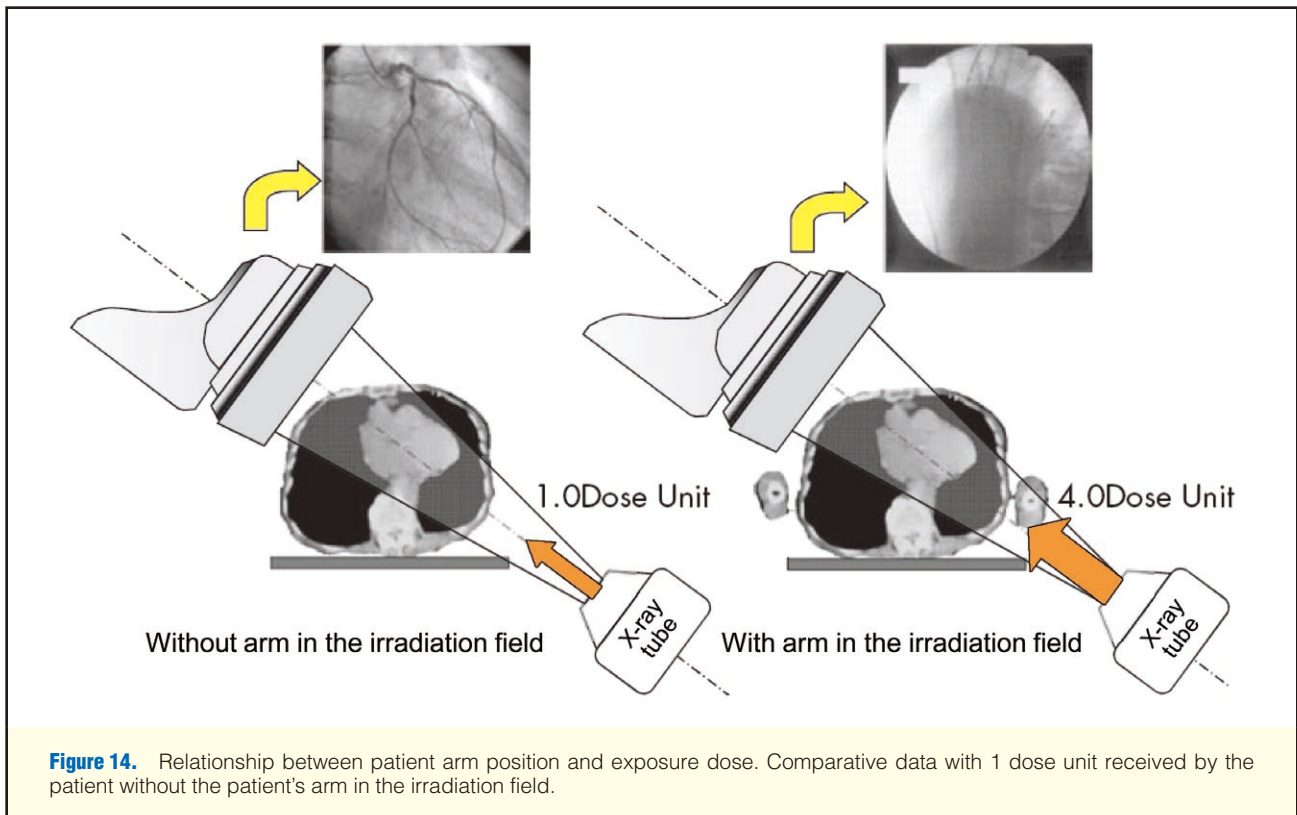
Figure 14.   Relationship between patient arm position and exposure dose. Comparative data with 1 dose unit received by the patient without the patient's arm in the irradiation field.

Table 2.   How to Reduce the Patient Dose During Percutaneous Coronary Intervention
1. Avoid unnecessary fluoroscopy and imaging.
2. Set the frame rate to as low a level as possible and shorten the imaging time to minimize imaging-related irradiation.
3. Have a good understanding of the relationship between dose and image quality, and perform the examination under irradiation conditions suitable for the system and examination procedure. For example, fluoroscopy and imaging using high tube voltages generally leads to reduction of skin-absorbed doses due to its favorable X-ray penetration, although contrast may decrease slightly due to increased Compton scattering.
4. For fluoroscopy, use the minimum possible pulse rate acceptable to the operator.
5. Use a supplementary filter.
6. Distance the X-ray tube from the patient as much as possible.
7. Bring the image intensifier into a position as close to the patient as possible (avoid frequent use of geometric magnification).
8. Minimize the use of magnification during fluoroscopy and imaging.
9. For patients of small body size and in procedures in which the image intensifier remains away from the patient, remove the grid.
10. Be sure that the irradiation field is always kept in the narrowest range possible.

not be exposed, the distance between the X-ray source and skin is decreased by the thickness of the arm, and the dose at the skin entrance surface increases. Furthermore, if an arm is located at the center of the X-ray image receptor, more intense irradiation is required due to the presence of the arm, and the distance between the X-ray source and skin decreases, so the dose received by the part of the arm in the irradiation field is extremely high. Every effort should thus be made to keep the upper arm away from the irradiation field to the maximum extent possible by, for example, changing the X-ray entrance angle and positioning the upper arm distal from the trunk appropriately so that it does not enter the irradiation field.[7,19]

4. Efforts Toward Reduction of Patient Exposure Dose

1. General Rules for Reduction of Exposure Dose
Q21: Please show how to reduce the patient dose during PCI.
A: The general rules for protection from sources of radiation, such as X-rays, outside the patient's body during PCI are as follows:
(1) Time (shorten the time of irradiation)
(2) shielding (block radiation), and
(3) distance (ensure sufficient distance from the source).
   Table 2 shows specific ways of following these rules.[3,6,20]

2. Considerations of Exposure During Emergency Examination/Treatment
Q22: A patient with acute myocardial infarction is undergoing PCI. The monitored dose has exceeded the level that can cause skin injuries, but the examination cannot be terminated prematurely because no other means of treatment is available. Is there any way of continuing the examination without causing skin injury?
A: Although priority should be placed on saving the patient's

life, rather than avoiding skin injury, skin injury should be minimized to the extent possible. To avoid skin injury, the system's arm may be rotated to change the site of irradiation on the patient's skin surface to a different position. We found that overlapping exposure of regions of skin to primary X-ray beams can be eliminated by rotating the X-ray entrance angle by 40° or more (**Figure 15**). The same applies not only to the axial direction (RAO-LAO) but also the cranio-caudal direction. Since PCI is performed at an angle that enables the best identification of the lesion, it is sometimes difficult to change the angle midway, though this may need to be considered, and it is useful that the operator be aware of the angles of radiation overlap of the system used in his or her institution.[11]

5. Patient Variables Affecting the Onset of Radiation-Induced Skin Injuries

Q23: Are some patients more susceptible to radiation-induced skin injury than others (due to the age and body type of the person exposed, which part of the skin is exposed, underlying disease, drugs, and other variables)? Are there any age-related differences in the likelihood of radiation-induced skin injury? If the elderly are particularly likely to suffer skin injury, is it better to consider the patient's age in deciding whether to perform restudy CAG?
A: The likelihood of radiation-induced skin injuries depends on the following variables on the patient side.

(1) Age
The biological effects of radiation are thought to vary depending on the patient's age at the time of exposure. Generally, younger cells are more sensitive to radiation. Radiation injuries are essentially the result of impairment of cell proliferation by X-rays; cells with shorter cycles of proliferation are more radiosensitive than slowly proliferating cells and resting cells. On the other hand, the rate and degree of recovery of damaged tissues also affect the manifestation of radiation-induced skin injuries. It thus remains unclear whether the elderly are particularly likely to suffer skin injuries.

(2) Body Type
For patients with thick thoracic cage due to obesity, muscularity, or other factors, greater doses are required than for thin patients because of the decrease in X-ray permeability. Additionally, in obese patients, the position of the diaphragm is relatively high, so the abdominal organs are often included in the irradiation field; the X-irradiation dose is thus further increased. For these reasons, obese patients tend to be exposed to greater doses, and are hence more likely to suffer radiation-induced skin injury (see **Q12** and **Figure 6**).

(3) Site
The degree of susceptibility to radiation also depends on which part of the skin receives exposure. According to Kalz et al the parts of the skin most likely to exhibit acute responses are the frontal surface of the neck and the bending portions of the limbs, such as the anterior cubital region and popliteal fossa, followed by the chest, abdomen, face, back, outer aspects of the limbs, nape of the neck, scalp, hands, and ankles. The hair follicles are more sensitive than other skin structures.

(4) Underlying Disease
It is reported that radiation-induced skin injury is exacerbated
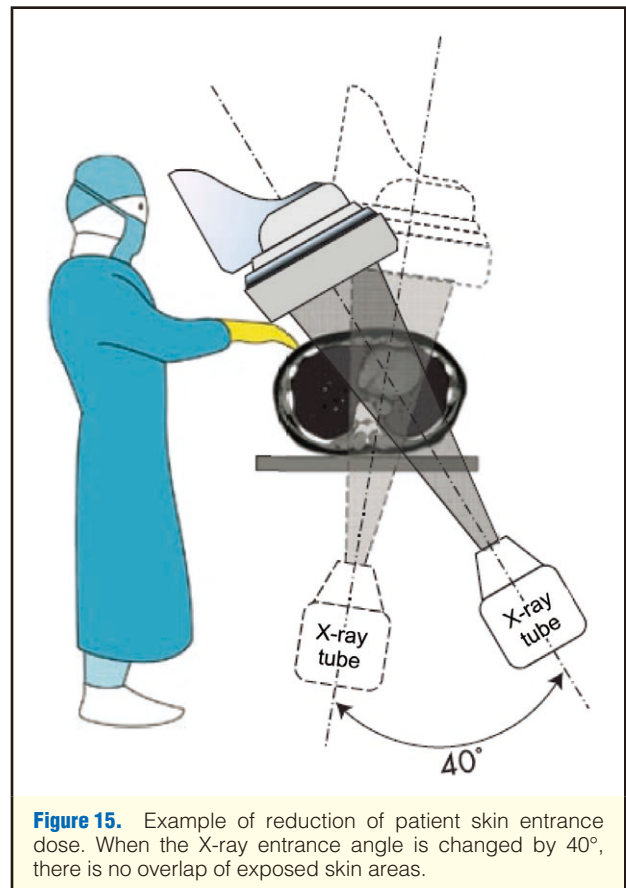
Figure 15. Example of reduction of patient skin entrance dose. When the X-ray entrance angle is changed by 40°, there is no overlap of exposed skin areas.

in systemic sclerosis, systemic lupus erythematosus (SLE) and mixed connective tissue disease (MCTD) patients, but no clear correlation has been established. Diabetes mellitus and hyperthyroidism intensify radiation injuries. A report is available on a patient complicated by MCTD and diabetes mellitus who suffered severe necrotic ulceration after undergoing IVR. Ataxia telangiectasia patients with a homozygous genotype are particularly susceptible to radiation.

