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RUSSIAN PRACTICAL GUIDANCE ON RADIOLOGICAL SUPPORT FOR JUSTIFICATION OF X-RAY AND NUCLEAR MEDICINE EXAMINATIONS

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An important part of the justification process is assessment of the radiation risks caused by exposure of a patient during examination. The authors developed official national methodology both for medical doctors and sanitary inspectors called 'assessment of radiation risks of patients undergoing diagnostic examinations with the use of ionizing radiation'. The document addresses patients of various age groups and a wide spectrum of modern X-ray and nuclear medicine examinations. International scale of risk categorisation was implemented by the use of effective dose with account for age dependence of radiation risk. The survey of effective doses in radiology, including CT, mammography, and intervention radiology, and nuclear medicine, including single-photon emission tomography and positron emission tomography, for patients of various age groups from several regions of Russia was used for the risk assessment. The output of the methodology is a series of tables for each diagnostic technology with lists of examinations for three age groups (children/adolescents, adults and seniors) corresponding to various radiation risk categories.

INTRODUCTION

Radiological examination of a patient is justified by the opportunity of obtaining the image of the patient's organs or other information that will lead to the proper diagnosis and the subsequent treatment. This is regulated by the medical guidelines, sometimes in the form of national or regional documents, e.g. from the European Union[1]. These guidelines are based on the principle that the diagnostic benefit of examinations is obviously superior to the possible detriment to the patient from the medical exposure.

However, this issue deserves attention for higher-dose procedures, sometimes for individual patients. This is most obvious considering the deterministic effects of ionising radiation (skin and underlying tissue injury), which are occasionally caused by interventional examinations under X-ray control[2]. This is also true for other higher-dose examinations such as X-ray computed tomography (CT), single-photon emission tomography (SPECT), positron emission tomography (PET) and the combinations of them, especially if they are repeated for the same patient. What is meant here is the potential increase in the radiation risk of the stochastic effects, such as cancer and hereditary diseases.

Decision to perform a certain radiological examination is taken by a referring physician and a radiologist. Thus, they should have a clear view on the risk connected to the radiological examinations. By Russian Federation state law, it is obligatory to inform a patient about the dose for examination and the corresponding risk[3]. There are available Russian regulations on the assessment of the effective dose to the patient from the X-ray[4] and nuclear medicine[5] studies, but the risk assessment and interpretation present difficulties.

The current study aims at development of a scientifically based but simple and practical method for assessment of the radiation risk for stochastic effects for patients of different age and gender, undergoing radiological examinations. This method can be used in the process of the justification of an examination for a certain patient or a group of patients, as well as for informing the patients. The method is intended for the radiologists, nuclear medicine specialists, referring physicians and for inspectors of the regulatory bodies.

METHODOLOGY

To select a proper and easy method for patient's radiation risk assessment, the risk values related to the common radiography examinations of the skull, chest, abdomen and pelvis were calculated. Lumbar spine radiography and mammography were additionally selected as the examinations with the definite age and gender effect. Mean absorbed doses in the irradiated organs and tissues and the effective doses for adult and paediatric patients were calculated based upon the procedure parameters collected in St. Petersburg hospitals[6]. The methodology of dose calculation using software 'EDEREX' (similar to PCXMC, Finland[7]) developed at the Institute of Radiation Hygiene is described by Golikov *et al.*[8]. For those six X-ray examinations, the lifetime detriment-adjusted stochastic radiation risk was assessed[9]. Two methods were used: (a) considering age and gender, using mean organ doses and age- and gender-dependent radiation risk coefficients[9, 10]; (b) formally—using the effective dose, multiplied by nominal radiation risk coefficient, equal to 5.7×10^{-5} mSv^{-1} for the whole population, regardless of age and gender, and 4.2×10^{-5} mSv^{-1} for adults of both gender in working age (18–64 y)[9]. Methods of calculations are presented in detail by Balonov *et al.*[6] and Balonov and Schrimpton[11].

