National Cardiology Hospital

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PATIENT DOSE MONITORING AND OCCUPATIONAL EXPOSURE AS PART OF RADIATION PROTECTION AND QUALITY ASSURANCE IN INTERVENTIONAL PROCEDURES

ABSTRACT
of DSc Thesis

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The thesis contains 169 pages. It includes 18 figures, 23 tables in 6 chapters, summary conclusions, contributions and 2 appendices. The list of cited literature includes 252 titles, of which 14 in Cyrillic.

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Content

List of commonly used abbreviations and symbols

CA - coronary angiography
CERAB - covered endovascular repair of aortic bifurcation
CFA - common femoral artery
CTO - chronic total occlusion
E - effective dose
EAM - electroanatomic mapping
EP - electrophysiological
FGI procedure - fluoroscopy guided interventional procedure
FT - fluoroscopy time
IAEA - International Atomic Energy Agency
ICRP - International Commission on Radiation Protection
ICRU - International Commission on Radiation Units and Measurements
IQR - Interquartile Range
$K_{a,r}$ – reference air kerma
MoH - Ministry of Health
NCI - US National Cancer Institute
NCRRP - National Centre of Radiobiology and Radiation Protection
NDRL - National Diagnostic Reference Level
PAD - peripheral arterial disease
PCI - percutaneous coronary intervention
P_{KA} - kerma-area product
PSD - peak skin dose
PTA - percutaneous transluminal angioplasty
SFA - superficial femoral artery
UNSCEAR - United Nations Scientific Committee on the Effects of Atomic Radiation

1. Introduction

Interventional radiology have made extensive contributions to medicine in recent decades. The extreme precision and minimal invasiveness of the methods have changed the way diagnostic and therapeutic interventions are performed. The benefits of interventional radiology are numerous and indisputable, but the radiation risk to the patient and medical professionals must be assessed and minimized. Due to the increasing complexity and duration, the high requirements for image quality, and the need for the team to work in close proximity to the patient and the x-ray source, interventional procedures involve significant radiation exposure to the patient and staff.

The introduction of new diagnostic and therapeutic modalities with greater clinical capabilities and the expansion of interventional radiology activity has led to a significant increase in the number of procedures performed per capita in the country. According to the National Centre of Radiobiology and Radiation Protection (NCRRP) for the period 2007-2022, the number of interventional procedures performed in Bulgaria is increasing steadily over the years, from 4 (in 2007) to 17 per 1000 people in 2022. Despite the small contribution to the total incidence of X-ray examinations, 2.2% in 2022, their contribution to the collective dose is significant, increasing from 11% in the period (2007-2010) to 22.5% in 2022.

UNSCEAR encourages the development of more scientific publications and research in the field of methods with the greatest contribution to medical ionizing radiation exposure and emphasizes the importance of regular data collection and publishing of data on medical exposures.

Cardiac rhythm disorders have been intensively studied in the last 3 decades and the number of performed interventional cardiac electrophysiology (EP) procedures per year has been increasing exponentially worldwide. Some of the routinely performed fluoroscopically guided EP procedures are complex and might require prolonged fluoroscopy times. Special attention is required in order to minimize the probability for potential radiation-induced effects, such as skin injury, or lower the risk of cardiovascular tissue reactions and life-time malignancy. The new technological advances, and their proper use, such as systems for non-fluoroscopic navigation and three-dimensional electroanatomic mapping (EAM), reduced number of cine images, noise suppression and proper choice of exposure parameters, may significantly decrease patient and medical staff exposure.

Interventional electrophysiology is a method that has been practiced for over 30 years in the country. In November 2014, an electronic register for interventional electrophysiology, BG-EPHY, was introduced in the country, in which each electrophysiological department also registers dose information from the performed procedures. Despite the long history of the method in Bulgaria, studies on typical doses of interventional electrophysiological procedures (diagnostic and ablation) have not been published.

Some of the FGI procedures are often performed in hybrid surgical rooms, where the X-ray equipment is installed and used in the sterile environment of the operating room. In the case when minimally invasive x-ray procedures are not sufficient to treat the patient, for more complex and urgent interventions, these rooms are suitable for conventional surgery. Hybrid surgery (mainly remote endarterectomy) and endovascular revascularization are two methods that are complementary and often prior to conventional open surgery for the treatment of peripheral arterial disease (PAD). The prevalence of PAD varies between 4.3% and 29% depending on the age of the patient and is now recognised as a global pandemic affecting over 202 million people worldwide. Over the past few decades, minimally invasive endovascular treatment of patients with stenotic lesions and short occlusions involving the aortoiliac segment has shown good clinical results. The number of endovascular treatment procedures performed in patients with aortoiliac occlusive disease has increased due to lower morbidity and mortality compared with bypass surgery. In the treatment of patients with multifocal lesions of the major arteries of the extremities, the hybrid single-incision inguinal surgery provides the options of treating the injured common femoral artery, performing remote endarterectomy of the external iliac artery, and endovascular treatment of the common iliac artery. Hybrid surgery combines the advantages of both conventional surgery and endovascular interventions.

FGI procedures can result in relatively high patient doses, especially for complex interventions. Radiation protection is an important issue for vascular specialists. Clinical dosimetry is an important component of the program to provide quality healthcare for patients. Real-time dose monitoring allows the physician to achieve a good balance between the expected clinical benefit to the patient and the radiation risk of a prolonged procedure. Periodic analysis of patient dose data provides valuable feedback for quality improvement and process optimization purposes, as well as for the monitoring and follow-up of individual patients. This can be important for the follow-up process of patients after high-dose procedures, especially in cases where the patient returns for a subsequent procedure.

Patient radiation exposure is a problem that is often underestimated and not considered by some vascular surgeons. Patient doses depend on the characteristics of the X-ray system and patient-related factors. The dose rate is highest in the area of the skin where the X-ray radiation enters the patient. Patients with endovascular revascularisation of the lower limbs are expected to be exposed to higher radiation. Clinically important dose-related factors are: the type of vascular access and the type of procedure (e.g. balloon angioplasty, subintimal angioplasty, stent placement).

Due to the expected higher doses, a number of studies in the field of vascular interventions have reported patient radiation exposure in the magnitude of the kerma-area product (P_{KA}) for endovascular revascularization of the lower limb, with reported values in the range 25-179.9 Gy.cm^2. Overall, the risk of patient radiation injury resulting from X-ray irradiation during these procedures is low. The actual incidence of deterministic skin effects during endovascular or hybrid lower limb revascularisation is still unknown. This is an often unreported and underestimated problem, presenting a risk of radiation-induced skin damage. This type of lesion can be long-term and painful for the patient.

The reduction of doses to the patient during procedures under X-ray control is an important aspect that decreases the risk of radiation-induced tissue reactions. The latter requires continuous and detailed studies, not only focusing on dosimetry, but also on radiation protection, knowledge and training of medical staff involved in endovascular procedures.

Various studies have shown large variations in the annual occupational exposure of medical staff working in interventional cardiology departments, ranging from 0.1 mSv to exceeding the annual effective occupational dose limit of 20 mSv. The assessment and monitoring of occupational exposure should be considered as an important part of quality assurance programmes. The resulting occupational exposure may vary by more than one order of magnitude for the same type of procedure and for a similar patient dose. The reasons for these variations are differences between X-ray systems and their specific exposure settings and routine protocols, the level of radiation protection training of medical staff, the frequency of use of radiation protection equipment and personal dosimeters and, last but not least, the different workload of the professionals. Many publications have presented studies of staff doses and radiation protection measures taken to reduce them. Various international and national organisations, including UNSCEAR, the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA), are making major efforts to improve radiation protection in interventional cardiology. The European Society of Cardiovascular and Interventional Radiology (CIRSE) has made numerous and major efforts to improve radiation safety in interventional cardiology. Over the years, various approaches have been applied to reduce occupational exposure of staff, which have shown good results to one degree or another. Despite all these efforts, a large proportion of staff do not use protective equipment effectively, as revealed by a large historical survey of practice in the USA.

An ICRP publication recommends that occupational exposure reduction be linked and integrated with radiation protection for patients.

The first large-scale national survey of patient doses in interventional radiology in Bulgaria was performed in the period 2007-2009, followed by a second, and so far the last, in the period 2016-2017. NDRLs have been proposed for only two interventional procedures expressed in terms of the kerma-area product (P_{KA}): for coronary angiography (CA) (4600 μGy.m^2) and percutaneous coronary intervention (PCI) (13400 μGy.m^2), and a reference interval for the typical total fluoroscopy time in minutes of (3-5:30) for (CA) and (10-13:20) for (PCI) has been proposed for both.

In addition to the purpose of developing the NDRLs, studies were also organized to evaluate the eye lens dose in medical personnel performing the interventional procedures. The main conclusion of the studies is that there is a risk of exceeding the annual eye lens dose limit of 20 mSv, especially for persons who do not use individual radioprotective equipment, operate X-ray equipment with the tube above the patient table, or do not have additional radiation protection in the procedural room.

As a result of the first national survey, training activities for interventionalists were initiated and recommendations for optimizing fluoroscopy guided interventional (FGI) procedures were developed. Dissemination of these recommendations and information on possible skin injuries started with radiation protection training courses for interventionalists performed by NCRRP. In 2013, an educational poster was developed to inform medical staff about possible skin injuries, and guidelines for follow-up of patients after complex interventional procedures, based on international recommendations.

A systematic modern study and summary of the data on the status of radiation protection in the field of FGI procedures and interventional radiology in our country is needed in order to reduce the exposure of patients and staff to the minimum necessary to achieve the required diagnostic performance or therapeutic outcome.

2. Purpose and objectives of the thesis

The purpose of this work is by investigating and monitoring the doses to patients and medical staff of the interventional procedures with the greatest contribution to radiation exposure, to recommend and take measures to improve radiation protection and quality assurance.

To achieve this purpose, the following objectives were set:

1. To learn lessons from the first documented cases of radiation-induced skin injuries in Bulgaria, to assess the risk and frequency of their occurrence, to develop recommendations for their prevention and an algorithm of their management.
2. To survey the patient doses of the most frequently performed FGI cardiac and vascular procedures in several departments in Bulgaria, to compare them with the published national and international diagnostic reference levels and to propose diagnostic reference levels for the country.
3. To develop a detailed methodological guideline for the verification of dose indexes in angiographic equipment and mobile C-arm fluoroscopy equipment as part of an expanded methodological guideline to harmonize quality control tests for this type of equipment.
4. To investigate the 17-year dynamics in personal dosimetry records of medical staff and typical patient doses in one interventional cardiology department in Bulgaria and to demonstrate the effect of implementing an improved radiation protection and quality assurance program.

3. Materials and methods

3.1. Implementation of a procedure to inform and follow-up patients after high-dose procedures

To identify patients at risk for radiation-induced skin effects, follow-up levels for patients submitted to interventional procedures with greater complexity and long fluoroscopy times have been proposed in Regulation 2 of the Ministry of Health (MoH). In order to improve radiation protection in the departments where FGI procedures are performed, a template of instruction entitled: "Patient instruction after an interventional procedure with higher complexity and long fluorocopy time" was developed, published, presented at a series of scientific forums and training courses and made available for free use.

3.2. Study of patient doses for the most commonly performed interventional cardiac and vascular procedures

Patient dose studies of the most commonly performed interventional cardiology and vascular procedures include diagnostic and interventional cardiology procedures, electrophysiology (EP) studies, and catheter ablation and endovascular and hybrid revascularization procedures of the lower extremities (below the inguinal ligament) and of the aortoiliac segment. The total number of interventional procedures analyzed was 4420. Studies were retrospectively performed for CA and PCI procedures in nine invasive cardiology departments, with fourteen angiographic devices, diagnostic EP studies and ablation procedures with two different levels of complexity in 3 EP centers, and endovascular and hybrid revascularization procedures in one vascular surgery department. Depending on the procedures performed and the dosimetric information available, the values for the quantities of fluoroscopy time (FT), P_{KA}, and cumulative air kerma ($K_{a,r}$) were recorded, and the latter two quantities were used to estimate patient dose.

The results were processed and analyzed using descriptive statistical methods, with Jamovi 2.3.2 for statistical analysis of EP procedures and SPSS v.13.0 for vascular procedures.

For the purpose of a more correct presentation, the materials and methods related to the different studies are discussed in separate subsections.

3.2.1. Dose studies in diagnostic and interventional cardiology procedures

For the purpose of analysis of CA and PCI procedures is used data collected by input from medical professionals in connection with various projects or used data samples provided by medical physicists in order to regularly determine typical doses on the departments. Some of the data were sorted and extracted from the dose monitoring systems in the medical institutions where available.

The typical values for the relevant procedures were determined as the average of the monitored values in the submitted sample for the PCI and CA procedures, in accordance with the methodology used by the NCRRP in determining the most recent up-to-date NDRLs. In accordance with the European Commission recommendations, the median for each data sample was also calculated for the purpose of the analysis and determination of the typical dose value. For the identification of patients at risk of developing radiation-induced tissue reactions, the monitoring levels regulated according to the current national legislation and proposed in Regulation 2 were used. For completeness, for the period of data collection, data on other cardiac FGI procedures performed in the departments were also used in estimating the number of patients at risk of developing radiation-induced skin effects and the percentage of patients with exceeded levels relative to the total number of procedures performed.

3.2.2. Survey of patient doses in electrophysiological studies and catheter ablation procedures in Bulgaria

A retrospective study encompassing the highest volume electrophysiological (EP) centers in Bulgaria, was performed. Overall, five centers in Bulgaria had the necessary equipment and certified cardiac electrophysiologists to perform diagnostic EP studies and ablations of cardiac arrhythmias during the studied period. However, two of these centers performed <30 ablations per year and were excluded from the study due to the very small number of procedures. Each of the three remaining centers included in the survey performs regularly more than 100 procedures per year. Overall, more than 95% of all ablation procedures in Bulgaria were performed in these three centers.

By definition, NDRLs are based on data from a representative sample of centers performing a given type of clinical procedure in a country. We assumed the selected 3 healthcare facilities are a representative sample for our country with a sufficient workload, because they perform more than 95 % of all ablation procedures. This is the reason to use the data to propose NDRL for EP studies and catheter ablation procedures.

Data were extracted from the electronic registry for invasive electrophysiology BG-EPHY. The registry is designed, maintained and owned by the Association for Cardiac pacing and Electrophysiology in Bulgaria. Data entry for each diagnostic EP study and/or catheter ablation of cardiac arrhythmia performed in the country is mandatory for reimbursement by the National Health Insurance Fund. In this way the registry encompasses all invasive EP procedures (diagnostic studies and ablations), performed nationwide by board-certified cardiac electrophysiologists according to the requirements of the National Health Insurance Fund.

For the purposes of this study an anonymized automatic data extraction was done for each EP procedure within the time frame April 1st 2019 – February 5th 2021. Data from the period January 1st 2019 – March 31st 2019 were manually extracted from the old registry. The two data sets were merged for further statistical processing. In this way data for 25 consecutive months became available for analysis.

Data for the type of EP procedure and the use of EAM, were also collected in order to group the different procedures by level of complexity for the purposes of establishment of local DRL for EP procedures. EP procedures were divided into catheter ablations and diagnostic EP studies and for the purposes of the analysis ablations were defined as simple or complex. Simple ablations included ablation of AV nodal reentrant tachycardia (AVNRT), AV reentrant tachycardia (AVRT) using manifest or concealed accessory pathway (including Mahaim type fiber and PJRT), typical cavotricuspid isthmus-dependent atrial flutter, and ablation of the AV junction. All these ablations do not require EAM and in our country are generally performed under fluoroscopic guidance only. Complex ablations included ablation of focal atrial tachycardias, atypical atrial flutter and atrial macroreentrant/incisional tachycardias, atrial fibrillation (pulmonary vein isolation), idiopathic ventricular arrhythmias, and scar-related ventricular tachycardias. In complex ablations, the use of electroanatomic mapping is typically required for elucidation of the arrhythmia mechanism, reconstruction of a complex cardiac chamber anatomy, and very precise lesion placement.

The statistical analysis was performed with jamovi 2.3.2. Data distribution was assessed by Shapiro-Wilk test. Continuous data were presented as median (interquartile range IQR 25%-75%, minimum – maximum). Proportions were presented as percentages. Descriptive statistics were used, as well as the median of the distribution of the data for the K_{AP} for a given type of procedure to set the typical doses. Due to the relatively small number of centers the differences in K_{AP} according to the type of procedure (diagnostic or ablation) and to the level of complexity of ablation procedures were assessed by robust independent samples T-test with bootstrapping. Between-hospital differences were assessed by robust ANOVA with pairwise comparisons. There were insufficient data to use the third quartile (75th percentile) of the distribution of the medians to set the local DRL. The median values of the distribution of the data for each department were compared with the 75th percentile of all performed procedures of a given complexity. The proposed national DRL value for each level of complexity was also set to be equal to the 75th percentile, but only after excluding all KAP values lower than the 2.5th percentile or higher than the 97.5th percentile in order to eliminate outliers and data with gross error from analysis. A P-value <0.05 was considered significant.

3.3. Survey of patient doses in endovascular and hybrid revascularization of the lower extremities and the aortoiliac segment

A mobile C-arm fluoroscopy x-ray unit with a 30 cm (12 in) image intensifier (Radius R 12, Intermedical), 3.5 mmAL total filtration, equipped with a carbon fiber patient table, was used and installed in 2023 in a dedicated hybrid operating room. The X-ray unit is equipped with a built-in P_{KA} -meter whose readings are used to record the patient's dose. The reading of the P_{KA} meter is verified by additional measurements during the periodic quality control of the device. The deviation between the displayed on the device and the measured P_{KA} values is within 5 %. All revascularizations were performed by three experienced vascular surgeons and their teams. Data recorded for each procedure included: patient age, sex, P_{KA} value (Gy.cm^2), number of series in digital recording mode, type and number of accesses, type and complexity of procedure, number of stents implanted, and endovascular team. Retrospectively recorded data were available in the postoperative protocol and in the local HIS for all patients regarding P_{KA} values. The cine-runs were used to plan the endovascular intervention as well as to verify and confirm the results of each phase of the procedure.

The mobile C-arm does not have real-time peak skin dose (PSD) monitoring software, and dosimetry equipment was not available during the study period for routine measurements of patient skin dose during the procedures. PSD is the best indicator of potential skin injury, but its estimation from P_{KA} is complicated by the movement of the X-ray tube around the patient during endovascular procedures, thus irradiating different areas of the skin. The entrance beam field changes continuously as the tube is rotated around the patient to control the guidewire, catheter, stent implantation, etc., and oblique projections are rarely used during endovascular interventions.

The PSD was calculated using a published conversion formula for interventional procedures, which is an approximation for most fuoroscopy devices and is not an accurate surrogate for the actual maximum skin dose, especially for P_{KA} values below 50 Gy.cm^2.