(5) Effects of Drugs
Skin radiosensitivity also increases in the presence of chemotherapeutics such as actinomycin D, adriamycin, bleomycin, fluorouracil (5-FU), and methotrexate (MTX). It has been reported that even several months after healing of initial reactions following X-irradiation, skin injuries recurred locally only with administration of actinomycin D for several weeks.

When the clinical benefits of catheter techniques are considered very significant and outweigh the risk of radiation-induced skin injury, catheterization for the examination and/or treatment of the target disease should be considered reasonable. It should be noted, however, that obtaining informed consent is essential.[7,19]

6. Strategies for Reducing Exposure in Medical Personnel

1. Medical Personnel Exposure
Q24: I've heard that regarding operator exposure, the radiation produced from the patient's body is more impor-
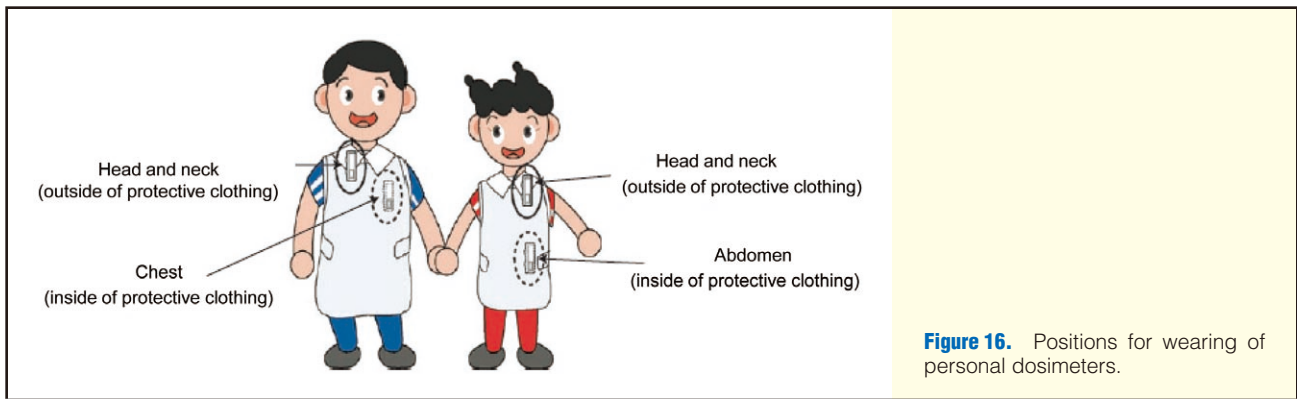
Figure 16. Positions for wearing of personal dosimeters.

tant than that from the X-ray tube. What is meant by this?
A: Since operator exposure is for the most part due to scattering of X-rays from the patient, to reduce the dose received by the operator, emphasis should be placed on controlling the X-rays scattered from the patient. In particular, minimizing the dose received by the patient leads to a reduction in the dose received by the operator.

Q25: Persons engaged in PCI procedures receive high exposure doses, and I am anxious about the radiation injuries that may result from this. Please describe the radiation injuries that can occur in PCI personnel. How long per year can we be involved in PCI or CAG without injury to our health?
A: In PCI, since X-ray fluoroscopy is performed at high dose rates for prolonged periods of time, the exposure dose for the PCI operator, who works in the vicinity of the patient, is higher than that for other persons involved in interventional radiological procedures, and cases of radiation cataract has been reported. Cataract can occur from exposure to a total of 2 Gy or more over a short period of time, or from an exposure to a total of 5.5 Gy or more over 3 months or longer. Recently, it was reported that a physician in charge of IVR developed ocular cataract even with radiation exposure that did not exceed 2 Gy in the USA. "The Chernobyl Cataract Study" has suggested that radiation cataract can occur even at relatively low doses of approximately 250 mSv; these findings are consistent with the results of studies of atomic bomb victims, astronauts, and patients undergoing X-ray CT scan examination of the head. With these considerations in mind, the catheterization laboratory manager should endeavor to prevent radiation injuries in the medical personnel working in the laboratory.

Accordingly, the upper dose limit for PCI personnel has been set at 150 mGy/year for the ocular lens, and 500 mGy/year for the skin. Prevention using protective devices such as protective spectacles and management of exposure should be emphasized to ensure that these upper limits will never been exceeded. Laws and regulations stipulate that the catheterization laboratory manager must ensure that persons involved in interventional radiological procedures in cardiac catheterization examinations and other interventional techniques will not be exposed to doses exceeding the following limits:
(1) 100 mSv in 5 years
(2) 50 mSv in 1 year
(3) For females, 5 mSv in 3 months, in addition to the two limitations above
(4) For pregnant women, in addition to the above, 1 mSv of

internal exposure during the period from the time when the hospital or clinic manager becomes aware of her pregnancy as a result of her reporting it or other means to delivery
(5) For the abdominal surface of a pregnant woman, 2 mSv during the period specified in (4) above
(6) For the ocular lens, 150 mSv in 1 year
(7) For the skin, 500 mSv in 1 year
The catheterization laboratory manager is required to ensure that the persons involved in radiological medical procedures, including CAG, carefully observe these dose limitations, no matter how many examinations they perform. To this end, it is important that efforts be made to reduce exposure by making the best use of protective clothing and protective devices, and that workers wear personal dosimeters such as glass badges and do their work in an environment controlled to avoid exposure exceeding the dose limit.[14,21,22]

2. How to Use Personal Dosimeters
Q26: Personal dosimeters (photoluminescent glass dosimeters and optically stimulated luminescent [OSL] dosimeters) are available to wear on the head and chest. Where should we put them on? And if we put them on under protective clothing, where should they optimally be placed?
A: Figure 16 shows recommended positions for wearing personal dosimeters. During PCI procedures, two dosimeters should be worn, one inside the protective clothing and the other outside of it. For protection inside the protective clothing, personal dosimeters should be worn on the abdomen in the case of female workers, and on the chest in the case of males and females who have been diagnosed to have no chance of getting pregnant or who have submitted a written statement that they are not willing to be pregnant to the manager of the hospital or clinic (Notification No.188 of the PMSB [Pharmaceutical and Medical Safety Bureau] dated March 12, 2001). Outside of the protective clothing, personal dosimeters should be worn on the head and neck to monitor lens exposure doses.

3. Types and Effects of Protective Clothing and Effects of Lead Equivalent
Q27: What type of protective clothing should I wear during PCI? Protectors with lead equivalents of 0.25 mmPb and 0.35 mmPb are available. Please tell me the efficiency of protection for each type of clothing compared with exposure without protective clothing. Is a 0.35 mmPb protector more effective? Otherwise, is a 0.25 mmPb protector sufficient?
A: Regarding protective clothing, the higher the protective performance is, the better, though generally items with high

Figure 17. (**A**) Shielding effect of protective clothing. Comparison of 0.25 mmPb and 0.35 mmPb (tube voltage: 120 kV). Comparative data with 1 dose unit received by the operator without protective clothing. (**B**) Shielding effect of protective clothing in coronary angiography. Comparison of doses on the operator's chest. Cited from Awai K, editor. Radiation exposure and protection in vascular imaging. Radiology and Medical Technology Library (17). Kyoto: Japanese Society of Radiological Technology, 1999.

protective capacity are heavy. Wearing heavy protective clothing can affect the operator's concentration, and can cause lumbago.

The current version of the Japanese Industrial Standards (JIS) specifies lead-containing sheets with lead equivalents of 0.25 mmPb, 0.35 mmPb, and 0.50 mmPb as materials for protective clothing. Generally, the greater the lead equivalent is, the higher the protective performance is, though protective clothing becomes proportionally heavier with the increase in lead equivalent. **Figure 17A** shows the relationship between

the shielding material thickness and shielding power of protective clothing between 0.25 mmPb and 0.35 mmPb lead equivalents. **Figure 17B** shows actually measured shielding effects in coronary examination. Sufficient shielding power was obtained with the 0.25 mmPb lead equivalent, with no significant difference found in this respect between 0.25 mmPb and 0.35 mmPb. It is recommended that the operator use a relatively light item of about 0.25 mmPb lead equivalent in combination with other protective devices, rather than covering his or her entire body surface with heavy material. Light-weight

Figure 18. (**A**) Protective devices. Cited from The guidelines on prevention of radiation-related skin disorders following interventional radiological procedures – Q&A and Discussions. Booklet Series 3. Japan Association on Radiological Protection in Medicine; 2004. (**B**) Effects of protective devices. Comparative data with 1 dose unit received by the operator without each protective device.

protective clothing which is as effective as lead-containing clothing are currently available and may be used as appropriate.[14,22,23]

Q28: There are various types of protective clothings, including the apron type, which does not include lead in the back; the coat type, which includes lead both in the front and back; and the top-bottom separation type. Are there any differences among them in degree of protection from radiation exposure? Which is the ideal type?

A: Generally, wearing a protective coat designed to protect the operator's back prevents entry of the X-rays produced when the operator is working with his or her back to the patient in fluoroscopy, and entry of the X-rays scattered against the patient and further scattered against walls and equipment. When the back is covered with 0.25 mmPb protective clothing, the tissue-absorbed dose on the back can be reduced by half or so. However, provided that the operator does not have his or her back to the patient, the amount of X-rays entering the operator's body from the back is not much, so the effective dose remains almost unchanged. It is thus practical for the operator to wear lightweight protective clothing of the apron type, rather than covering his or her body with protective clothing of the coat type, which is heavy and may affect operator performance, and to be careful not to have his or her back to the patient during the operation. Whereas the apron type places weight mainly on the operator's shoulders, the weight of the separate type is dispersed over the shoulders and hips, with less induction of fatigue and improved work performance. Some protective aprons are designed to disperse its weight by using frames.[14,21,22,24]

4. Maintenance and Management of Protective Clothing

Q29: I've heard that protective clothing is not damage-resistant. Please explain quality control for protective clothing.

A: Protective clothing is comprised of a sheet-like base material uniformly containing an element of high atomic number such as lead, and a sheet of rubber or synthetic resin covering the base. Since it is tough enough that breakage and tears do not occur readily, it might be thought that it can be used on a semi-permanent basis. However, wearing it can cause physical fatigue in the material, which in turn can produce ruptures of the shielding material inside. Adhesion of liquids such as sweat, blood, and contrast media can decrease durability. Usually, commercially available protective clothing bears an expiration date; it is necessary to stop using the clothing before that date, and to periodically implement quality control to confirm the safety of protective clothing.

In using protective clothing, the following points of note should be borne in mind.

