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REVIEW

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Radiation Safety in Nuclear Medicine Procedures

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Abstract Since the nuclear disaster at the Fukushima Daiichi Nuclear Power Plant in 2011, radiation safety has become an important issue in nuclear medicine. Many structured guidelines or recommendations of various academic societies or international campaigns demonstrate important issues of radiation safety in nuclear medicine procedures. There are ongoing efforts to fulfill the basic principles of radiation protection in daily nuclear medicine practice. This article reviews important principles of radiation protection in nuclear medicine procedures. Useful references, important issues, future perspectives of the optimization of nuclear medicine procedures, and diagnostic reference level are also discussed.

Keywords Diagnostic reference level · Justification · Optimization · Nuclear medicine · Radiation safety

Introduction

Since the first use of I-131 for the treatment of thyrotoxicosis by Saul Hertz in 1941, nuclear medicine procedures have served as prerequisites in the diagnosis and treatment of various human diseases. Since the introduction of nuclear medicine in 1959, there has also been an explosive growth in nuclear medicine imaging and therapeutic procedures in Korea, especially in F-18 fluorodeoxyglucose positron emission tomography (FDG PET) and I-131 ablation therapy.

However, the disaster at the Fukushima Daiichi Nuclear Power Plant in 2011, which was a combined disaster involving a radiation accident, earthquake and tsunami, resulted in deep concerns and even social phobia about exposure to ionizing radiation. As a result, radiation safety emerged as a priority issue in medical fields using ionizing radiation, and is now extremely important as is the medical contribution of nuclear medicine in clinics.

In such perspectives, the Korean Society of Nuclear Medicine (KSNM) began standardizing nuclear medicine procedures, as the first important step of radiation exposure management. The first standard procedure for F-18 FDG PET was completed in 2013 [1]. Besides, the preliminary data of diagnostic reference levels (DRLs) for nuclear medicine procedures in Korea were also reported by the Medical Radiation Safety Research Center (MRSRC) [2–4]. Those recent products are encouraging, but most of the other aspects of radiation safety still remain uninvestigated in Korea. So, it is quite difficult to refer to the important principles of radiation protection when necessary.

In this article, the authors described principles of radiation protection in nuclear medicine and useful references about medical radiation exposure management. Because scientific data about the biological effects of ionizing radiation are converted into recommendations by the International Commission on Radiation Protection (ICRP), the main references are regarding ICRP recommendations. In addition, the recent efforts of the MRSRC in optimizing nuclear medicine procedures will also be discussed. However, detailed procedure standards and work processes are not included in the context, which should be adapted according to many institutional and individual factors.

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Principles of Radiation Protection in Nuclear Medicine

Medical Radiation Exposure

The ICRP Publication 60 [5] classifies radiation exposures into three categories: occupational, medical, and public. Medical exposures include not only those for medical diagnosis or treatment but also those exerted to individuals in the support and comfort of patients undergoing diagnosis or treatment. The definition of medical radiation exposure is more clearly defined in details by the ICRP Publication 105 [6] (Table 1).

It is inappropriate to apply dose limits—one of the three major principles of radiation protection—to medical radiation exposure. Because medical exposure is usually intended to directly benefit the exposed individual, further application of limits might be to the patient's detriment. However, this does not necessarily mean that medical radiation should not be included as an objective of radiation protection. It is still subject to the other two principles, justification of a practice and optimization of protection. Accordingly, benefits should be sufficient to offset the detriment caused (justification), and radiation exposure should be as low as reasonably achievable (optimization) [5]. The concepts of the two principles, issues, and efforts to follow them are described below.

Justification of Nuclear Medicine Procedures

Medical radiation exposure can be justified when the benefit exceeds the harm. The ICRP Publication 73 [7] defines the justification of medical radiation exposure as follows: "No practice involving exposures to radiation should be adopted unless it produces at least sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes". That is, selecting and performing nuclear medicine procedure should be subject to appropriate use criteria, and their appropriateness should be continuously reviewed.