Various aspects of endovascular radiology practice for surgeons and their teams were evaluated and compared for this study. The retrospective data collection for endovascular and hybrid revascularization of the lower extremities (below the inguinal ligament) included procedures performed over a two-year period and 41 months for the aortoiliac segment. The start of the period was 1 year after the teams began their routine activity in this hybrid room. Analyses were performed separately for each team. The relationship between dose and operators' skills, competence, experience, and training was also examined.

Statistical analysis was performed using SPSS v.13.0. Descriptive analysis, ANOVA, and independent samples key tests were used for endovascular and hybrid revascularization of the lower extremities (below the inguinal ligament). For endovascular and hybrid revascularization of the aortoiliac segment, descriptive analysis and nonparametric K-tests for independent samples (Kruskal-Wallis and Median) were used. A p value <0.05 was considered statistically significant.

3.4. 17-year follow-up of occupational exposure in an interventional cardiology department

In the period 2007-2023, five different angiographic units were used in the interventional cardiology department, and only two were working simultaneously most of the time, installed in different rooms: Siemens, Bicor T.O.P., installed in 1995 and used until 2009; Toshiba, Infinix CFi, installed in 2009 and used until 2020; Siemens, Axiom Artis DFC, installed in 2006 and used until 2022; Siemens, Artis Q, installed in 2021; and a second Siemens, Artis Q", installed in 2022.

The follow-up of occupational radiation exposure of interventional cardiologists was performed in a cardiology-focused medical facility with more than 2000 procedures per year (outside the COVID-19 pandemic period), in two catheterization labs with a consistent number of 5 active interventional cardiologists over the last 10 years.

Routine individual dosimetry monitoring is performed using thermoluminescent (TLD) dosimeters worn under lead aprons at chest level. The quantity used for individual dosimetry control is the personal dose equivalent, Hp(10), to estimate the effective dose. The personal dose equivalent is defined as the equivalent soft tissue dose (taken as 4-element tissue by ICRU) at a depth of 10 mm into the body below a specific point in the body. According to EC, Radiation Protection 160, for photons in in practice settings, Hp(10) provides a reasonable estimate of effective dose, E(mSv), although some underestimation may occur. In the very beginning, individual dosimetry monitoring is reported every 3 months. Since July 2007, monthly personnel dose monitoring has been introduced. The dosimeters were read by a dosimetry laboratory accredited and audited by the Nuclear Regulatory Agency.

Regular dosimetry analysis of individual dosimetry monitoring ensures that dose limits for occupational exposure will not be exceeded. The analysis is also used to track occupational exposures over time in order to optimise radiation protection in the department or to compare with other cardiologists performing similar interventional cardiology procedures in the same facility or in other facilities. The radiation protection officer, who in this case is the medical physicist, always contacts the cardiologist directly to determine the cause of abnormal dose values and provides suggestions for optimising practice so that individual exposure is at the lowest possible level.

The study was performed between 2007 and 2023 and included 31 interventional cardiologists. For each of them, data from all individual dosimetry monitoring reports were studied. The number and complexity of interventional procedures were analysed on an annual basis. A total of 39639 procedures performed over 17 consecutive years were classified and analyzed.

All 39639 procedures were divided into two main groups: diagnostic and interventional and one subgroup to interventional procedures, complex. The main procedures classified as complex are: chronic total coronary artery occlusion (CTO), peripheral vascular interventions (aorto-iliac, ileo-femoral, popliteal artery interventions), interventional treatment of pulmonary embolism, thoracic endovascular aneurysm repair (TEVAR), and interventional treatment of structural heart disease, endovascular treatment of periprosthetic paravalvular regurgitation using device, transcatheter aortic valve implantation (TAVI), invasive treatment of acute pulmonary embolism (fragmentation, thrombospiration and fibrinolysis) and treatment of patients with chronic pulmonary hypertension based on recurrent thromboembolic events (CTEPH).

According to the distribution of the number of procedures performed per operator and the annual individual doses received, three different trends of the type of work in the department were observed. For the purpose of analysis, the individual dosimetry data were grouped into three different time periods in order to explain the observed trends and better interpret the results.

First period (2007-2009): period with good teamwork and experienced team. Second period (2010-2011): period with constant change of team members and poor teamwork. Third period (2012-2023): a period in which a new team starts its progress and development towards good teamwork, but starts with less experienced interventional cardiologists and a smaller number of team members.

The number of procedures performed by different cardiologists in each year is expressed as a percentage of the total number of procedures performed in the department in that year. The number of complex procedures performed by the different cardiologists in each year is expressed as a percentage of the total number of interventional procedures performed in that year. For some of the years, the sum of the percentage values per year mathematically exceeds 100%. This is because some of the procedures require more than one interventional cardiologist as an operator and in the final medical record they are listed as the first or second operator. These are the cases where a procedure of higher complexity is performed or where a resident is included in the team.

Since 2010, dose indexes and FT have been regularly recorded for all diagnostic and interventional procedures performed in the department. Data on typical patient doses for CA and PCI procedures have been available since 2006 and are produced periodically. Median P_{KA} values for the entire study and full FT were calculated from the sample of standard patients (70±20 kg) for the respective diagnostic and therapeutic procedures. The results obtained over the years were compared with values from similar studies reported in the literature and with the trend over the years depending on the replacement of the X-ray units, their technical condition, the change in personnel and the experience gained by the interventional cardiologists. Since 2015, a procedure has been in place to follow-up patients at risk of radiation-induced skin injury and to take timely action when necessary.

Statistical analysis was performed with SPSS v.13.0. Descriptive, graphical and non-parametric correlation analysis were used. Since the study data did not have a normal distribution, Spearman's parametric analysis was used to assess the relationship between the study variables. A value of $p<0.01$ was considered significant.

4. Results and discussion

4.1. Cases of Radiation Induced Skin Injuries in Fluoroscopic Procedures in Bulgaria

This section describes the first reported cases of radiation-induced skin injury from Bulgaria, as well as their lessons learned and educational value.

Prior to 2015, there were no reported cases of radiation-induced skin injury in Bulgaria. Taking into account the data cited above on the theoretical risk of one potential case of skin injury in 10,000 to 100,000 patients, and considering the current number of interventional procedures performed in Bulgaria, one would expect between one and 12 cases of skin injury per year in the country, but these numbers are not supported by documented cases.

<u>Case 1:</u> A 62-year-old man, 92 kg, 175 cm, with chronic total occlusion (CTO), underwent two percutaneous coronary interventions (PCI), the first in late October 2013 and the second in December 2013, followed by a short coronary angiography (CA) performed one hour after the second PCI. Three weeks after the last procedure, skin erythema was detected on the left side of the patient's back. The patient complained of itching of the skin but was unsure exactly when it started. One year after the procedure, the information about this case was reported to the medical physicist, who then started a detailed study of the possibility of radiation injury to the skin. The dates of the procedures were

recovered from the medical records in the interventional cardiology department. As an already established practice in the department, the dosimetry index data are automatically entered in the report generated by the equipment with data on the procedure performed and the protocol used. For all procedures performed in the department, manual entry of the data into the operative report immediately after the procedure follows. These records contain data on fluoroscopy time and P_{KA} values, but do not contain data on the cumulative air kerma ($K_{a,r}$) value due to lack of staff awareness of the importance of this parameter. Automatic transfer and co-archiving of dosimetry data with the recorded images from a given procedure for a given period is technically impossible. Records of P_{KA} values were only available on the workstation of the angiography unit for a short period of time after procedures, then permanently deleted when the unit's memory became full. Because of this practice, no P_{KA} records were found in the operative protocol of the procedure, and therefore no detailed assessment of skin dose to the patient was made.

The first part of Table 1 provides a summary of the fluoroscopy time, P_{KA}, number of series recorded, and number of images obtained from the different procedures performed on this patient, as well as summary values.

According to the description provided by the patient and his family, the first appearance of the skin effect was erythema on the left side of the patient's back, which healed without any special treatment. However, the hyperpigmentation persisted for more than a year. The photograph in Figure 1 was taken in February 2015, approximately 13 months after the last procedure.

Table 1. Case 1 and Case 2: Summary of the information for the FGI procedures.

Case	Date of procedures	30 October 2013	4 December 2013	4 December 2013 (1 hour later)	Total
Case 1	Procedure	PCI	PCI	CA	
	Fluoroscopy time (min)	14.15	52.54	1.1	67.79
	P_{KA} (Gy.cm^2)	141.795	420.894	NA	>562.69
	Number of cine runs	26	29	5	60
	Number of cine images	1376	1458	358	3192

Case 2	Date of procedure	22 April 2014
	Procedure	Selective coronary arteriography
	Fluoroscopy time (min.sec)	76.1
	P_{KA} (Gy.cm^2)	868.02
	Number of cine run	25
	Number of cine images	1365

Fig. 1. Case 1: Skin lesion of NCI toxicity grade 1. The photo was taken 13 months after the last procedure as per details in Table 1. Earlier pictures are not available.

Case 2: In April 2014, a 76-year-old man, 94 kg, 173 cm, underwent prolonged selective coronary arteriography via a percutaneous approach to the right radial artery. Just two days after the procedure, the patient reported a "brown spot on the right shoulder" to a cardiologist in the hospital's emergency room. The medical provider stated that the patient's skin injury was the result of a thermal burn. The injury was not related to a previously performed interventional procedure. Details of the treatment received after this visit were not available.

An internal audit performed after the case was disclosed, based on the patient's history, dose records, and information about the patient's treatment, showed that two months after the procedure, the patient was hospitalized for placement of a pacemaker. No dose records were found for this procedure. Since 2010, the hospital has implemented regular recording of patient dose-related parameters from diagnostic and interventional procedures, but it appears that the Department of Electrocardiology did not implement these until 2014. Currently, with the upgrading of the X-ray equipment available at the facility, dosimetry reports are generated in DICOM format after each examination and sent automatically to the hospital's archiving system (PACS). In the departments where high-dose procedures are performed, the practice of manually entering the patient dose parameters into the operative report and entering the data into HIS is additionally implemented.

The medical specialist who prepared the hospitalization document for pacemaker insertion described the skin area as "on the right shoulder with a macular rash brown in color with a demarcation line." Similar to the previous case, no association with the previous interventional procedure was found. Eleven months after the procedure, a lesion appeared in the same area of skin. The patient visits a surgeon and reports severe pain and a shoulder wound. The wound is treated, which involves daily visual inspection, dressing the area, keeping the treated skin clean, and applying lotions. The treatment is yielding results and the wound is slowly decreasing in size. A month after the wound appeared, herpes zoster appeared in the same skin area and was treated with medication and lotions.

As the wound is difficult to heal, the surgeon refers the patient to the interventional cardiology department. If the interventional cardiologist express suspicion of radiation-induced skin injury, contact with the medical physicist follows. Figure 2 shows a photograph taken at this stage showing the condition of the affected skin area one year and three months after the interventional procedure. Previous photographs are not available as no one suspected the presence of radiation-induced skin damage. The photograph clearly shows the skin damage with the presence of necrotic tissue and several smaller sized macular rash lesions of brown colour.

Fig. 2. Skin lesion of NCI toxicity grade 4. The photo of the skin was taken 1 year and 3 months after the interventional procedure and 4 months after the appearance of the skin lesion.

The internal skin injury emergency action plan was followed and the patient was referred to the Medical Surveillance Laboratory and the Emergency Planning Laboratory at the NCRRP with suspected radiation skin injury, accompanied by available medical and patient dose documentation. The radiobiology specialist, who is an experienced professional in the field of radiation-induced effects, was also surprised to observe the first case in his practice of radiation-induced skin injury resulting from an interventional procedure.

After an in-depth literature search performed using electronic medical literature databases performed by two specialists in radiobiology together with the medical physicist, the skin lesion was classified as the toxicity grade 4, according to the classification of the National Cancer Institute (NCI).

The second part of table 1 shows the derived from the medical records radiological parameters and patient dose of the interventional procedure. The total fluoroscopy time was 76.1 min, the total number of cine runs 25, and the total P_{KA} was 868.02 Gy.cm^2. Information for $K_{a,r}$ was not available.

Lessons from reported cases of skin injuries can be summarized as follows:

- Lack of enough awareness on the part of interventionalists about the possibility of radiation-induced skin injury at that time;
- misdiagnosis and untimely diagnosis after the injury due to lack of awareness and knowledge among general practitioners, dermatologists and surgeons who follow up skin injury cases;
- lack of mechanisms to monitor patients with relatively high doses resulting from medical exposure in the field of diagnostic imaging at that time;
- the important role of the medical physicist in diagnosing the injury and in taking action in general;
- the role of training and information materials displayed in interventional facilities.

Restoration of patency of chronic total occlusion (CTO) is usually associated with prolonged fluoroscopy time and interventionalists should be aware of the increased likelihood of inducing radiation injury. PCI and interventional procedures of higher complexity require awareness of radiation risks and knowledge of the occurrence and treatment of skin injury.

Cases of skin injuries that were not treated in time due to lack of sufficient knowledge and awareness of interventionalists, general practitioners and dermatologists have been reported. Despite the availability of specialists in the country with sufficient knowledge of radiation-induced skin injury, the lack of actual experience with cases of injury following complex interventional procedures, and the lack of attention to this aspect in the education and clinical training of staff working in interventional radiology, interventional cardiology and radiobiology, the history of these cases provides an opportunity for learning and lessons to be drawn. It appears that, despite the existence of national guidelines, until the time of reporting these two cases, there was no real procedure in place for systematic follow-up of patient doses in the majority of facilities, and follow-up of patients for likely skin injury did not take place in any facility in the country. If every patient who exceeds a certain dose threshold is asked to contact the department where the procedure was performed in the event of redness or itching of the skin, and if a proactive mechanism is in place to call or contact the patient after about 30 days in a complex procedure involving a higher dose to rule out a tissue reaction, skin injuries will not be missed and will be diagnosed promptly and treated appropriately.

At the hospital where the two cases described were observed, regular recording of doses for diagnostic and interventional procedures has been in place since 2010. For all interventional procedures, records are kept regarding P_{KA} and fluoroscopy time. In the interventional cardiology department, regular records of doses and time of occurrence of the events were kept, but as mentioned above, no records were kept for $K_{a,r}$. Experience has shown that the available dose records were not sufficient to reconstruct the patient's dose and investigate these two cases of skin injury appropriately. According to the national guidelines and regulations in the country, patients should be followed up within the period of 30 days to three months after the procedure if any of the parameters exceeded the specified follow-up level.

In both patients reported here, four of these values were exceeded, but they were not followed up and were not informed of possible skin damage. In both cases, the medical physicist was not informed in a timely manner. This is a matter of insufficient awareness among professionals and lack of a well-established procedure for action. Discussion of radiation risk in high-dose interventional procedures at conferences and clinical meetings among professionals involved in interventional radiology could have influenced the effective implementation of a management algorithm. Detailed consideration of the causes and consequences associated with the cases of skin damage described strongly indicated the need for this topic to be included in the curriculum for all clinicians performing these types of procedures, as well as for dermatologists and general practitioners. In addition, having an established reporting procedure would help the patient and their relatives. If the procedure required the provision of information to patients and their family members, as well as the follow-up of patients in whom the threshold level was exceeded, radiation-induced skin damage would not be missed.

There is not much difference between the line of events associated with the cases of these two patients and other reported cases in different parts of the world where the diagnosis was missed long after the procedure. It was often found that the patient, when confronted with the occurrence of a tissue effect, would usually approach their general practitioner who had rarely seen such damage and would diagnose it as a thermal burn or allergic reaction. If the injury is severe, the patient may be referred to a dermatologist, who is also often unfamiliar with radiation-induced injury. After a period of suffering, the patient finds the information and help he needs on the Internet. These two cases have clearly demonstrated the need to increase the knowledge of medical professionals about the possible complications after complex procedures under scopic control, about the severity of suffering associated with skin injuries, about their diagnosis, classification and correct treatment.

As a result of these two reported cases and the subsequent actions, the awareness of the medical staff in the interventional cardiology department increased and the relationship with the medical physicist improved significantly. The complexity of therapeutic cardiology procedures at this hospital is high, with 28% of all PCI procedures performed on CTO patients at some point in the years. A system has been established to record the following patient radiation data in the medical report: scopic time, total P_{KA} and $K_{a,r}$. In addition, medical staff were instructed to strictly follow national guidelines for patient follow-up if any of the current trigger levels were exceeded. In the case of a prolonged procedure, the patient is informed to call the department immediately if skin reddening or itching occurs. It is hoped that adherence to all of these guidelines will allow all cases of skin injury to be detected in a timely manner, and that adherence to the rules for optimizing radiation protection during each procedure will result in no more such cases occurring.

The national regulatory framework for radiation protection in Bulgaria requires all specialists working with ionizing radiation, including interventional cardiologists, to undergo basic training in radiation protection once every five years, with ongoing training taking place in the meantime. Licensed training institutions are advised to apply international recommendations for the content of this training. One of the objectives of this training is to acquire the knowledge and skills so that the exposure of personnel and the patient is minimized and situations in which radiation-induced effects are prevented or, if they do occur, are detected and diagnosed promptly, and the patient treated correctly.

Conclusion

The first two cases of skin injuries in Bulgaria, reported here and published in an international journal with an impact factor in 2017, were discovered as a result of systematic actions and established trust between the expert in medical physics and the clinical staff of the Department of interventional cardiology.

In order to avoid the occurrence of tissue injury during interventional procedures, it is extremely important to implement a procedure that includes:

- regular monitoring of dose indexes during the procedure, with an emphasis on those directly related to skin injury, namely PSD and $K_{a,r}$. When neither of the first two indicators is available, it is recommended to use the lower priority ones, P_{KA} and FT;
- establishing tracking levels;
- introducing a follow-up procedure for the patient within a certain period after the procedure (eg 30 days) if any of the follow-up levels are exceeded, to check for early signs of skin injury; noting in the patient's file that this has been done;
- instructing a patient who has received exposure above the follow-up level to self-monitor for itching/redness of the irradiated skin area and report this to the appropriate department before seeking advice from other professionals.

These actions should not negate the need to implement a program to keep doses below the threshold levels for the occurrence of radiation-induced effects.

4.2. Multicentric study of patient doses for diagnostic and interventional cardiac procedures - comparison with diagnostic reference levels and follow-up levels for patients at risk of radiation-induced skin effects

Following the effective implementation of the dose monitoring programme, which aims to monitor patients for exceeding any of the monitoring levels and to identify patients with potential radiation-induced effects in one of the medical facilities, a new study was initiated with three main objectives:

1) to present and analyze the typical P_{KA} values for the most commonly performed FGI cardiology procedures - PCI and CA, in several cardiology departments in Bulgaria and compare them with the NDRL (2018);

2) to compare patient doses with the published Regulation 2 follow-up levels to identify patients at risk of developing radiation-induced effects;

3) to further justify the need to introduce a procedure for systematic monitoring of patient dose, thereby optimising not only the radiation protection of the patient but also of the staff.