(1) Protective clothing does not completely block X-rays.
(2) If protective clothing is used beyond the expiration date specified by the manufacturer, safety should be confirmed by the user's facility.
(3) When storing protective clothing, avoid folding and use hangers or hooks capable of keeping it smooth (folding may cause ruptures of the shielding material inside).
(4) Do not place excessive stress on protective clothing (do not leave it on chairs and do not sit on it).
(5) Wipe off blood and contrast media adhering to protective clothing with lukewarm water or other appropriate detergents to keep it clean.
(6) Check the appearance of protective clothing periodically to confirm the absence of breakage of the cover sheet.
(7) It is also recommended that protective clothing be checked by fluoroscopy periodically to confirm the absence of breakage and loss of protective material.[22,25,26]

5. Effects of Goggles and Neck Protectors

Q30: I perform PCI many times every day, and am curious about my exposure. Please show protective devices, other than protective clothing, that are effective during PCI. If I wear such devices, to what extent will exposure dose be reduced?

A: Neck guards for protection of the neck and thyroid gland, protective spectacles and goggles for protection of the eyes, face guards for the face, and protective gloves for the hands and similar types of protective equipment are available. Some examples are shown in **Figure 18A**. In choosing these devices, as with protective clothing, avoid those that are too heavy; it is recommended that you choose ones that do not prove bothersome even when worn for a long period of time. Generally, the angiographic system has the X-ray tube positioned below the patient (under-the-table type), suggesting that the dose to the upper half of the body is not high. In PCI, however, X-rays are delivered over a broad range of directions, so protection of the upper half of the body as well is required.

Protective spectacles and goggles are a protective device to be worn over the face to protect the face, and particularly the ocular lenses, from radiation exposure, and are made of lead-containing glass or lead-containing acrylic resin. Lead-containing glass permits use with high lead equivalent values, so it can be processed into protective devices that are strongly protective, though they are heavy. Lead-containing acrylic resin is light and highly workable, so it can be fabricated into a broad range of shapes. However, its transparency is less than that of glass, so it is difficult to fabricate with high lead equivalent values. Use of protective spectacles is also recommended not only to guard against X-ray irradiation but also to protect the eyes against scattered blood and other body fluids. Neck guards are protective devices for protection of the thyroid gland, and are made of lead-containing sheets, as with protective clothing.

Figure 18B shows the protective effects of 0.07 mmPb protective spectacles made of lead-containing acrylic resin and 0.25 mmPb neck guards made of lead-containing sheets. Even relatively thin protective spectacles of 0.07 mmPb lead equivalent have a protective effect of about 60%. The 0.25 mmPb neck guards made of lead-containing sheets have a protective effect of about 90%, as with protective clothing.[14,21,22]

6. Protective Devices Recommended for Installation in the Imaging Laboratory and How to Use Them

Q31: Please describe the variety of protective devices that are helpful in the catheterization laboratory where PCI is performed, and show where to set them for effective use and how to use them.
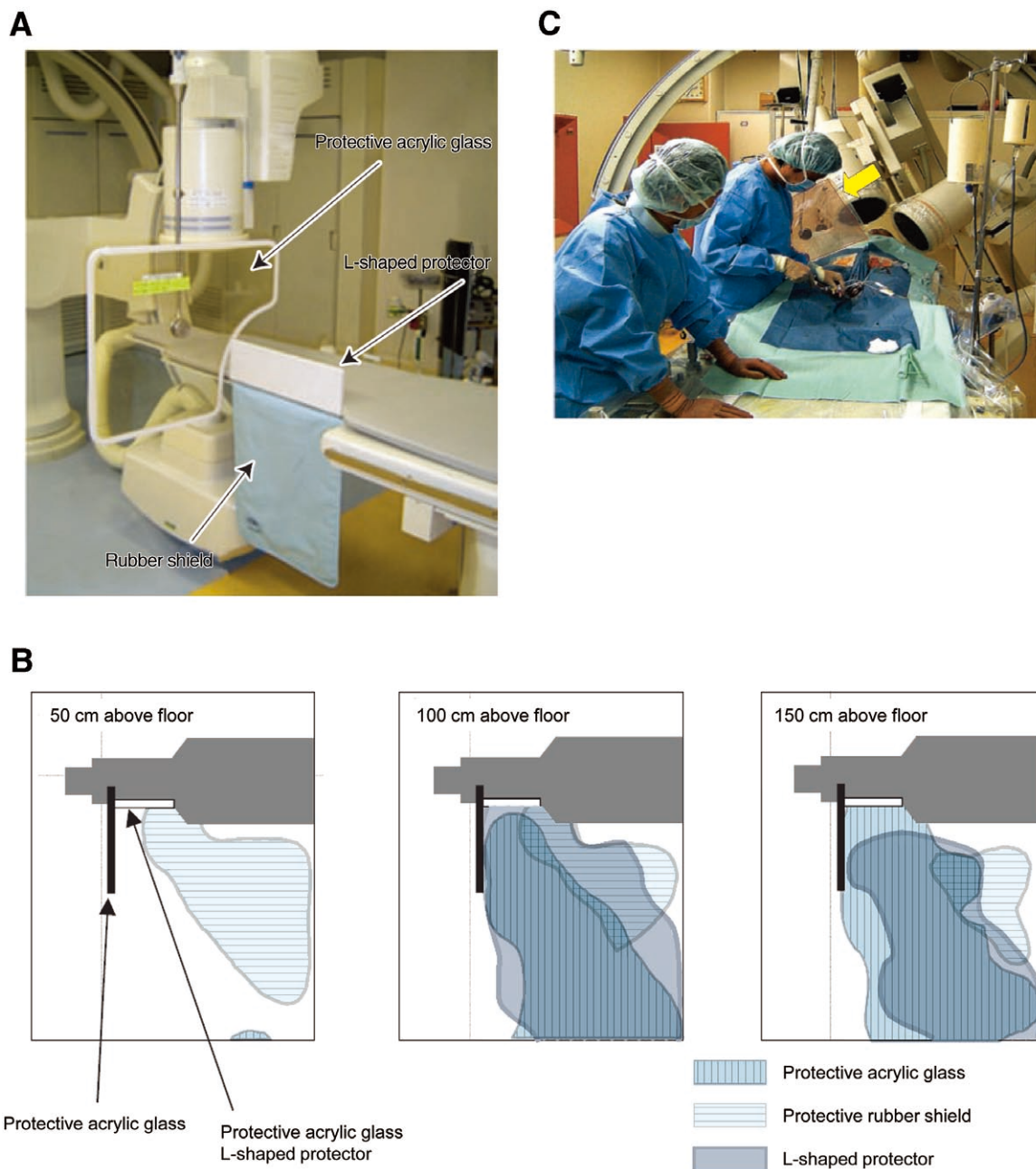
A: When a protective device is attached to the imaging system, medical personnel can lessen their fatigue since wearing lightweight protective clothing is sufficient to obtain the desired protection. If a single protective device is used to obtain all protection, the increased overall size hampers movement of the system's arm and catheter table, so it is recommended that a number of protective devices of various shapes be combined as appropriate for the patient's position. Protective devices recommended to be installed in the catheterization laboratory room are shown below. Their appearances and shielding effects are shown in **Figures 19A** and **19B**. It can be seen that combination use of the three types produces a still broader range of shielding effect.

(1) Type for protection of the lower half of the operator's body (rubber shield): These are made of lead-containing rubber, to be suspended from the catheter table.
(2) Type for protection of the operator's abdomen (L-shaped protector): L-shaped protective devices for insertion between the catheter table and the patient's back are both radioprotective and function as a patient arm rest. Although the protective effect increases with the height of the screen portion, workability decreases. The device shown in **Figure 19A** is 15 cm high.
(3) Type for protection of the upper half of the operator's body (protective acrylic glass): Lead-containing acrylic panels attached directly to ceilings or placed on ceiling rails are commonly used. If a panel of this type is placed on a ceiling rail, a broad range of motion is obtained; however, since it can interfere with the FPD and other equipment at some angles of the system's arm, caution is needed in handling the panel. X-ray exposure to the operator comes for the most part from X-rays scattered against the patient. For this reason, the protective panel is effective if placed as close as possible to the patient to separate the patient from the operator (not between the operator and the X-ray tube), and as close to the patient as possible. **Figure 19C** shows an example of placement for maximum effect.[14,21,22]

7. Dose Distribution in the Catheterization Laboratory

Q32: Please show the dose distribution in the catheterization laboratory during PCI.

A: Since knowledge of the dose distribution in the catheterization laboratory allows smooth operation with lower exposure doses, it is important that medical personnel entering the labo-

Figure 19. (**A**) Protective devices attached to the instrument. (**B**) Effects of three protective devices attached to the instrument. Outlined areas indicate 50% shielding areas on horizontal cross-sections 50 cm, 100 cm, and 150 cm above the floor. Cited from The guidelines on prevention of radiation-related skin disorders following interventional radiological procedures – Q&A and Discussions. Booklet Series 3. Japan Association on Radiological Protection in Medicine; 2004. (**C**) Effective position of guard screen (arrow).

ratory be aware of this distribution.

(1) Dose Distribution During Fluoroscopy
Figures 20A, **20B**, and **20C** show the dose distributions for various directions of entry of X-rays. In PCI, X-rays are projected from different directions, and the dose distribution changes with each change in direction; however, in general, greater doses are delivered on the side where the X-ray tube is

present. Hence, the dose is greater on the patient's left side in the RAO direction, and on the patient's right side in the LAO direction and left lateral direction.

(2) Dose Distribution During Imaging
The dose rate is more than 10 times greater during imaging than during fluoroscopy (**Figure 20D**). Even in the peripheral areas of the catheterization laboratory, where the dose rate is

Figure 20. Dose distribution in the catheterization laboratory. (**A**) Fluoroscopy in posterior-anterior (P-A) view. (**B**) Fluoroscopy in right anterior oblique (RAO) 30° view. (**C**) Fluoroscopy in left anterior oblique (LAO) 60° view. (**D**) Imaging in P-A view. Cited from Awai K, editor. Radiation exposure and protection in vascular imaging. Radiology and Medical Technology Library (17). Kyoto: Japanese Society of Radiological Technology, 1999.

relatively low during fluoroscopy, the dose rate occurring during imaging is comparable to that observed at the operator's position during fluoroscopy. It is recommended that medical personnel working in the catheterization laboratory use a guard screen during the imaging procedure, or leave the laboratory.

Taking into account these dose distributions, ICRP Publ.85 (Avoidance of Radiation Injuries from Medical Interventional Procedures) recommends that the operator stand on the side of X-ray image receptor such as FPD. However, this is often impossible or unrealistic, depending on the type of examination and the shape of the system. It is feasible for the operator to stand on the opposite side of the X-ray image receptor with appropriate protective devices.[6,14,23]

8. Education and Re-Education of Medical Personnel

Q33: What are the legal requirements concerning education and re-education related to radiation for physicians, nurses, and radiologic technologists engaged in PCI?

