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Radiation protection in cardiology cath labs. Expert review and opinion of the Association of Cardiovascular Interventions, the Working Group on Echocardiography of the Polish Society of Cardiology and the Polish Society of Medical Physics

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ABSTRACT

The number and complexity of percutaneous interventions performed by cardiologists, vascular surgeons and radiologists is constantly growing. These procedures utilize ionising radiation that on some occasions can be significant, causing serious health hazard for medical team members, including physicians, nurses, technicians, and, more frequently, echocardiographers, anaesthesiologists, and medical physicists. All these groups require special attention, including law regulations, training, radiation protection that utilises modern angiographs and shields, monitoring, and treatment. This multidisciplinary approach may significantly decrease their and patients' health-related burden. This article aims to comprehensively review the basics of ionising radiation, principles of radiation protection, organisation of radiology catheterization laboratories, formal and legal requirements for the personnel, and discusses medical consequences of X-ray radiation.

Key words: invasive cardiology, invasive radiology, ionising radiation, occupational hazard, radiation protection

INTRODUCTION

For decades, the number of percutaneous interventions being performed in cardiology, vascular surgery, and radiology has constantly grown. These procedures use ionising radiation that allows for the visualisation of anatomical structures. Unfortunately, radiation exposure can be significant and may cause serious health risks for the entire medical team working close to the radiation source. Many conditions, including cancer, cataracts, neurodegenerative disorders, hypertension, radiation-induced cardiac dysfunction and others, have been reported among interventional cardiologists [1, 2]. It is also well known that physicians specialized in performing percutaneous interventions have the highest radiation exposure of all professions, significantly exceeding the yearly dose of nuclear power plant workers [3].

These facts indicate that radiation protection should play a significant role in the everyday work of each medical team member. This document is a comprehensive review that explains the basics of ionising radiation, principles of radiation protection, organisation of radiology catheterization laboratories, formal and legal requirements for the personnel, and discusses medical consequences of X-ray radiation.

BASICS OF IONIZING RADIATION

Ionising radiation is generated by bombarding a target (e.g. tungsten) with electrons whose kinetic energy is in the order keV [4]. X-rays can ionise the medium through which they pass and belong to the harmful factors affecting the living organism.

The absorbed dose is the basic quantity used in radiation protection. According to the definition, it is the energy deposited in the mass element of the medium. The SI unit of absorbed dose is Gray [1Gy = $\frac{J}{kg}$]. Regarding imaging procedures (diagnostic energy range of X-type ionising radiation), the dose absorbed in a given material equals kinetic energy released per unit mass (kerma) [5]. This means that the kinetic energy imparted to the mass is wholly absorbed in this range.

The effective dose (E) is the sum of equivalent doses (H_T) from external and internal radiation in all organs (tissues), considering the appropriate weighting factors [6, 7]. For X-ray energy radiation, an effective dose of 1 Sv produces the same stochastic effects as an absorbed dose of 1 Gy, assuming uniform whole-body irradiation with ionising radiation with a weighting factor of 1 (e.g. X-rays). Equivalent doses should be considered for all organs/tissues in the human body that are perceived to be sensitive to stochastic effects. E is determined for a reference human. Therefore, effective dose should be used for comparative purposes (for example, medical procedures and radiological devices) rather than for determining it for a specific person [7].

Equivalent dose (H_T) takes into account differences in relative biological effectiveness (RBE) of different types of ionising radiation (X, gamma, alpha, beta, neutrons).

Siewert is the equivalent and effective dose SI unit [1Sv = $\frac{J}{kg}$].

IONISING RADIATION — DOSE LIMITS

According to the Polish Atomic Law, the dose limit is the value of the ionising radiation dose, expressed as an effective or equivalent dose. This limit is set for specific groups engaged in controlled professional activities and, except for cases outlined in the Polish Atomic Law, must not be exceeded [8]. The Polish Atomic Law introduces additional concepts of dose constraints (usable dose limit), which should be considered when planning radiological protection for optimization purposes.

Under current regulations, the dose limit for employees occupationally exposed to ionising radiation is 20 mSv/year, expressed as an effective dose. This dose may be exceeded by the specific conditions specified in the Polish Atomic Law. Poland's workers exposed to ionising radiation are divided into A and B categories. The first covers workers who may be exposed to an annual effective dose exceeding 6 mSv or an equivalent dose exceeding 15 mSv per year for eye lenses or 150 mSv per year for skin or limbs. Category B includes employees not included in Category A [8] So far, no dose limits have been established for occupational exposure to the brain [9].

Changes regarding the dose limit values in the Polish Atomic Law (2023) relate primarily to lowering the dose threshold for eye lenses. They were introduced following the recommendations of the International Commission on Radiological Protection (ICRP) in connection with scientific reports suggesting the occurrence of deterministic effects on the eye lens at much lower doses than previously assumed, also because of chronic occupational exposure to ionising radiation [10]. The annual dose limit expressed as the dose equivalent to the eyes' lenses is 20 mSv. This value (in a given calendar year) may be exceeded up to 50 mSv, provided that over the next 5 years (including the year the dose was exceeded), it may not exceed 100 mSv [8].The ICRP 139 report defines the value of the average dose per eye lens for the operator of the X-ray treatment unit in the range of 40 to 60 μSv/procedure (DSA, angioplasty, embolisation). Considering the specificity of the staff's work in the environment of the X-ray treatment unit, the eye lens closest to the source of ionising radiation is the most exposed. In the absence or improper use of anti-radiation shields and with many procedures performed, the 20 mSv/year limit can easily be exceeded. Studies conducted in recent years have shown that the value of the annual equivalent dose for the lens can reach even 50–100 mSv [10].

The effective dose for cardiology/interventional radiology department employees depends on the specifics of the work (operator, nurse, anaesthesiologist, echocardiographer) and, thus, the location related to the radiation source and the type of anti-radiation shields used. According to the ICRP 139 report, the typical value of the effective dose received during the year by professionally active operators working in interventional radiology is up to 2–4 mSv [10]. Measurements among interventional cardiologists showed that the effective dose received during a single medical procedure ranges from 0.2 μSv to over 100 μSv, with an average value between 8 and 10 μSv [11]. Considering the procedures in which the effective dose is 10 μSv/procedure, the annual value of the effective dose may even reach 10 mSv [10] for active interventional cardiologists performing about 500 procedures a year and even 300 mSv during thirty years of professional work [11]. Studies conducted among 14 interventional cardiologists from nine hospitals in Norway showed an annual effective dose in the range of 1–11 mSv, with an average value of 5 mSv [12]. The measurement methodology was based on two dosimeters placed under and over the individual anti-radiation shield. On the other hand, measurements made in the hospital in Glasgow among interventional cardiologists, using one dosimeter placed under a personal cover, showed the maximum annual effective dose of 1.2 mSv [10].