Establishing typical doses for PCI and CA procedures and comparison with 2018 NDRLs

The results for typical values for a PCI procedure are presented in Table 2.

In two of the observed departments (ID1, ID2), the calculated typical values for P_{KA} exceeded the NDRL by a factor of 1.4 to 1.6. The FT (ID1, ID2) value was above the NDRL by a factor of 1.9 and 1.7. The P_{KA} value is not exceeding significantly the NDRL for ID9 unit. For ID10 and ID14 systems, the typical value for P_{KA} is lower than the NDRL, but the typical value for FT is higher than that suggested in the NDRL by a factor of 1.5 and 1.7. Seven of the units (ID1, ID2, ID3, ID5, ID6, ID7 and ID14) have a typical FT above that proposed in the NDRL for this parameter, and for ID5 the exceeding is not significant.

Results for typical values for the CA procedure are presented in Table 2.

For four of the surveyed X-ray units (ID1, ID6, ID9, and ID12), the estimated typical values for P_{KA} exceeded the NDRL by a factor of 1.1 to 1.5. For a device with ID2, the exceedance of the NDRL for the P_{KA} value is not significant. For two of the units (ID1, ID2), a typical FT above the NDRL by a factor of 2.0 and 1.5 was observed. For ID5 and ID11 installations, the typical value for P_{KA} is lower than the NDRL by a factor of 0.9 and 0.3, respectively, but the typical value for FT is higher than the proposed NDRL by a factor of 1.4 and 1.9, respectively.

Identification of patients at risk for radiation-induced effects

Table 4 presents the number and percentage of patients with an exceeded value of at least one of the follow-up levels for patients at risk of developing radiation-induced effects, as well as the total number of procedures studied for the specific department.

The last column in Table 4 provides information on the stage of implementation of a procedure for mandatory follow-up of patients in case of exceeding trigger levels.

Analysis of the results for the observed values for the P_{KA}, $K_{a,r}$ and FT values for the two procedures considered showed the presence of large differences between the minimum and maximum values of patient doses in the data samples presented for some of the facilities (hospitals 1, 2,8). The reason may be due to: the different degree of complexity of the procedures performed; the different radiological and interventional practice between departments and specialists in performing the respective procedure; and the anatomical features of the patients and their body size. For this reason, the average P_{KA} and FT values can be offset with respect to the prevailing daily practice. In this case, the median value (50th percentile) is closer to the typical value for the respective study procedures. Thus, for hospital 1, the median values for P_{KA} and FT for the PCI procedure for ID1 are -14163 cGy. cm^2, respectively and 16.5 min, and for ID2 14986 cGy.cm^2 and 15.5 min. For the CA procedure, these values were 3775 cGy.cm^2 and 6.2 min for the ID1 arrangement, and 3701 cGy.cm^2 and 5.4 min for the ID2 arrangement. For both different units and procedures, the typical values thus determined are relatively close and do not differ significantly from the National Diagnostic Reference Level. The same trend was observed for units ID4 (hospital 2), ID12 and ID13 (hospital 8).

The calculated typical values for P_{KA} for CA for hospital 7 show a typical level for P_{KA} lower than the NDRL by a factor of 0.3, while the typical value of FT is almost 2 times higher than the NDRL. The likely explanation for the presence of significantly lower P_{KA} values, but 2 times longer FT than NDRL is the unsatisfactory image quality, necessitating the longer use of fluoroscopy for better visualization of the object of interest. The results raised awareness to the need for further assessment of the quality of the images according to the relevant medical standard. A similar trend was observed for a PCI procedure in hospital 9.

Table 2. Summary patient dose results in P_{KA}, $K_{a,r}$, and FT magnitudes for the PCI procedure.

ID	No	P_{KA} AV (min- max), med, [cGy.cm^2]	$K_{a,r}$ AV (min- max), med, [mGy]	FT AV (min- max), med, [min]
(ID1)	31	20773 (1268-64833), 14163	*	**24,6 (6,2-99,0), 16,5**
(ID2)	37	18433 (372-52570), 14986	*	**22,5 (5,2-62,8), 15,5**
(ID3)	39	8681 (1352-30180), 6174	1585 (242-4238), 996	**15,9 (3,7-51,2), 12,7**
(ID4)	38	8514 (437-89275), 4962	1427 (85-11 408), 757	**12,9 (3,3-44,9), 8,7**
(ID5)	23	8274 (2660-26104), 7400	1827 (522-5040), 1685	**13,9 (3,6-57,6), 9,4**
(ID6)	23	8734 (1201-25002), 6450	1476 (190-4308), 1029	**20,5 (4,3-115,1), 11,2**
(ID7)	30	9102 (1675-23 620), 8094	832 (81 – 2911) 722	**8,6 (2,1-19,7), 7,3**
(ID8)	50	8592 (1967-26731), 6990	1440 (136 – 4043), 1152	**10,0 (3-44), 7,5**
(ID9)	18	16585 (3243-58233), 13860	2634 (986-9020), 2452	**7,4 (4,3-14,3), 6,1**
(ID10)	39	9004 (972-27112), 7191	426 (51-1504), 336	**21,1 (4,2-84,4), 13,4**
(ID11)**	-	-	-	-
(ID12)	190	7091, (332-55437), 5200	*	**10,4, (1,0-50,0), 7,0**
(ID13)	305	7372 (111-43633), 5523	*	**11,7 (2.0-95.0), 9,0**
(ID14)	17	10377 (2236-34719), 7239	1616 (25 – 8395), 875	**21,9 (6,3-73,0), 19,1**
NDRL		13 400	***	**10:00 – 13:20**

*** The angiographic unit presents data for the Ka,r value, but these were not recorded.**
**** The PCI data sample is small and not included in the presentation.**
*****No published Bulgarian NDRL for $K_{a,r}$**

Table 3. Summary patient dose results in P_{KA}, $K_{a,r}$, and FT magnitudes for the CA procedure.

ID	No	P_{KA} AV (min- max), med, [cGy.cm^2]	$K_{a,r}$ AV (min- max), med, [mGy]	FT AV (min- max), med, [min]
(ID1)	55	6717 (582-33080), 3775	*	**11,0 (1,4-45,5), 6,4**
(ID2)	54	4698 (635-16029), 3701	*	**7,5 (1,2-28.2), 5,4**
(ID3)	58	2269 (38-10316), 1495	353 (9-1943), 251	**4,8 (1,0-27,4), 3,5**
(ID4)	57	2490 (55-13457), 2125	226 (5-1579), 230	**5,0 (0,8-37,0), 3,6**
(ID5)	26	4016 (546-8773), 4260	747 (127-1863), 616	**7,4 (1,2-25,1), 6,2**
(ID6)	30	4841 (826-14600), 4299	646 (111-1513), 609	**5,5 (1,4-15,1), 4,1**
(ID7)	30	2565 (735-6741), 2383	1520 (54-31089), 200	**2,8 (0,9- 6,9), 2,2**
(ID8)	65	2724 (431-12239), 2281	499 (63-5163), 359	**3,0 (0,4-18,5), 2,2**
(ID9)	16	5560 (1283-10902), 5437	1266 (199-9091), 806	**2,9 (1,4-12,4), 2,2**
(ID10)	110	2624 (328-7878), 2234	378 (37-1125), 332	**5,4 (1,3-25,5), 4,1**
(ID11)	17	1397 (107-5374), 1092	145 (12.6-414), 128	**10,8 (0,5-34,1), 8,9**
(ID12)	111	5539 (221-54491), 2035	*	**4,7 (0,6-40), 3,0**
(ID13)	194	3163 (209-50043), 2019	*	**3,8 (1-26), 3,0**
(ID14)	43	3548 (397-56900), 1804	277 (22-886), 233	**2,8 (0,5-10,4), 2,1**
NDRL		4600	**	**3:00 – 5:30**

*** The angiographic unit presents data for the Ka,r value, but these were not recorded.**
**** No published Bulgarian NDRL for $K_{a,r}$.**

Table 4. Percentage of patients with at least one trigger level exceeded in relation to the risk of developing radiation-induced effects following cardiac procedures of any type. To estimate the percentage ratio, all data on FGI cardiac procedures for the data collection period were used, where available.

Hospital	% patients exceeding at least one trigger level	P_{KA}, number of patients	$K_{a,r}$, number of patients	FT, number of patients	series, number of patients *	Follow-up
Hospital 1	3% (16 of 535 surveyed procedures)	15	**	13	**	in process
Hospital 2	2% (4 of 208 surveyed procedures)	1	1	4	**	in process
Hospital 3	31% (32 of 102 surveyed procedures)	**	5	1	31	in process
Hospital 4	6% (11 of 173 surveyed procedures)	0	7	4	**	yes
Hospital 5	16% (6 of 37 surveyed procedures)	**	3	**	4	no
Hospital 6	3% (5 of 176 surveyed procedures)	1	0	4	**	in process
Hospital 7	0% (17 surveyed procedures)	0	**	0	**	**
Hospital 8	1% (6 от 800 surveyed procedures)	5	**	1	**	in process
Hospital 9	5% (3 от 59 surveyed procedures)	0	2	1	**	no
* Where the information was recorded. ** No data is presented for the relevant measurable quantity.						

Typical values for P_{KA} and FT that are lower than the NDRL are not always indicative of well-optimized procedures. On the other hand, even when good work practices are applied, in the case of a procedure with a high degree of complexity, it is not recommended to limit patient exposure below the threshold for the development of deterministic effects. The presence of patients in the departments with doses above the threshold for skin effects is not necessarily an indication of poor practice and quality of work, nor an indication that unreasonably prolonged procedures are being performed. Analysis of the data regarding patients at risk of developing deterministic effects shows that exceeding the follow-up levels occurs predominantly in the PCI procedure, with only one case of exceeding for the CA procedure for all hospitals. The reason for this is that the CA procedure is a diagnostic procedure with a shorter fluoroscopy time and a lower degree of complexity. In general, the percentage of patients with a trigger level exceedance ranged between 1% and 6%, with the FT parameter being the predominant exceedance in the data presented. In hospital 3, this percentage was 31%, with the exceedance mainly on the parameter number of series, and in hospital 5, 16%. In hospital 7 no such cases were recorded, which is probably due to the data presented for the CA procedure only and the relatively small number of patients in the sample. It should be noted that in the data sample presented, the majority of patients had an exceeded trigger level for FT. FT is not recommended as the sole indicator to monitor for possible radiation-induced skin effects, as it does not account for either the dose rate or the fluoroscopy modes used. More appropriate parameters for assessing patient dose in the first place are patient $K_{a,r}$, P_{KA}, and the number of series/frames recorded.

Table 4 (column 7) shows the extent to which a follow-up procedure was implemented for patients after high-dose procedures. At the time of the study, a fully implemented follow-up procedure, with a developed and implemented "Patient Instruction after a High Complexity and Long FT Interventional Procedure" was available in one of the participating facilities. No case of skin burns recorded during the study was reported in this facility. In five of the health facilities, medical professionals are aware of the trigger levels published in Regulation 2 and of the availability of patient instruction, but, probably for administrative and organizational reasons, the systematic follow-up of patients with exceeded trigger levels is not in place.

A drawback of the survey is a lack of the data for $K_{a,r}$ in hospitals 1 and 8, as well as a lack of information on the number of recorded series in all departments except hospitals 3 and 5. As a result, the number of patients at risk of developing radiation-induced skin effects may be underestimated.

Due to the presence of units involved in the study with a small number of patients in the determination of the typical dose, the lack of data on the body weight of patients and the number of series for the whole procedure, a new and more complete study is recommended with the inclusion of the number of series and images and investigating whether an increase in the sample is necessary to follow up patients with exceeded trigger levels.

Diagnostic reference levels are a tool to optimize the radiation dose to patients during diagnostic and/or therapeutic procedures. Compliance with the diagnostic reference levels is not in itself a criterion for achieving maximum optimisation in performance. The proposed NDRL values by NCRRP are based on third quartile of the average values for the typical doses from the participating facilities. Our study, as well as international recommendations, indicate that the use of average values in determining typical values, for any of the monitored quantities, does not always reflect the true work practice in a given department. The analysis of data from the participating hospitals demonstrates that there are departments with typical values for P_{KA} and FT above the NDRL, which is an indication of the possibility to optimize the work in the departments in terms of the exposure parameters of the angiographic devices used.

At each of the facilities reviewed, there were patients with an exceeded follow-up level for the PCI procedure. Informing and following up the patient within 3 months for any radiation-induced effects is essential for recognizing and taking adequate and timely measures for diagnosis and timely treatment of radiation-induced effects. Lack of accurate information about the medical history and correctly taken history combined with lack of data on P_{KA}, $K_{a,r}$, FT values and number of series for the complete procedure delay the correct diagnosis for months. For cases of milder skin reactions, the diagnosis might never be made in patients who are not informed to find the correct medical care. An individualized approach is needed in the decision to follow up the patient depending on the type of level exceeded and/or the combination of values of the other parameters. The development and implementation into practice of procedures for the routine implementation of the "Patient Instruction following interventional procedure(s) of greater complexity and long FT" will allow timely diagnosis and treatment of skin effects following cardiac procedures under radiological control.

Conclusion

The study of patient doses for the most commonly performed interventional cardiac and vascular FGI procedures in several departments in Bulgaria and their comparison with published national and international diagnostic reference levels showed that in each of these departments there were patients with an exceeded follow-up level for skin injury in the PCI procedure. Routine recording and tracking of patient doses leads to increased awareness by medical staff regarding typical doses for procedures performed with the x-ray equipment. Self-recording of patient doses by the operator who performed the procedure leads to optimization of radiation protection and personal practice, and facilitates timely detection of a potential technical problem that could lead to increased radiation exposure for staff and patients.

4.3. Survey of patient doses in electrophysiological studies and catheter ablation procedures in Bulgaria

The main purpose of this study is to propose for the first time in Bulgaria DRL for interventional EP procedures (diagnostic and ablation) with two different levels of complexity. Independently of the proposed DRL, the study also aims to make a comparison between typical doses and the radiological practice of the participating centres in diagnostic and ablation procedures with two levels of complexity.

The database for the entire study period comprised 2102 procedures, of which 1999 (95.1%) were performed in the three participating centers. After excluding 30 fluoroless ablations, 12 EP procedures in pediatric patients (11 ablations and 1 diagnostic EP study), and 113 EP procedures with missing data on P_{KA} (104 ablations and 9 EP studies), overall, 1844 fluoroscopically guided procedures performed on adult patients (> 15 years) during the study period were available for analysis – 1728 ablations (93.7 %) and 116 diagnostic EP studies. Male patients were 1136 (61.6 %)

at a median age 58 years (IQR 49-66 years, min-max 15-91 years). Women were 708 at a median age of 58 years (IQR 44-68 years, min-max 15-88 years). In total, there were 845 simple ablations (48.9 %) and 883 complex ablations.

The third quartile P_{KA} value in diagnostic studies was 5.4 Gy.cm² (min-max 0.2-41.8 Gy.cm²). The third quartile P_{KA} value in simple ablations was 26.8 Gy.cm² (min-max 0.10-269.4 Gy.cm²), while in complex ablations it was 54.1 Gy.cm² (min-max 0.2-717.1 Gy.cm²).

After the exclusion of the data points on the extreme ends of the surveyed datasets the median P_{KA} values of the samples didn't change, but the third quartile P_{KA} values became lower: 5.2 Gy.cm² (diagnostic studies), 25.5 Gy.cm² (simple ablations) and 52.1 Gy.cm² (complex ablations).

The procedures' descriptive distribution by participating hospital, number of procedures, level of complexity, and P_{KA} values before and after the exclusion of the outliers from the dataset is presented in Table 5.

Table 5. Descriptive distribution of the performed procedures by participating center, number, level of complexity, and P_{KA} values (values are rounded to one decimal place). The very right column shows the values after removal of the highest and lowest 2.5% of the total.

Hospital	1	2	3	Total	2.5% – 97.5% of the Total
Diagnostic procedures					
Number of procedures (N)	77	30	9	116	110
Median P_{KA} (Gy.cm²)	2.5	5.7	3.5	3.0	3.0
25th percentile	1.3	3.2	2.4	1.7	1.9
75th percentile	5.0	12.0	4.6	5.4	5.2
Minimum	0.2	0.6	1.3	0.2	0.5
Maximum	19.8	41.8	18.6	41.8	25.3
Simple ablations					
Number of procedures (N)	338	341	166	845	801
Median P_{KA} (Gy.cm²)	5.0	19.3	16.1	10.5	10.5
25th percentile	2.9	10.1	7.1	5.0	5.0
75th percentile	9.7	37.3	36.8	26.8	25.5
Minimum	0.2	1.3	0.1	0.1	1.2
Maximum	212.5	269.4	231.6	269.4	103.0
Complex ablations					
Number of procedures (N)	547	209	127	883	837
Median P_{KA} (Gy.cm²)	30.4	45.0	21.9	34.0	34.0
25th percentile	15.0	26.1	10.2	16.8	17.9
75th percentile	50.2	62.3	49.1	54.1	52.1
Minimum	0.2	2.6	0.8	0.2	2.6
Maximum	717.1	255.6	196.1	717.1	146.0

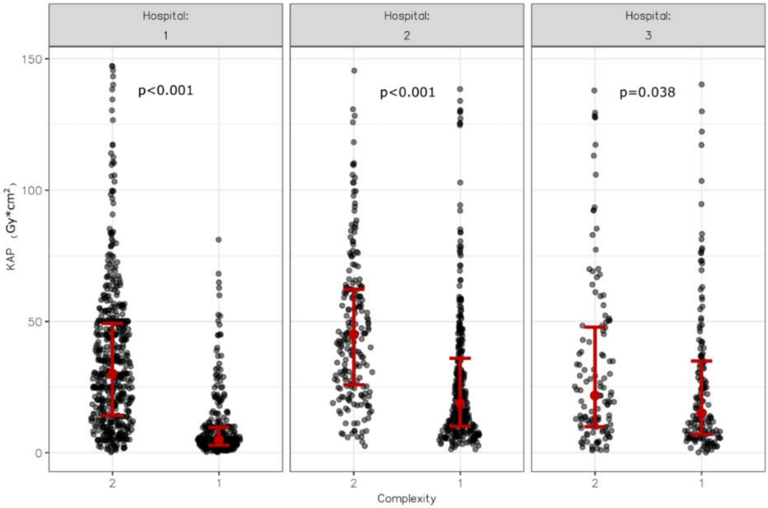

Fig. 3. Differences in P_{KA} (Gy.cm^2) (or KAP as popular in the literature) stratified by complexity [simple (1) vs complex (2) ablations]. Each gray circle represents a single procedure (n=1699 overall). The red dots represent the median P_{KA}, the red whiskers represent the 25th and 75th percentiles. Outliers (n=29) with P_{KA} values over 150 Gy.cm^2 are excluded.

