In this midterm plan at NIRS, the Medical Exposure Research Project (MER-project) has a mission to investigate the frequencies and doses of Japanese medical radiation uses, both diagnostic and therapeutic. The data are being collected in collaboration with local hospitals and academic societies. These data will be stored into a national database of medical exposure (details for this are under contemplation) and used as scientific and practical basis for the justification and optimization of radiation protection in medicine. They will also be provided for the UNSCEAR global survey project.

Five studies are being undertaken currently: (i) Estimations of examination frequencies and doses in X-ray CT, PET, and PET/CT in collaboration with local hospitals and academic societies; (ii) Organ dose estimations of patients for diagnosis and radiotherapy; (iii) Study of radiobiology in radiation use in medicine; (vi) Development of the method for risk-benefit communications in medicine and (v) Running an organization (J-RIME: Japan Network for Research and Information on Medical Exposure) for the exchange of information on radiation protection in medicine. Their short descriptions follow.

(1) Estimation of CT and PET doses

**CT dose.** We continued to collect the data of frequencies and dose (DICOM) in CT examinations in collaboration with local hospitals such as the National Center for Child Health and Development (NCCHD) Hospital and local hospitals in Chiba Prefecture in addition to the academic bodies including the Japan Radiological Society and Japanese Society of Radiological Technologists.

There are three methods to estimate the radiation dose by CT examination. One is to measure radiation dose directly for an anthropomorphic phantom inside of which many glass dosimeters are set. However, this method is expensive and time consuming, and therefore only a few hospitals have the capability to use it. The second method is to simulate the dose by Monte Carlo calculation, using a virtual mathematics phantom or MIRD phantom. This method inputs detailed scan parameters of each CT examination; however, it does not adapt to recent CT devices with auto exposure control (AEC). The third method is to multiply a coefficient (k factor, ICRP 102) by the CT scan dose (DLP; dose length product) to convert to effective dose. However this method also does not adapt to devices with the AEC or cannot calculate organ dose. The dose difference among these dosimetry methods was less than 30% for the data we collected.

**PET dose.** Internal doses in nuclear medicine have been estimated based on the MIRD method, which utilizes biokinetics of radiopharmaceuticals by using compartment models and specific absorbed energy data. For the internal dose estimation for FDG-PET examinations, a basic physiologically-based pharmacokinetic model (PBPK-model) has been modified and applied, which can consider the differences among patients who have different body sizes and metabolisms with the parameters of organ size, blood flow rate and so on. This would be useful for pediatric patients to estimate their internal doses. Currently, the adjustment of the model parameters has been performed to fit the biokinetics of the radiopharmaceuticals. We confirmed that the concentrations of the radiopharmaceuticals in the organs were dependent on the physiological parameters and it would be possible to reproduce the concentrations of the radiopharmaceuticals in the organs.

(2) Estimation of organ dose in radiotherapy of cervical cancers and childhood brain tumors

Recent progresses in radiotherapy can provide benefits to patients with extended survival. On the other hand, the secondary cancer risk by undesired irradiation to non-target healthy tissue is of concern to the survivors. We have developed the 3D system for estimation of non-target organ doses of the pelvic field using an anthropomorphic phantom and polymer gel dosimeter in radiotherapy for uterine cervical cancer, and compared results to the doses calculated by a treatment planning system. To evaluate 3D dose distribution directly in uterine cervical radiotherapy, the anthropomorphic phantom of a female pelvis was developed. Containers filled with polymer gel in the phantom simulated organs. Additionally, 4 or 5 glass dosimeters were set in each organ for the dose calibration. The standard treatment plan in Japan, for both external-beam radiotherapy (EBRT) and intra-cavitary brachytherapy (ICBT), was performed for the phantom. After irradiations the gel dosimeters were read with MRI, and the values were calibrated by the absorbed dose measured with the glass dosimeters set in each organ. This is the first study to show the 3D dose distributions in uterine cervical cancer radiotherapy using the female pelvic phantom and gel dosimeters.

Concurrently, we are establishing a method, which allows an
estimation of the dose distribution of pediatric patients after proton therapy. We performed a pilot test for the possible use of radio-activation of the phantom material for verification of the dose delivery distribution. We could provide an integrity verification of treatment planning and clinical examination devices. Now we are examining the reproducibility of dose verification.