Table 1 The definition of medical radiation exposures (ICRP Publication 105 [6])

Exposure of individuals for diagnostic, interventional, and therapeutic purposes, including exposure of the embryo/fetus or infant during medical exposure of patients who are pregnant or breastfeeding.
Exposures (other than occupational) incurred knowingly and willingly by individuals, such as family and close friends (or other comforters), helping either in hospital or at home in the support and comfort of patients undergoing diagnosis or treatment.
Exposures incurred by volunteers as part of a program of biomedical research that provides no direct benefit to the volunteers.

ICRP, International Commission on Radiation Protection

Choosing Wisely®, an initiative of the American Board of Internal Medicine, is a good example of justification issues in nuclear medicine procedures. It has recently announced a "Top 5" list of things that physicians and patients should question in nuclear imaging procedures [8]. According to the appropriateness of several nuclear imaging studies for specific indications, recommendations and discouragements were listed as follows: 1. Do not use PET/CT for cancer screening in healthy individuals. 2. Do not perform routine annual stress testing after coronary artery revascularization. 3. Do not use nuclear medicine thyroid scans to evaluate thyroid nodules in patients with normal thyroid gland function. 4. Avoid using a computed tomography (CT) angiogram to diagnose pulmonary embolism in young women with a normal chest radiograph; consider a radionuclide lung study ("V/Q study") instead. 5. Do not use PET imaging in the evaluation of patients with dementia unless the patient has been assessed by a specialist in the field. In the view of radiation protection, the recent insurance debate on the use of F-18 FDG PET in Korea is another good example. Diagnostic accuracy and prognostic benefit from F-18 FDG PET can vary according to different clinical situations. So further justification of F-18 FDG PET should be done on an individual cancer basis, regarding various clinical situations.

Optimization of Radiation Protection in Nuclear Medicine Procedures

Optimization refers to as the principle that the radiation dose to the patients should be "as low as reasonably achievable (ALARA)". The main efforts for optimization of radiation protection in nuclear medicine have been made in terms of the reduction of administered radiopharmaceutical activity. However, the balancing between maintaining efficacy and radiation protection is still quite difficult [7]. It results from that the benefits and potential harm from certain procedures using ionizing radiation can differ among countries, institutes, and/or patients. For example, the most appropriate administered dose of I-131 is still under controversy even after prospective randomized controlled trials demonstrated non-inferiority of low-dose I-131 ablation therapy [9, 10]. It should be kept in mind that an "optimal" dose is not a fixed dose throughout the world. Therefore, to keep the rule of "ALARA", economic and societal factors, as well as medical factors should be taken into account [6].

Particularly in nuclear medicine procedures, internal radiation is the most cumbersome issue for optimizing radiation protection. For quantification of internal radiation dose, the radiopharmaceutical pharmacokinetics and dosimetric calculation data are essential. SNMMI and the European Association of Nuclear Medicine have dosimetry task forces similar to those for procedure standards. Information about internal radiation exposure of patients in major nuclear imaging or therapeutic procedures can be obtained in their reports and guidelines [11, 12]. Besides, very detailed information of the dosimetry of radiopharmaceuticals used in humans is described in ICRP Publications 80 [13] and 106 [14]. They describe radiopharmaceuticals and organs for dose calculation, biokinetic models for human organs, organ weighting factors, and the calculations of absorbed and effective doses. The mass and blood content of each human organ are given in detail and appropriate kinetic models are shown in schematic figures. Specific information for several organs, such as glomerular filtration rate in the kidneys and biliary excretion in the liver and bile tracts, are also presented using appropriate models. In addition to the biokinetic modeling, dose monitoring and safety issues for medical workers are also included, as are breast-feeding interruption periods in patients following imaging with specific radiopharmaceuticals. These kinds of information provide us with useful guidance in clinical practice. For example, water intake and voiding can be recommended for the renal-excreted radiopharmaceuticals, such as I-131 and F-18 FDG.