The robust independent T-test showed significant between-hospital difference in KAP for diagnostic procedures (p=0.02) and for both simple and complex ablations (p<0.001) . The more detailed robust ANOVA pairwise comparisons of P_{KA} values for diagnostic EP studies, simple and complex ablations between each pair of hospitals are presented in Table 6 (hospital 3 has been excluded from the comparison of diagnostic EP studies due to a very low number of procedures).

EAM was used in 74 simple ablations (4.3 %) and not used in 100 complex ablations (5.8 %). The median and third quartile P_{KA} values for ablation with or without the use of EAM irrespective of the level of complexity were 34.0 Gy.cm^2 and 53.2 Gy.cm^2, and 11.1 Gy.cm^2 and 27.7 Gy.cm^2, respectively, (p<0.001) and were almost identical to median KAP in complex and simple ablations. The median and third quartile P_{KA} values were 34.9 Gy.cm^2 and 54.2 Gy.cm^2 in complex EAM-guided ablations, and 10.3 Gy.cm^2 and 25.1 Gy.cm^2 in simple non-EAM ablations. Again, these results were very close to the reported in Table 5, thus reinforcing the validity of complexity concept based on the use of EAM.

Table 6. Pairwise comparisons between the different hospitals – diagnostic procedures, simple and complex ablations.

Hospital vs Hospital		Psi-hat	95% CI		p
			Lower	Upper	
Pairwise comparisons – P_{KA} for simple ablations					
1	2	-15.57	-18.51	-12.63	<.001
1	3	-13.83	-18.46	-9.20	<.001
2	3	1.74	-3.63	7.10	0.44
Pairwise comparisons – P_{KA} for complex ablations					
1	2	-11.98	-17.399	-6.56	<.001
1	3	7.01	-0.581	14.61	0.028
2	3	18.99	10.589	27.39	<.001
Pairwise comparisons – P_{KA} for diagnostic procedures					
1	2	-3.52	-6.42	-0.625	0.02

This is the first multicenter survey of patient exposure during electrophysiology studies and catheter ablation procedures in Bulgaria. National DRLs for EP and ablation procedures of two different levels of complexity are proposed. The analysis of the correlation between patient dose and the complexity of the procedure shows that patient exposure increases with increasing the level of complexity. The highest median dose values were observed in the center performing EP procedures on an old C-arm without any modern radiation protection and optimisation features. The results are lower or comparable to the published data of other surveys.

There is a significant variation in P_{KA} values for procedures with the same degree of complexity within each center (Table 5). The observed variation for diagnostic procedures was up to factor of 132 in Hospital 1, 66 (Hospital 2) and 14 (Hospital 3, with very limited sample of patients). Dose values vary with a factor of up to 966 in (1), 201 in (2) and 2316 in (3) for simple ablations and 3201 in (1), 100 in (2) and 236 in (3) for complex ablations.

Although data from only three EP centers is included in the survey, the fact that 95 % of all EP procedures in the country are performed in those particular centers gives us the reason to propose NDRLs for diagnostic EP studies and ablations of different complexity. The median values may not be representative for the country to establish national DRLs due to the limited number of centers performing EP procedures on a regular basis. The relatively low number of EP centers suggested the third quartile (75th percentile) of the distribution of all performed procedures of a given level of complexity [after removal of the highest and lowest 2.5% in accordance with previous recommendations to be used to set the national DRL values for EP studies and ablations in Bulgaria (Table 5). The proposed NDRL in terms of P_{KA} were the following: 5.2 Gy.cm^2 for diagnostic EP studies, 25.5 Gy.cm^2 for simple ablations and 52.1 Gy.cm^2 for complex ablations. The proposed NDRL value is exceeded only for diagnostic procedures by Hospital 2. For all other type of procedures performed by the different EP centers, the NDRL value is not exceeded.

The highest median doses for diagnostic EP and ablation procedures were observed in Hospital 2 – 5.7 Gy.cm^2 (diagnostic), 19.3 Gy.cm^2 (simple ablations) and 45.0 Gy.cm^2 (complex ablations) (Table 5). The lowest median P_{KA} values for diagnostic EP studies (2.5 Gy.cm^2) and simple ablations (5.0 Gy.cm^2) were observed in Hospital 1. The lowest patient exposure during complex procedure was in Hospital 3 – 21.9 Gy.cm^2. One of the main reasons for such an observation was in the X-ray equipment used for the procedures – a mobile C-arm with image intensifier, a model popular in the period 1997 – 2000, with limited options for optimisation of X-ray exposure parameters in one of the centers. The other two centers are equipped with modern X-ray units for fluoroscopy-guided procedures, with digital flat panel detectors (FPD), both of them installed in 2018, with improved image-quality and dose-saving tools. The technology of the digital flat panel detectors has improved the detective quantum efficiency compared to image intensifiers, which reduces patient exposure for the same level of image quality, especially in a magnification mode.

Table 7 presents the comparison of the results for the proposed NDRL value, in terms of P_{KA}, from the current study with the limited number of available published data for the same type of procedures. Studies reporting diagnostic procedures are also shown in the comparison. For better interpretation of the published data, the dose values from the different studies are combined in ranges because of differences in the analysis of the results by the authors according to the type and complexity of the performed procedures. Some authors have reported results divided by diagnostic and ablation procedures, without analysing the level of complexity. Others have reported dose values for all diagnostic and ablation procedures performed in the surveyed department. There are few authors presenting more detailed information about the type of performed procedure, but for limited number of patients. The survey of the available published data showed that patient dose in diagnostic EP studies is typically lower compared to procedures when an ablation is performed. As shown in Table 7, the reported radiation doses for diagnostic and ablation procedures from the current study are lower or in the same range as the results from previous studies. It is difficult to perform direct comparison with the published data because of the various type of procedures. A proper nomenclature and categorization of the procedures should be used for better identification of the clinical complexity of a given type of procedure and grouping the data based on it.

Statistical analysis of the data collected shows significant difference in the patients' dose values between simple and complex ablations in all hospitals (see fig. 3).

Table 7. Comparison with published data on P_{KA} values.

Procedure/description	Reference	PKA (Gy.cm2)
Diagnostic EP Studies		
Diagnostic EP Study (3rd quartile)	This work	5.2
Diagnostic EP Study	Casella et al	8.82
Diagnostic EP Study	Efstathopoulos et al	12.5
Diagnostic EP Study	Omidvar et al	14.06
Diagnostic EP Study	Hadid-Beurrier et al.	5
Ablations		
Simple Ablations (3rd quartile)	This work	25.5
Simple Ablations	Efstathopoulos et al	48.7
Complex Ablations (3rd quartile)	This work	52.1
Complex Ablations	Efstathopoulos et al	10.9-133.4
Complex Ablations	Jiang et al	25.9
Ablations (3rd quartile, merged data for all ablations)	This work	43.3
Ablations	Casella et al	38.84-234
Ablations	Omidvar et al	153.34
Ablations	McFadden et a	123
Ablations	Vos	66
Ablations	Aroua et al	140
Ablations	Chida et al	110
Ablations	Dragusin et al	47
Ablations	Ponti et al	59-196
EP All		
EP All (3rd quartile, merged data)	This work	41.7
EP All	Siiskonen et al	12
EP All	Padovani et al	22.3
EP All	STUK	25
EP All	Cho	38-88

Comparison of diagnostic EP studies by center shows significant difference between hospitals 1 and 2 ($p=0.02$, see table 6). No significant difference in dose values is found between hospitals 2 and 3 and statistically significant difference between hospitals 1 and 3, as well as 1 and 2 in simple ablations ($p<0.001$, see table 2). In complex ablations, the difference in KAP values between each pair of hospitals is statistically significant (see table 6).

The analysis of all collected data shows that despite the use of non-fluoroscopic navigation and mapping, the median P_{KA} values in complex EAM-guided ablations were still almost 3 times higher than in simple non-EAM ablations. These results demonstrate the need for further optimisation of the EP procedures and protocols. Despite the use of EAM, significant fluoroscopy exposure is still accrued for navigating the EP catheters in complex procedures, which corresponds to other surveys.

For some patients the performed EP procedure might not be the only one in their lifetime and often is connected to the use of additional type of X-ray imaging modalities including cardiac computed tomography angiography, coronary angiography and etc. Two procedures were performed on 141 patients: 48 female and 93 male patients. Three EP procedures were performed on 7 male and 4 female patients. Studies show that patients are expected to undergo on average 1.25-1.5 ablation procedures in their lifetime.

Limitation of the current study is the relatively low number of EP centers performing ablation procedures in Bulgaria. Another limitation is the missing detailed information about the fluoroscopy time, air kerma at the patient entrance reference point and patient weight, which can be useful for more detailed analysis of the radiology practice for such procedures in our country.

Conclusion

This study is the first to propose national DLRs for EP studies and ablation procedures of two levels of complexity in Bulgaria. The results identified EP procedures requiring further optimization of patient protection and provided a basis for comparisons and standardization with future research on the topic. The proposed NDRLs are recommended to be used for better management of radiation exposure during EP procedures of different levels of complexity.

4.4. Survey of patient doses in endovascular and hybrid revascularization of the lower extremities

The purpose of this study was to: (1) evaluate the dose parameters describing exposure of patients undergoing endovascular or hybrid revascularization of the lower limb (below the inguinal ligament); (2) compare the data available in the literature with the evaluations of patients' dose values and related factors, for patients undergoing such procedures; (3) examine the correlation of doses with certain parameters; (4) estimate the peak skin dose and assess the potential for radiation induced skin injuries during the procedures.

A total number of 327 patients, between the age of 38 and 95, were included in the study. The mean value for patients age was (66.8 ± 9.5) years. 239 (73.1 %) patients were male and 88 (26.9 %) patients were female. Endovascular procedures were performed in 189 (57.8 %) of the cases while hybrid procedures were performed in 70 (21.4 %) of the cases. A total of 68 (20.8 %) out of all 327 patients had their procedures with unknown vascular access and respectively were excluded from the cohort, thus leaving 259 procedures for further analysis.

Among the procedures included in the study, the most common were percutaneous transluminal angioplasty (PTA), recanalization (intraluminal/subintimal) and stent insertion. The vascular access was ipsilateral common femoral artery (CFA) for procedures on popliteal and tibial arteries; contralateral femoral artery for procedures on superficial femoral artery (SFA) and deep femoral (DFA); popliteal retrograde for ipsilateral SFA; brachial artery for both CFA and DFA.

The endovascular procedures were divided by degree of complexity in the following four groups: PTA (0); PTA and stenting (1); recanalisation and PTA (2); recanalisation, PTA and stenting (3). The correlation between KAP values, the number of inserted stents and the types of stents (Supera) was studied.

The following hybrid surgery procedures were included in the study: conventional CFA and/or DFA endarterectomy and remote endarterectomy of SFA with Vollmar ring stripper. During the study, the remote endarterectomy was always performed under fluoroscopy to verify presence of intimal flap. In case a flap was found, it was treated by a prolonged PTA or stent insertion. In the cases of acute thrombosis, due to stenosis of SFA, a thrombectomy was performed with Fogarty catheter, control angiography and PTA or stenting of the stenosis.

The routine protocol used during most of the procedures was in automatic exposure mode including pulsed fluoroscopy with 7 frames per second and no magnification mode. Proper collimation was applied for all procedures. In some cases magnification mode of 15 cm (6 inch) or 10 cm (4 inch) was used for precise stent implantation. Digital subtraction angiography (DSA) was used only for the final angiography documentation purposes. The results from the quality control measurements showed that the patient entrance surface air-kerma rate was 16.85 mGy/min for the fluoroscopy mode with 7 frames/s. The P_{KA} -meter display was verified by additional measurements, and the accuracy of the displayed P_{KA} values was found to be within 5 %. The calibration protocol for the P_{KA} meter included the table and the mattress in the X-ray beam. No additional correction has been applied to the presented P_{KA} values.

The results for P_{KA} and PSD values and fluoroscopy time (FT) for procedures with different vascular access, in terms of median value, range (minimal-maximal value) and interquartile range (IQR), are presented in Table 8. Table 9 shows the results of endovascular procedures of different complexity. The statistical analysis of the procedures' parameters and their correlation with the number of inserted stents per patient are presented in Table 10.

Table 8. Results for P_{KA}, PSD and FT for endovascular procedures with different vascular access. IQR is the interquartile range.

Vascular access	Group size: Total number (% of all)	P_{KA}, Gy.cm^2: Median value, range (IQR)	FT, s: Median value, range (IQR)	PSD, mGy: Median
Ipsilateral CFA	133 (51,3)	96 1,7-208 (100)	78 21-337 (81)	748
Contralateral CFA	32 (12,4)	207 2,2-711 (218)	153 14-340 (160)	1325
Brachial artery	6 (2,3)	347 32-836 (N/A)	N/A	2053
Ipsilateral PA (retrograde)	18 (6,9)	61 0,6-157 (110)	53 18-89 (48)	566
Hybrid	70 (27)	77 11-144 (111)	41 28-152 (69)	649

The P_{KA} values for the procedures balloon angioplasty, PTA with stenting, recanalization with balloon angioplasty are in the range 67-75 Gy.cm^2. The values for the most complex procedures - recanalization (including subintimal), balloon angioplasty and stent(s) insertion are significantly higher - 121 Gy.cm^2 ($p<0.01$).

Table 9.. The results for P_{KA}, PSD and FT for endovascular procedures of different degree of complexity. IQR is the interquartile range.

Degree of complexity	Group size: Total number (% of all)	P_{KA}, Gy.cm^2: Median value, range (IQR)	FT, s: Median value, range (IQR)	PSD, mGy: Median
(0) PTA	78 (41,3)	67 0,6-711 (83)	39 14-162 (59)	597
(1) PTA and stenting	20 (10,6)	78 2,3-237 (93)	59 26-150 (71)	655
(2) Recanalization and PTA	39 (20.6)	75 3,5-353 (102)	84 42-263 (100)	639
(3) Recanalization, PTA and stenting	52 (27,5)	121 3-160 (292)	110 25-340 (142)	878

Table 10. The results for P_{KA}, PSD and FT for endovascular procedures with different number of inserted stents per patient. IQR is the interquartile range.

Number of stents	Group size: Total number (% of all)	P_{KA}, Gy.cm^2: Median value, range (IQR)	FT, s: Median value, range (IQR)	PSD, mGy: Median
0 (PTA only)	170 (65,6)	76 0,6-129 (85)	79 14-290 (73)	644
1	70 (27)	106 1,3-160 (86)	64 25-340 (88)	800
2	16 (6,2)	161 7,6-507 (361)	111 39-325 (209)	1086
3	3 (1,2)	366 27-427 (N/A)	221 105-337 (N/A)	2152

The statistical analysis for the number of procedures performed and patient exposure in terms of P_{KA} for the three different surgical teams is presented in Table .

Table 11. Number of procedures and patient dose in terms of P_{KA} for three surgical teams.

	Team 1		Team 2		Team 3	
	№ of procedures	%	№ of procedures	%	№ of procedures	%
*> Median (P_{KA})	90	56	21	36	17	46
**<= Median (P_{KA})	72	44	37	64	20	54
***Total	162	100	58	100	37	100

*Number/percentage of procedures with P_{KA} values higher than the median value.

**Number/percentage of procedures with P_{KA} values lower than the median value.

***For two of the procedures the team information is not available.

Statistical analysis of the data collected shows that the type of vascular access is the most important influence on the P_{KA} and PSD values (Table 8). Statistical analysis of the available data concerning the P_{KA} and FT values for brachial artery (Median: 347 Gy.cm^2/ FT: NA; Range: 32-836 Gy.cm^2/FT: NA) and contralateral (Median: 207 Gy.cm^2/153 s; Range: 2.2-711 Gy.cm^2/14-340 s; IQR: 218/160) CFA approach show that they are significantly higher than for ipsilateral CFA (Median: 96 Gy.cm^2/78 s; Range: 1.7-208 Gy.cm^2/21-337 s; IQR: 100/81), hybrid surgery (Median: 77 Gy.cm^2/41 s; Range: 28-152 Gy.cm^2/18-89 s; IQR: 111/69) and ipsilateral retrograde popliteal approach (Median: 61 Gy.cm^2/53 s; Range: 0.6-157 Gy.cm^2/18-89 s; IQR: 110/48) ($p<0.01$). The same tendency is observed for the PSD values: they are highest for brachial artery (2053 mGy) and contralateral CFA (1325 mGy) approach, followed by the ipsilateral CFA (748 mGy), hybrid surgery (649 mGy) and ipsilateral retrograde popliteal approach (566 mGy). Such procedures include fluoroscopy of different areas of the thorax and abdomen for the purposes of successful CFA, DFA and SFA manipulation where the X-ray beam goes through thicker tissues. A contralateral approach results in higher radiation doses to patients than other approaches because the aortoiliac bifurcation needs to be crossed and because of the extra pelvic fluoroscopy time needed to accomplish this. The contralateral CFA and brachial artery approaches do not exhibit any significant difference in their respective P_{KA} values. The explanation is that for both of them the significant part of the doses is achieved in the beginning of the procedure when an abdominal fluoroscopy is obtained to cross the aortic bifurcation. The P_{KA} and PSD values for ipsilateral retrograde popliteal artery approach are significantly lower than other approaches, because the X-ray beam is crossing through the thinner tissues.

There is a significant variation in P_{KA} and PSD values, up to factor of 100 for procedures with the same degree of complexity (Table 9). Dose values vary with a factor of up to 300 for procedures with the same vascular access and the same number of inserted stents. The P_{KA}, PSD and FT values increase significantly with the increase of the number of inserted stents ($p<0.01$). There is a strong dependence between the P_{KA} values and patient's weight and BMI index ($p=0.003$ and $p=0.002$ respectively). The use of Supera-Abbott stent system, which requires the use of magnification mode for accurate placement did not increase significantly the dose values ($p>0.05$). There is a statistically significant correlation between the number of series and the patient's dose ($p=0.005$ with 2.54 $Gy.cm^2$ per series).

For hybrid surgical procedures, the fluoroscopy is used only to control the remote endarterectomy, for intimal flap fixation (if needed) and then a final angiography is performed. As a result, the dose values and the fluoroscopy times are reduced. Significantly higher P_{KA} values are observed only for the most complex endovascular procedures.