(3) Dose Index Registry

The importance of tracking dose of patients with medical radiation exposure, which is the concept behind the IAEA’s “Smart Card/SmartRadTrack project”, has been acknowledged. We are developing an automatic dose collection system and database for CT examinations, which enables the transfer of DICOM data from devices of different manufacturers into one database. This system can collect CT radiation dose information in large quantities more correctly, compared to conventional questionnaire method. By 2015, we will have connected data acquisition tools to hospital PACS servers or CT devices of about 20 medical institutions directly, and will have collected information on 300,000 CT examinations for setting DRL in real time. In addition, this system is able to compare the data with those of other medical institutions, so we hope to reduce the variations of CT radiation doses among medical institutions. In the future, we will unite this database with the WAZA-ARI system that will calculate tissue/organ dose and effective dose in real time from collected radiation dose information and scan parameters. These data will be used for the analysis of not only radiation risk but for justification and optimization as well.

(4) WAZA-ARIv2

WAZA-ARI is the web-based open system for the CT dose calculation, which has been developed by Oita University of Nursing and Health Sciences and the Japan Atomic Energy Agency (JAEA). From December 2012, it has been installed in the web server of NIRS, and is available to the public for trial use.

This year, WAZA-ARI was improved to accommodate the patient’s age and body size (WAZA-ARIv2). For that purpose, we installed the simulation data of organ doses and effective doses for several phantoms on the WAZA-ARI system. And we added the database function that stores the calculation results in each facility in order to compare exposure levels of CT examinations done in each medical facility in Japan.

(5) Dialogue seminar with WHO on pediatric imaging

Increasing awareness and knowledge about radiation protection in medicine is necessary to answer the public’s concerns on health risks of low-dose radiation exposure including medical exposure. Toward that end, a dialogue seminar on benefit and risk communication of radiation imaging in pediatrics was held on December 7, 2014 in cooperation with WHO. Distinguished experts, including invited speakers from international agencies, shared their views on improving medical exposure protection in pediatrics with participants such as medical staff members, experts on radiation effects and radiation protection, and government officers. The main topics were global trends of medical exposure, dose assessment of medical exposure in Japan, radiation risk of diagnostic imaging in pediatric patients, benefits of radiation imaging in pediatrics, improving radiation protection in pediatric imaging, creating better communications between medical staff members and parents of patients, and creating a dialogue among pediatric imaging specialists. WHO is developing a tool on radiation risk communication to support risk/benefit dialogue in pediatric imaging. We are contributing by gathering users’ comments on this tool.

(6) J-RIME

For nation-wide exchange of the information on medical exposures, general meeting of the Japan Network for Research and Information on Medical Exposure (J-RIME) was held in April 2014, and it was decided to establish a Working Group for diagnostic reference levels (DRL) for each radiation examination. Group members from eleven academic organizations have discussed to determine DRL since August 2014 and summarized the DRLs of computed tomography, plain radiography, mammography, dental radiography, fluoroscopically-guided interventional procedures and nuclear medicine procedures in a report on March, 2015. This is the first trial to approach for national DRL of radiation imaging in Japan.

(7) WHO-CC symposium

In FY2014, the International symposium on “Children and Radiation in Medicine” was held on December 8-9, 2015 as a Research Center Symposium of NIRS, conjointly with WHO. More than 100 researchers including people from 14 institutes outside Japan participated. The symposium covered dose in medical examinations, epidemiology, justification/optimization, mechanism of radiation carcinogenesis, cancer prevention and risk communication to support the risk/benefit dialogue. The symposium was very fruitful for the Center and all participating organizations.
Introduction

X-ray CT (computed tomography) is a very popular and helpful diagnostic tool. But its high exposure dose as compared with simple roentgenography should be assessed on a clinical basis as input to its justification and optimization. The IAEA has called for enhanced Radiation Protection of Patients (RPoP).

The number of CT scanners in Japan, about 13,000, has been acknowledged to be the largest in the world, as published in reports from the OECD (Organization for Economic Co-operation and Development) in 2014. And the number of CT scanners per million persons is about 92; this is by far the largest. On the other hand, the number of CT scanners in America is the second largest and is comparable with Japan, but the number per million persons is about 32. These statistics point to the need to assess the patient dose on a clinical basis as input to the justification and optimization of CT in Japanese medical practice.

