AMDD Enabling a Healthier Japan

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CONTENTS

Current Situation and Issues of Radiation Exposure, and New Technologies in the Field of Cardiology

"The Influence of Radiation on the Medical Frontline and the Latest Technology for Reducing Radiation Exposure" was the second part of a media lecture titled "Safety of Medical Practitioners," held by the American Medical Devices and Diagnostics Manufacturers' Association (AMDD) in July. Summaries of the lectures that were delivered by Dr. Toshiaki Nitatori, Dr. Takashi Miyamoto, and Dr. Takashi Moritake are featured below.

The Current Situation of Medical Exposure

Looking at the history of surgical medical care, the discovery of X-rays by Wilhelm Röntgen in 1895 brought a new form of medical care using radiation. Currently, radiation is used in various examinations and treatments, and what draws attention to radiation exposure of healthcare professionals is interventional radiology (IR, or abbreviated to IVR in Japan). This literally refers to "image-guided diagnosis and treatment." It allows medical professionals to provide treatment with minimally invasive techniques, while they look at images, for example, in cardiac catheterization. It can reduce risks because only tiny incisions need to be made into the body. On the other hand, IVR is accompanied by the issue of radiation.

When cardiac catheterization is performed, patients are exposed to a radiation dose of a little over 1 gray. Although the effect of radiation on patients may be small because they receive such surgery only once or twice in their lives, healthcare professionals are repeatedly exposed.

There is an occupational dose limit for radiation exposure and the limited dose of radiation for the entire body is 50 mSv/year or 5 mSv/3 months for women. Medical institutions are legally required to install a radiation exposure dosimeter on site and report the measurements to an administrator every month. However, people's awareness of radiation exposure is still low and it is hard to say whether such requirements are strictly observed.

However, the radiation exposure among healthcare professionals is more serious than anticipated. The prevalence of lens opacity is 52% for cardiologists and 45% for nurses. The risk related to malignant brain tumors is also high. Specifically, an investigation into cardiologists with brain tumors revealed that many are unilateral and that the tumors are more concentrated on the left side. In other words, it is considered that tumors appear more commonly on the left because cardiologists operate the catheter with their right hand during surgery and are often exposed to radiation on the left side. These are relatively shocking figures.

Protection from Radiation Exposure

Finally, healthcare professionals have started to think about how to protect themselves from radiation exposure. Various kinds of devices are being developed for protection and a robot navigation method is one of them. It is a magnetic navigation system that the user operates with the use of a strong magnetic field without directly touching an electrode catheter. However, while this can prevent operators from being exposed to radiation, it cannot prevent patients from such exposure. Because it creates a large magnetic field, there are concerns about its effect on the surroundings. As a result, the robot navigation system is not so popular.

The hottest device now is a 3D mapping method. This is a catheter navigation system which creates CT- and MRI-produced 3D images of the heart on a computer screen, adds electrical information to the images, and displays an electrode catheter on the images after obtaining maps of the cardiac form and arrhythmia.

With this technology, CT scanning is performed every 3 seconds. This is technology which utilizes a technique used by Israel's Air Force. It achieves accurate navigation by building up 3D visual information on 2D images which are recorded beforehand. Since it can correct the patient's body movements and heart rate, it can shorten the procedure time and reduce the level of radiation exposure.

Medical devices are constantly evolving and healthcare professionals' awareness of radiation is also changing. Because IVR is applied not only to heart surgery but also to surgery of the brain, kidney, liver, and other organs, the importance of protecting people from radiation exposure continues to grow.

Dr. Toshiaki Nitatori
Chief Professor
Kyorin University, Department of Radiology

Graduated from the School of Medicine, Iwate Medical University in 1978. Studied at the University of California in San Francisco (USA) in 1989. Worked as an Instructor and Assistant Professor at the

Department of Radiology, School of Medicine, Kyorin University before assuming his current post in 2001.

Medical Devices as a Growth Strategy

The Significance of Health and Longevity, and Healthcare and Medical Strategy

While Japan is the world's top country in terms of life expectancy, what is noteworthy is its healthy life expectancy. Healthy life expectancy refers to the period where someone's daily life is not restricted by things such as nursing care. The difference between the average life expectancy and the healthy life expectancy is 9 years for men and 12 years for women in Japan.

The Strategic Market Creation Plan, one of the measures of the Japan Revitalization Strategy promoted by the Abe Administration, aims to create new markets driven by issues. Of those, "Extending the nation's healthy life expectancy" has become a main pillar of the plan.

With the rapid pace of an aging population, social security expenses will spiral if things continue as they are. In order to control the growing expenses, closing the gap between the average life expectancy and healthy life expectancy will be a big point. To do this, the Prime Minister has assumed the post of Director and set up the Headquarters for Healthcare and Medical Strategy Promotion, laid out the promotion framework, and is currently working on this issue.