A: According to the Laws Concerning the Prevention from Radiation Hazards due to Radioisotopes and Others, Ministry of Health, Labour and Welfare (MHLW) Ordinance on Prevention of Ionizing Radiation Hazards, the Rules of the National Personnel Authority, and similar laws and legulations, education and training of medical personnel in radiology is mandatory. The MHLW Ordinance stipulates that special education concerning radiation safety be provided for persons engaged in operation of X-ray systems. In addition to the mandatory education/training in radiology, individuals who are engaged in duties involving the delivery of radiation to patients must educate themselves to obtain knowledge and expertise proactively to ensure their own and their patients' safety.

[Items for Education and Training]
(1) Effects of radiation on the human body [30 minutes]
(2) Safe handling of radioisotopes and radiation generators [4 hours]
(3) Laws and regulations concerning the prevention of radiation injuries due to radioisotopes and radiation generators [1 hour]
(4) Rules on prevention of radiation injuries [30 minutes]

Note that for those with adequate knowledge and skills, all or part of the education/training programs may be skipped.

[Frequency]
The Laws Concerning the Prevention from Radiation Hazards due to Radioisotopes and Others indicates that healthcare professionals in radiology should be educated and trained once before their first access to controlled areas, and every period that does not exceed 1 year after such access.

7. Management of Imaging Systems

1. Maintenance and Management of Imaging Systems

Q34: Please show the points to note for users of angiographic systems in maintaining the quality of such systems.

A: The amount of X-rays that a patient is exposed to cannot be kept constant unless the tube voltage and tube current are constant. Variation in X-ray quality influences the onset of skin injury in patients, and the size of the irradiation field is closely related to both patient and operator exposure doses. In ensuring the safety of angiographic systems and maintaining good quality and performance, it is important that not only self-inspections but also periodic maintenance and inspections be implemented by the manufacturers of the systems. In particular, the luminance of I.I. decreases over time, so if reduced luminance is left as is, the automatic exposure mechanism will adjust the dose, resulting in delivery of a greater exposure dose to the patient. Although dose variation among different institutions may be due, in part, to intrinsic features of the systems used, the status of implementation of dose adjustment during system inspections may also affect it. It is important that on the occasion of periodic inspections, the luminance of the I.I. be measured, and that the iris diaphragm and other components affecting the quality of images be adjusted whenever necessary to prevent the dose from increasing.

Note that if the luminance falls beyond the adjustable range, increase in the dose irradiated to the patient will be inevitable; replacement of the I.I. must then be considered. The Japan Industries Association of Radiological Systems (JIRA) has specified two cases in which the I.I. should be replaced with a new one:

(1) In cases in which the reference conditions as of the time of installation cannot be maintained even after adjustment, and the exposure dose has increased by 50% or more from the initial level.

(2) In cases in which the X-ray conditions as of the time of installation can be maintained by adjustment, but the diagnostic performance has evidently decreased from the initial level to an extent that hampers diagnosis.

Currently, few hospitals use cine film to record images. Angiography is increasingly performed using an angiographic system with a FPD of which a luminance does not decrease over time. Automatic developing machines should no longer be maintained, and routine maintenance of instruments has become easier. Since troubles of the system often affect the quality of cine film, the manager could find defects of the system indirectly through the resultant cine film images. We also had paid careful attention to the luminance of I.I. because it decreases over time. When digital angiography using a FPD becomes a standard, we can no longer grasp the condition of X-ray systems during routine use. Daily checkup and manufacturer's service and maintenance will become even more important.[26–30]

2. Measures to Reduce Exposure

Q35: I've heard that new angiographic systems are provided with a number of functions for ensuring the safe performance of PCI. When such a system is used, don't skin injuries occur in the patient?

A: Recently developed angiographic systems are provided with digitized features and many PCI aid functions as shown below. These functions, if utilized effectively, enable the operator to perform PCI smoothly while reducing both patient and operator exposures.

(1) Low pulse rate fluoroscopy function is included to reduce exposure.

(2) A supplementary filter to reduce exposure is provided.

(3) Reference image display and roadmap functions for smooth advancement of the catheter and guidewire to the target site are included.

(4) Image storage and retrieval are facilitated by digital image acquisition.

(5) Digital fluoroscopy is available, offering good visibility of the guidewire and stent.

It should be understood, however, that these functions never ensure the prevention of skin injuries, although they include measures to reduce exposure. Because erroneous use can lead to irradiation at higher-than-expected dose rates, it is important that the user have a clear understanding of these performance features before using them.[11]

8. Non-Coronary Intervention

1. Precautions in Head and Neck IVR

Q36: Please show the points to note for head and neck IVR, such as in internal carotid artery stenting.

A: The head has hair: Which is a significant difference from the skin of the trunk irradiated during cardiac intervention. Exposure to doses exceeding 3 Gy can cause temporary epilation. Even when it is temporary, epilation can have a major mental impact on the patient, so you should always be sure to the extent possible to avoid irradiation of the same site in the head for a prolonged period of time. Because direct exposure of the patient's eyes to X-rays can induce cataract, shielding and irradiation angle must be taken into account. According to ICRP Publ.85, the threshold dose for cataract caused by a single exposure is 2 Gy; this document also suggests that exposure to 5 Gy or more may produce progressive change. In ICRP Publ.60, it is stated that lens opacity without visual impairment can occur even with exposure of 0.2 Gy or less, so prolonged irradiation of the lens must to the extent possible be avoided.[5,6]

2. Precautions in Percutaneous Transluminal Angioplasty (PTA) in Lower Limbs

Q37: Please show what to note during lower limb PTA.

A: PTA is an effective means of treatment for arteriosclerosis obliterans (ASO), and the number of cases in which it is performed is steadily increasing in Japan. Since patients with ischemic heart disease often develop ASO as a complication, cardiologists are now more commonly engaged in its treatment. Access is usually through either the ipsilateral or contralateral femoral artery or an artery of the upper limb. Because of the proximity of the puncture site and the treatment site, the operator is exposed to relatively large amounts of scattered X-rays. In addition, a large-diameter FPD or I.I. is often used, and produces larger amounts of scattered X-rays than a small-diameter FPD or I.I. In performing examination for PTA, it is important that the irradiation field be narrowed to the maximum possible extent required, and that the appropriate image size be used.

Because the target vessels are often delineated in the posterior-anterior views rather than the oblique views commonly used in PCI, protective rubber shields and protective acrylic glass equipped with the radiation system or the examination room are effective (**Figure 19A**). It is recommended that the operator obtain radioprotection using these protective devices.[11,14,22]
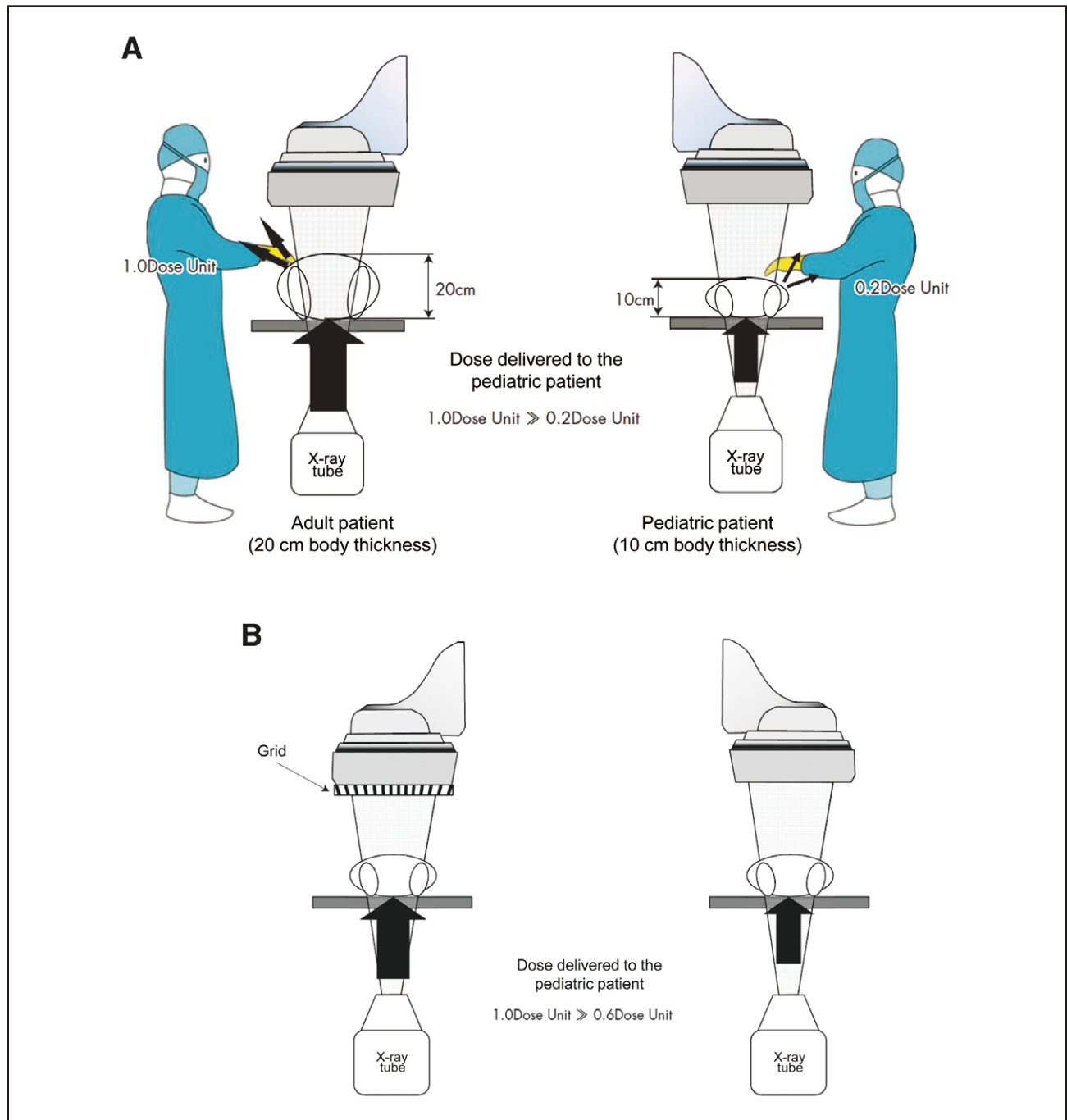
Figure 21. (**A**) Comparison of the exposure dose between the adult and pediatric patients. Doses received by the patient/operator are expressed relative to those in the adult patient case, with the latter considered 1 dose unit (9-inch, pulsed fluoroscopy at 15 p/s). (**B**) Comparison of the exposure dose between imaging with and without grid. Dose received by the patient during imaging without grid is expressed relative to that in the patient with grid, with the latter considered 1 dose unit (10 cm body thickness, 9-inch, pulsed fluoroscopy at 15 p/s).

9. Electrophysiological Examinations and Treatments

1. Exposure Doses to Patients Undergoing Catheter Ablation

Q38: What are the distinct features of radiation exposure in electrophysiological examinations and treatments, such as catheter ablation and pacemaker implantation compared with those in PCI? Are there any aspects of such procedures that require special attention as regards protective measures?