WAZA-ARI is the web-based open system for the CT dose calculator, which has been developed by Oita University of Nursing and Health Sciences and the Japan Atomic Energy Agency (JAEA) [1-3]. From December 2012, it has been installed on the web server of NIRS, and has been made available to anyone beyond medical personnel for trial use. In this version, users can select 3 phantoms (adult male, adult female or 4-year old girl) for the dose calculation.

To better consider a patient's age and body type, we installed the simulation data of organ doses and effective doses for several phantoms on the WAZA-ARI system. And we added the database function of storing the calculation results in each facility in order to check the exposure levels of the CT examination in each medical facility in Japan. We developed the WAZA-ARIlv2 associated with the improved above functions (Fig.1).

Methods

1) Measurements

The organ doses in CT exposure depend on radiation quality and fluence distribution of the X-rays. This information for each scanner was measured using an ionization chamber and a glass dosimeter. Fig.2 shows photos of the experimental setup of X-ray source information measurements.

2) Calculations

The organ doses in CT exposure were calculated by the Particle and Heavy Ion Transport code system, PHITS and voxel phantoms. Eighteen types of phantoms were used. The adult phantoms were developed by JAEA [4], and these have different body types; normal, fat, fatter and thin types. The child phantoms were developed by Florida University [5, 6], and these have several ages: 0, 1, 5, 10, 15 years old. Fig.3 shows the selectable phantoms in WAZA-ARIlv2.

In the Monte Carlo simulation, a voxel phantom was divided into 5-mm thick cross-sectional slices and a slice was irradiated with a fan-shaped photon beam rotating in the plane normal to the body axis.
3) Database function

Users can register the calculation results on the WAZA-ARIv2 server by following simple steps. The registered data can be checked as histogram statistics. Fig.4 shows a sample histogram of dose distribution. In this histogram, users can compare the exposure level of the CT examination in their own facility with all registered data in the system.

Results

WAZA-ARIv2 was made available to anyone beyond medical personnel on January 31, 2015. A corresponding homepage was made and uploaded onto the NIRS web server. Fig.5 shows the top page of the homepage. The homepage offers a user’s manual, tutorials, Q&A contents, and the login site for WAZA-ARIv2 system.

Users can utilize the WAZA-ARIv2 system after making a user registration. Over a hundred persons had registered as WAZA-ARIv2 user by the end of May 2015. The number of utilizations of the WAZA-ARIv2 system has been increasing gradually and reached 2,500 visits per month by May 2015.

Conclusion

WAZA-ARIv2 is the web-based open system for the CT dose calculator, which was improved by adding functions to WAZA-ARI. WAZA-ARIv2 was made available to anyone, and its use had gradually increased. WAZA-ARIv2 is intended to be helpful to check the exposure levels of CT examinations in every medical facility in Japan.

References

NIRS constructed a database system that automatically collects data pertaining to medical radiation exposure from computed tomographic (CT) devices and other diagnostic imaging equipment in collaboration with medical institutions and manufacturers in order to ascertain the current levels of medical radiation exposure in Japan.

The International Commission on Radiological Protection (ICRP) has been recommending the use of Diagnostic Reference Levels (DRLs) as a reference for promoting appropriate reductions in radiation exposure doses in radiological diagnostic procedures. DRLs are radiation exposure dose indicators that determine if the radiation exposure dose of the radiological diagnostic procedure is appropriate. They are established for different age groups, examinations, and body parts with consideration of individual nations’ or regions’ exposure-related circumstances. Western countries have started to use DRLs, and they are making good use of them for reducing radiation exposure doses. Japan, which has the world’s highest medical exposure value per person, has not established DRLs yet. For medical radiation exposure protection, DRLs should be used in Japan. To establish DRLs usage, grasping the actual state of radiation exposure doses from diagnostic procedures in Japan is required first.

Therefore, the NIRS has started a collaboration with five medical institutions on a study to automatically collect the data pertaining to medical radiation exposure and compile it into a database using an original tool, the NIRS collection tool. This tool collects the data stored in the diagnostic imaging equipment or Picture Archiving and Communication System (PACS), and in the tools that have also been developed by various diagnostic imaging equipment manufacturers. As the first step, data collections have already been started at Tohoku University Hospital and Osaka Police Hospital with the NIRS collection tool and manufacturer assistance tools (GE Healthcare Japan Co., Ltd., Tokyo, Japan). In addition, other three institutions plan to collect the data for one month each. Approximately 4,000 cases are expected for each institution. Thus, it is anticipated that the collected data will surpass 20,000 cases in the next six months.