The pioneering work of Crowhurst et al. [13] on the X-ray exposure of echocardiographers monitoring percutaneous procedures showed that this exposure is at least as high as that of the first operator. The observation mainly concerned transcatheter aortic valve replacement interventions in which the echocardiographer was positioned at the head of the patient, toward the patient's left side and stood obliquely, predominantly with their back to the X-ray source. Procedures using predominantly right anterior oblique (RAO) and steep RAO projections were associated with higher exposition to radiation than posteroanterior (PA), left anterior oblique (LAO), and steep LAO. In summary, it should be underscored that the dose is lower anytime a person faces the X-ray lamp, while standing next to it, the dose is higher.

MEDICAL CONSEQUENCES OF X-RAY RADIATION FOR PERSONNEL

Over the last decades, there has been a rapid increase in the application of radioactive substances and ionising radiation in several disciplines, including interventional cardiology [14, 15]. Due to the vast development of radiology techniques, the number of people affected by long-term radiation exposure worldwide is large. It is estimated that practising interventional cardiologists' exposure equals approximately 250 chest X-rays each year. For a patient, coronary angiogram carries a radiation exposure of around 350 chest X-rays (range 100–800), whereas percutaneous coronary intervention (PCI) corresponds to about 750 chest X-rays (range 350–2650) [16].Understanding the potential radiation-related health hazards among the catheterization laboratory staff members is relevant to improving cutaneous radiation syndrome prevention and early detection.

A study based on the National Dose Registry of Canada extracted data about a cohort of 67 562 medical workers (23 580 males and 43 982 females) regarding mortality and cancer incidence. The cohort worked with ionising radiation in varied fields of medicine, not specifically in invasive cardiology, over 36 years (1951–1987). The mortality caused by cancer and non-cancer causes was below expected as compared to the general Canadian population. However, thyroid cancer incidence was significantly elevated both among males and females [17]. A decreasing trend of radiation doses obtained from dosimeters in the later years was observed, with the reasonable explanation being better, safer medical equipment and stricter radiological protection guidelines [18].

Another disease associated with ionising radiation in medical personnel is eye cataract [19]. One study examined the prevalence of lens opacities in interventional cardiologists and nurses. Among interventional cardiologists, 52% were diagnosed with radiation-associated posterior lens opacities and in 45% of nurses, the same disease was found. On the other hand, lens opacities were present only in 9% of the control group. The relative risk for interventional cardiologists was 5.7% and 5.0% for nurses [20]. A study by Chodick et al. [21] presented the results of a prospective cohort of 35 705 US radiologic technologists, ages 24–44 years, who did not suffer from eye cataracts at baseline. The study group mainly consisted of females (82.6%), and 66% of the radiologic technologists started working at 20 or younger. The follow-up was nearly 20 years long and involved two questionnaires. During this period, 2382 cataracts (591 before 50 years of age) and 647 cataract extractions were reported (183 before 50 years of age) — the risk of developing a cataract increases by 15 per cent per year. Moreover, increased cataract risk and extraction were observed with an increasing number of personal diagnostic X-rays. Several comorbidities at baseline were associated with an increased risk of an eye cataract, e.g. smoking tobacco (≥5 pack-years), BMI ≥25 kg/m^2, diabetes mellitus, hypertension, hypercholesterolemia, and arthritis [21].

An analysis of Khafaji et al. [22] showed that in paediatric interventional cardiologists, a significant difference was found between the left and the right eye measurements (P = 0.034), with higher doses administered to the left eye. Interestingly, the authors also measured thyroid and did not find a difference between the right and left thyroid doses (P = 0.281) [22].

Several studies have touched on the matter of breast cancer and skin cancer among medical staff working with ionising radiation, mainly radiologic technicians [23–25]. A study by Doody et al. evaluated the incidence of breast cancer between 1983 and 1998 among 56 436 female radiologic technicians who were certified from 1925 to 1980. Breast cancer risk was significantly increased among staff experiencing low doses of radiation over several years, presumably resulting in a high cumulative exposure. With the introduction of new, improved technology and protection, the risk of breast cancer decreased in relation to the total years worked before 1940, but not after [25]. Yoshinaga and all emphasise that there is no clear evidence of an increased risk of cancer in medical workers currently exposed to ionising radiation. However, one should bear in mind the relatively short period of observation of these workers and the increase in the use of radiation in medicine. Hence, further observation of their health is critical.

Ionising radiation can also cause DNA and chromosome damage among medical personnel [26–28]. A study by Gaetani et al. [29] evaluated the influence of low doses of ionising radiation on DNA damage in the cells of medical workers. The study population was divided into two groups depending on the exposure dose, with 6 mSv/year being the splitting point. Both groups were compared to a control group of healthy individuals who had never been occupationally exposed. The DNA of lymphocytes was analysed in terms of single-strand breaks, oxidised pyrimidine and purine bases, all of which are markers for DNA damage. DNA repair was measured concerning repair activity, amount of repaired DNA and half-time to repair DNA damage. In both groups subjected to chronic low-dose ionising radiation, the DNA repair activity was increased; however, only the group with high exposure accumulated DNA damage in lymphocytes. Moreover, a significant accumulation of DNA damage and reduced repair activity of one mechanism were found among subjects who had a family history of cancer. The authors concluded that low-dose ionising radiation in occupational settings may be mutagenic, thus leading to cancer [29]. Nonetheless, extensive prospective cohort studies must be performed to prove this thesis. Another study found increased chromosomal aberrations and sister chromatid exchanges in hospital radiation workers, indicating a cumulative effect of low-level, chronic ionising radiation exposure [30]. The cytokinesis-block micronucleus are a reliable marker of radiation-induced chromosome damage [31]. A study on Tunisian hospital workers assessed the lymphocytes of 67 workers exposed to low levels of ionising radiation and compared the results to a control group of 43 people. A significant increase of cytokinesis-block micronucleus among medical workers was found. Multivariate regression analysis showed that only the exposure time to ionising radiation significantly impacted the level of cytokinesis-block micronucleus [32]. However, the direct impact of such DNA and chromosome changes on long-term health consequences is unknown.

FORMAL AND LEGAL REQUIREMENTS FOR THE CARDIOLOGY CATHETERISATION LABORATORY PERSONNEL

Staff employed in the cardiology catheterisation laboratories should meet certain conditions both in terms of qualifications and health requirements. These conditions are related to direct exposure to ionising radiation and the need to minimise patient's and medical personnel's health risks. The current Polish regulations [33] define the minimum conditions for providing health services in X-ray diagnostics and interventional radiology. Based on this legal act, the interventional cardiology (and radiology) laboratory should have an X-ray system with appropriate software and equipment to perform vascular procedures, including radiation shielding.

The cardiac catheterization laboratory staff has to include at least one physician specialised in the field of medicine, corresponding to the radiological procedures performed, and who holds a current certification from the accredited body. In the case of cardiologists, this condition is met by the implementation of the specialisation program and by the rules set out by the Association of Cardiovascular Interventions of the Polish Society of Cardiology (AISN PTK, *Asocjacja Interwencji Sercowo-Naczyniowych Polskiego Towarzystwa Kardioogicznego*) in obtaining a certificate of an independent diagnostician and an independent operator. The importance of these listed documents was confirmed in the Notice of the Minister of Health on Radiological Reference Procedures of 2015 [34].