Efforts for the Research and Development of Medical Devices

The healthcare and medical strategy has four pillars: research and development of the healthcare field, creation of new industries, global expansion of healthcare, and promotion of ICT for healthcare. The plan to promote research and development in the healthcare field sets ten basic policies, including the establishment of circulation between basic research and clinical settings, creation of a system that puts the accomplishments of basic research into practical use, the expected functions of the Japan Agency for Medical Research and Development (AMED), and nine collaborative projects. These nine projects include the development of medical devices.

The size of the medical device market in Japan had been hovering at approximately 2 trillion yen for some time, but it grew to 2.8 trillion yen in 2014, the largest size on record. Looking at its breakdown, devices for treatments such as catheters account for 53% and devices for diagnosis, such as endoscopes and CTs, account for 25%. Since total medical expenses in Japan as a whole are approximately 40 trillion yen, the proportion of medical devices accounts for about 7%.

The Japan Revitalization Strategy 2016, which was approved by the Cabinet in June this year, includes a plan to promote the development of medical devices, and a basic plan based on the Act on Promotion of Medical Devices was also formulated. According to this plan, five areas in technology development of medical devices have been selected to focus on: surgery support robots/systems, artificial tissues/organs, minimally invasive treatment, imaging (image diagnosis), and home medical devices. These areas require technological development in the medical device industry.

Development Based on Needs in Medical Settings

A major feature of this effort is to promote development based on needs in medical settings. The staff of AMED will directly visit 11 core clinical facilities across the country to interview doctors and other healthcare professionals to determine their needs. Based on these needs, AMED is also attempting to publicly solicit new research and development.

Furthermore, the Medical Device InCubation Platform (MEDIC), which was launched in 2014, has started offering consultations. Although AMED is the headquarters of MEDIC, one-stop contacts have been set up at 71 regional support bodies across the country to provide consultations about medical devices. Recently, we have been witnessing a spate of consultations from different industries such as electrical and electronic manufacturers, and organizations related to automotive parts, optics and chemistry. The so-called practice of "escort consultation," which means giving advice until the release of a medical device, is growing.

However, there is a possibility that we may be left behind amid global competition unless we put the developed medical devices into practical use as quickly as possible. Thus, back-up measures for early commercialization of medical devices are being taken.

The first measure is the transfer of the Pharmaceutical Affairs Law to the Pharmaceutical and Medical Device Act which is based on the characteristics of medical devices. The second measure is the effort being made in nationally strategic special zones. The improvement of various systems is being promoted to shorten the period of clinical trials and speed up the process from development to approval and release onto the market. The strategic special zones are currently located in the Kansai area, Sendai, and Tokyo. The third measure is to improve and strengthen the system of the Pharmaceuticals and Medical Devices Agency (PMDA) and expand the preparatory consultation system. It promotes the early commercialization of medical devices by giving instructions and advice to medical device manufacturers from the initial stage of development. Finally, though this will be a future issue, the establishment of an early approval system for innovative medical devices is being reviewed.

Creation of a New Industry in the Healthcare Field

We will promote the creation of a new industry in the next-generation healthcare service, which is different from the public healthcare service. In order to expand the healthcare service not covered by public health insurance, the relaxation of regulations will be needed. For example, there is a service business related to a simplified test on self-collected blood. However, there are always concerns that such blood collection may correspond to a medical practice. We would like to promote a private service by asking such business vendors to use the system to eliminate regulatory gray zones. We are aiming to take advantage of the vitality of the private sector more in the future.

Promotion of ICT and Global Expansion

Although the digitalization and standardization of information on medical service fee bills are making progress, the reality is that there is little progress with regards to the content of doctor's interviews, results of tests/examinations, etc. In order to use such information in a more integrated manner, we are reviewing a way to set up a new information-collecting body. We plan to establish a mechanism that can efficiently collect an enormous amount of information.

The overseas expansion of Japanese-style healthcare has already begun. Under the Asian Human Well-Being Initiative, we will provide support and cooperation to rapidly growing Asian countries and regions primarily in the nursing care field. We presented the "G7 Ise-Shima Vision for Global Health" during this year's G7 Ise-Shima Summit to push forward with global health. The world is paying attention to the further development of this vision in the future.

Mr. Hiroto Izumi
Special Advisor to the Prime Minister

Graduated from the Department of Urban Engineering, the University of Tokyo in 1976. Mr. Izumi started his career in 1976 at the Ministry of Construction, and has served in various posts, such as Director-General at the Housing Bureau in 2007, Director-General at the Regional Revitalization Bureau in the Cabinet Secretariat in 2009, and Special Advisor to the Cabinet in 2012. He has been in his present position since 2013, and has been a professor of the National Graduate Institute for Policy Studies since 2006. Mr. Izumi has a doctorate degree in engineering.