As the next step, the ratios of organ-dose-based radiation risk due to the X-ray examination for various patient groups to risk estimation based on the effective dose were calculated[9]. The more realistic risk values assessed by means of organ doses are higher by a factor 1.4–2.6 for children, lower by a factor of 1.6–3 for all adults and the risks for senior people are lower by about an order of magnitude. Overall, the radiation risk for whole-body irradiation is almost by 40 % higher for women than men[6, 11].

The largest underestimation of risk (by a factor of 4), when effective dose was used, occurred in the case of chest radiography of girls, where both radiosensitive lungs and breast are exposed. In the case of mammography on adult women, the risk assessed via effective dose is also underestimated by a factor of 1.5, since the effective dose does not account for patient gender[9].

A similar, more wide-scale study was conducted in the UK for 20 types of X-ray examinations, including radiography, fluoroscopy (with interventional examinations) and computer tomography[11, 12]. In these studies, the lifetime risks of radiation-induced cancer for the patients of different age and gender were assessed, based on the typical organ doses and the corresponding risk coefficients[9], and referred the risk values to the corresponding effective doses. The risk values assessed by means of organ doses are higher by a factor of 1.5–3.5 for children, slightly lower for all adults and the risks for senior people are lower by a factor of 2–10, compared with the risk values, assessed by the effective dose.

Results of those studies bring the following conclusions:

(a) Although the effective dose was not intended for the radiation risk assessment, and especially not for patients, a simple correction on patient's age makes it a useful instrument for the justification of the radiological examinations that was used in this study.
(b) For a rough radiation risk assessment, it is reasonable to divide the patients into three age groups: children and adolescents (<18 y), adults in the working age (18–64 y) and seniors (65+ y).
(c) Age-dependent multipliers of the nominal risk coefficients[9] should be applied to those age groups: 2 for children and adolescents, 1 for the adults and 0.1 for the seniors.
(d) Gender-dependent risk coefficient multipliers should not be applied due to the fact that radiation risk for women exceeds the radiation risk for men in average only by 40 %.

RESULTS AND DISCUSSION

For classification of the patient's lifetime health risk from medical intervention in the form of X-ray examinations, international risk value scale[13, 15], which is presented in the left column of Table 1, was used. These risk categories match the effective dose intervals, calculated using the risk coefficients with age-dependent multipliers given for the three age groups earlier—Table 1. Data from Table 1 were used to categorise X-ray examinations by the radiation risk level.

To determine the radiation risk category for patients from one of the three age groups undergoing a radiological examination, we need to know the effective dose value for that examination. In Russia, the effective dose for patients of the six age groups can be assessed using established methods for X-ray[4] and nuclear medicine[5] examinations. The effective dose value calculated by these methods and based on the examination parameters should be compared with the data provided in Table 1 for the matching age group. The leftmost column of the table would present the risk category characteristic for the matching group of patients for the planned or conducted examination.

Approximate risk category assessment due to the radiological examinations for the Russian patients from one of the three age groups can be performed using Table 1 and the typical effective dose values collected by the authors from the hospitals in different regions of Russia for the past 5 y[16–19].

The calculations were performed for the following types of radiological examinations and for the different body parts: conventional X-ray examinations (radiography, fluorography, fluoroscopy, mammography, osteodensitometry, etc.), CT, dental X-ray examinations, interventional diagnostic examinations, nuclear medicine planar examinations (scintigraphy, renography, etc.), nuclear medicine tomography examinations (SPECT, PET) and combinations of the CT and nuclear medicine examinations (PET/CT, SPECT/CT). Results are presented in the format of table set for the mentioned types of radiological examinations, where the categories of the lifetime

Table 1. Risk categories and corresponding ranges of effective dose (mSv).

Radiation risk, dimensionless	Effective dose range (mSv)		
	Children and adolescents (<18 y)	Adults (18–64 y)	Seniors (65+ y)
Negligible ($<10^{-6}$)	<0.01	<0.02	<0.2
Minimal (10^{-6} to 10^{-5})	0.01–0.1	0.02–0.2	0.2–2
Very low (10^{-5} to 10^{-4})	0.1–1	0.2–2	2–20
Low (10^{-4} to 10^{-3})	1–10	2–20	20–200
Moderate (10^{-3} to 10^{-3})	10–30	20–60	—

radiation risk match different radiological examinations for the different patient age groups. Two tables for X-ray and nuclear medicine tomography studies are given as examples.