In addition, a radiology technician and a nurse (if the administration of a contrast medium is required) must be employed in the invasive cardiology laboratory. The regulation indicates that the employment of a nurse is necessary when other personnel do not have the appropriate qualifications to administer the contrast agent. In the case of an invasive cardiology laboratory, this condition is met by an employed cardiology physician specialist. However, it should be emphasised that nurses in invasive cardiology laboratories perform other tasks related to instrumentation for procedures and assistance for the instrumenting nurse. Unfortunately, this is not reflected in the above-mentioned legal provisions and should be defined as part of the organisational standard for invasive cardiology laboratories developed by the AISN PTK.

A specialist in medical physics or a person authorised by the head of the health care unit to perform tasks in X-ray diagnostics or interventional radiology referred to in Art. 33h section 9 and 10 of the Polish Atomic Law (a medical physicist in the field of X-ray diagnostics and interventional radiology) supplements the personnel in the catheterization laboratory [8]. These qualifications are required to ensure the optimisation of radiological protection for patients and other people undergoing medical exposures, define quality criteria for radiological devices, prepare technical specifications of radiological devices and auxiliary devices, and select devices needed to conduct measurements in the protection field against ionising radiation. In addition, the specialist must analyse any incidents of unintentional or accidental exposures. At this point, it should be noted that a medical physicist should be employed in a health care unit in amount one for every 20 000 radiological procedures carried out annually.

A separate problem concerning the personnel of the invasive cardiology laboratory is the health protection requirements of the employees employed in a catheterization laboratory. The requirements are specified in the Polish Atomic Law in several articles of the document, in particular in Art. 14 (pregnant or breastfeeding employees), Art. 17 (employee categories), and Art. 30 (medical supervision of employees, medical documentation) [8].

In addition, it should be emphasised that the Act introduces two categories of employees exposed to ionising radiation - categories A and B, as mentioned earlier. Category A employees should have periodic examinations yearly. This category may apply to operators of surgical X-ray units due to the dose per lens exceeding 15 mSv (Polish Atomic Law, Art. 17.1.1.b). A medical certificate confirming the employee's ability to perform the profession should be kept in records for inspection by authorised inspection bodies. This rule applies to employees working under an employment contract, civil law, or other contracts.

Another mechanism for controlling the degree of exposure to ionising radiation is the introduction of a dosimetry passport into the legal system, which collects data on employees' exposure to ionising radiation. This is particularly important in the case of external employees providing services in many healthcare units. The dosimetry passport allows for individual personnel exposure monitoring and quicker capture of situations that force the employee to be referred for periodic examinations. The dosimetry passport is issued by the President of the Atomic Energy Agency upon a written request. Detailed regulations are contained in the Regulation of the Council of Ministers of November 30, 2020 [35] The formal requirement for the staff of the invasive cardiology laboratory is to hold a radiation protection training certificate — this has been discussed in Chapter 9 [8].

The invasive cardiology laboratory, as well as other units that use ionising radiation, should cooperate with the radiation protection inspector, who is responsible for supervising compliance with the requirements of radiological protection and may conduct an operational assessment of the level of exposure to ionising radiation of individual employees on an ongoing basis, as well as participate in commissioning and operation of angiographic devices for interventional radiology. The scope of powers of the radiological protection inspector is defined in the Polish Atomic Law (Art. 7) and the Regulation of the Minister of Health [36].

RADIOLOGICAL PROTECTION OF PATIENTS (INCLUDING SPECIAL POPULATIONS — PREGNANCY, CHILDREN)

Per the Polish Atomic, radiological protection of the patient is a set of activities and restrictions aimed at minimising the patient's exposure to ionising radiation, which will not excessively hinder or prevent obtaining the desired and justified diagnostic information or therapeutic effects. Legal requirements regarding the use of ionising radiation for medical purposes and non-medical imaging are included in Chapter 3a of the Polish Atomic Law Act [8].

Cutaneous radiation injury

Cardiology and interventional radiology procedures (especially therapeutic interventions) often generate doses of ionising radiation to the patient's skin that are comparable or higher than the daily fractional dose received in radiation therapy for cancer treatment (2 Gy).

Skin damage is one of the primary deterministic effects caused by ionising radiation. They take the form of cutaneous radiation injury (CRI), which covers the skin, subcutaneous fat layer, and muscle [37]. Scientific reports on skin damage and epilation under the influence of X-ray radiation from the range used in radiological diagnostics are mainly described in the case of computed tomography scans (brain perfusion) and PCIs [38]. The timing and severity of the individual effects of CRI depend on the dose and other factors (Figure 1). For a single fraction of radiation, the threshold for the appearance of the transient form of erythema is about 2 Gy, the definite form of erythema is about 6 Gy and about 3 Gy for transient epilation [39]. Most severe skin damage occurs 4 to 8 weeks after exposure (Table 1).

It should be noted that the dose thresholds for individual effects of CRI are approximate values, which are affected by different individual sensitivity to ionising radiation and other factors. The most common predictive factors include obesity and irradiation of the part of the skin previously exposed to ionising radiation [9, 38].

If it is necessary to repeat the procedure using ionising radiation, it is important to maintain an appropriate time interval if the patient's condition allows it. This time is related to repairing sublethal damage and repopulation, i.e., proliferation (multiplication) of cells that survived irradiation. The first process usually ends within 24 hours, and the second lasts several months [37]. Repopulation begins much later (about two weeks after irradiation) and lasts longer the higher the absorbed dose because the number of surviving cells decreases with increasing dose. Post-radiation skin lesions are similar in size to the beam field on the patient's skin, where the threshold dose value has been deposited (single beam/overlapping fields of different beams — so-called hot spots) [9]. In addition to the deterministic effects discussed above, even low-dose irradiation can lead to stochastic impacts (skin cancers) with a latency period of more than 15 years [38].

In diagnostic examinations that use ionising radiation, patients' effective doses should be limited to the lowest possible level. This level should ensure obtaining an examination result of the assumed diagnostic quality. Optimisation of the patient's radiological protection is also achieved by reducing unnecessarily repeated examinations. In addition, in interventional radiology/cardiology, necessary steps should be taken to prevent radiation damage to the skin and underlying tissues as a result of long-term exposure, particularly with a high-dose X-ray beam (Polish Atomic Law, Art. 33d p. 2, 3) [8].

In Polish legal recommendations [40], there were two response thresholds for the skin dose (i.e., the dose to the patient's skin, including diffuse radiation): 1 Gy and 3 Gy. However, since the skin dose was difficult to calculate, and programs capable of performing such calculations are not routinely used in clinical practice, the two recently published regulations include new dose thresholds: 1.7 Gy (or 170 Gy·cm^2) and 5 Gy (or 500 Gy·cm^2) [41, 42].These thresholds refer to the total value of the kerma at the reference point ($K_{air,ref}$) or the DAP parameter (the total dose area product — the product of the dose and the X-ray field area), i.e. the parameters included in the dosimetry report generated after the end of the examination/procedure. During exposure, these parameters are also visible on the X-ray monitor of the X-ray unit. When the threshold of 1.7 Gy (or 170 Gy·cm^2) is exceeded, the patient's medical documentation should record the dose information. The referring physician should provide the dose information if the procedure requires repeating (referring physician — a physician, dentist or other person authorized to refer people for medical radiological procedures [Polish Atomic Law Act]) [41].