Patient's Voice
Issues and the Future of Treatment for Pediatric Cancer

CCAJ
公益財団法人 がんの子どもを守る会
Children's Cancer Association of Japan

Public Interest Incorporated Foundation
Children's Cancer Association of Japan

The Children's Cancer Association of Japan is an association for children with pediatric cancer and their families which was established in 1968. Currently, we are engaged in a wide range of activities including consultation, helping to cover medical expenses, information-provision, and PR activities in cooperation with volunteers and medical personnel. We work mainly at the Headquarters in Tokyo, the Osaka Office, and 21 other branches across the country.

Pediatric cancer is a collective term for over several hundred different types of pediatric malignancy, including leukemia and brain tumors which appear more commonly in early childhood. The number of children diagnosed with pediatric cancer is said to be about 2,500 to 3,000 per year in the entire field of pediatric cancer, and most of them are orphan diseases of unknown causes. The treatment period for pediatric cancer is long and the burden of medical and treatment expenses are significant despite such expenses being subsidized, including the medical subsidy for infants and children, and grant-in-aid program for chronic diseases in childhood. On top of that, both patients and their families are subjected to a great deal of mental and economic stress during treatment, including the double life of families,

collaboration with schools and kindergartens during treatment, and taking care of the patients' brothers and sisters.

Depending on the type of disease, it is said that about 70% to 80% of the children can now complete treatment. However, as a result of an improvement in the cure rate, the increase in economic and psychosocial burdens after completing treatment itself has become a new issue. This is due to the aftereffects of treatment, late complications, and prolonged treatment of unresectable remaining tumors, in addition to the post-treatment issues of returning to school/work, marriage, and future childbearing, etc. On the other hand, pediatric cancer still ranks first in terms of the number of children who die from disease, and the lives of about 500 small children are lost every year.

The early diagnosis of pediatric cancer is considered difficult because the proliferation of cancer cells is fast and because pediatric cancer often occurs in deeper parts of the body. Also, it is reported that early diagnosis does not become a factor which affects the prognosis of pediatric cancer in many cases. However, it is said that the outcome of pediatric cancer has improved since it is now possible to accurately evaluate the cancer site and progression as a result of improved diagnostic techniques such as image diagnosis. Thus, reliable diagnosis is required.

There are a wide range of cancer types to differentiate between and, in pediatric cancer which appears more commonly in early childhood, reliable diagnosis is becoming possible not only with imaging and pathological tests, but also with diagnosis by advanced medical technologies such as chromosomal/genetic testing and immunological tests. It is expected that such advanced medical care will lead to subsequent personalized medicine.

In treatment, too, a less invasive treatment is required, such as particle therapy which was recently introduced to the public health insurance system. It can prevent aftereffects caused by the effect of concentrated treatment during childhood and onset of diseases and/or disorders (late complications) which newly occur over time. At the same time, I sincerely hope that medical care for aftereffects and late complications, such as regenerative medicine with devices that can supplement functional disorders as a result of quadruple amputations or artificial joints, and visual and visual field disorders or iPS cells, will achieve significant development. I also hope that patients with pediatric cancer can receive advanced medicine that places less burden on them.

Voice from the Local Government
Aiming for a Hub Cluster in Asia - Arrival of base for open innovation in "Fujinokuni" (home of Mt. Fuji) Shizuoka Prefecture

Mr. Hideki Mizuguchi
Manager
Research and Development Management Division
Commerce and Industry Bureau
Economy and Industry Department
Shizuoka Prefectural Government

Shizuoka Prefecture has the country's largest gross production value of drugs, medical devices, and cosmetics and research institutes, and the production plants of many companies are concentrated there. Especially in the east area of the prefecture around Mt. Fuji, companies such as Terumo which have a top-class share of medical devices in Japan, and Beckman Coulter, which manufactures laboratory test equipment, are located. In order to take advantage of the buildup of such leading companies in Japan for further regional revitalization, Shizuoka Prefecture has started a Pharma Valley Project, utilizing the opportunity of the opening of the Shizuoka Cancer Center in 2002. This project aims to support the prefecture to have the world's longest healthy life expectancy, using the two measures of "overcoming diseases and promoting health" and "industrial development" as the main drivers.

One of the characteristics of this project is that we have formed an industrial cluster — a so-called "Medical Castle Town"— by establishing a network among government, industry, academia, and financial institutions. It centers on the Shizuoka Cancer Center which is the country's top-class advanced cancer specialized hospital equipped with a proton therapy system and with abundant experience in robot surgery.

More than 500 organizations, including the National Institute of Genetics, a core base of genetics in Japan, and medical device/drug makers, local companies, universities, research institutes, and financial institutions, are participating in and collaborating with this project. More than 70 products have been produced from this project to date.