A: In electrophysiological examinations and treatments, fluoroscopy is mainly used, with imaging performed only mini-

mally. In addition, since catheter electrodes, which are more radiopaque than guidewires, are used, it is common practice to perform the examination at reduced fluoroscopy pulse rates. These features offer protective advantages compared with PCI. It should be noted, however, that since catheter ablation is likely to involve continuous fluoroscopy at a fixed X-ray entrance angle, irradiation of the same site is often repeated. In case of a long period of irradiation in the LAO position, in particular, concentrated exposure can occur in the right subscapular region and right upper arm; special caution is required with regard to this. LAO, in which the heart is observed through the vertebral column and mediastinum, requires higher doses then other projections (see **Q4** and **Figure 4**). Also, when the right upper limb enters the view field, the system detects an increase in radiopacity to increase the radiation dose, and the dose delivered to the skin of the right upper arm, which is placed near to the X-ray tube, will be substantially high (see **Q20** and **Figure 14**). Efforts should be made to use low pulse rate fluoroscopy, and to keep the upper arms away from the irradiation field, by, for example, distancing the upper arms from the trunk as far as possible.

2. Precautions for Pediatric Patients

Q39: What are the points to note for pediatric patients? I've heard that paralysis can occur when the upper limbs are placed in a raised position for a long time. Is there any effective method of preventing this?

A: When a pediatric patient undergoes catheterization or intervention under general anesthesia, frontal and lateral views using biplane fluoroscopy are often used; to secure a field for lateral fluoroscopy, the upper limbs are sometimes immobilized while raised. Prolonged immobilization can cause injuries to the brachial plexus, brachial nerve, ulnar nerve and other nerves which in turn can result in paralysis and hypesthesia in the ulnar side of the palm, as well as distal from the shoulder joints or cubital joints. This is attributed to ulnar nerve hyperextension due to elbow abduction under the weight of the arm, or to damage to the entire brachial nerve due to axillary hyperextension, as a result of inappropriate immobilization. Although signs and symptoms such as motor paralysis and hypesthesia are for the most part transient, recovery can take 6 months or longer in some cases. This can be prevented by avoiding immobilization in a constant limb position. If immobilization is unavoidable, it is recommended that the immobilization be loosened, with upper limb adduction, to achieve transient decompression of the nerves, at intervals of about 30 to 60 minutes.

Q40: Cardiac interventions for pediatric patients are becoming common. Since cardiac interventions need prolonged X-ray irradiation and pediatric patients are more susceptible to radiation exposure, the radiation risk of cardiac interventions to pediatric patients is a concern. What should we do to reduce the radiation exposure as much as we can?

A: Although children are susceptible to radiation exposure, the dose delivered per unit time is lower in children than adults because their body is small (**Figure 21A**). Although low pulse rate fluoroscopy is beneficial to reduce the dose delivered to the pediatric patients, some institutions are not using this technique for a reason that the heart rate is generally high in children. We recommend to try it without preconceptions.

Removing the grid is a good method to reduce the dose delivered to the pediatric patient. The grid is a device placed in front of the FPD or I.I. to remove scattered rays and maintain the quality of images. Since the body is smaller in children than adults and does not produce a large amount of scattered rays, fluoroscopy without the grid may be performed for children. The effect of scattered X-rays on images may be eliminated in part by separating the FPD or I.I. and the patient by about 10 to 20 cm. **Figure 21B** shows the doses delivered to the pediatric patient during fluoroscopy with and without the grid using an FPD placed 20 cm away from the patient. Generally, the dose delivered to the patient increase as the distance of the patient and the FPD increases, but the dose delivered to the patient may be reduced by removing the grid. A long distance between the FPD and the body may produce a larger image that cannot be visualized within the image among adults, but does not cause such problems in children of which the target organs and vessels are small.

10. Nuclear Imaging

1. Precautions in Performing PCI on the Same Day as Tl Myocardial Scintigraphy or the Following Day

Q41: Please indicate the precautions in performing cardiac catheterization on the day of or the day after Tl-201 scintigraphy to evaluate myocardial viability. What issues exist concerning the risk of radiological exposure due to isotopes remaining in the patient's blood and catheter devices?

A: Because the amounts of isotopes administered to the patient in nuclear imaging are small, it is generally believed that cardiac catheterization poses no problem related to exposure of the operator and other staff even when it is performed on a patient who received an isotope on the same or the following day. However, because the patient's blood contains a residual portion of the isotope, although it may be quite small, the injection needles, catheters, and related equipment used in the cardiac catheterization may be contaminated. For this reason, used disposable instruments should be stored until their radioactivity level becomes undetectable with a counter, and then disposed of as infectious waste. In addition, since isotopes are excreted at high levels in the urine, the patient's urine should be handled with greater care than the blood. The urinal bags and used diapers of patients undergoing nuclear imaging should be handled in the same fashion as catheters and injection needles.
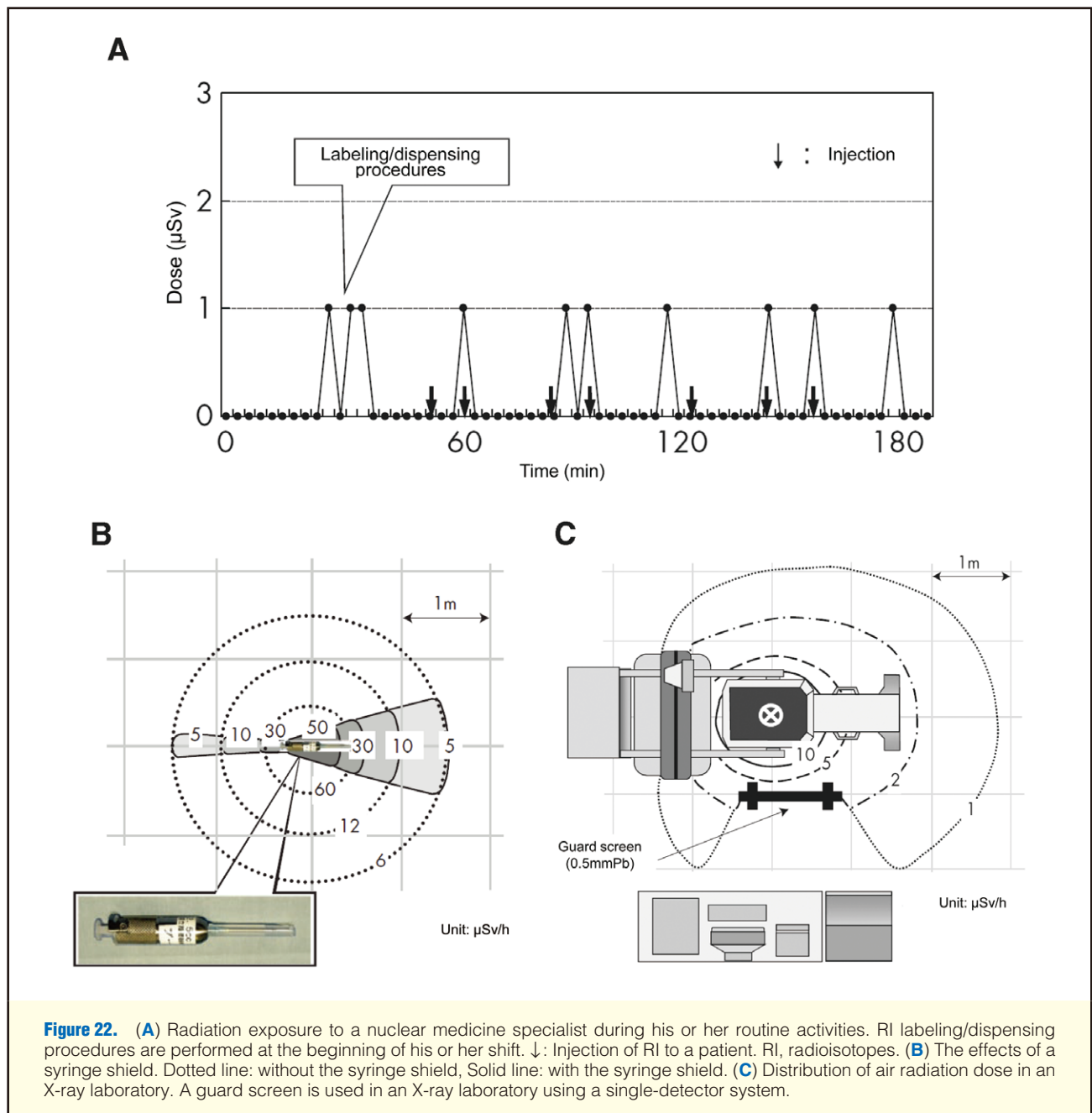
2. Exposure of Medical Personnel Engaged in Tl Myocardial Scintigraphy

Q42: I perform intravenous injection of isotopes during Tl myocardial scintigraphy. What is the extent of exposure of my fingers and body? Is any method available to reduce this exposure?

A: According to a 1995 survey by the Japanese Society of Nuclear Medicine Technology, exposure doses to the trunk of radiologic technologists involved in nuclear imaging were ≤0.2 mSv/month in ≥75% of the institutions that participated in the survey, whereas the exposure doses to the fingers exceeded 0.5 mSv/month in as many as 30% of the institutions. **Figure 22A** shows radiation exposure to a physician who opened 15 syringes, eluted 740 mBq of technetium (Tc)-99 m from the generator, and administered the radiopharmaceutical to patients. The graph indicates that the physician was exposed to radiation when he handled the radiopharmaceutical such as dispensing the Tc-99 m radiopharmaceutical from the generator, opening syringes, and giving the radiopharmaceutical to patients.