In the second case (5 Gy or 500 Gy·cm^2), the patient should undergo control examinations in the medical unit performing the procedure at least once a week within 21 days following the exposure [42]. In addition, exceeding the threshold of 5 Gy or 500 Gy·cm^2 should be classified as category II events (unintentional exposures and accidental exposures) if, within 21 days of the interventional procedure, there is an effect of radiation skin damage of at least second degree [41]. If the dose exceeds 5 Gy or 500 Gy·cm^2, the patient must undergo a follow-up examination, including at least a skin inspection. Category II events in the field of interventional radiology also include (in the absence of clinical justification) four times the value of the diagnostic reference level and, in the case of procedures carried out for diagnostic purposes — exceeding 2.5 Gy of the total value of kerma in the air at the reference point or 250 Gy·cm^2 of the total DAP.

Unjustified repetition of an interventional procedure leading to a cumulative dose exceeding the above levels is classified as a category I event, including performing a procedure that results in an unexpected deterministic effect, performing the procedure on a wrongly identified person, and procedures in the wrong anatomical area. A protocol is drawn up from the events, which should be submitted to the appropriate national or voivodeship consultant in the relevant medical field related to the use of ionising radiation and to the National Center for Radiological Protection in Health Care.

The National Council on Radiation Protection and Measurements organisation, in report no. 168 of 2010, recommends additionally introducing a threshold for peak skin dose and fluoroscopy time (Table 2) [38, 43].

It is essential to note that the value of the DAP parameter refers to a specific field dimension. This means that this level should be lower in procedures such as cardiology or neurology. The fluoroscopy time is not a good indicator. It should be used in conjunction with the other levels, as it only informs about the duration of fluoroscopy without such important information as X-ray dose rate or pulsed fluoroscopy parameters. Fluoroscopy time is related to the dose rate of ionising radiation. Therefore, its monitoring will be justified (a higher dose value in a shorter time vs. a lower dose value in a longer time).

Reference levels

We do not use ionising radiation dose limits for patients. Instead, diagnostic reference levels (DRL) are utilised to assess and optimise patient exposure. According to the Polish Atomic Law, DRL in interventional radiology is the level of ionising radiation dose in typical diagnostic examinations/interventional procedures performed on patients with a standard body structure concerning broadly defined equipment categories.

Table 3 shows established and proposed DRLs for interventional radiology procedures—notably, few procedures for which DRLs have been published in Poland. To date, no diagnostic reference levels have been established in Poland for pediatric interventional procedures. In the literature, there are publications about the values of diagnostic reference levels for procedures other than those listed in Table 3 (see Table 4) [44–49] and procedures carried out in a Polish hospital.

Factors affecting X-ray dose

Factors influencing the dose can be divided into X-ray machine, operator, and patient dependent.

Medical procedures performed under the supervision of fluoroscopy are characterised by the most variable dose values for a single procedure [11]. Thus, in interventional cardiology, there is a possibility of receiving high doses of ionising radiation by both patients and staff. The primary beam of ionising radiation generated by the X-ray tube is the main source of radiation reaching the patient. Proper patient placement in the X-ray tube-image detector system affects the operation of the automatic exposure and image quality control system. This system is sensitive to many factors depending primarily on the radiological thickness (patient and all elements in the field of view of the radiation beam, including in the patient's body, table, mattress (silicone mattresses increase the exposure parameters), or collimator shutters (blinds) if they are in the active area of the image detector (applies to flat digital/panel detectors)) and the geometry of the X-ray tube - patient - image detector system [9]. Placing the patient too low will bring the patient too close to the source of ionising radiation, negatively affecting the dose he receives. However, placing them too high will also cause the image recorder to move away from the X-ray tube. Thus, it will be necessary to increase its efficiency so that the determined dose value at the level of the image detector is achieved. By good clinical practice, the image detector should be placed as close as possible to the patient's body, thus eliminating unnecessary geometric magnification that generates a higher dose. This solution causes the detector to absorb part of the scattered radiation generated by the patient, which reduces the exposure of the personnel standing nearby [11]. Radiation scattered on the surface of the image detector may also affect image quality degradation.

The parameters of the primary source (directly affect the dose received by the patient) include accelerating voltage (kV)/peak voltage (kVp), half layer (HVL in mm Al), beam-filtration (in mm Al) to absorb low energy photons, detector field of view size, magnification, brightness optimisation system (sensor, optimisation algorithm), LIH option (last image hold function), fluoroscopy duration, image acquisition time and clinical protocol parameters related to these times, i.e., current (mA), continuous fluoroscopy mode/pulse (frames per second (fps), pulse length (ms), dose per pulse (typically in nGy/pulse), pulse power (pulse/s), additional filtration, size of the primary beam field (collimation).

It is essential to ensure the proper operation of the X-ray device, its calibration, and quality control, which assess and maintain accuracy. It should be noted that, per the Polish Atomic Law, X-ray equipment may not be used if quality control tests have not been carried out with the appropriate frequency and if the results of these tests are outside the tolerance range.

Pregnancy

Particular protection concerning medical exposure applies to, among others, women of childbearing age, pregnant women, and patients under 16. Performing an examination or procedure using ionising radiation in a pregnant woman is possible only if the alternative examinations, procedures, or postpartum treatments does not provide important clinical information or does not bring the desired therapeutic effect [8].

In interventional radiology, the attending physician must ensure the exposed woman is not pregnant (attending physician — a doctor, dentist or other person authorised to assume responsibility for subjecting a patient to medical exposure [Atomic Law Act]). In a situation where a woman is pregnant (or when pregnancy cannot be ruled out), particular attention should be paid to the justification for the examination/procedure in the field of interventional radiology, medical indications, and optimisation of exposure of the pregnant woman and the unborn child, with particular emphasis on exposure, including abdominal or pelvic area. In the case of exposure in this area, the health care unit is obliged to assess the dose of ionising radiation for the unborn child.

According to the Minister of Health regulation on the special protection of specific categories of people in connection with medical exposure in diagnostic tests, procedures, and treatment, the woman should be informed about the results of this assessment immediately after the examination or procedure [51].

Optimisation of radiological protection of pregnant women should be carried out with the participation of a specialist in the field of medical physics or a medical physicist in the field of X-ray diagnostics and interventional radiology, referred to in the Atomic Law. Performing a diagnostic test or surgery in the abdominal cavity of a pregnant woman, if the pregnancy status has been established after the procedure, and the dose to the embryo or fetus exceeds 20 mSv, is classified as category III of the events referred to above, unless the performance was directly related to saving the life of a pregnant woman.

RADIATION PROTECTION SYSTEMS

Anti-radiation shields

The set of anti-radiation shields used in the cardiology/interventional radiology laboratory includes personal shields (e.g., aprons, suits, thyroid shields — item 4 of the photo in Figure 2, as well as glasses and visors), collective protective equipment (screens, ceiling shields, curtains — items 3, 2, 1 of the photo in the figure below), shields for the patient and fixed shields (according to the design of the fixed shields, they constitute a barrier of individual protective zones in the laboratory). Personal shields can be individual and collective shields. Personal face shields should fit snugly to reduce leakage.