The risk range for different CT examinations presented in Table 2 for the patients of the three age groups covers two orders of magnitude. Radiation risks for children and adults (<65 y) are classified as low and for the seniors as very low. There are no types of examination classified as associated with negligible and minimal risk. It is possible to achieve moderate radiation risk while conducting several CT examinations for children and adults (<65 y).

The risk range for different nuclear medicine tomography examinations for patients of the three age groups (Table 3) is more than two orders of magnitude. For the majority of the examinations, patients receive doses that match very low and low risks. However, for whole-body examinations with ^{67}Ga for neoplasia, patient's doses can approach 20 mSv, which is close to moderate risk level.

Table 2. Classification of X-ray CT examinations by radiation risk of patients of various age groups.

Radiation risk (dimensionless)	CT examinations		
	Children and adolescents (<18 y)	Adults (18–64 y)	Seniors (65+ y)
Very low (10^{-5} to 10^{-4})	—	—	Scull, chest, abdomen, pelvis and thigh
Low (10^{-4} to 10^{-3})	Scull, chest and abdomen	Scull, chest, abdomen, pelvis and thigh	—

For the modern SPECT or PET equipment, combined with CT scanner, X-ray exposure for certain procedures can create a patient's dose being similar to the dose from the radiopharmaceutical. In this case, some procedures (whole-body or a skeleton examination) will be assigned a higher-risk category (Table 3).

Prescription and conduction of the radiological examinations should be justified by clinical goals at first. However, we should compare the diagnostic benefits of the examinations with the radiation detriment it may cause, taking the alternative methods using non-ionising radiation into consideration.

When a patient is informed by a physician about the benefit of the planned radiological examination and the related radiation risk to make a decision whether to conduct it or not, one should compare the dose from the examination with the dose from the background exposure; and the radiation risk to the lifetime cancer incidence with anthropogenic risk factors for the matching age group.

The simple method proposed in this study does not pretend to a high accuracy of the radiation risk assessment for the patients. However, it might be sufficient for the radiological support for the justification of the radiological examinations, because this process is dominated by the clinical diagnostic considerations and the radiation risk factor plays the support role. Risk assessment result in the form of a risk category with an order of magnitude accuracy seems to be enough for the physicians.

That is why it is considered that it is possible to make a rough risk assessment based on the effective dose with the according age correction, although the effective dose is primarily a 'protection' quantity and not intended for the risk assessment[9].

It is possible to assess the lifetime risk of the long-term stochastic consequences for the patient of the gender G and the age of A from the medical exposure

Table 3. Classification of nuclear medicine tomography examinations by radiation risk of patients of various age groups.

Radiation risk (dimensionless)	Nuclear medicine examinations		
	Children and adolescents (<18 y)	Adults (18–64 y)	Seniors (65+ y)
Very low (10^{-5} to 10^{-4})	—	—	SPECT of heart, brain, whole body; PET of brain, whole body; PET/CT of brain, whole body
Low (10^{-4} to 10^{-3})	PET of brain, whole body; PET/CT of brain	SPECT of heart, brain, whole body; PET of brain, whole body; PET/CT of brain, whole body	—
Moderate (10^{-3} to 10^{-3})	SPECT/CT of skeleton; PET/CT of whole body	—	—

more accurately using the absorbed doses in the organs and tissues and their radiosensitivity dependence from age A using a linear non-threshold model. Method and results of such calculations as, for example, those published by Ivanov *et al.*[20] can be used for more accurate radiation risk assessment, for example, for research.

The methodical approach developed, as well as Tables 1–3 and the other tables for other types of radiological examinations, was used as the basis for the official Russian recommendations[21] intended for the health-care and sanitary service specialists.

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