Procedures for patients with a higher degree of complexity or higher number of inserted stents required the use of longer fluoroscopy times. For example, for a patient of 80 kg (0 degree of complexity, 0 stents, ipsilateral CFA vascular access, Team 3), a FT of 162 s was registered and a total P_{KA} of 5.3 $Gy.cm^2$, or for a 70 kg (3 degree of complexity – drug eluting balloon used, 0 stents, ipsilateral CFA vascular access, Team 3) patient these values were 290 s and 7.7 $Gy.cm^2$, while for a 86 kg (3 degree of complexity, 1 stent, ipsilateral CFA vascular access, Team 1) patient, they were 55 s and 80 $Gy.cm^2$. These examples show that the P_{KA} values do not always correlate well with patient weight or fluoroscopy time. Patient's weight is not usually expected to increase FT but it is expected to increase P_{KA} as a result of the higher kV and mA values forced by the AEC system to achieve a satisfactory image quality. Procedures of lower complexity require shorter time than others regardless of the patient weight.

The three vascular surgeons started their endovascular practice at the same time, in the year of installation of the C-arm. The results show that "Team 1" performed the highest number of procedures with the higher degree of complexity (Table 9-11). There is a statistically significant correlation between the team of endovascular surgeons and the patient's dose, number of patients and the categorizations that they treated ($p<0.05$) (Table 11). 56 % of all procedures performed by the Team 1, 36 % by the Team 2 and 46 % by the Team 3 had dose values exceeding the median. Possible reason for the higher P_{KA} values for Team 1 could be the more frequent use of the brachial approach or the contralateral CFA (Table 8). The most complicated procedures were performed by Team 1.

The dose values in terms of FT, P_{KA} and PSD for all procedures of different complexity do not exceed the proposed by the IAEA trigger values, for follow-up of patients for radiation induced skin injuries. The results also show that the PSD values are below the dose threshold for radiation-induced erythema with only few exceptions. The PSD threshold for radiation-induced erythema was exceeded only for two of the recorded procedures, both of them performed on obese patients, weighting more than 120 kg, BMI > 37.8. However, it should be reminded that these doses are received from a single procedure and if an additional procedure is required for the same patient, there is a risk of exceeding the dose threshold for erythema. In this study, additional procedure was required for 37 (14.28 %) of all 259 patients. Such results show that the cumulative air kerma should be recorded, stored and archived in the patient records.

Table 12 presents the comparison of the results from the current study for the KAP values and fluoroscopy time after the therapeutic endovascular lower extremity interventions with some published studies that have assessed lower extremity interventions. Studies reporting diagnostic procedures are also shown in the comparison. The survey of the published data shows that radiation dose in purely diagnostic procedures is typically lower compared with procedures when an intervention is performed. As shown in Table 12, the reported radiation doses in lower extremity endovascular interventions from the current study are in line with previous studies.

Table 12. Comparison with published data on P_{KA} and FT for endovascular procedures.

Procedure/description	Rererence	P_{KA} (Gy.cm²)	FT, s
Peripheral/low. extr. interv., 0 compl.	This work	67	39
Peripheral/low. extr. interv., 1 compl.	This work	78	59
Peripheral/low. extr. interv., 2 compl.	This work	75	84
Peripheral/low. extr. interv., 3 compl.	This work	121	110
Peripheral/diagn. femoral	Steele et al.	43	222
Peripheral/diagn. low. extr. ang.	Vano et al..	67	-
Peripheral/diagn. femoral ang., analog	Hoskins et al..	24	102
Peripheral diagn. femoral ang., digital	Hoskins et al..	74	138
Peripheral/diagn. femoral art.	Thwaites	26	144
Peripheral/diagn. low. extr.: conv./dig.	Ruiz-Cruces et al..	28/58	324/336
Peripheral/diagn. low. extr. ang., dig.	Ruiz-Cruces et al.	30	222
Peripheral/diagn. low. extr. ang.	Williams	77,9	-
Peripheral/diagn. femoral ang.	McParland	46,7	432
Peripheral/diagn. low. extr. ang.	McParland	79,8	450
Peripheral/lower extr.: diagn./therap.	Bor et al.	14/18	60/132
Peripheral/diagn. low. extr.	Kaufman et al..	20	-
Peripheral/diagn. av. of two locations	Kicken et al.	46	282
Peripheral/diagn. femoral ang.	Castellano et al.	13,1	-
Peripheral/diagn. low. extr.	Gfirtner et al.	45	270
Peripheral/diagn. low. extr.	Mini et al.	16	144
Peripheral/lower extr.: diagn./therap.	Zoetelief	16/41	-
Peripheral/low. extr. interventions	Struelens	71,85	-
Peripheral/low. extr. interventions	Segal et al..	66,2	960
Peripheral/low. extr. interventions	Majewska	109,9	-
Peripheral/ low. extr. interventions	Bor et al..	58,2	-
Peripheral/ low. extr. interventions	Kicken et al..	52,9	-
Peripheral/ low. extr. interventions	McParland	61,7	-

All procedures were analysed as endovascular revascularization performed in the area of the lower extremity. It is difficult to perform direct comparison with the published data because of the various anatomic locations for this type of procedures. The procedure-related details were not available in a large number of the publications. Previously reported radiation doses in lower extremity endovascular interventions are in the same range as the results from our survey.

The findings of this study indicate that the type of vascular access has the highest impact on radiation dose levels. The conclusion is based on small number of cases in a single center and warrants further investigation. However, all procedures were performed in the same room, by few operators, thus minimizing variability. There is also a significant increase in the dose values with the increase of the number of inserted stents and the level of complexity. In cases of long and complex occlusions, only a single long stent implantation has to be considered. The results from the current study show that another important factor affecting radiation dose in a procedure is the operator, which is in compliance with findings from similar studies.

A limitation of the study is also the lack of information in PACS/RIS for the cumulative air kerma. The two cases in which patients' doses exceeded the IAEA recommended trigger levels for patients' follow up and the finding that additional procedure was required for 14 % of the patients resulted in an improvement of the future data recording in the department. The data for the cumulative air kerma values was included in the patient history records.

All results and conclusions for the PSD values are based on an approximation of the real peak skin dose, particularly below P_{KA} of about 50 Gy.cm^2 [39]. 91 % of the received doses in the department during the survey are below the value of 50 Gy.cm^2.

Conclusion

Endovascular lower extremity interventions involve significant radiation dose, which should be considered in procedure planning, especially for patients who undergo multiple diagnostic and therapeutic studies.

4.5. Survey of patient doses in endovascular and hybrid revascularization of aortoiliac segment

The purpose of the current survey was to estimate dose-modifying factors and the radiation exposure itself for patients after endovascular or hybrid revascularization in the area of the aortoiliac segment in terms of air kerma-area product (P_{KA}). Different correlations have been analysed between the P_{KA} values and a number of series in acquisition mode with the following factors –type and complexity of procedure, number and type of endovascular/hybrid access and number of stents implanted.

A total number of 285 procedures performed in 223 patients were included in the current study. The mean value for patient's age was 65.8 (±8.7) years, ranging between the age of 40 and 87 years. Analysis of gender distribution shows that 206 (72.28 %) of all surveyed patients were male while 79 (27.71 %) were female.

Series in acquisition mode were used for planning the endovascular intervention and verifying the results of each the procedure's phase. The number of endovascular/hybrid accesses varied between one and three amongst different procedures. The types of access used were as follows: endovascular retrograde common femoral artery (CFA), contralateral CFA, left brachial and hybrid CFA or superficial femoral artery (SFA). Different procedures that were included in the study were divided as follows: endovascular, hybrid and covered endovascular repair of aortic bifurcation (CERAB).

Every vascular surgeon was asked to record the complexity level in hospital information system (HIS), after a given procedure. The retrospectively recorded data were available from the post-operative protocol and in the local HIS for all patients in terms of KAP values. The number of series in acquisition mode was available for 284 procedures. The duration of the fluoroscopic exposure was missing for the greatest number of procedures performed and it was excluded as a parameter from the final analyses.

Four different complexity grades for endovascular procedures were defined according to the number of guidewires and catheters used, the duration of the procedure and the number of inserted devices (balloons/stents):

(Ie) Percutaneous transluminal angioplasty (PTA) – in cases of stenosis as target lesion, resolved only by balloon angioplasty;

(IIe) PTA and stenting – in cases of unsatisfactory results for the stenotic segment after PTA and need of stent implantation;

(IIIe) Recanalization and PTA;

(IVe) Recanalization, PTA and stenting – in cases of total occlusion intraluminal or subintimal recanalization.

The defined complexity levels for hybrid surgery procedures were:

(Ih) Thrombectomy and intraoperative angiography – no additional PTA and stent required; (IIh) Remote endarterectomy and intraoperative angiography – no PTA and stent implantation required;

(IIIh) Thrombectomy and endovascular procedure – balloon angioplasty and/or stent insertion required for improved results;

(IVh) Remote endarterectomy and endovascular procedure – after remote endarterectomy and intraoperative angiography. Prolonged PTA procedure and/or stent insertion were required for intimal flap fixation.

Results about the type of procedure, degree of complexity, type and number of accesses, number of implanted stents, group size, P_{KA} values, number of series and PSD values, in terms of median value and range, are summarized and presented in Table 13. Summarized results for the number of procedures performed by degree of complexity, type of procedure and operator (team) are presented in Table 14. The results from the median test are presented in Table 15.

Table 13. Summarized results for the type and complexity of all performed procedures, type and number of accesses, number of inserted stents with their group size, P_{KA} values, number of series and PSD values in terms of median value and range.

Criteria	Group size, Total (%)	P_{KA}, Gy.cm^2, MED (Range)	Number of series, MED (Range)	PSD, mGy, MED (Range)
Type of procedure				
Endovascular	174 (61)	22,9 (2-237,7)	8 (1-27)	368 (260-1485)
Hybrid	100 (35)	13,0 (0,2-240,9)	6 (1-26)	316 (250-1502)
CERAB	11 (4)	100 (30,5-162,5)	16 (7-24)	769 (408-1094)
Number of accesses				
1	228 (80,0)	16,7 (0,2-173,9)	6 (1-20)	336 (250-1153)
2	47 (16,5)	57,0 (3,6-240,9)	11 (2-27)	545 (268-1502)
3	10 (3,5)	102,3 (52,4-162,5)	15 (2-27)	781 (521-1094)
Type of access (single access)				
Retrograde CFA/SFA	77 (34)	13,2 (4-59,5)	7 (3-14)	318 (270-558)
Contralateral CFA	37 (16)	33 (1,1-133,8)	8 (1-20)	421 (255-945)
Left brachial	33 (15)	38,3 (14,1-173,9)	7,5 (2-18)	448 (322-1153)
Hybrid	81 (36)	10,1 (0,2-122,3)	5 (1-14)	301 (250-885)
Degree of complexity (endovascular procedures)				
(Ie)	74 (43)	16,8 (4-110,2)	6 (1-19)	336 (270-822)
(IIe)	35 (20)	17,5 (2,1-173,9)	8 (3-17)	340 (260-1153)
(IIIe)	10 (5)	33,3 (7-87,2)	10 (5-20)	422 (285-702)
(IVe)	55 (32)	40,7 (7-237,7)	10 (2-27)	461 (285-1485)
Degree of complexity (hybrid procedures)				
(Ih)	30 (30)	3,7 (0,2-78,6)	3 (1-11)	268 (250-658)
(IIh)	13 (13)	7,9 (1,2-126,3)	5 (1-16)	290 (255-906)
(IIIh)	32 (32)	14,8 (2,4-240,9)	8 (1-16)	326 (261-1502)
(IVh)	25 (25)	25,3 (4,4-127,5)	9 (2-26)	381 (272-912)
Number of inserted stents per patient				
0 (PTA only)	137 (48)	11,0 (0,2-127,6)	5 (1-20)	306 (250-913)
1	88 (31)	21,9 (2,1-240,9)	8 (2-27)	363 (260-1502)
2	35 (12)	24,7 (5,9-173,9)	10 (4-19)	377 (280-1153)
3	21 (7)	90,3 (30,5-237,7)	13 (7-27)	718 (408-1485)
4	4 (1)	83,6 (64,7-114,6)	17 (14-18)	684 (585-845)

Table 14. Summarized results for the number of performed procedures divided by degree of complexity, type of procedure and operator (team).

Team	Endovascular				Hybrid				CERAB N, (%)	Total (%)
	(Ie) N (%)	(IIe) N (%)	(IIIe) N (%)	(IVe) N (%)	(Ih) N (%)	(IIh) N (%)	(IIIh) N (%)	(IVh) N (%)		
1	22 (32)	18 (55)	9 (60)	35 (62.5)	8 (33)	9 (64.3)	16 (45.7)	25 (86)	11 (100)	153 (54)
2	23 (34)	7 (21)	4 (27)	11 (19.6)	6 (25)	2 (14.3)	9 (25.7)	2 (7)	0	64 (22)
3	23 (34)	8 (24)	2 (13)	10 (17.9)	10 (41)	3 (21.4)	10 (28.6)	2 (7)	0	68 (24)
Общо	68 (100)	33 (100)	15 (100)	56 (100)	24 (100)	14 (100)	35 (100)	29 (100)	11 (100)	285 (100)

The procedures with higher frequency performed in the department were “PTA only”, followed by “recanalization, PTA and stenting”. The most common vascular accesses were hybrid and retrograde CFA/SFA.

The median values for P_{KA}, the number of series and the PSD ($p<0.05$) increase significantly when increasing the number of vascular accesses. As shown in table 13, the median P_{KA} value, the median value of the series number and the median PSD value for 1 access site were respectively 16.7 Gy.cm^2, 6 and 336 mGy, for 2 - 56.9 Gy.cm^2, 11 and 545 mGy, and for 3 - 102.3 Gy.cm^2, 15 and 781 mGy.

Significant dependence was observed in the case of single access site between the type of access and the P_{KA} and PSD value or the number of series ($p<0.05$). Hybrid and retrograde CFA/SFA endovascular accesses showed lower doses, 10.1 Gy.cm^2/301 mGy and 13.2 Gy.cm^2/318 mGy respectively, in contrast with the contralateral CFA and left brachial access, 33 Gy.cm^2/421 mGy and 38.3 Gy.cm^2/448 mGy respectively. For procedures of IIIe and IVe level of complexity, as part of the first phase of the procedures, a guidewire had to be advanced to the target lesion through multiple sites with higher tissue density, such as pelvis (contralateral CFA) or thorax, abdomen and pelvis (left brachial), before initializing recanalization, PTA or stent insertion.

The median P_{KA} value, PSD value and the median value series number increased significantly with the complexity of the endovascular and hybrid procedures ($p<0.05$). The results for the median value for P_{KA}, PSD and the series number for endovascular procedures of lower complexity were: Ie (16.8 Gy.cm^2/336 mGy and 6 series); IIe (17.5 Gy.cm^2/340 mGy and 8 series). For the most complex endovascular procedures, the results were: IIIe (33.3 Gy.cm^2/422 mGy and 10 series) and IVe (40.7 Gy.cm^2/461 mGy and 10 series). The analysis of the results for the hybrid procedures of different complexity showed smooth increase in the median dose values and number of series, starting from (3.7 Gy.cm^2/268 mGy and 3 series) for Ih, followed by IIh (7.9 Gy.cm^2/290 mGy and 5 series), IIIh (14.8 Gy.cm^2/326 mGy and 8 series) and IVh (25.3 Gy.cm^2/381 mGy and 9 series).

The higher the number of stents implanted per patient, the higher the dose values and the series number in acquisition mode ($p<0.05$) (Table 13). The median values of the parameters surveyed were: PTA only (11.01 Gy.cm^2/306 mGy and 5 series), 1 inserted stent (21.9 Gy.cm^2/363 mGy and 8 series), 2 stents (24.7 Gy.cm^2/377 mGy and 10 series), 3 stents (90.3 Gy.cm^2/718 mGy and 13 series) and 4 stents (83.6 Gy.cm^2/684 mGy and 17 series).

Analysis of the results demonstrated that more than one procedure in the aorto-iliac segment for a given patient was performed in 11% (31) of the cases. Redo procedures in the same segment in one year period were performed in 10 % (28) of the surveyed procedures. Analyses of the results for the total P_{KA} values for each patient with two repeated procedures in the same segment, showed significant variations with minimal value of 12.0 Gy.cm^2 and maximal value of 191.9 Gy.cm^2. Three repeated (for one or both limbs, including redo) procedures in aorto-iliac segment per patient were performed in 3 patients (1.0 %), with total P_{KA} value ranging between 30.0 Gy.cm^2 and 186.9 Gy.cm^2.

Results from the our survey demonstrate that the number and type of vascular accesses were the most important factors increasing dose values, followed by the combination between inserted stents number and the complexity of the procedure.

Significant variation was observed between the minimum and maximum P_{KA} and PSD values (Table 13), up to factor of 870 for procedures of the same number of vascular access (for 1 access) and 122 for groups of patients with the same type of vascular access (contralateral CFA). The highest doses were registered for patients with left brachial approach and three different vascular accesses. Such procedures are typically performed with an X-ray beam penetrating through different areas of the patient’s body and through thicker tissues. The minimum and maximum dose values vary up to a factor of 105 for procedures with the same degree of complexity and up to a factor of 638 for procedures with the same number of inserted stents (Table 13). The contralateral CFA and brachial access lead to higher but similar patient doses due to a combination of thicker tissues and prolonged fluoroscopy during the guidewire advancing, before the beginning of the actual revascularization.

The dose values are significantly lower for retrograde CFA/SFA vascular access compared to other types of vascular access because the target lesion is much closer to the vascular access and there is no need for crossing the aortic bifurcation or advancing the guidewire through the aortic arch and the descending aorta.

The hybrid type of vascular access and all hybrid procedures, irrespective of their level of complexity, are leading to lower patient doses, compared to all types of endovascular procedures. The reason is that during hybrid procedures, fluoroscopy is used mostly for planning the procedure and verifying the results.

More than half of the endovascular procedures were above the median P_{KA} value for all procedures performed during the surveyed period, contrary to the results for the hybrid procedures ($p<0.05$). The same trend was observed for the number of series in acquisition mode ($p<0.05$). All of the CERAB procedures were above the median P_{KA} value, which corresponds with the multiple vascular accesses (two inguinal for stents insertion and one brachial approach for angiographic control).

Analysis of the results comparing dose values and number of inserted stents, for the group of patients with four inserted stents, showed lower median values compared to the group with three inserted stents. A possible explanation is in the small group size, only 4 patients with 4 inserted stents, compared to 21 with 3 stents, and lower variation in the dose values, less than factor of 2 for patients with 4 inserted stents, compared to variation up to factor of 8 for the group with 3 inserted stents.

As shown in Table 14 and Table 15, the procedures performed by Team 1 had significantly higher dose values compared to Team 2 and Team 3 ($p<0.05$), a reason for which might be found in the non-homogenious distribution of procedures of different complexity between the three teams. 62 % of all procedures performed by Team 1, 36 % (Team 2) and 32 % (Team 3), had P_{KA} values exceeding the median. Team 1 performs most of the procedures of higher complexity (IIe - 55 %, IIIe - 60 %, IVe - 63 %, IIh - 64 %, IIIh - 46 %, IVh - 86,2 %) and all of the CERAB procedures.