The radiation-absorbing material consists mainly of lead (collective protective equipment, personal shields, patient shields, and fixed shields). However, individual shields are increasingly made based on elements other than lead. This solution primarily reduces the weight of the material. It involves using bismuth or, increasingly, a combination of bismuth, antimony, and tin. The parameter describing the degree of protection is the absorption expressed in the equivalent absorption of a thickness of the lead sheet, with the following being most often used: 0.25 mm, 0.35 mm, 0.50 mm Pb or Pb equivalent (eq.). The transmission of ionising radiation through the shield is a variable value and depends on the radiological thickness of the shield and the parameters of the X-ray beam. Exemplary literature data indicate that for the voltage range of 70–100 kVp, the transmission is typically 0.5%–5.0% [52], where 0.5 mm eq. Pb absorbs 95% of radiation at 70 kVp and 85% at 100 kVp [11].

Shields of lightweight or lead-free materials do not have the same X-ray transmission as lead ones. Light materials are more effective (more excellent absorption of radiation) in the energy range of 40–88 keV compared to lead. Therefore, they are recommended for potential acceleration voltages in the range of 70–80 kVp [53]. The combination of light elements (antimony with Z = 52 or tin with Z = 50) with heavier elements (bismuth with Z = 83 or lead with Z = 82, absorbing radiation more effectively >88 keV) allows minimising the weight of the shield while maximising radiation absorption in significant X-ray energy bands used in diagnostics. This shielding material consists of two layers: the antimony closer to the X-ray source and the heavier element closer to the body. The layer of the heavier element, apart from absorbing photons with higher energies, also absorbs the secondary fluorescent radiation generated in the first layer. Of some importance, second at scatter radiation from the patient is typically lower in energy, around 4–55 keV.

The basic factor protecting the operator's head and neck is the use of a ceiling shield (usually 0.5–1.0 mm Pb), reducing the dose received in these areas from 2 to 10 times (this value is variable depending on the correct use of the shield) [53], and the eye dose by a factor of 19 [11]. Adding a flexible shield curtain attached to the lower border of the rigid acrylic shield allows the shield to approximate the patient's body better and markedly improves shielding effectiveness, including protecting the operator's hand [54].

In clinical trials with interventional procedures and phantom simulations, the DRF of ceiling suspensions (including lead panes) is 0.7–19. Higher DRF values have been achieved in studies where ceiling cups have been precisely positioned [53].

A properly placed ceiling shield should be directly above the patient's irradiated area, and the operator should look through it at the irradiated area. In interventional procedures in which a variable angle of the primary beam is used (variable angulation of the C-arm), movement of the operating table and correct placement of the ceiling shield requires relocation as the X-ray gantry and table are moved, which can be quite burdensome, reducing the effectiveness of the shielding. The protection of the head area of the personnel working in the environment of the X-ray treatment apparatus is also provided by face shields and protective glasses. The largest part of the scattered radiation reaches from below to the upper parts of the operator's body and assisting personnel.

For most of the examination/procedure, the operator looks at the monitors presenting the fluoroscopic acquisition image. Therefore, his eyes are not directly directed at the scattered radiation's source. In this situation, the radiation can reach the eyes through the gap between the glasses and the face, generating the largest share of diffuse radiation reaching the eyes. Therefore, the correct fit and reinforcement of the frames and sides with protective material is essential. Head protection covers also include protective caps, the legitimacy of which is, however, intensely discussed and undermined in the literature, as evidenced by the fact that ionising radiation reaches the upper parts of the staff’s body almost entirely from the patient's side (diffuse radiation), i.e. from below. The effectiveness of visors, protective glasses, or the lack of justification for the use of protective caps in clinical conditions is discussed in the literature [55].

Personal protective equipment also includes protective gloves. However, their use requires increased attention. Manipulation with such protected hands in the area of the primary beam of ionising radiation may increase the radiation emitted by the X-ray units, increasing exposure to ionising radiation and thus reducing the effectiveness of protective gloves [56]. These gloves (and other high-density items) should, therefore, be kept out of the active area of the image detector so as not to affect the operation of the automatic brightness control (ABC) system. The lower part of the staff's body is covered by curtains attached to the table. Security measures with a thickness of 0.5 mm Pb are routinely used. These curtains reduce the dose received by the legs by a factor of 10 to 20; in practice, however, this value is between 2 and 7 [54, 57].

As can be seen from the above considerations, the proper selection of the appropriate protective measure requires considering the working conditions of the personnel. The following factors should be considered: workplace — distance from the radiation source (first operator, second operator, imager, nurse, support team, radiology technician), location in relation to the source (orientation of the shielded surface), presence and effectiveness of collective protective equipment at the workplace, time of exposure and the settings of the X-ray system (so-called low-dose, high-dose). The selection of a personal cover (apron, suit) is always a process of optimising the ergonomics of the workplace (covering properties versus the weight of the cover). Personal shields must be airtight to do their job. Using them properly and checking their technical condition (visual and X-ray inspection) is crucial.

Another approach to reducing radiation dose is using additional shields, plates, or different types of protective surgical drapes. For example, a special board can be placed under the patient's arm, but its effectiveness in reducing radiation is doubtful. One such solution is the Rad Board® patient arm plate. Although the manufacturer claimed that it reduced the radiation dose to 44% and 25% at the waist and neck level, these favourable observations were not confirmed by subsequent analysis, which brought the opposite results, saying that the operator was more exposed to radiation. This could be related to the inability to mount the vertical shield used in the control group [58].

Another way to protect the operator is shields placed below the level of the table where the radiation from the X-ray tube is emitted. In the EXTRA-RAD study, using shields under the table resulted in lower exposure to the radiation dose at the pelvis and chest level of the operator [59]. Another study showed that the installation of protective curtains leads to a reduction of radiation dose by as much as 64% [60].

Disposable surgical drapes, which absorb ionising radiation due to tin, antimony, bismuth, or barium content, work similarly. According to the available data, using such a drape reduces the dose in the eye, thyroid, and hand areas: 12-fold, 25-fold, and 29-fold [61]. Despite reducing the amount of radiation reaching the operator, the presented solution is associated with twice the dose of radiation received by the patient during the procedure [62].

A similar solution is sterile, disposable, lead-free RadPad™ drapes (Worldwide Innovations & Technologies, KS, US). They are placed directly on the patient, acting by absorbing the diffuse radiation coming from the patient and creating a "shadow zone" in which the operator can perform the procedure. Studies have shown that the use of RadPad™ drapes can reduce radiation by 44%–59%, depending on the study [63–66]. In these studies, however, the dose reduction is measured at the chest or neck level; the reduction below the operator's waist is negligible, and the head dose is modestly reduced.