Many of the recently launched isotopes are supplied in shielded syringes with tungsten and lead glass. As such, greater

Figure 22. (**A**) Radiation exposure to a nuclear medicine specialist during his or her routine activities. RI labeling/dispensing procedures are performed at the beginning of his or her shift. ↓: Injection of RI to a patient. RI, radioisotopes. (**B**) The effects of a syringe shield. Dotted line: without the syringe shield, Solid line: with the syringe shield. (**C**) Distribution of air radiation dose in an X-ray laboratory. A guard screen is used in an X-ray laboratory using a single-detector system.

consideration is given to reduction of exposure of medical personnel than ever, although no shielding is provided on the injection needle side and the plunger side (**Figure 22B**). Skillful handling of shielded pre-filled syringes is essential to reduce radiation exposure. It is also important to establish a venous access before giving the radiopharmaceutical. Guard screens are also effective in protecting healthcare professionals from radiation exposure during a nuclear medicine (**Figure 22C**).[31,32]

3. How to Handle Subcutaneous Leakage of Isotopes

Q43: I have erroneously injected an isotope into subcutaneous tissue of a patient during myocardial scintigraphy. Please tell how to handle this.
A: Subcutaneous leakage on intravenous injection is not rare in the clinical setting. If a subcutaneously leaked isotope remains

localized at the site, it is possible that the local tissue will absorb a high dose, indicating that caution is needed even if the isotope has a short half-life. In a case reported in Japan, Tl-201 leaked from subcutaneous blood vessels during myocardial scintigraphy; despite immediate treatment, the portion of the skin around the site of leakage necrotized 2 weeks later, followed by ulceration with scar epithelialization 3 months later, and severe scarring, depigmentation, skin atrophy and vascular dilation in the center of the affected part, and peri-pigmentation 4 years later; chronic radiation dermatitis was eventually diagnosed. If leakage of an isotope is detected during examination, it is important that the maximum expected skin-absorbed dose be roughly calculated by, for example, quickly obtaining images of the site of leakage to obtain dose information, and that the patient be followed over time.[33,34]
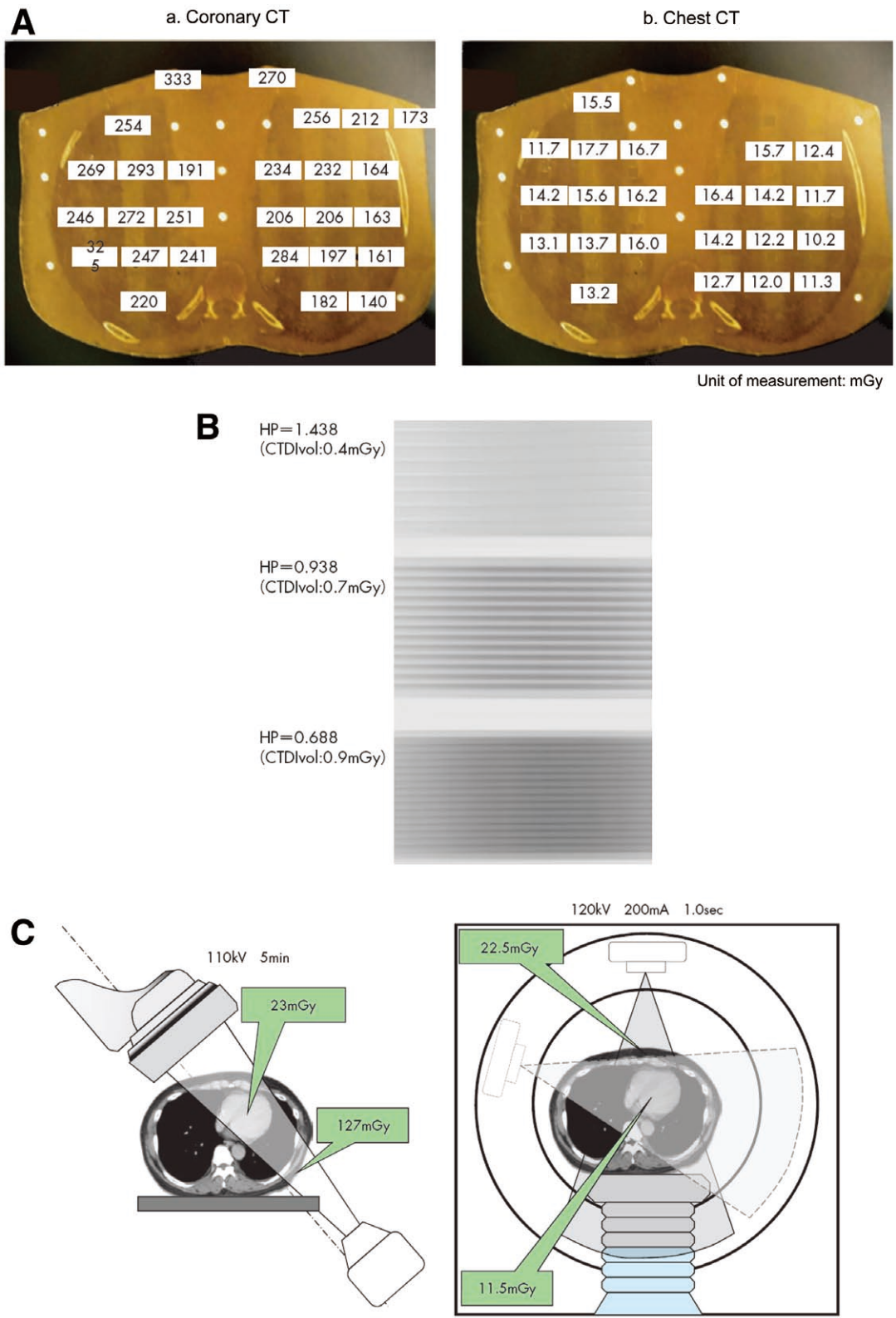
Figure 23. (**A**) Comparison of doses received by a patient undergoing chest CT and coronary CT. Data courtesy of Fujita Health University. (**B**) Images on film placed around a phantom. Darker colors indicate higher doses (tube voltage 120kV, 10mA, 0.4s/rotation, slice thickness 5mm). (**C**) Comparison of patient exposure doses in coronary angiography and coronary CT. Angiographic data courtesy of Kanazawa University. CT, computed tomography; HP, helical pitch; CTDIvol, volume computed tomography dose index.

11. CT

1. Exposure Dose to Patients Undergoing Coronary CT

Q44: Recently, evaluation of coronary lesions by multi-detector computed tomography (MDCT) has become increasingly common. What is the average exposure dose in such cases? How about a comparison with CAG?

A: The dose delivered during coronary CT is larger than that during conventional chest CT (**Figure 23A**). In coronary CT, it is necessary to choose very thin slice thickness (0.5 mm) to obtain high-resolution three-dimensional (3D) images, and to choose a small helical pitch (HP) to obtain images in multiple time phases. **Figure 23B** shows the results of observation of scan traces with three different pitches in a phantom with a film placed around it. Although smaller HPs produce more dense images, they also produce greater doses. This is the reason why the patient receives larger doses in coronary CT.

In conventional CAG for diagnostic purposes, the patient receives doses similar to those during coronary CT. **Figure 23C** shows dose distributions around a phantom during conventional CAG and coronary CT using a common imaging protocol. In CAG, the highest dose occurs on the skin surface where X-rays have entered. In CT, the dose in the center of the body is not widely different from the skin surface dose because the trunk is irradiated circumferentially. For this reason, with the same maximum dose, a greater effective dose is produced in CT, where similar doses are irradiated over the entire imaging area, than in CAG, where doses are localized on the skin surface. The risk of carcinogenesis thus appears to be higher with CT. However, it remains unclear whether this difference is clinically significant.[34–37]

Q45: There are concerns about the effect of radiation exposure during coronary CT. How should healthcare professionals consider radiation exposure during CT and deal with it?

A: Since in CAG and PCI the highest dose occurs on the skin surface where X-rays have entered, the maximum skin dose and its deterministic effects (radiation-induced skin injuries) are concerned. On the other hand, in CT where the body is irradiated extensively, the effective dose and its stochastic effects (tumors and genetic effects) are concerned.

In 2007, Einstein et al determined organ doses from 64-slice CT coronary angiography (CTCA) through standardized phantom to estimate lifetime attributable risk (LAR) of cancer incidence associated with radiation exposure from a CTCA study, and reported that organ-specific LARs were highest for lung cancer and breast cancer, especially in women and younger patients. The researchers used the linear no-threshold risk model assuming that "the risk of cancer proceeds in a linear fashion at lower doses". In the study, the LAR for a 20-year-old woman with chest pain undergoing a combined scan of the heart and aorta (effective dose: 29 mSv) was about 1%, which was about 50-fold the LAR for an 80-year-old man undergoing a low-dose CTCA with ECG-based tube current modulation (effective dose: 9 mSv).[38]

In 2009, the American Heart Association (AHA) published a Science Advisory to validate and explain the Einstein's estimations, which raised considerable concerns for radiation exposure during CT. The AHA explained as follows: Using the example of a typical coronary CT angiogram, the estimated increase in the lifetime risk of dying of a malignancy associated with 10 mSv of ionizing radiation is about 0.05%. This 0.05% increase in risk is added to the 21% background risk for the USA population. Specifically, the estimated increase in the lifetime risk for younger women of developing breast cancer associated with a coronary CT scan is about 0.7%, which is substantially smaller than the lifetime risk for younger women of developing breast cancer (12.45%). Although it has been described that the risk of cancer associated with radiation exposure during coronary CT is substantially smaller than the lifetime risk of cancer, this conclusion is not based on sufficient data but was obtained with estimation and extrapolation not supported with compelling evidence. Healthcare professionals should carefully weigh the benefits versus risks of coronary CT in the clinical setting to determine whether it is indicated or not.[39]

CTCA in patients suspected of having coronary artery disease is a relatively common procedure among middle-aged and older man. Researchers have stated that since there is a latent period of 10 to 40 years before development of cancer associated with radiation exposure, patients over 50 years of age may not be affected significantly by radiation exposure, and may enjoy the benefits of diagnosing coronary artery diseases over its risk. However, the total dose delivered to a patient with a middle or high risk of coronary artery diseases is often lower for the strategy of conducting CAG followed by ad hoc PCI in a case of significant stenosis than performing CTCA first. The combined use of CT and CAG should be avoided whenever possible. Physicians should carefully determine whether CT scan is indicated for young or middle-aged women with chest pain considering the fact that the effects of radiation exposure are higher in young people and women.
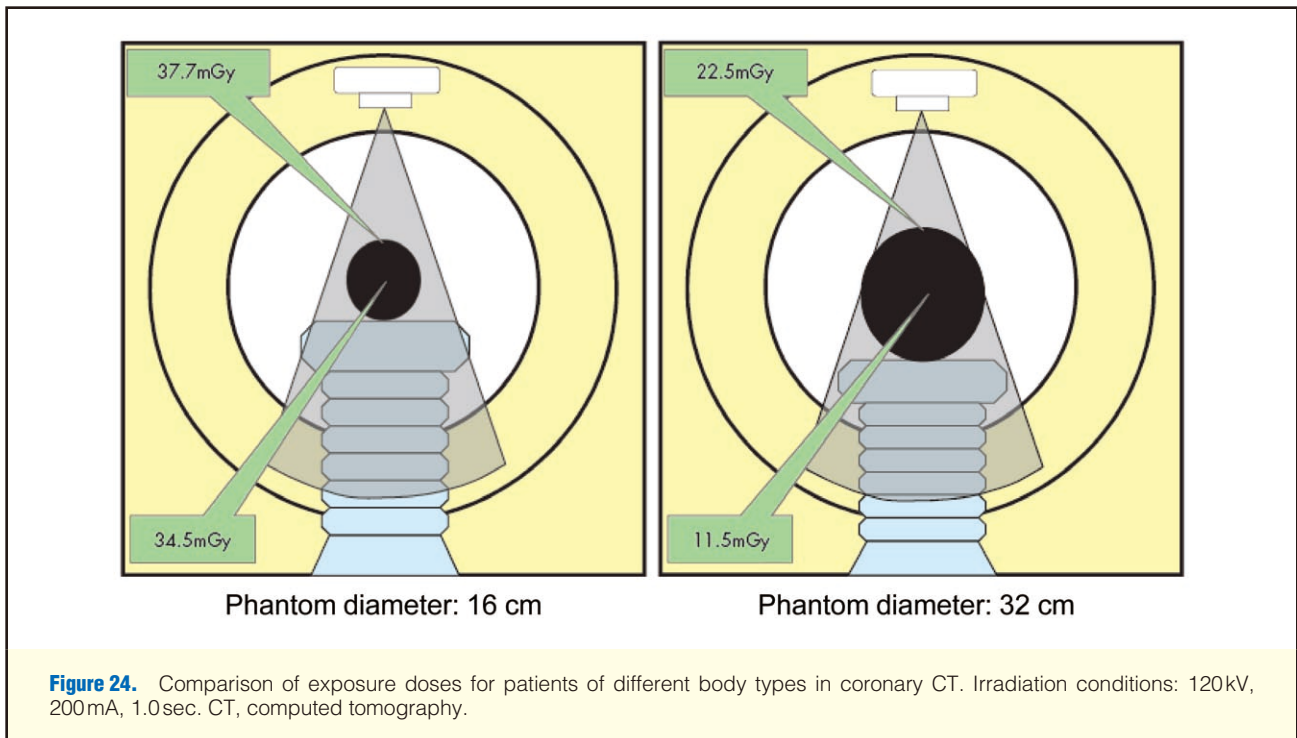
Q46: Does the exposure dose vary depending on the patient's body type in CT as in CAG? Is this variation clinically problematic?