Many joint campaigns (i.e., Image Wisely® and Image Gently®) regarding optimization issues are now available online. Image Wisely® includes comprehensive recommendations on patient dose, radiation dosimetry, selection of radiopharmaceuticals, image acquisition, and reconstruction methods for each imaging modality. Image Gently® specifically describes radiation protection issues in medical imaging studies for children and adolescents. Based on the association of low-level radiation in children or adolescents with cancer risk during adulthood [15–17], Image Gently® mainly focuses on the exposure by CT, which contributes approximately two-thirds of the pediatric medical exposure [18]. It recommends CT voltage and current be tailored for each child ("One size does not fit all."), while avoiding repetitive studies and scanning only the indicated area. Recommendations on nuclear imaging are also available, providing with the estimation of radiation exposure of adolescents and children in nuclear medicine.

Diagnostic Reference Level (DRL) as an Effort for Optimization of Radiation Protection in Nuclear Imaging

Despite the continuing efforts for optimization of radiation protection in nuclear imaging, the complexity and diversity of individual, physical/geometric, and biological factors make it more difficult to provide with a single, identical dose prescription guide to nuclear medicine professionals. As a result, no further instructions of tailoring individual radiation exposure in nuclear medicine have been provided. Optimization of radiation protection in nuclear medicine still depends on a dose prescription according to the patients' body weight or fixed dose tables.

DRL can additionally guide radiation protection, by setting the highest limit of administered radiopharmaceutical activity. Originally, reference levels were described in ICRP Publication 60 in 1991 [5], as values of measured quantities above which a specified action or decision should be taken. The concept of DRL was specifically defined in ICRP Publication 73 [7], a particular form of reference level that applies to dose management in medical imaging. It is distinguished from dose limit or dose constraint (Table 2). A discrete percentile cutoff (75th percentile within a community or country) is usually used as a DRL in X-ray studies [20] to indicate relatively over-exposured cases. DRL should be continuously modified as the practices change, so it can be the most up-to-date parameter of optimization of radiation protection in nuclear medicine imaging.

Table 2 Comparison among dose limit, diagnostic reference level, and dose constraint [19]

	Diagnostic reference level	Dose limit	Dose constraint
Objectives	Avoid unnecessary radiation in an imaging procedure	For screening (regulatory requirement)	Limit the range of options in optimization of certain occupation/operation*
Legal regulation	Non-regulatory	Regulatory	Non-regulatory
If exceeded	Investigation of the reason	Legal sanction	Investigation of the reason
Orientation	Prospective	Retroactive	Prospective
	Source-oriented	Individual-oriented	Source-oriented
Exposure situations	Existing Emergency (controllable)	Planned	Planned
Sources	Single source	Sum of all sources	Single source
Application to medical radiation exposure	Yes	No	No**

* ICRP Publication 60 [5]

** According to the statement "With regard to medical exposure of patients, it is not appropriate to apply dose limits or dose constraints, because such limits would often do more harm than good" in ICRP Publication 105 [6].

Specific Issues of Radiation Protection in Nuclear Medicine

Release of Patients after Radiopharmaceutical Therapy

The ICRP Publication 94 [21] has comments on the release of patients after I-131 ablation therapy, which is the most frequent radiopharmaceutical therapy in the world. It proposes a dose limit of 1 mSv/year for the public, and a dose constraint of 5 mSv/episode for relatives as acceptable limits. According to those values, legal restriction of patient isolation is applied at 33 mCi of I-131 and dose survey should be performed at 1-m distance and fulfill a dose rate < 70 uSv/hr in Korea. Moreover, it has recently become mandatory to provide appropriate instruction to patients who are treated with radioiodine and expected to deliver significant radiation to the public. However, the public radiation exposure from I-131 ablation therapy outpatient was reported to reach up to 6.5 mSv, which would exceed the public dose limit of 1 mSv/year [22]. So, the maximal activity of I-131 for outpatients is debatable. Besides, crowding of the patients after release from isolation ward can be a concentrated source of public radiation and environmental contamination. Especially in Korea, population density is quite high, which further limits the release of patients after I-131 ablation therapy. With these issues in hands, it should be remembered by nuclear medicine practitioners that the ICRP recommendations should be interpreted according to the environmental differences among countries. Although the maximal activity with which patients can be released is 1100 MBq for I-131 as standardized in the IAEA International Basic Safety Standards 1996 [23], the regulatory threshold for patient isolation—33 mCi in Korea—can be flexibly adapted to different levels when practically or socially needed.