ADDITIONAL PROTECTIVE SOLUTIONS

Protective clothing is heavy and, combined with the operator's unergonomic posture, may result in back pain and, in the long term, lead to posture defects affecting everyday functioning [67, 68]. The manufacturer of the Zero Gravity® system devised a solution to this problem, aiming to increase radiation protection while relieving the doctor. This solution uses unique weighted levers to which protective clothing is attached. Such a system reduces operator fatigue and ailments in the osteoarticular system while not limiting freedom of movement [69]. A solution that gives greater freedom of movement and reduces ergonomic posture risk for the operator is an Exoskeleton-Based Radiation Protection System (StemRad MD). The anti-radiation effectiveness of this solution was confirmed in research conducted by Katsarou et al. [70]. According to the authors, the effects of the StemRad MD exoskeleton-based system are particularly impactful for the brain, eye lens, and head areas.

Free-standing protective cabins, made of materials that absorb ionising radiation, are also available on the market. Their main advantage is significantly reducing the dose to which the personnel are exposed. This is possible due to using more radiation-retaining materials compared to protective clothing. Companies with such devices offer various models specific for electrophysiological procedures or interventional cardiology procedures [71]. Doubts are primarily raised by the functionality of this solution, especially during long or complicated procedures. Recently reported on the Cathpax® AIR cabin resulted in a 78% reduction in radiation exposure without affecting the quality of procedures, both in complex PCI and during structural procedures.

Radiation Shielding System (Radiation Medical Ltd., Tel Aviv, Israel) provides radiation protection by using an additional casing, like a tunnel, within the C-arm between the tube and the image intensifier. This reduces the space through which radiation can pass. The outer protective shell is triggered by the operator using a special button. This system reduces exposure to ionising radiation by up to 97% [58, 63–66, 72].

Another way of protection is the EggNest- XR™ System (Egg Medical, Arden Hills, MN, US), which aims to protect the entire cath-lab medical team. It is a carbon fiber-based platform with flexible and adjustable modular shielding components. Studies have confirmed its effectiveness at a 91% reduction of incoming radiation [63–66].

Finally, when considering protective solutions, one must consider all possible steps to reduce the need for invasive angiography, including proper indications for interventional procedures. Dębski et al. [73] proposed an interesting approach to this topic. The authors showed that vessels with <50% diameter stenosis on quantitative computed tomography and hemodynamically insignificant CTA-derived FFR results might be omitted during coronary angiography. Such an approach would result in substantial reductions in contrast media volume used and patients' exposure to radiation during ICA, while not leading to misdiagnoses.

Robotics based solutions

Robots performing procedures within the coronary arteries are currently a dynamically developing branch of invasive cardiology. The latest generations of these devices enable interventions even in complex lesions, such as interventions within the left main coronary artery. They are characterised by a significant reduction in exposure to ionising radiation [74–76].

Compared to the previously mentioned solutions, robots make it possible to move the operator away from the radiation source, and the additional barrier reduces the amount of radiation even more effectively. Such products include the Sensei ® X robotic system (Hansen Medical, CA, US) designed for cardiology or electrophysiology procedures. Another robot used is the CorPath GRX (Corindus Inc, Waltham, MA, US). Assisted by the CorPath robot, the operators remain in stations additionally protected against radiation, from where they control the entire procedure. The CorPath system was approved by the Food and Drug Administration for PCI in 2012. Unfortunately, the device was recently withdrawn from the market. The only available angioplasty robot is now an R-one device from Robocath company [77, 78].

However, despite the progress, robots performing coronary interventions still need to be evaluated in large randomised clinical trials confirming the reduction of radiation exposure with a satisfactory angiographic and clinical effect of the intervention [79].

THE ROLE OF OPERATOR AND PERSONNEL TRAINING IN REDUCING RADIATION DOSES

The safe use of ionising radiation for medical purposes is defined in Chapter 3a of the Polish Atomic Law [8], which also imposes additional obligations on persons using the sources of ionising radiation mentioned above in the treatment process. To fulfil this obligation, individuals performing diagnostic tests, procedures, or treatments involving ionizing radiation and those supervising their performance are required to obtain a minimum of 20 training points within the next 5 years. In addition, the issues of patient radiological protection are regulated by European Union documents, particularly the Euratom Directive of 2013 [80], which was implemented into Polish legislation by the Atomic Low and the Regulation of the Minister of Health on March 6, 2020 [81].

The documents mentioned above define the forms and topics of training for all employees who come into contact with ionising radiation and define the examination rules, allowing them to obtain a certificate to work with it. The certificate is issued for five years, after which the training must be repeated. From the point of view of the cath lab, the obligation to undergo training applies to physicians performing interventional radiology procedures (including cardiological procedures) and radiology technicians. Of note, the regulation does not include nurses (nurses have no influence on the patient dose).

The groups of participants mentioned above should undergo a 17-hour training, during which, in addition to the basic knowledge on the physical basis of radiation, general assumptions of radiological protection, permissible doses, and issues related to quality assurance programs in radiological protection are discussed. The latter issue seems to be important in the daily work of the invasive cardiology laboratory because, in conjunction with the implementation of standard procedures, the establishment of rules defining the minimisation of exposure to ionising radiation, the registration of doses in term of $K_{air,ref}$ exceeding 1.7 and 5 Gy and the management of patients exposed to such events and the procedure in the case of repeated, is of great importance for the correct and safe use of ionising radiation. Indeed, the constant improvement of qualifications in this area reduces late complications often unnoticed by invasive cardiologists, such as skin or hematological changes in treated patients, especially those who undergo multiple invasive cardiology procedures.

Patient Radiological Protection (PRP) training points may also be obtained by participating in other PRP-related training courses than those discussed above, at national or international scientific congresses, meetings, conferences, or symposia, or by giving a lecture or presentation at a national or international scientific congress, meeting, conference or symposium.

X-RAY PROTECTION FOR ECHOCARDIOGRAPHERS IN THE CATH LAB

Echocardiography, especially transesophageal (TEE), is an important monitoring tool for performing structural heart procedures in hemodynamic and hybrid rooms. The principles of radiological protection applicable to all staff working in them should also apply to imaging cardiologists and ensure their safety. In the literature, however, there is disturbing, though scarce, data on X-ray doses to which doctors performing ultrasound examinations during these procedures are exposed. These doses are comparable to those received by the patient and higher than the doses to which the invasive cardiologist is exposed.

This is due to several reasons. The first one is due to echocardiographer's location - near the patient's head, at a short distance from the radiation source. He often holds the probe in direct radiation, especially during transthoracic examination or when manipulating the TEE probe (Figure 3A). The second problem is the difficult conditions for using standard lead shields. Unlike the interventional cardiologist, who stands near the patient's groin area and is protected by shields suspended under the table and the glass on the boom, the echocardiographer is located near the X-ray tube, where the use of such shields is more difficult because they can interfere with the moving C-arm. Some laboratories use special mobile shields between the patient and the TEE echocardiographer (Figure 3B–C), but this is uncommon. New solutions are also available on the market, like EggNest, which delivers protection to the entire team of the catheterization laboratory (as described above). The lack of standardisation of radiological protection for intra-procedural echocardiographers also applies to other European countries.

According to the regulations, all persons in the laboratory must comply with the principles of individual radiological protection: using lead aprons, shields for the thyroid gland, glasses, and newer technologies. Training in radiation protection, dosimeters, and regular medical examinations are also necessary.