A: When CT images are taken under the same conditions, patients of smaller body size receive greater exposure doses. **Figure 24** compares doses in the center and surrounding area, two phantoms 16 cm and 32 cm across, respectively, imaged under the same irradiation conditions. Because the X-rays used for diagnostic purposes only minimally permeate the patient's body and lose much of their energy, irradiation under the same conditions produces greater mean absorbed doses in lighter than in heavier patients. In addition, patients of smaller body size exhibit smaller dose differences between the center and surrounding area, and hence receive higher doses at any position on the phantom; irradiation conditions suitable for the patient's body type should therefore be chosen before obtaining images. When a child is being examined, in particular, measures to prevent excessive irradiation, such as reducing the tube current, should be taken. Automatic irradiation control, a function widely used recently to allow automated adjustments of irradiation conditions according to the acquisition site based on scout views, is expected to facilitate imaging at appropriate doses without affecting image quality.

2. Effects of the Use of Multi-Row Detectors

Q47: Does the patient exposure dose increase with the number of detectors in MDCT? What is the difference in exposure dose from conventional CT in major blood vessels?

A: Basically, provided that the slice thickness and HP are the same, the dose received by the patient is expected to the same irrespective of the number of detector arrays. However, the radiation dose is higher in recent MDCT scanners with a large number of slices than conventional systems to obtain better images, because a higher tube currents is needed to obtain

Figure 24. Comparison of exposure doses for patients of different body types in coronary CT. Irradiation conditions: 120 kV, 200 mA, 1.0 sec. CT, computed tomography.

high-quality images in a shorter scan time; the slices are substantially overlapped due to the use of small HP and radiation is delivered repeatedly; and large tube currents are required to use small detectors. One of the major benefits of high-resolution MDCT is the shorter breath-holding time, which is 20 to 30 seconds for 16-slice MDCT, 5 to 10 seconds for 64-slice MDCT, and less than 1 second for 320-slice MDCT.

For the above reasons, the dose delivered during coronary CT is higher than that during conventional chest CT, and may differ substantially among hospitals since the conditions and protocols for imaging vary. It has been reported that the effective dose for CTCA is about twice that for chest CT (typical dose, 16 mSv vs. 7 mSv; range, 5 to 32 mSv vs. 4 to 18 mSv, respectively) (See **Q 44**).[36,37,39]

3. The Effects of Repeated CT Scans

Q48: MDCT is becoming a common procedure for the diagnosis and treatment of coronary artery diseases and follow-up of thoracic/abdominal aortic aneurysms. What should we consider about the effects of radiation exposure during repeated CT scans?

A: MDCT is a minimally invasive procedure and has been increasingly used as a beneficial tool for the diagnosis and follow-up of coronary artery diseases and follow-up of thoracic/abdominal aortic aneurysms. The indication of MDCT as well as the length and interval of follow-up should be determined based not only on the radiation exposure but also on the necessity for the patient. When the technique is absolutely necessary, healthcare professionals should make every effort to obtain high-quality images adequate for the purpose and avoid the effects of radiation exposure as possible. The dose should be carefully selected to ensure a minimal necessary dose required to obtain images adequate for the diagnosis.

4. Effects on Pacemaker and Implantable Cardioverter Defibrillator (ICD)

Q49: What are the points to note in performing CT examination on a patient with a pacemaker or ICD?

A: It was recently reported from more than one institution that partial resets occurred during CT of patients with an implanted pacemaker or ICD. This was attributed to unwanted currents produced as a result of a photoelectric effect induced by irradiation of the CMOS circuit, which amplifies the electrical excitation of the heart. As a result, in patients with a pacemaker, transient suppression of pacing pulse output due to oversensing can lead to cardiac arrest. In ICD, the defibrillator can operate erroneously due to oversensing.

If CT or delivery of a relatively high dose of radiation is performed on a patient with either device implanted, attention should be paid to the following:
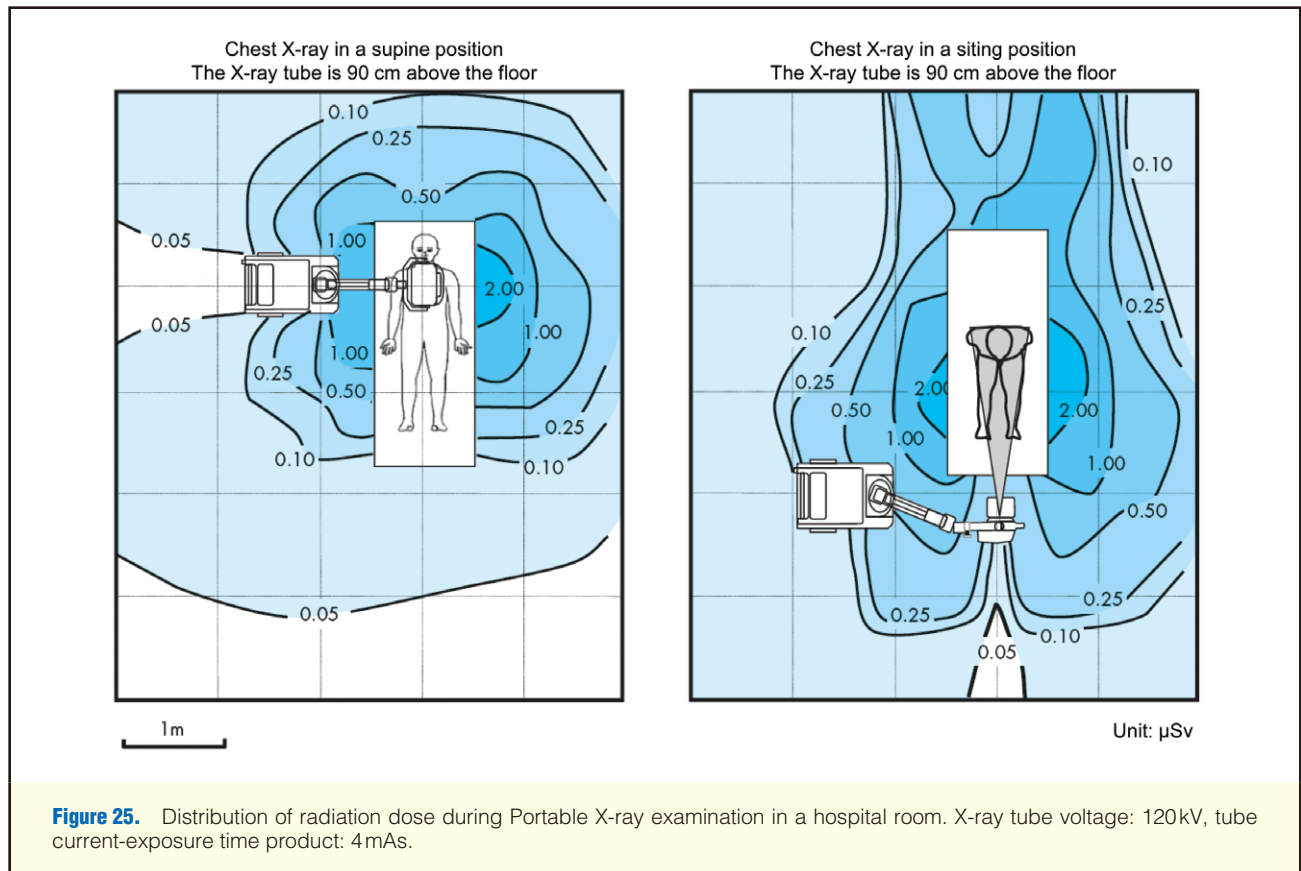
(1) How to Handle Pacemaker-Related Problems
- Do not irradiate the implantation site for 5 seconds or longer.
- If an X-ray beam must be continuously directed at the implantation site for 5 seconds or longer, take appropriate measures to distance the irradiation site from the pacemaker as much as possible, such as asking the patient to raise both of his or her arms.
- If irradiation of this type for 5 seconds or longer cannot be avoided, perform the examination in the fixed pacing mode without competitive pacing, or prepare for external pacing in case of pacemaker-related problems.

(2) How to Cope With ICD-Related Problems
- Do not irradiate the implantation site.
- If X-ray irradiation of the implantation site is unavoidable, take appropriate measures to distance the irradiation site from the ICD as much as possible, such as asking the patient to raise both of his or her arms.

Figure 25. Distribution of radiation dose during Portable X-ray examination in a hospital room. X-ray tube voltage: 120 kV, tube current-exposure time product: 4 mAs.

- If irradiation of this type cannot be avoided, perform the examination only after turning off the tachycardia detection function.
- Be prepared to use an temporary external defibrillator or a external pacing during the examination.

  In all cases, a specialist capable of responding quickly, including reset cancellation, should attend the examination, and it is essential that the pulse be monitored via an ECG monitor.[40]

12. Radiation Exposure During Portable X-Ray Procedures in CCU

Q50: I am a CCU nurse and concerning about radiation exposure associated with a portable chest X-ray. What distance from the patient is safe?

A: The use of X-ray devices outside the X-ray laboratory is generally prohibited, but is allowed when there are compelling reasons such that the patient requires X-ray testing to examine his/her conditions but cannot be transferred to the laboratory. The guidelines recommend that appropriate protective measures be taken, but it is not practical to use radioprotective devices such as screens. The most common measures to avoid radiation exposures are selecting of appropriate radiation conditions and ensuring an appropriate distance from the source of X-rays.