Table 15. Median test. Summarized results for the type and complexity of all performed procedures, type and number of accesses, number of implanted stents and team.

Criteria	P_{KA}, N (%)			Number of series, (%)		
	>MED	≤MED	Total	> MED	≤MED	Total
Type of procedure						
Endovascular	98 (56)	76 (44)	174 (100)	89 (51.4)	84 (49)	173 (100)
Hybrid	33 (33)	67 (67)	100 (100)	35 (35)	65 (65)	100 (100)
CERAB	11 (100)	0	11 (100)	10 (91)	1 (9)	11 (100)
Number of accesses						
1	96 (42)	132 (58)	228 (100)	91 (40)	136 (60)	227 (100)
2	36 (77)	11 (23)	47 (100)	34 (72)	13 (28)	47 (100)
3	10 (100)	0	10 (100)	9 (90)	1 (10)	10 (100)
Type of access (single access)						
Retrograde CFA/SFA	24 (31)	53 (69)	77 (100)	40 (52)	37 (48)	77 (100)
Contralateral CFA	31 (84)	6 (16)	37 (100)	30 (81)	7 (19)	37 (100)
Left brachial	31 (94)	2 (6)	33 (100)	17 (53)	15 (47)	32 (100)
Hybrid	25 (31)	56 (69)	81 (100)	27 (33)	54 (67)	81 (100)
Degree of complexity (endovascular procedures)						
(Ie)	24 (32)	50 (68)	74 (100)	10 (14)	64 (87)	74 (100)
(IIe)	13 (37)	22 (63)	35 (100)	15 (43)	20 (57)	35 (100)
(IIIe)	7 (70)	3 (30)	10 (100)	6 (60)	4 (40)	10 (100)
(IVe)	43 (78)	12 (22)	55 (100)	35 (65)	19 (35)	54 (100)
Degree of complexity (hybrid procedures)						
(Ih)	5 (17)	25 (83)	30 (100)	4 (13)	26 (87)	30 (100)
(IIh)	4 (31)	9 (69.)	13 (100)	2 (15)	11 (85)	13 (100)
(IIIh)	20 (62.5)	12 (37.5)	32 (100)	19 (59.4)	13 (40.6)	32 (100)
(IVh)	21 (84.0)	4 (16.0)	25 (100)	17 (68.0)	8 (32.0)	25 (100)
Number of inserted stents per patient						
0	44 (32.1)	93 (67.9)	137 (100)	33 (24.1)	104 (75.9)	137 (100)
1	50 (56.8)	38 (43.2)	88 (100)	49 (55.7)	39 (44.3)	88 (100)
2	23 (65.7)	12 (34.3)	35 (100)	28 (82.4)	6 (17.6)	34 (100)
3	21 (100)	0	21 (100)	20 (95.2)	1 (4.8)	21 (100)
4	4 (100)	0	4 (100)	4 (100)	0	4 (100)
Team						
Team 1	95 (62.1)	58 (37.9)	153 (100)	81 (53.3)	71 (46.7)	152 (100)
Team 2	23 (35.9)	41 (64.1)	64 (100)	32 (50)	32 (50)	64 (100)
Team 3	22 (32.3)	46 (67.7)	68 (100)	23 (33.8)	45 (66.2)	68 (100)

Conclusion

Results of this survey demonstrate strong relationship between type and number of vascular access and patient dose. A possible drawback of the survey is the limited information of fluoroscopy time for each patient. A significant increase in dose values was also observed as the complexity of the procedure and the number of inserted stents per procedure increases.

All types of endovascular and hybrid procedures, regardless of their level of complexity, had significantly lower P_{KA} and PSD values (P_{KA} < 500 Gy.cm2 and PSD <3000 mGy) when compared to the trigger levels for the follow-up of patients with potential radiation induced skin injuries, proposed by the IAEA. The results from our survey showed that PSD values for a single procedure were between 2 and 12 times lower than those proposed as values increasing the direct risk of skin erythema.

Our study does not show outreaching of radiation-induced skin erythema even for patients with repetitive (more than one) procedure in aortoiliac segment for a year period.

4.6. 17-year follow-up of occupational exposure in an interventional cardiology department

The purpose of this study was to investigate 17-year dynamics in personal dosimetry reports of medical staff in one interventional cardiology department in Bulgaria.

Number of performed procedures

The number of interventional and diagnostic procedures performed in the department during the period 2007-2023 is shown in Figure 4.

The relative proportion of the annual number of complex procedures to interventional procedures performed in the department during the period 2007-2023 is presented on fig. 5.

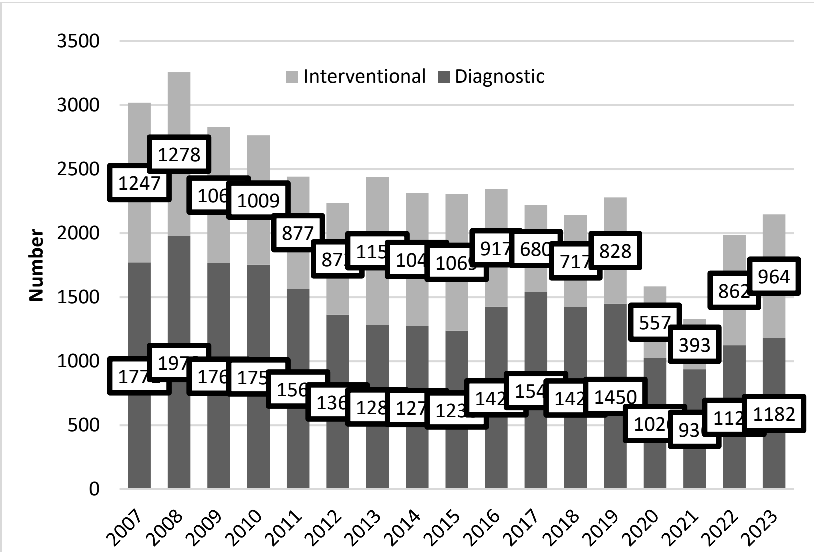

Figure 4. Distribution of interventional and diagnostic procedures, performed in the department during the period 2007-2023.

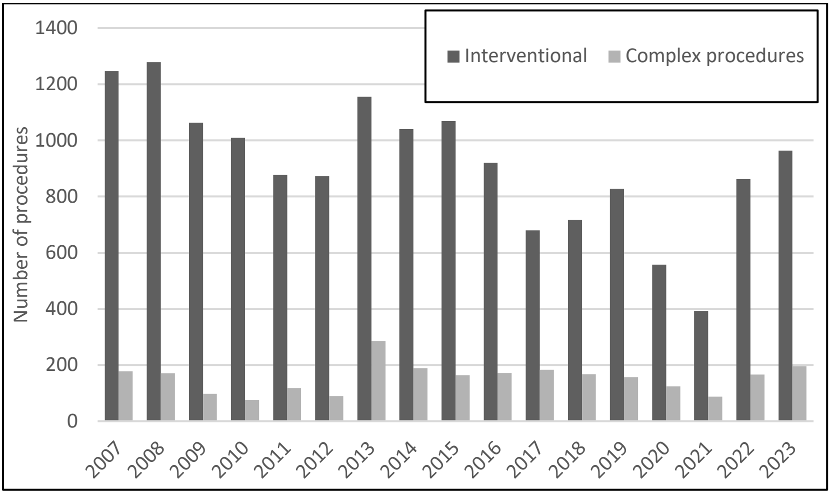

Fig. 5. The relative proportion of the annual number of complex procedures compared to the interventional procedures performed in the department during the period 2007-2023.

Eight cardiologists were excluded from the analyses due to lack of a complete set of information on them. One cardiologist was missing dosimetry report information, three were found not to be wearing dosimeters during procedures, and the remaining cardiologists provided partial information on procedures performed due to their pediatric focus, with the missing information regarding pediatric interventional procedures. A detailed analysis of the number and complexity of procedures was performed for 4 of the cardiologists who have been actively involved for a longer period of time and actually wear their individual dosimeters during procedures.

The number of interventional procedures performed per year, depending on the operator, for the entire study period ranged between 4 and 593 per year, with an average of 152 procedures, a median of 146, and a standard deviation of 99. The number of complex procedures performed per year ranged widely, between 0 and 234, with an average of 27, median of 16, and standard deviation of 32.

First period (2007-2009)

The distribution of interventional and diagnostic procedures performed in the department during 2007-2009 is presented graphically on fig. 6. Fig. 7 shows the distribution by operator of the percentage of complex procedures performed out of all complex procedures for the department and the annual effective dose during 2007-2009.

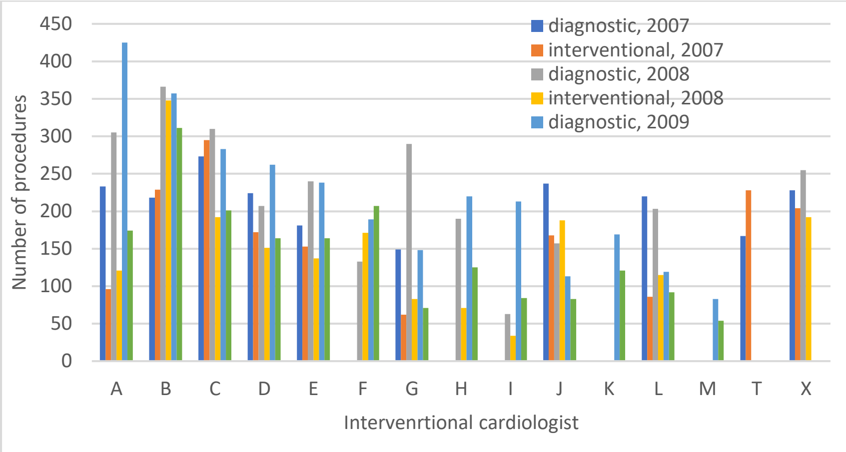

Fig. 6. Distribution by operators for interventional and diagnostic procedures, performed in the department during the period 2007-2009.

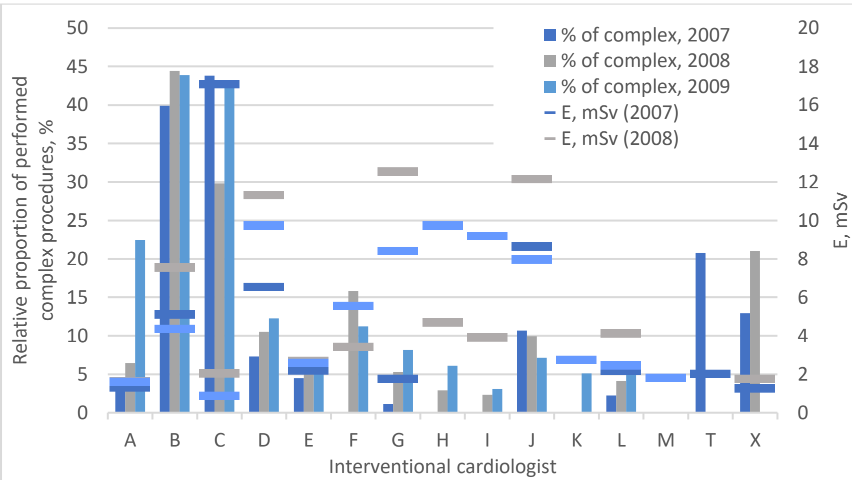

Fig. 7. Distribution by operator of the relative proportion of complex procedures performed and the annual effective dose in the period 2007-2009. Each individual colour corresponds to a specific year. The value for the effective dose for the specific year is in the form of a slash.

Second period (2010-2011)

The distribution of the interventional and diagnostic procedures performed in the department during the period 2010-2011 is presented graphically form on fig. 8. Fig. 9 shows the distribution by operators of the percentage of complex procedures performed out of all complex procedures for the department and the annual effective dose during 2010-2011.

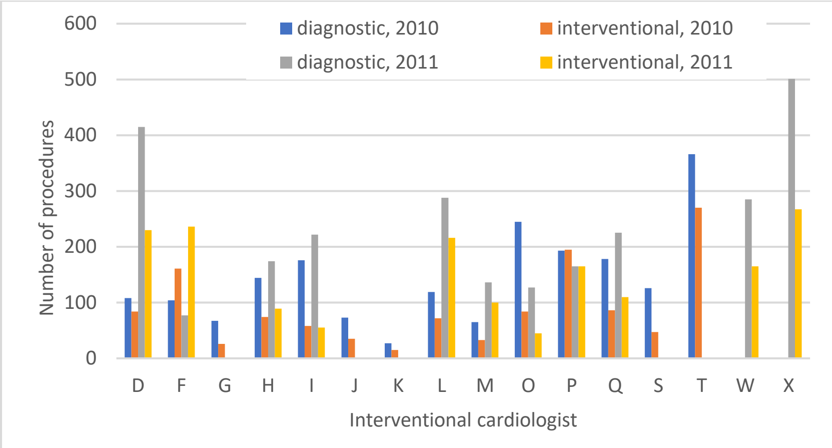

Fig. 8. Distribution by operators for interventional and diagnostic procedures, performed in the department during the period 2010-2011.

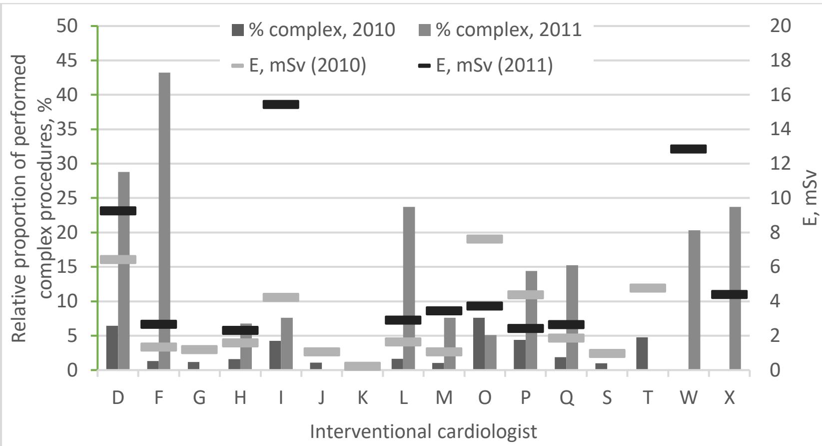

Fig. 9. Distribution by operator of the relative proportion of complex procedures performed and the annual effective dose in the period 2010-2011. Each individual colour corresponds to a specific year. The value for the effective dose for the specific year is in the form of a slash.

Third period (2012-2023)

The distribution of interventional and diagnostic procedures performed in the department in the period 2012-2023 is presented in tabular form in Table 16. The distribution by operator of the relative percentage of complex procedures performed out of all complex procedures for the department, the relative percentage of the total number of diagnostic and interventional procedures performed out of the total number of procedures for the department and the annual effective dose over the period 2012-2023 is presented in Table 17.

For all operators actively wearing their individual dosimeters during the interventional procedures, a statistical analysis was performed on the dose dependence of the type and number of procedures performed. The results are presented in Table 18. Statistical analysis revealed no statistically significant relationship between operator dose and the total number of diagnostic and therapeutic procedures performed per operator ($p>0.01$), whereas for interventional and complex procedures, a statistically significant relationship between the number of procedures performed and operator dose was clearly demonstrated ($p<0.01$).

Table 16. The distribution of interventional and diagnostic procedures performed in the department during the period 2012-2023.

Operator		D	F	H	I	L	M	Q	W	X	AB	BC	CD
2012	diagn.	276	149	222	205	87	217	213	218	725			
	interv	161	181	129	95	288	96	124	227	378			
2013	diagn.		476	133	194	88	259	335	266		158		
	interv		593	134	140	74	194	298	349		105		
2014	diagn.		126	13		15	499	456	229	155	238		
	interv		208	12		27	359	331	292	119	181		
2015	diagn.						381	366	249	394	239		
	interv						293	348	310	290	193		
2016	diagn.						487	459	363	220	182		
	interv						326	214	226	170	184		
2017	diagn.						511	459	459	156	233		
	interv						207	214	214	77	130		
2018	diagn.					107	364	332	261	24	370	172	
	interv					49	140	176	211	14	186	72	
2019	diagn.					150	391	347	209		361	172	
	interv					70	167	174	237		214	72	
2020	diagn.			19		56	259	226	156		237	84	38
	interv			18		27	113	139	155		116	22	9
2021	diagn.			51		32	199	228	104		211	86	31
	interv			8		17	79	100	103		108	18	10
2022	diagn.			75		27	289	237	122		302	79	61
	interv			17		37	160	197	198		256	72	19
2023	diagn.			1		36	367	290	147		359	8	15
	interv			2		28	243	229	239		321	4	14

Table 17. Distribution by operator of the relative proportion of complex procedures performed and the annual effective dose over the period 2012-2023.

Operator		D	F	H	I	L	M	Q	W	X	AB	BC	CD
2012	compl, %	21	33	16	11	3	9	3	39	43			
	total, %	20	15	16	13	17	14	15	20	49			
	E, mSv	4,3	1,1	2,7	0,9	1,9	5,6	4,0	19,5	5,2			
2013	compl, %		82	8	7	2	6	29	33		3		
	total, %		44	11	14	7	19	26	25		11		
	E, mSv		12,4	2,8	2,7	1,2	5,0	3,8	19,1		1,3		
2014	compl, %		40	1		2	15	31	37	13	10		
	total, %		14	1		2	37	34	22	12	18		
	E, mSv		5,3	1,1		1,2	4,6	3,1	6,3	4,5	2,1		
2015	compl, %						19	46	57	19	13		
	total, %						29	31	24	30	19		
	E, mSv						2,8	3,1	6,9	8,1	1,7		
2016	compl, %						17	40	49	8	15		
	total, %						35	29	25	17	16		
	E, mSv						3,2	2,9	8,1	6,0	2,5		
2017	compl, %						11	31	50	5	11		
	total, %						32	30	30	10	16		
	E, mSv						2,8	2,1	8,1	3,6	1,4		
2018	compl, %					4	9	35	53	2	17	6	
	total, %					7	24	24	22	2	26	11	
	E, mSv					1,5	1,1	2,5	4,5	1,1	0,6	5,3	
2019	compl, %					3	9	26	56		24	6	
	total, %					10	24	23	20		25	11	
	E, mSv					2,9	1,2	1,8	5,5		0,3	2,3	
2020	compl, %					4	12	23	54		19	5	
	total, %			2		5	23	23	20		22	7	3
	E, mSv			0,4		1,1	0,6	2,5	3,3		0,4	0,7	0,9
2021	compl, %			1		0	11	26	61		28	3	
	total, %			4		4	21	25	16		24	8	3
	E, mSv			0,2		1,5	1,2	2,7	3,7		1,1	0,8	0,5
2022	compl, %					2	7	23	54		42		
	total, %			5		3	23	22	16		28	8	4
	E, mSv			0,4		0,7	0,5	3,9	4,4		0,4	0,5	0,7
2023	compl, %			1		2	14	25	57		41		
	total, %					3	28	24	18		32	1	1
	E, mSv			0,1		0,4	0,8	2,1	3,7		1,1	0,1	0,3

Table 18. Results for the assessment of the presence of a statistically significant relationship between operator dose and the number and type of procedures performed by an operator in a given year. The distribution of the parameters did not demonstrate a normal distribution, which required the use of a non-parametric analysis.