It is also advisable to collimate the X-ray beam and stop the imaging when the echocardiographer's arm is in the radiation field (Figure 3B). Studies presenting the exposure of echocardiographers demonstrate very different values of absorbed doses, the direct comparison of which has limitations. The differences probably result from the types of procedures, the duration of fluoroscopy, the quality of the fluoroscopy technique, the type of radiological protection used, and the position of the echocardiographer in relation to the X-ray tube and the patient. However, they all indicate the highest exposure of the echocardiographer to X-rays among cath lab personnel.

Another analysis of absorbed radiation doses for different parts of the body showed the highest values for the echocardiographer, lower for the first operator, and lowest for the second operator. These differences were significant — the average radiation doses absorbed by the head were 2.5 times higher, the arm 6 times larger, the hand 3 times larger, and the foot 7 times higher in echocardiographers compared to the first operators. Cumulative doses were also many times higher, e.g., cumulative dose for the head: echocardiographer 5.931 μSv, first operator: 2.109 μSv, second operator: 959 μSv; cumulative dose for the hand: echocardiographer 20.720 μSv, first operator: 7.043 μSv, second operator: 4.629 μSv [5]. The highest radiation doses were associated with complex procedures, lower during left atrial appendage occlusion (LAAO), transcatheter edge-to-edge repair (TEER), and transcatheter aortic valve replacement, and lowest during atrial septal defect closure [82, 83].

In the publication comparing the individual dose equivalent during TEER and LAAO, the exposure of the echocardiographer was also significantly higher than the exposure of the invasive cardiologist: LAAO 10.6 vs. 3.5 μSv; TEER 10.5 vs. 0.9 μSv. At the same time, over 25% of echocardiographers received a dose higher than 20 μSv, which is about 10 times higher than the average dose received by an invasive cardiologist during a standard structural procedure [83].

It is important to relate these observations to the contemporary limits of the annual absorbed dose for the whole body — 5 rem (50 mSv) (according to the Occupational Safety and Health Administration — US). This comparison indicates that the echocardiographer working in the operating room is at risk of exceeding its [83].

From a practical point of view, it is worth paying attention to the echocardiographer's location in relation to the X-ray tube. In the work of McNamara et al. [83], the echocardiographer stood at the height of the patient's head, facing the patient and the primary source of the radiation.

In the cited work of Crowhurst et al. [13], the echocardiographer, stood on the other side of the operating table in relation to the invasive cardiologist, with his/her back or side to the patient, at a 45% angle to the patient's head, which seems to be more advantageous. Reducing X-ray exposure of echocardiographers during structural procedures is extremely important and should be considered [84–86].

To summarise, regardless of general principles of radiation protection, the specific rules related to the role of TEE in the cath lab should be as follows:

- maximum distance of the echocardiographic device and its lateral position in relation to the X-ray tube (limitations: length of the TEE probe);
- limiting the manipulation of the probe in the patient's mouth only to its occasional insertion and removal (other manipulations can be carried out using the probe handle located behind the cover and using the device’s panel);
- use of optimal echocardiography imaging (including 3D) to reduce the use of X-ray radiation.

With the increasing number of structural procedures, echocardiographic monitoring and staff radiation exposure are becoming increasingly important. This also applies to anaesthesiologists and nurses, who periodically stay near the patient’s head. Awareness of the significant problem of exposure to X-ray radiation should result in implementing preventive measures, including effective radiation protection and active monitoring of side effects.

SUMMARY

The team members of the catheterisation laboratory constitute an occupational group that is particularly vulnerable to ionising radiation with potentially serious health consequences. The growing number and complexity of interventional procedures engage physicians, nurses, technicians, and, more frequently, echocardiographers, anaesthesiologists, and medical physicists. All these groups require special attention, including law regulations, training, radiation protection that utilises modern angiographs and shields, monitoring, and treatment. Such a complex approach may significantly decrease their and patients' health-related burden.

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Table 1. The course of radiation skin syndrome in the case of single-dose irradiation [9]

Effect	Radiation dose, Gy[a]	Time of occurrence	Time of maximum presentation
Transient erythematous phase	2	Hours	~ 24 h
Transient epilation	3	~ 3 weeks	–
Main erythematous phase	6	~ 10 days	~ 2 weeks
Permanent epilation	7	~ 3 weeks	–
Skin atrophy (1 phase)	10	>52 weeks	–
Telangiectasias	>12	>52 weeks	–
Dry desquamation	14	~ 4 weeks	–
Late erythematous phase	15	8–10 weeks	–
Moist desquamation	18	~ 4 weeks	–
Dermal atrophy/necrosis	18	>10 weeks	–
Secondary ulceration	20–24	>6 weeks	–

[a]Single exposure, dose to the patient's skin including scattered radiation, ~ about