The goal of this study is to contribute to justification and optimization including the establishment of the DRLs in Japan by grasping the actual situation of radiation exposure dose in medical treatment made at Japanese medical institutions. For this purpose, full operation of the automatic medical radiation exposure dose data collection and analysis system with the cooperation of more medical institutions and makers are desired.

**Background of this study**

The use of medical radiation is increasing worldwide. The member states of the Organization for Economic Cooperation and Development have an average of 23.2 X-ray CT devices per 1 million persons. On the other hand, this number is even higher, 101 devices per 1 million persons, in Japan (Health Data 2011[1]). It has been pointed out that the Japanese medical radiation exposure dose per one nation is larger than other countries. Limitations of the radiation exposure dose that is used for diagnostic procedures in hospitals have not been established in Japan. This is because, too low a radiation level when using certain models can hinder patient diagnoses and treatment; for example, the appropriate treatment might not be conducted due to the failure to correctly diagnose a disease. There are, however, concerns regarding radiation exposure if the radiation levels are too high.

Therefore, the ICRP has recommended that DRLs be used as reduction target values in order to reduce radiation doses as much as possible and to optimize medical exposure within ranges that will not affect diagnosis. The DRLs are applied to all radiation examinations, excluding radiation therapy, and the radiation doses are set respectively for different age groups, examinations, and body parts.

Currently, due to differences in radiation equipment, there is a disparity in the radiation exposure doses. Establishing the DRLs will be useful for reducing this disparity (optimizing radiation exposure). DRLs are currently being used and have been incorpo-
rated into regulations in western countries. They have, however, not been used in Japan. The determination of the DRLs requires an enormous amount of imaging radiation dose data for each of a patient’s many examinations and for many ages at various medical facilities. Nevertheless, there is no comprehensive system for ascertaining the actual situation of radiation exposure doses from radiation diagnosis nationwide in Japan. Ascertaining those data would require a system that automatically collects, integrates, and analyzes the data. The NIRS has therefore attempted to establish a system that collects the data automatically and compiles them into the database in order to solve this problem.

Contents and progress of the actual proof

As shown in Fig.1, the collection tool that was developed by the NIRS or the supporting tool that was made by GE connects the existing CT equipment and PACS in the cooperating hospitals. The radiation exposure dose data of each examination are collected automatically. In this case, the data from the CT equipment are certain to be standardized by The Digital Imaging and Communications in Medicine (DICOM). There are two methods to send this data to the NIRS database from those collection tools: sending via online direct, or using media such as CR-R. The choice depends on the security policy of the medical institution.

Actual data collection was already been started at Tohoku University Hospital and Osaka Police Hospital. Those data were stored to the NIRS database in late January 2015.

The collected data are analyzed and used in calculations such as for DRLs. Also, the cooperating institutions will be able to compare their information with that of other institutions and they will be able to consult with them on the web. Suppressing the variance in radiation exposure doses in medical institutions is expected as a long-term result.

Expected results and future tasks

This approach makes it possible to collect a large amount of data in an integrated way with more objectivity on the basis of the DICOM standard than in paper-based questionnaire surveys. This means that standardized and highly accurate data are collected from each medical institution. This will contribute to establishing DRLs. By publishing the results of the data analysis of the medical institutions, institutions can easily compare their radiation exposure doses with other institutions. The reduction of radiation exposure dose in each medical institute is expected as a long-term result.

In terms of future tasks, there are plans to expand the number of participating medical institutions to about 20 facilities. Also, the investigation period at each medical institution will be extended. Therefore, it is expected that nearly 300,000 data will be collected by the end of March 2016. This will allow improvement of the accuracy of the calculation of DRL values in Japan and make it easier to make analyses based on individual imaging techniques, body parts, age, and gender.

Additionally, there are future plans to combine these data with data on the organ dose/effective dose to construct an integrated medical radiation exposure dose database. It will be used in research for justification and optimization of domestic medical exposure.

The future aim is to grasp the entire situation in Japan regarding radiation exposure doses from diagnostic procedures in order to advance to a system for managing individual patients’ medical radiation exposure doses.

References