Operator dose to total number of performed diagnostic and interventional procedures per year (p>0,01)				
			E, mSv/y	Total number
Spearman's rho	E, mSv/y	Correlation coefficient	1	-0,05
		Significance level sig. (2-tailed)	.	0,77
	Total number	Correlation coefficient	-0,05	1
		Significance level sig. (2-tailed)	0,77	.
Operator dose to number of interventional procedures performed per year (p<0,01)				
			E, mSv/y	interv.
Spearman's rho	E, mSv/y	Correlation coefficient	1	0,445
		Significance level sig. (2-tailed)	.	0,00
	interv.	Correlation coefficient	0,445	1
		Significance level sig. (2-tailed)	0,00	.
Operator dose to number of complex procedures performed per year (p<0,01)				
			E, mSv/y	complex
Spearman's rho	E, mSv/y	Correlation coefficient	1	0,41
		Significance level sig. (2-tailed)	.	0,00
	complex	Correlation coefficient	0,41	1
		Significance level sig. (2-tailed)	0,00	.

For four of the invasive cardiologists who have worked together for the longest period of time in the department, the trend over the years of complex procedures performed and the annual effective dose received is presented graphically (Figure 10 and Figure 11).

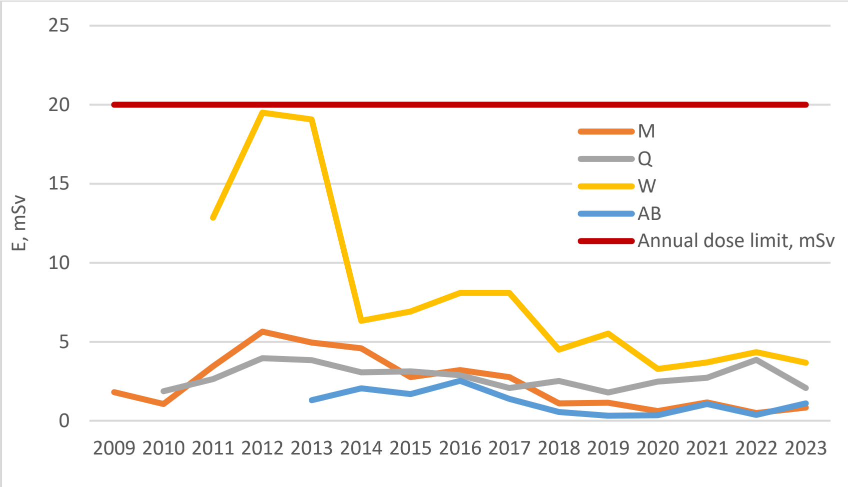

Fig. 10. The trend over the years of individual annual effective dose for four of the interventional cardiologists with the longest experience in the department and the longest time working together.

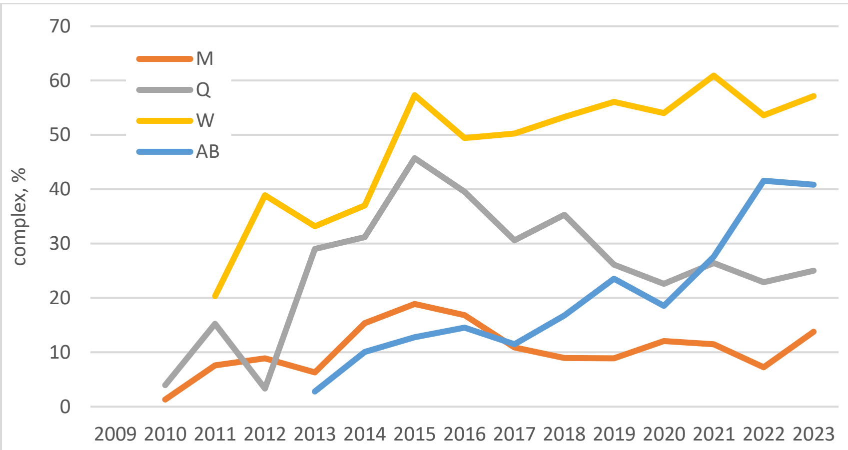

Figure 11. The trend over the years of the percentage of complex procedures performed for the four interventional cardiologists with the longest experience in the department and the longest time working together.

Typical patient doses during the period (2006-2023)

Table 19 presents the typical patient doses for CA and PCI interventional procedures that are periodically prepared in the department. The establishment of typical doses started in 2006, and the frequency of their establishment follows trends in staff changes, the technical condition of the equipment and changes in the complexity of procedures.

Table 19. Typical patient doses from CA and PCI procedures in the Department of Invasive Cardiology for the period 2006-2023. P_{KA}, FT and $K_{a,r}$ values are presented as median values.

Procedure	CA			PCI		
Year	P_{KA}, Gy.cm^2	FT, min	$K_{a,r}$, mGy	P_{KA}, Gy.cm^2	FT, min	$K_{a,r}$, mGy
2006 (Bicor)	30,9	4	-	47,2	8,6	-
2009 (Bicor)	36	4,8	-	110	22	-
2009 (Axiom Artis)	40	6,7	-	146	21,3	-
2015 (Axiom Artis)	22,7	2,2	300	71,7	7,6	1085
2015 (Toshiba)	23,8	2,4	320	80,9	7,7	1150
2017 (Axiom Artis)	23,8	2,3	195	81,2	7,4	722
2017 (Toshiba)	22,6	2,3	339	69,9	7,8	1152
2019 (Axiom Artis)	29	2,3	288	78,3	7,7	1000
2019 (Toshiba)	28,4	2,3	285	83,2	7,6	986
2023 (2xArtisQ)	14,8	2,1	234	51,2	7,4	795

Analysis of data on the number of procedures performed

The total number of procedures performed in the department increased from 3018 in 2007 to a peak of 3256 in 2008, followed by a decline to 2235 in 2012, When the COVID-19 pandemic started in Bulgaria (at the end of March 2020), due to the implemented restrictions, there was a significant reduction in the number of interventional and diagnostic procedures performed in 2020 and 2021. Routine work in the department was restored in 2022, reaching the same steady workload as before the pandemic.

Analysis of the results shows that between 2007 and 2012, the relative proportion of procedures categorised as complex ranged from 8-14%. In 2013, the department became a chronic total occlusion (CTO) training centre with two CTO experts, resulting in a significant increase in the proportion of complex procedures performed, accounting 25% of interventional procedures performed. Since 2014, there has been little fluctuation in the relative proportion (18%-27%, average 21%) of complex to interventional procedures.

Analysis of individual dosimetry data and procedures performed

First period (2007-2009)

Figure 6 and Figure 7 show that there was a three (2007) to seven (2009) fold difference in the total number of procedures performed by interventional cardiologists over the years. Extremely large variations are observed in the number of complex procedures performed between different operators: a 39-fold difference in 2007, 19 (2008) and 14 (2009). Two cardiologists differed significantly in the relative percentage of complex procedures performed compared to the others: 40% (B) and 44% (C) in 2007, 44% (B) and 30% (C) in 2008, and 44% (B) and 43% (C) in 2009. The majority of the remaining operators performed less than 10% of the complex interventions in the ward: (A), (D), (E), (G), and (L) in 2007, (A), (E), (G), (H), (I), and (L) in 2008, and (E), (G), (H), (I), (J), (K), and (L). The others perform between 10 % and 20 % of the complex procedures. The highest observed percentage of the number of procedures performed individually by a single operator was 24% (C) for this period.

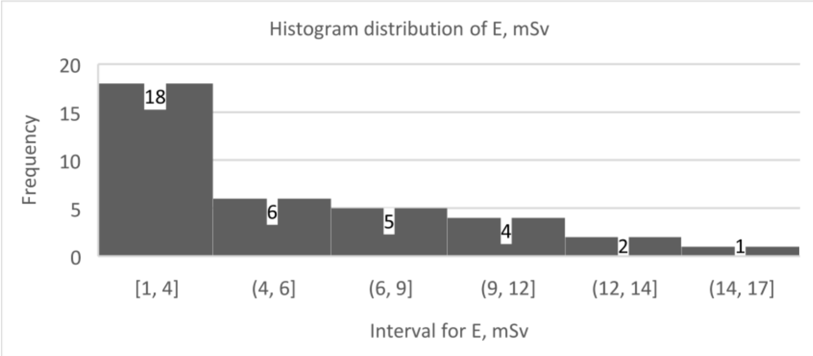

Fig. 12. Histogram representing the frequency distribution of the individual effective dose for the period (2007-2009).

Figure 12 shows the frequency distribution of individual effective dose for the period (2007-2009). Most of the reported values, 18 out of 36, from the individual dosimetry monitoring are in the range below 4 mSv/year. Values higher than 6 mSv/year were recorded for 4 interventional cardiologists in 2007, for 4 cardiologists in 2008 and for 5 cardiologists in 2009. An individual dose value of 6 mSv is defined as the level of investigation at which a full assessment of the radiation protection conditions during the employee's routine work should follow and corrective action is suggested. Operator (C), who performed the highest number of procedures in 2007 and the highest proportion of complex procedures, had the highest dose value of 17.1 mSv. Higher doses for the period were observed for (D), (G), (H), (I) and (J), who were either in the process of specialisation or with minimal work experience in the specialty.

Second period (2010-2011)

This period was characterized by greater variation in the total number of procedures performed by individual interventional cardiologists, as well as in the relative proportion of complex procedures compared with the previous period (Figure 8 and Figure 9). The greatest variation occurred in 2010, when an entirely new team of eight interventional cardiologists joined the department and many of the specialists with more experience than in the previous period were no longer part of the team or progressively stopped working for the department. The distribution of procedures, whether diagnostic, interventional, complex or total, is at both ends of the range. Less than 10% of the annual procedures in the department were performed by 13 of the 19 cardiologists in 2010. The highest observed relative percentage of procedures performed individually by a single operator to the total number of procedures for the department was 35% (R), but was excluded from the final analysis due to refusal to wear their individual dosimeter. The same was observed for four other interventional cardiologists whose dosimeter readings were below the registration level of 0.10 mSv for X-rays and gamma-rays with energy less than 0.2 MeV according to Regulation 32. The largest percentage of procedures, 43%, were performed by (T), a highly experienced cardiologist.

In 2011, there was another more smooth change in the team members of interventional cardiologists in the department. The distribution between the total number of procedures performed per operator was relatively homogeneous in contrast to the previous year, with 7 of the 13 operators performing between 10% and 20% of all procedures. The largest percentage (31%) of procedures were performed by one of the most experienced cardiologists (X). The largest percentage of complex procedures in 2011 were performed by a cardiologist (F), 43%, who is at the top of his learning curve for high complexity procedures.

Figure 13 shows the frequency distribution of the individual effective dose for the period (2010-2011). Most of the reported values from the actual dosimeters worn, 17 out of 28, from the individual dosimetry monitoring are in the range below 3 mSv/year. Values higher than 6 mSv/year were recorded for 2 interventional cardiologists in 2010 and for 2 in 2011. Cardiologist (W) started his specialization in 2011 and specialized under (F), performing the procedures with the highest degree of complexity. Lack of sufficient experience, practice and training on radiation protection principles and methods for optimization, resulted in an individual effective dose of 12.9 mSv. The same cardiologist remained in the clinic during the next study period, and the dynamics of his work, experience, learning curve and professional exposure were studied in detail (Figure 10 and Figure 11).

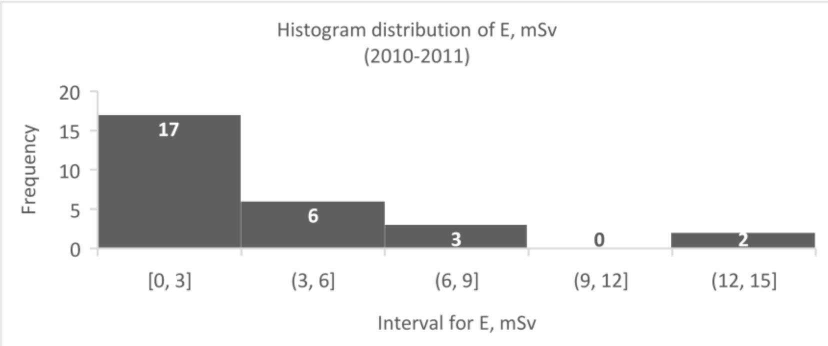

Fig. 13. Histogram representing the frequency distribution of the individual effective dose for the period (2010-2011).

Higher doses for the period were also observed for (D) and (I), who were either in the process of specialization or in the process of intensively improving their skills by increasing the volume and complexity of procedures performed.

Third period (2012-2023)

In the period (2012-2023), there was a strong increase in individual doses for some of the cardiologists as a consequence of changes in the organisation of the department and team members. There are two main reasons for this trend: the first is the uneven distribution of the number of patients among cardiologists, and the second is the uneven distribution of the most complex interventional procedures, which is shown in Table 18 and Table 17.

The period started with significantly fewer interventional cardiologists in the department. Some of the team members are long-standing employees in the department who have either worked continuously over the years or paused for the period (2010-2011) and returned afterwards. The second main group are residents who started their specialisation in the previous period. The typical pattern of this period is the formation of a new team, the building of teamwork and the small number of highly experienced operators. Extremely large variations were observed in the number of complex procedures performed between different operators at the beginning of the period, up to more than 14 times the difference, with a relatively homogeneous distribution of the total number of procedures performed by operator (10%-20%). One of the cardiologists with the most experience, (X), performed most of the procedures as a second operator in conjunction with the supervision of the residents and hardly participated as a first operator. This also contributes to the relatively lower individual dose for (X) of 5.2 mSv compared to the 19.5 mSv received by fellow (W) for a similar proportion of complex procedures in 2012. In 2013, the team was reduced by two experienced cardiologists, but a new specialist was added. At the same time, the department became a training centre for the treatment of chronic total occlusions (CTO) with two CTO experts in the same year, resulting in a highly inhomogeneous distribution of the number of complex interventions and individual doses received. CTO cases are complex coronary interventions that result in increased radiation exposure and prolonged fluoroscopy time. According to the EuroCTO Club, the treatment of patients with CTO is associated with additional training and greater experience. 82 %

of complex procedures are performed by (F, CTO expert) with an annual effective dose of 12.4 mSv, 33 % by (W, specialist-CTO expert) with 19.1 mSv and 29 % by (Q) with 3.8 mSv. For the cardiologist (W), Figure 10 and Figure 11 shows a distinct trend in increasing annual effective dose up to 19.5 mSv in the years of his specialization, as recorded by a dosimeter worn under the radiation protection apron, the value being close to the regulatory dose limit of 20 mSv per year. The two consecutive years with too high levels of occupational exposure for (W) led to periodic audits in the procedures used, exposure parameters and operating technique. After an exposure level of 6 mSv has been exceeded by any member of staff, a discussion is arranged about possible causes, an analysis of the type of procedures for the reporting period and an investigation into options for optimising radiation protection. The optimization of practice, the experience gained not only from the technique of performing the procedure from a clinical point of view, but also from the application of basic radiation protection methods, has led to a gradual decrease in individual doses with a continuing trend towards an increase in the number of complex procedures (Figure 12, Figure 13). The performance optimization curve of (W) is graphically demonstrated by a steep decline in individual doses until a plateau is reached, despite a continuous smooth rise in the number of complex procedures performed. A similar curve is demonstrated for the other three cardiologists, part of the established team in the department over the last ten years. The optimisation of performance in the department is also evidenced by the twofold reduction in typical patient dose values over the 17 year period studied (Table 17).

Figure 14 shows the frequency distribution of the individual effective dose for the period (2012-2023). Most of the reported values from the actual dosimeters worn during the years, 50 out of 82, from the individual dosimetry controls are in the range below 3 mSv/year. Values higher than 6 mSv/year were recorded 9 times during the last period, with the last recorded higher value in 2017.

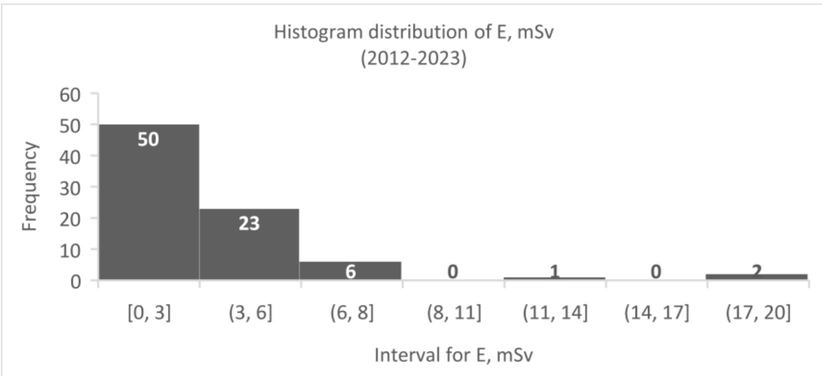

Fig. 14. Histogram representing the frequency distribution of the individual effective dose for the period (2012-2023).

All interventional cardiologists, part of the latter team that has proven to work well together over the years, have significantly improved their awareness of the potential risks for radiation-induced effects associated with interventional procedures. The results of the study suggest that when a newly formed team gains clinical experience, the focus also shifts towards optimizing procedures to reduce radiation exposure to patients and staff. The optimization process in the department was slow but consistent, starting with the routine application of basic methods to reduce the likelihood of skin injury. Any practical implementation of a methodology or process requires periodic training to raise awareness of the topic and the use of different strategies to put it into practice. Routine clinical protocols have been developed and approved for different types of interventional procedures in the department. Interventional cardiologists are well trained to understand and use the dosimetric information displayed on the display, and it is recorded manually in the patient's record. The routine recording of doses for each individual patient results in a reduction in patient doses, focusing the attention of specialists on typical values and also results in a reduction in individual staff doses. Understanding that the primary source of medical staff exposure results from patient-scattered radiation, and that reducing patient dose is the operator's personal responsibility and results in a proportional reduction in individual staff exposure, has led to a significant optimization of practice in the department (Figure 10, Figure 11 and Table 17). All patients are informed of the risks associated with the use of X-rays during procedures and monitored for radiation-induced injury when necessary.

Most of the reported values from individual dosimetry monitoring are in the range below 4 mSv/year, which is consistent with the summarised results from other studies.

Conclusion

Occupational radiation doses in the interventional cardiology department have been significantly reduced by the application of basic tools and techniques to optimize radiation protection.