  The Medical Care Law requires that "mobile/portable or surgical X-ray equipment should be able to be operated from a distance of at least 2 meters from the focus of X-ray tube and the patient". The Notification No. 69 of the Safety Division, PMSB dated June 30, 1998 requires that family members, care providers and visitors should be at least 2 meters away from the X-ray tube container and the patient. **Figure 25** illustrates the distribution of radiation dose in the hospital room during portable chest X-ray examination of the patient in a supine and sitting position on the bed. Radiation is almost undetectable in the surrounding areas 2 meters away from the bed, and people in the these areas do not need protective clothing.

13. Examination and Treatment of Pregnant Patients

Q51: What are the points to note in catheterization studies of pregnant women in the middle gestational stage or later?

A: Irradiation of pregnant patients should be avoided to the extent possible. Since maternal health benefits the fetus, any required examination should be performed with due caution concerning the matters indicated below. In such cases, it is important that adequate informed consent be obtained from the patient after a full explanation of the possible effects on the fetus and other related matters, and that the dose received by the fetus be limited to 100 mGy or less. When the irradiation field is in the lower abdomen (direct exposure on the fetus), or when a catheterization study of the pelvis is required, it is necessary to reconfirm the need for examination, and to determine whether the examination can be delayed until the end of gestation. In examinations in which the dose received by the fetus is likely to markedly exceed 100 mGy, a method of examination not involving the use of radiation should be considered.

To minimize the dose to which the fetus is exposed, the following should be noted.

(1) In examination of parts of the mother's body relatively far from the fetus, such as the chest, upper limbs, and head, a catheter insertion site that does not cause direct exposure of the fetus to irradiation (e.g., cubital artery, radial artery) should be chosen.

(2) Rigorous use of common techniques for reduction of exposure (e.g., low pulse rate fluoroscopy, limitation of the irradiation field, use of a supplementary filter, and shortening of the distance to the FPD or I.I.).

(3) Determine the dose to which the fetus is exposed.[41]

References

1. Guidelines for the Diagnosis and Treatment of Cardiovascular Diseases (2004–2005 Joint Working Groups Report). Guidelines for Radiation Safety in Interventional Cardiology (JCS 2006). *Circ J* 2006; **70**(Suppl IV): 1247–1299 (in Japanese).
2. JCS Joint Working Group. Guidelines for radiation safety in interventional cardiology (JCS 2006). Digest version. *Circ J* 2010; **74:** 2760–2785.
3. Hirshfeld JW Jr, Balter S, Brinker JA, Kern MJ, Klein LW, Lindsay BD, et al. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. *Circulation* 2005; **111:** 511–532.
4. Manual on management and measurement of radiation exposure 2003. Japan Association on Radiological Protection in Medicine, 2003 (in Japanese).
5. ICRP Publication 60: 1990 Recommendations of the International Commission on Radiological Protection, 60, Japanese version. Japan Radioisotope Association, 1991 (in Japanese).
6. ICRP Publication 85: Avoidance of radiation injuries from medical interventional procedures, 85, Japanese version. Japan Radioisotope Association, 2003 (in Japanese).
7. Koenig TR, Wolff D, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: Part 1, characteristics of radiation injury. *Am J Roentgenol* 2001; **177:** 3–11.
8. Ishikawa M, Soh I, Sueki H, Iijima M, Hayashi K, Wakugawa M. Two cases of chronic radiodermatitis caused by cardiac catheterization. *The Nishinihon Journal of Dermatology* 1999; **61:** 731–736 (in Japanese).
9. Soh I, Ishikawa M, Iijima M. Radiodermatitis following cardiac catheter and hepatic artery embolization. *The Japanese Journal of Clinical Dermatology* 2000; **54:** 7–10 (in Japanese).
10. Soh I. Diagnosis and treatment of radiodermatitis following interventional radiological procedures. *Jpn J Interv Cardiol* 2002; **17:** 357–360 (in Japanese).
11. The guidelines on prevention of radiation-related skin disorders following interventional radiological procedures – Q&A and Discussions. Booklet Series 3. Japan Association on Radiological Protection in Medicine, 2004 (in Japanese).
12. Koga S. Comments on ICPR's draft recommendations by Japan Association on Radiological Protection in Medicine. *Newsletter of Japan Association of Radiological Protection in Medicine* 2000; **29:** 73–74 (in Japanese).
13. Saito I. Methods of description of parameters for pulsed fluoroscopy. *Newsletter of Japanese Society of Circulatory Technology* 2002; **5:** 20–21 (in Japanese).
14. Awai K, editor. Radiation exposure and protection in vascular imaging: Radiology and Medical Technology Library (17). Kyoto: Japanese Society of Radiological Technology, 1999; 22–25 (in Japanese).
15. Eguchi Y, Kinoshita J, Wakamatsu O, Ebihara Y, Kobayashi H, Uchiyama N. Clinical application of flat-panel detectors. *Japanese Journal of Radiological Technology* 2003; **59:** 29–43 (in Japanese).
16. Kitai T, Ogawa T, Sano S. Patient absorbed dose in coronary angiography determined by the flat panel digital detector X-ray system. *Japanese Journal of Radiological Technology* 2003; **59:** 423–426 (in Japanese).
17. Seguchi S, Ishikawa Y, Mizuno S, Saijou T, Nagao T, Nakamura A. Dose evaluation of a flat-panel detector system. *Japanese Journal of Radiological Technology* 2003; **59:** 1438–1443 (in Japanese).
18. Ichida T, Okusako K, Yokoyama K, Shougaki M, Ogawa T, Kawahata H, et al. Clinical study with angiography system using a flat panel detector. *Japanese Journal of Radiological Technology* 2004; **60:** 1143–1152 (in Japanese).
19. Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: Part 2, review of 73 cases and recommendations for minimizing dose delivered to patient. *Am J Roentgenol* 2001; **177:** 13–20.
20. Mizutani H; Scientific Research Group, Japanese Society of Radiological Technology. Research on the measurement of patient dose and protection in IVR. *Japanese Journal of Radiological Technology* 2003; **59:** 369–381 (in Japanese).
21. Awai K, Aoki Y, Ito T, Ohotakeno H, Fukutomi Y, Fujimoto N, et al. Study reports in radiation exposure for a medical workers and protective clothing in recent X-ray study. *Japanese Journal of Radiological Technology* 1998; **54:** 687–696 (in Japanese).
22. Mizutani H, Kobayashi Y, Saida T, Saito I, Saito Y. A report of "an examination group of the Standard Radioprotective Implement for the Angiographic Operators". *Japanese Journal of Radiological Technology* 2001; **57:** 1469–1478 (in Japanese).
23. Awai K, Oonobori K, Hayashida A, Fujii S, Mizutani H, Miyake H, et al. Report from the group of aerial-dosis measurement in case of IVR (PTCA). *Japanese Journal of Radiological Technology* 2001; **57:** 33–48 (in Japanese).
24. Inoue S, Matsumoto M, Matsuzawa R. Examination of optimal radiation quality in the lead equivalent examination of X-ray protective clothing. *Japanese Journal of Radiological Technology* 2004; **60:** 1682–1687 (in Japanese).
25. Working session report: A report on radiation exposure due to damage to protective clothing and guidelines for the management of protective clothing. *Japanese Journal of Radiological Technology* 2000; **56:** 552–557 (in Japanese).
26. Itou T. Evaluation and routine testing in medical imaging departments – Part 2-8: Constancy tests – protective shielding, -barriers and -devices JIS Z4752-2-8 (IEC 61223-2-8). *Japanese Journal of Radiological Technology* 2005; **61:** 1104–1105 (in Japanese).
27. Ikuse J. IEC standards regarding the constancy tests and acceptance tests. *Japanese Journal of Radiological Technology* 2001; **57:** 49–50 (in Japanese).
28. Iino T. An effective period of the use of medical appliances. *Japanese Journal of Radiological Technology* 2002; **58:** 274–279 (in Japanese).
29. Shinohara F, Ito T, Shitara A, Kato Y. Evaluation and routine testing in medical imaging departments – Part 2-5: Contancy tests – imaging display devices, JIS Z 4752-2-5: 2001 (Committee News). *Japanese Journal of Radiological Technology* 2000; **58:** 631–633 (in Japanese).
30. Shinohara F, Abe M, Miyazaki S. Evaluation and routine testing in medical imaging departments –Part 3-3: Acceptance tests – imaging performance of X-ray equipment for digital subtraction angiography (DSA) JIS Z 4752-3-3: 2003. *Japanese Journal of Radiological Technology* 2003; **59:** 621–624 (in Japanese).
31. Fukunaga Y, Matsuoka N, Mae T, Kouno T. Trial manufacture of a plunger to reduce finger exposure. *Kaku Igaku* 2001; **38:** 113–123 (in Japanese).
32. Hayashida A. The actual situation of operator radiation exposure in radioisotope examination. *Japanese Journal of Radiological Technology* 2007; **63:** 380–386 (in Japanese).
33. Inaba T, Nakayama K, Mizutani H. Radiology dermatitis due to thallium chloride. *Practical Dermatology* 2001; **23:** 919–921 (in Japanese).
34. Fukuda H. Radiation-induced skin injuries. *Kaku Igaku* 2003; **40:** 213–219 (in Japanese).
35. Nishitani H, Yasutomo M, Tominaga M, Fukui H, Yagi H. Radiation exposure in CT. *Nippon Igaku Hoshasen Gakkai Zasshi* 2002; **62:** 347–351 (in Japanese).
36. Nishizawa K, Matsumoto M, Iwai K, Maruyama T. Survey of CT practice in Japan and collective effective dose estimation. *Nippon Igaku Hoshasen Gakkai Zasshi* 2004; **64:** 151–158 (in Japanese).
37. ICRP Publication 87: Managing patient dose in computed tomography, 87, Japanese version. Japan Radioisotope Association, 2004 (in Japanese).
38. Einstein AJ, Henzlova MJ, Rajagopalan S. Estimating risk of cancer associated with radiation exposure from 64-slice computed tomography coronary angiography. *JAMA* 2007; **298:** 317–323.
39. Gerber TC, Carr JJ, Arai AE, Dixon RL, Ferrari VA, Gomes AS, et al. Ionizing radiation in cardiac imaging: A science advisory from the American Heart Association Committee on Cardiac Imaging of the Council on Clinical Cardiology and Committee on Cardiovascular Imaging and Intervention of the Council on Cardiovascular Radiology and Intervention. *Circulation* 2009; **119:** 1056–1065.

40. Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare. Effects of drugs and X-ray CT instruments on the function of an implantable pacemaker (Medtronic InSync 8040). *Medical Device Safety Information* No. 213, 2005 (in Japanese).
41. ICRP Publication 84: Pregnancy and medical radiation, 84, Japanese version. Japan Radioisotope Association, 2002 (in Japanese).

Appendix

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