Radiation Exposure of Pregnant Females and Fetus by Radiopharmaceuticals

The ICRP Publications 84 [24] and 88 [25] which were approved in 1999 and 2001, respectively, describe this issue in detail.

The radiation exposure of pregnant females and fetus can be considered in cases of two different radionuclides: those that do not cross the placenta and those that do. When a radionuclide that does not cross the placenta is administered to the mother, the radioactivity in maternal tissues acts only as an external source of irradiation to the fetus. So, the risk to the mother of not performing the examination is usually greater than the radiation risk to the fetus. Maternal hydration and frequent voiding can significantly reduce the fetal dose. On the other hand, in case of those cross the placenta such as I-131, the necessity or potential benefits by the procedures should be carefully weighed against the fetal risk of death or malformation by direct internal radiation to the fetus before the procedures.

In most cases, medical radiation exposure in diagnostic procedures does not increase the risk of fetal death, malformation or mental retardation. Therefore, fetal doses below 100 mGy should not be considered as a reason for terminating a pregnancy [24]. At fetal doses above 100 mGy, there can be fetal damage; its magnitude and type is a function of the dose and stage of pregnancy. Decreased intelligent quotient can occur as a consequence, especially when radiated within 8 to 25 weeks of the gestational age. The fetal risks of childhood cancer or leukemia are considered to be increased, but identical to those of children with radiation exposure [26–33]. There is no evidence to suggest that radiation exposure of parents' gonads increases childhood cancer or malformation, although contraception is usually recommended [34].

DRL for Optimization of Nuclear Medicine Procedures in Korea

Many countries have already established DRL for more optimized radiation protection in nuclear medicine procedures [35–42]. In Korea, the first DRL values for nuclear medicine imaging studies performed in Korea were reported by MRSRC in 2015 [2–4]. Now nuclear imaging studies in Korea have gained a potential guidance of radiopharmaceutical dose prescription which was not available before. The first DRL values were induced by a comprehensive review of the dosing data from 155 domestic hospitals. Additionally, expert discussions were also included as previously recommended [35], to maintain reasonable dose levels with acceptable image quality.

However, a DRL should not be regarded as a regulatory restriction against the practitioner's clinical decision. The administered activities are highly dependent on the procedures, so it is difficult to compare administered activities directly. Administered dose can highly vary among different regions, countries and indications, even when the sources used are identical [14]. Therefore, exceeding the DRL does not automatically mean that an examination is inadequately performed and meeting this level does not necessarily mean good practices [43]. DRL should be continuously reviewed and updated by sufficient discussion and agreement, especially in nuclear medicine. Continued collaborations among different institutions, societies, and governmental organizations are mandatory to optimize the nuclear medicine procedures in Korea.

Conclusion

Nuclear medicine is an essential part of medicine and will continue to grow in the future. Along with its advance, the important principles of radiation protection should also be firmly established in daily practice. The introduction of DRL can probably help the optimization of radiation protection in nuclear medicine. Eventually, the best and safest practices will be brought into clinical reality.

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Compliance with Ethical Standards

Conflict of Interest Sang-Geon Cho and Jahae Kim declare that they have no conflict of interest.

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Ethical Statement The study was approved by an institutional review board or equivalent and has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The institutional review board waived the need to obtain informed consent.

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