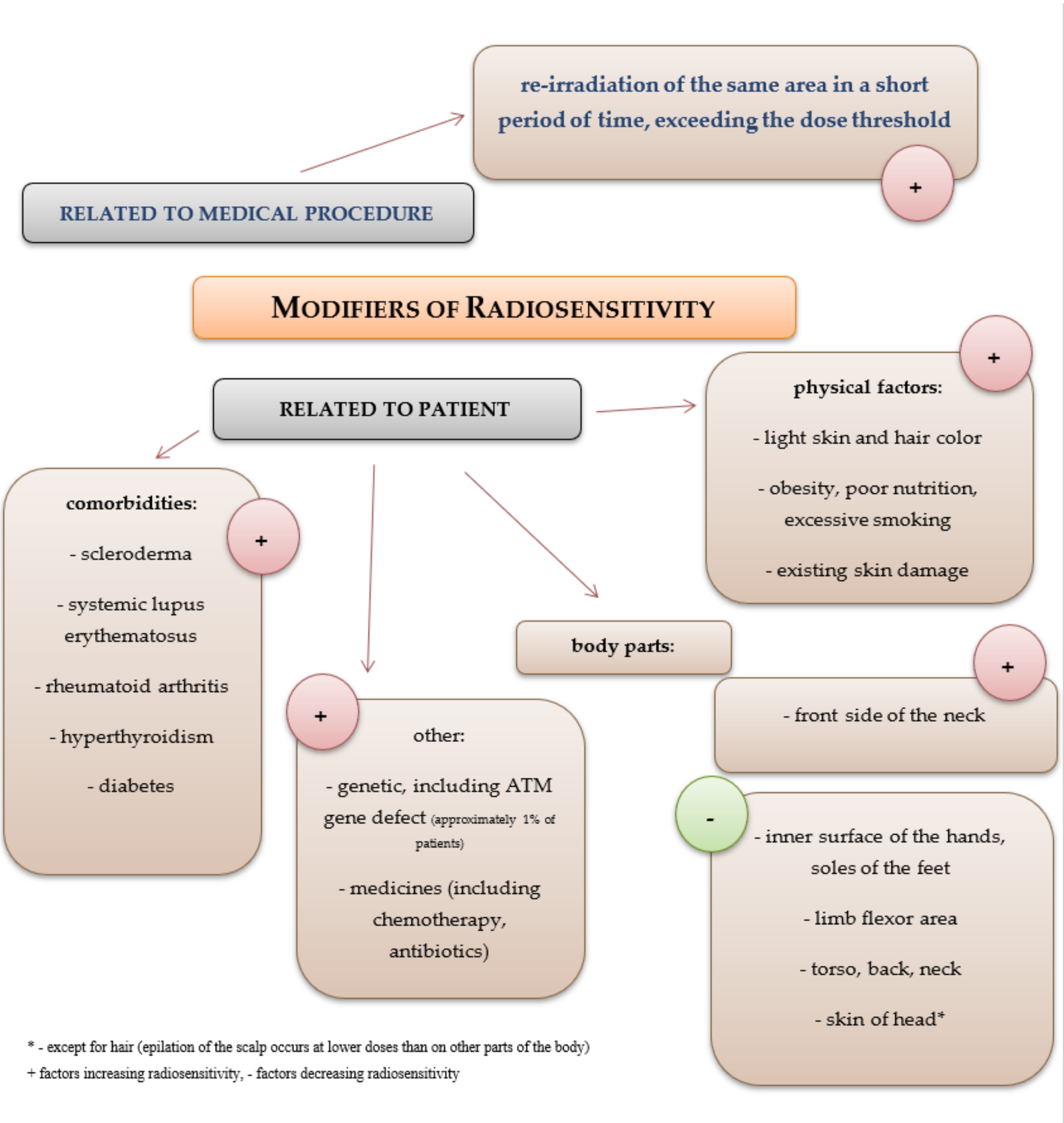

Figure 1. Factors influencing variable radiosensitivity [9]

Table 2. Dose notification levels according to National Council on Radiation Protection and Measurements No. 168 [43]

Dosimetric parameters	First notification level	Second notification (increments)	Substantial radiation dose limits (SRDL)
PSD, Gy	2	0,5	3
$K_{air,ref}$, Gy	3	1	5
DAP, Gy·cm^2	300	100	500[a]
FT, min	30	15	60

[a]For filed at the patient's skin equal 100 cm^2, for other fields the DAP needs to be adjusted proportionally (e.g. for 25 cm^2 the SRDL would be 125 $Gy \cdot cm^2$)
Abbreviations: DAP, dose area product; FT, fluoroscopy time; $K_{air,ref}$, air kerma at X-ray unit reference point; PSD, peak skin dose

Table 3. Diagnostic reference levels for adults in Poland; based on [50]

Type of procedure	Dose area product, $Gy \cdot cm^2$	Exposure time, min
Phlebography of the lower limbs and pelvis	9	–
Arteriography of the lower limbs and pelvis	85	–
Coronary angiography	60	–
Percutaneous transluminal angioplasty	100	18
Percutaneous coronary intervention	120	20

Table 4. The proposed diagnostic reference levels for interventional cardiology for adults; based on [37]

Type of the procedure	KAP, $Gy \cdot cm^2$
Coronary angiography	35
Percutaneous coronary intervention	85
Transcatheter aortic valve implantation	130
Electrophysiological procedures	12
Pacemaker implantation	Single-chamber — 2.5 Dual-chamber — 3.5 Resynchronization pacemaker — 18

Figure 2. A set of anti-radiation shields in the cath-lab (own figure), 1 — curtain, 2 — ceiling cover, 3 — screen, 4 — personal shields [9]

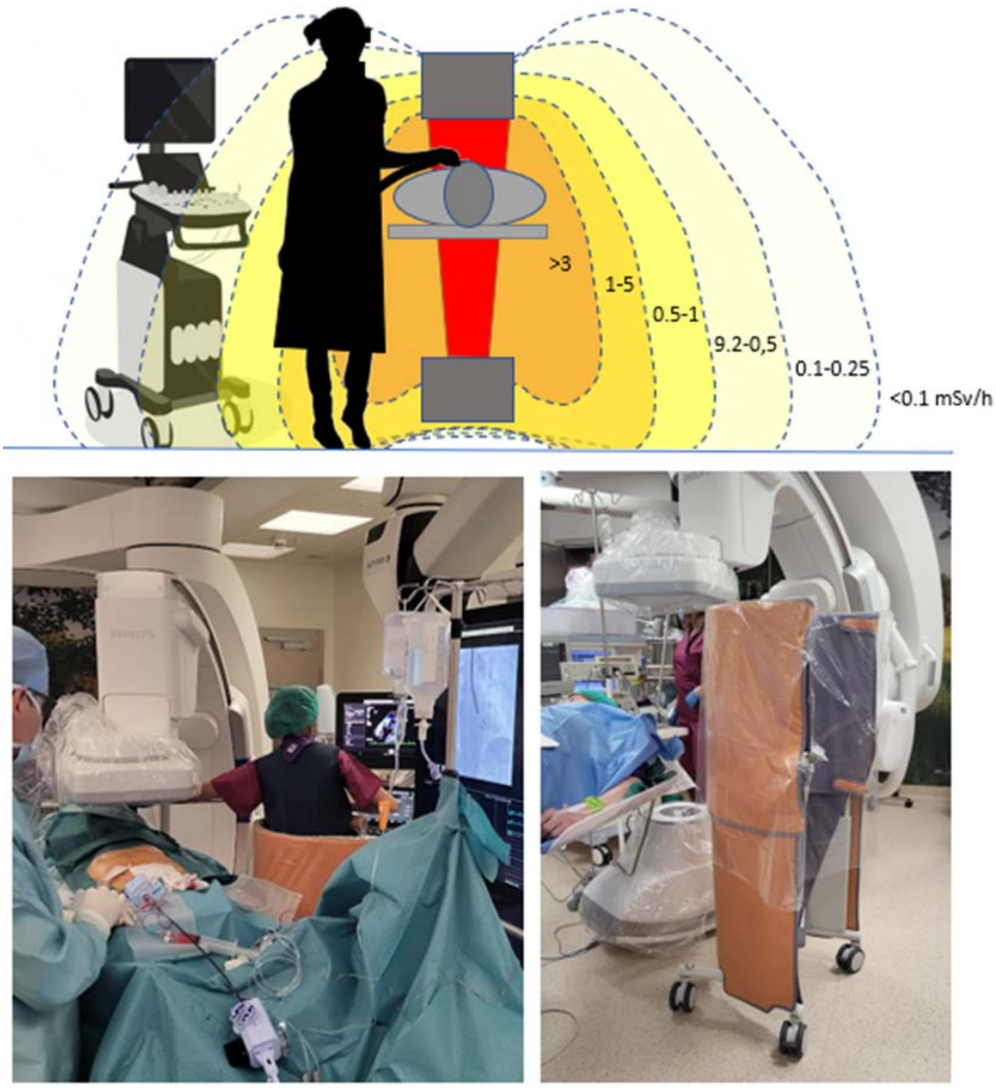

Figure 3. Approximate radiation power zones near the patient's head (**A**) [87]. During surgery, the echocardiographer reaches into the patient's mouth to reposition the probe (**B**). A special mobile guard in the shape of a half-barrel with adjustable height (**B, C**)