The observed trends have led to actions for better organization and quality assurance. The radiation protection awareness programme introduced in 2014 resulted in between a 2 and 6 fold reduction in individual effective dose for some members of the interventional cardiology team in the department and a 2 fold reduction in typical patient doses.

4.7. Methodological guideline for verification of dose indexes in angiography units and mobile C-arm fluoroscopy units.

Verification of dose indexes on the display of equipment used for interventional procedures ensures timely operator alerting and reliable patient monitoring for possible radiation-induced effects after high-dose procedures. Up to now, in Bulgaria the verification of the displayed dose values is not a mandatory element of the commissioning and routine quality control tests of equipment used for fluoroscopy examinations. The proposed detailed guidance is based on material provided by the IAEA in connection with participation in an international study of patient doses and tissue reactions from FGI procedures. This is the first time that the procedure has been described in this way as part of participation in an international study. Periodic quality control using detailed procedures and performed using the same methodology ensures reproducible results and supports the work of medical physicists.

A detailed methodological guideline for the verification of dose indexes in angiographic devices and mobile C-arm devices has been developed and proposed as an appendix. in the thesis.

5. Conclusions

1. The first two documented cases of radiation-induced skin injuries in Bulgaria and their late diagnosis led to the following conclusions:

a. Awareness of interventional specialists about the possibility of radiation-induced skin damage was insufficient at the time of the study;

b. Lack of awareness and knowledge among general practitioners, dermatologists and surgeons who follow up cases of skin injuries leads to misdiagnosis and untimely diagnosis and suffering for the patient;

c. At the time of the study, there were no mechanisms to monitor patients with relatively high doses of medical radiation in diagnostic imaging;

d. The medical physicist has an important role to play in diagnosing harm and taking action to investigate causes and change practice;

e. Training and availability of information materials on radiation-induced tissue injuries are important.

The need to introduce the proposed management algorithm for patients at increased risk for radiation-induced tissue injury, including identification, follow-up, timely diagnosis and treatment if injury occurs, has been demonstrated. Informing and following up the patient within 3 months after a procedure in which dose thresholds are exceeded is essential for the recognition and appropriate and timely treatment of radiation-induced effects. An improved quality assurance and dose monitoring system needs to be implemented in every department where complex interventional procedures are performed.

The correct recognition, classification, prevention and treatment of radiation-induced effects due to medical exposure requires the incorporation of this knowledge into training programmes for medical professionals in radiation protection and quality assurance in imaging.

2. A survey of patient doses for the most commonly performed interventional cardiac and vascular FGI procedures in several departments in Bulgaria and comparison with published national and international diagnostic reference levels showed that there were patients in each of these departments with an exceeded follow-up level for skin effect for the PCI procedure. Routine recording and tracking of patient doses leads to caution by medical staff regarding typical doses for procedures performed with the x-ray equipment. Self-recording of patient doses by the operator who performed the procedure leads to optimization of radiation protection and personal practice, and facilitates timely detection of a potential technical problem that could lead to increased radiation exposure for staff and patients.

3. The study of patient doses for invasive electrophysiological procedures (diagnostic and ablations) with two different levels of complexity identified procedures with the potential to optimize patient protection, and provided a basis for comparisons with future studies on the topic. The proposed NDRLs provide an objective criterion for optimizing EP procedures with different levels of complexity and dose reduction. The analysis showed that despite the use of navigation and mapping without the use of X-ray, median PKA values in complex EAM-guided ablations were still almost three times higher than in simple ablations without EAM. These results indicate the need for further optimization of EP procedures and protocols.

Increased attention is required for patients who, in addition to the EP procedure, often require X-ray imaging modalities such as cardiac CT, coronary angiography, etc.

4. The study in the field of endovascular or hybrid revascularization of the lower limb (below the inguinal ligament) and in the area of the aortoiliac segment shows a strong relationship between the type and number of vascular accesses and the patient's dose. The conclusion is based on a small number of cases in a single center and requires further study. There was also a significant increase in dose with increasing procedure complexity and number of stents implanted per procedure. In cases of long and complex occlusions, implantation of only one long stent should be considered. Another important factor influencing patient dose is related to the knowledge, experience and individual practice of the operator performing the procedure.

In all types of endovascular and hybrid procedures, regardless of the degree of complexity, PKA and PSD values are significantly lower compared with levels to monitor patients for potential radiation-induced skin injuries. The study results showed that PSD values for a single procedure were between 2 and 12 times lower than accepted follow-up levels, and they were not reached even in patients with repeated (more than one) procedures over a one-year period.

5. The study of 17-year dynamics in individual dosimetric control of medical staff and typical patient doses in one interventional cardiology department in Bulgaria, strongly demonstrates the positive effect of the introduction of a radiation protection and quality assurance program and its periodic updating. The radiation protection awareness programme introduced in 2014 has resulted in a reduction over the years of the individual effective dose, for some members of the interventional cardiology team in the department, by a factor of 2 to 6, and a reduction of up to 2-fold in typical patient doses.

The results suggest that as a newly formed team gains clinical experience, the focus also shifts toward optimizing procedures to reduce radiation exposure to both patients and staff. Optimization is a slow but consistent process that begins with the routine application of basic radiation protection methods and monitoring of patient doses. The practical implementation of a methodology or process requires periodic training to raise awareness of the topic and the use of different strategies to put it into practice. Years of collaborative work between medical physicist and interventional cardiologists has led to a better understanding of dosimetric quantities and their monitoring during procedures. The routine recording of doses for each patient has led to a focus of specialists on typical dose values and a reduction in patient exposure as well as a reduction in individual staff doses. Reducing patient dose is the personal responsibility of the operator and results in a proportional reduction in individual staff exposure.

6. A detailed methodological guideline to assist the medical physicist in verifying dose indices for angiographic devices and mobile C-arm scopic devices has been proposed and is ready for national implementation. Periodic quality control using detailed procedures and performed according to the same methodology ensures reproducible results and supports the work of medical physicists.

6. Contributions

Original

1. For the first time in the country, a new management algorithm and instructions for follow-up of patients at increased risk for radiation-induced tissue injuries have been proposed and successfully implemented in practice. They include criteria for follow-up, identification, timely diagnosis and treatment in case of injury. The algorithm has been promoted at scientific forums, postgraduate training courses, radiation protection and competency to work with ionising radiation.
2. The percentage of patients at risk of developing radiation-induced effects has been monitored in leading departments and training centres in the country. The quality assurance, dose tracking and radiation protection programme in place has increased awareness and interest of medical professionals in optimising practice, and is expected to minimise the observed number of cases of this type.
3. For the first time in Bulgaria, diagnostic reference levels for invasive electrophysiological procedures (diagnostic and ablative) with different levels of complexity have been proposed and actions have been implemented to optimize procedures and reduce radiation exposure.
4. The first detailed study of patient radiation exposure and practice in endovascular or hybrid revascularization of the lower limb (below the inguinal ligament) and in the aortoiliac segment was performed. Results have been presented in scientific forums, generating constructive discussions and increased interest in radiation protection among vascular surgeons and interest in participating in a larger study.

Confirmation

5. Analyzing the 17-year dynamics in individual dosimetric monitoring of medical staff and typical patient doses in an interventional cardiology unit, strongly demonstrates the effect of systematic monitoring of patient and staff doses and implementation of radiation protection and quality assurance programs.
6. It was demonstrated the importance and outcome of the active participation of medical physicists in the interventional radiology clinical teams.

Methodological

7. A guideline for verifying dose indexes in angiography and mobile C-arm fluoroscopy units is developed as part of an expanded guideline to assist medical physicists in ensuring reproducible results in periodic quality control.

7. Publications in connection with the thesis

Publications in foreign scientific journals and journals indexed in world databases:

1. **Kostova-Lefterova D.**, Vassileva J, Rehani MM. Lessons from two cases of radiation induced skin injuries in fluoroscopic procedures in Bulgaria. J. Radiol. Prot. 37 (2017) 938–946 (9PP). IF: 1.99 ISSN: 1361-6498; ISSN: 0952-4746. **IF 1.5**
2. **Kostova-Lefterova D**, Nikolov N, Stanev S, Stoyanova B. Patient doses in endovascular and hybrid revascularization of the lower extremities. Br J Radiol 2018; 91: 20180176. IF: 1.814 ISSN: 0007-1285; eISSN: 1748-880X. **IF 1.939**
3. Stanev S, **Kostova-Lefterova D**, Dineva S. Patient doses in endovascular and hybrid revascularization of aortoiliac segment. Br J Radiol. 2021 Dec;94(1128):20210439. doi: 10.1259/bjr.20210439. Epub 2021 Oct 5. PMID: 34591595; PMCID: PMC8631020. **IF 3.629**
4. **Kostova-Lefterova D**, Shalganov T, Stoyanov, M, Traykov V, Boychev D, Protich M, Bonev N. Proposing National Diagnostic Reference Levels for Electrophysiology Studies and Catheter Ablation Procedures in Bulgaria. Phys Med. 2023 Apr;108:102572. doi: 10.1016/j.ejmp.2023.102572. Epub 2023 Mar 28. PMID: 36989978. ISSN 1120-1797. **IF 3.4**

Publications in scientific journals in Bulgaria:

5. Zagorska A., Ivanova D., **Kostova-Lefterova D**., Simeonov F., V. Gelev, I. Bogov, H. Mateev, A. Aleksandrov, I. Jeleva, N. Stoyanov, K. Romanova, I. Dyakov, V. Krastev, D. Vassilev, V. Ivanov. Multicentric survey of patient doses in fluoroscopy guided diagnostic and interventional cardiac procedures: comparison with Diagnostic Reference Levels and follow-up levels for patients at risk for radiation induced skin effects. Bulgarian Cardiology 2020, 26(1): 44-52. https://doi.org/10.3897/bgcardio.26.e52193. ISSN 2683-1015 | ISSN 1310-7488
6. **Kostova-Lefterova D.**, Georgiev D. Radiation-induced effects of medical exposure – patient follow-up, recognition, classification, prevention and treatment. Science Cardiology, 2016, 4:188-193. ISSN 1311-459X
7. **Kostova-Lefterova D.** Two cases in Bulgaria of radiation skin injury after percutaneous coronary intervention. Science Cardiology. 2015, 6:326-328. ISSN 1311-459X

8. Scientific announcements in connection with the thesis

I. List of abstracts from scientific forums abroad published in relevant abstract supllements:

1. **Kostova-Lefterova D.**, I. Dyakov. Comparison of Practice and Patient Doses in Interventional Radiology and Cardiology Procedures Performed In Two University Hospitals. Physica Medica, 2014, Volume 30, Supplement 1, Page 13. **IF 2.403**
2. **Kostova-Lefterova D.** Estimating patient dose and radiology practice from interventional cardiology procedures in the paediatric cardiology department in bulgaria. Physica medica, 2016, volume 32: 183. **IF 2.403**
3. **Kostova-Lefterova D.**, H. Mateev, A. Aleksandrov. Comparison Of Occupational Doses And Practice Of The Interventional Cardiologists In One Department. Physica Medica, 2016, Volume 32: 253. **IF 2.403**
4. **Kostova-Lefterova D.**, H. Mateev, A. Aleksandrov, E. Ivanova, J. Vassileva. A 9-Years Follow-Up Of Occupational Radiation Doses In An Interventional Cardiology Department. Physica Medica, 2016, Volume 32: 262. **IF 2.403**
5. **Kostova-Lefterova D.**, H. Mateev, A. Aleksandrov, I. Bogov, K. Genova, N. I. Traykova, D. Ivanova, A. Zagorska. Implementation of system for follow-up of patients undergoing high dose interventional procedures. ECR 2017/EuroSafe Imaging 2017 / ESI-0049. http://dx.doi.org/10.1594/esi2017/ESI-0049. Vienna, Austria, 01-05 March 2017.
6. **Kostova-Lefterova D.**. Performing procedure appropriately: whose role is it? ECR 2019/ A-0617, C 17 Invited Speaker. Team approach and safety culture in the imaging department. Vienna, Austria, 27 February-03 March 2019.
7. **Kostova-Lefterova D.**, S. Stanev, D. P. Ivanova, B. Chesmedzhieva, S. E. Dineva, E. Georgiev, G. Rashev. Comparison of patient exposure and routine protocols for multidetector computed tomography angiography examinations of patients with peripheral artery disease. European Congress of Radiology, ECR 2022, July 13-17, Vienna. Categories: Physics in Medical Imaging, RPS 213 - Advances in CT and radiation protection
8. **Kostova-Lefterova D**, Stanev S, Ivanova D, Rashev G, Nikolov N, Cheshmedzhieva B, Aleksandrov A, Karamfiloff K, Martinov I, Dineva S. Patient exposure during lower extremity endovascular and hybrid procedures – a multicenter study. Poster presentation. 4th European Congress of Medical Physics. 17-20 August 2022. Dublin, Ireland. Physica Medica. Volume 104, Supplement 1, December 2022, Page S85.
9. **Kostova-Lefterova D**, Mateev H, Aleksandrov A, Ivanova E, Vladimirov G, Bankova A. A 14-years follow-up of occupational radiation doses in an interventional cardiology department. Oral presentation. 4th European Congress of Medical Physics. 17-20 August 2022. Dublin, Ireland. Physica Medica. Volume 104, Supplement 1, December 2022, Page S26

II. List of abstracts from scientific forums in Bulgaria, published in the relevant supplements of abstracts:

1. **Kostova-Lefterova D**., Milchev A. Two cases of radiation injuries of the skin after percutaneous coronary intervention. XVI Congress of the Bulgarian Radiology Association. September 25-27, 2015, Plovdiv.
2. A. Zagorska, **D. Kostova-Lefterova**. Radiation-induced effects in interventional cardiology. VIII National Congress of Interventional Cardiology November 9-12, 2017 Grand Hotel Plovdiv, Plovdiv.
3. Stanev S., **Kostova-Lefterova D.**, Nikolov N., B. Stoyanova, M. Stankev. Evaluation of radiation exposure in patients after endovascular or hybrid revascularization of the lower extremity. XXI National Conference of BNDSEHA with international participation. Kempinski Hotel Grand Arena Bansko, Bansko, October 12-15, 2017. Summary in Angiology & Vascular Surgery, 2017:2.
4. Zagorska A., **Kostova-Lefterova D**.. Radiation-induced effects in interventional cardiology. Invited lecture at the VIII National Congress of Interventional Cardiology, November 9-12, 2017, Grand Hotel Plovdiv, Plovdiv.
5. Zagorska A., D. Ivanova, **D. Kostova-Lefterova**. Patient skin dose map for x-ray controlled procedures. XXXVIth Colloquium: Physics in the protection of man and his environment. "Divite petli" hotel, Gyolechitsa area, June 29-July 1, 2018.

6. Zagorska A., Ivanova D., **Kostova-Lefterova D.**, V. Gelev, N. Rifai, V. Krastev, I. Zheleva, N. Stoyanov, K. Romanova, J. Vassileva. Multicentric study on patient doses in diagnostic and interventional cardiology and patient follow up: preliminary results. Physica Medica - European Journal of Medical Physics (EJMP) 2019, (68) P156
7. Ivanova D., **Kostova-Lefterova D.**. Initial results from a survey of the radiation dose to patients undergoing percutaneous transluminal angioplasty. Folia Medica 62 (3): 31, 2020. https://doi.org/10.3897/folmed.62.e60412
8. Zagorska A., Ivanova D., **Kostova-Lefterova D.**, F. Simeonov, K. Romanova, I. Dyakov. Multicentric survey of radiology practice and patient doses in fluoroscopy guided diagnostic and interventional cardiac procedures. Folia Medica 62 (3): 33-34, 2020. https://doi.org/10.3897/folmed.62.e60412
9. **Kostova-Lefterova D**. Radiation protection during FGI procedures. **Invited speaker**. Xth Anniversary Congress on Interventional Cardiology, September 30 - October 2, 2021, Congress Center, Burgas.
10. Stanev S., Cheshemedzhieva B., **Kostova-Lefterova D**.. Comparative analysis of radiation and contrast doses in patients who underwent interventional aorto-arteriography and computed tomography angiography. XXV National Annual Conference of BNDSEHA with international participation, Pamporovo Congress Center, 30.09-02.10 2021.
11. Stanev S., Cheshmedjieva B., **Kostova-Lefterova D.**, Advantages and disadvantages of interventional aortoarteriography compared to computed tomography angiography. Scientific conference of SUB - Plovdiv branch, "Science Days 2021" November 25 - 27, 2021, Plovdiv. Section "Clinical Medicine"
12. **Kostova-Lefterova D**. Role of radiation technologists/radiographers in the DRL - the importance to understand the dosimetry quantities for adequate collection of data and alarming if something suddenly changes (examples). Invited Speaker: SV-TUR9024-EVT2301609 - TC Scientific Visit on the methodology of establishing diagnostic reference levels and their use for optimization of patient radiation protection - Sofia, Bulgaria 23 October to 3 November 2023.
13. **Kostova-Lefterova D.** Examples from previous survey and clinical work -Comparing survey results with examples of improved practices. Invited Speaker: SV-TUR9024-EVT2301609 - TC Scientific Visit on the methodology of establishing diagnostic reference levels and their use for optimization of patient radiation protection - Sofia, Bulgaria 23 October to 3 November 2023.
14. **Kostova-Lefterova D.**, Simeonov F. Examples of other countries - good and bad practice. To compare or not to compare? How do we communicate our results to motivate the use of DRLs. Invited Speaker: SV-TUR9024-EVT2301609 - TC Scientific Visit on the methodology of establishing diagnostic reference levels and their use for optimization of patient radiation protection - Sofia, Bulgaria 23 October to 3 November 2023.
15. **Kostova-Lefterova D**. Personal dosses in interventional radiology and the role of x-ray technician. Example of 15 years in practise. Invited Speaker: SV-TUR9024-EVT2301609 - TC Scientific Visit on the methodology of establishing diagnostic reference levels and their use for optimization of patient radiation protection - Sofia, Bulgaria 23 October to 3 November 2023.
16. **Kostova-Lefterova D**. Patient follow-up in high-dose procedures. Invited Speaker: SV-TUR9024-EVT2301609 - TC Scientific Visit on the methodology of establishing diagnostic reference levels and their use for optimization of patient radiation protection - Sofia, Bulgaria 23 October to 3 November 2023.
17. **Kostova-Lefterova D.**. Patient dose studies and DRLs: Bulgarian experience. Invited speaker: National course on radiation protection and optimization in fluoroscopy guided interventional (FGI) procedures. 4-8 December, Sofia, Bulgaria.
18. **Kostova-Lefterova D.**. Implementation of follow-up programme: Experience from Bulgaria. Invited speaker: National course on radiation protection and optimization in fluoroscopy guided interventional (FGI) procedures. 4-8 December, Sofia, Bulgaria.