On September 1, 2016, the Pharma Valley Center (official name: Shizuoka Prefectural Medical and Health Industry Research and Development Center), a new base facility of this project, fully opened. This Center is a strategic facility that promotes the entry of local companies into the medical care field. It is also involved in the development of products and various functions for research and development, corporate support, development of human resources, and interaction/collaboration necessary for open innovation, packaged in an integrated manner. Terumo has moved into the Center to develop and manufacture ME products such as an artificial heart-lung machine, while Tokai Buhin Kogyo, a local company, has also moved in to develop and manufacture implants. Also, 8 companies including Olympus Terumo Biomaterials, Sunstar, and local companies, intellectual property offices, and consultants have moved into 23 laboratory offices.

The Shizuoka Industrial Foundation Pharma Valley Center, a public interest incorporated foundation, is a core support body of the project and designated manager of the facility. It fully backs up the tenant companies and local companies. With a collaboration going beyond boundaries among diverse companies, expectations for the birth of many innovative products that can compete globally are growing.

With the opening of this Center, the Pharma Valley Project has moved to a new stage. By taking full advantage of the functions of this Center, we will send messages about medical devices, drugs, and other products Made in Mt. Fuji to the world. We will create an attractive region so that pharmaceutical, medical device, and cosmetic makers and researchers inside and outside of the country will have an interest in this region in order to grow a hub cluster in Asia suitable as the "Capital of Beauty and Health."


Foreground: Pharma Valley Center
Background: Shizuoka Cancer Center (photos provided by Nagaizumi Town Office)

AMDD Holds the Extraordinary General Meeting

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held the AMDD Extraordinary General Meeting on September 15. Chairman Kosuke Kato (Managing Director of Edwards Lifesciences Corporation) expressed his appreciation to various people concerned and shared his expectations for future activities in the opening greetings. He then looked back at different events such as the revision of the reimbursement of medical fees in April and the public–private dialogue which occurred about 9 months after AMDD became a general incorporated foundation in January this year.

Mr. Hiroto Izumi, Special Advisor to the Prime Minister, was invited to give the special lecture and delivered a speech on the sustainable healthcare and medical strategy that the Japanese governments aims for under the leadership of Prime Minister Abe. He also talked about the role of medical devices in the strategy under the title of "Medical Devices as a Growth Strategy."

Kosuke Kato, Chairman of AMDD

AMDD Participates in "Kasumigaseki Kid's Day," a Summer Vacation Event

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) took part in a program called "Kasumigaseki Kid's Day", which was held from July 27 to 28. Various medical devices were exhibited in a booth by the Ministry of Health, Labour and Welfare, entitled "Touching Cutting-Edge Medical Devices That Save Human Lives." This

year, our booth was allocated next to a booth about related home medical care, which became the most popular area in the venue.

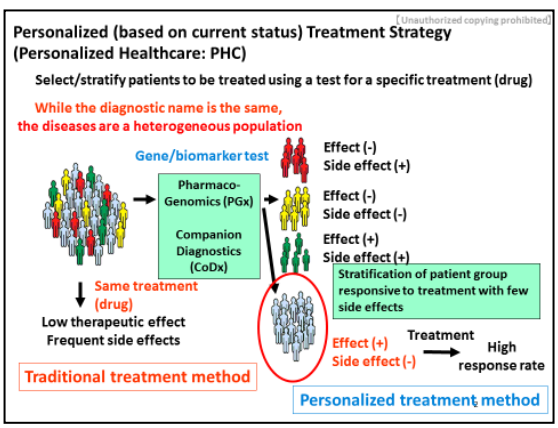
Children on their summer vacation accompanied by adults enjoyed operating different medical devices and touching a heart model. Although this has become an annual event, many member companies of AMDD took part in the event and eagerly explained their medical devices to children with whom they do not usually have the opportunity to communicate with.

The Value of Medical Technology ＜Cancer＞
Companion Diagnosis

The progress of molecular biology has enhanced our understanding of diseases to the molecular level, and the development of molecular target drugs is now making progress, primarily in the area of cancer treatment. Molecular target treatment controls the growth and progression of cancer by targeting molecules (genes, proteins) involved in the growth, infiltration, and metastasis of cancer cells. Therefore, it is essential to test cancer patients for the onset of such molecules. A companion diagnosis conducts that test.

For example, the excessive onset of HER2 proteins on tumor cells is observed at a rate of one in six patients with gastric cancer and at a rate of one in five patients with breast cancer. Since molecular target treatment using a monoclonal antibody drug can be given to such patients, a test using a companion diagnostic drug is performed. With the use of companion diagnosis, we can select the patient group for whom a high effect can be expected and optimize the treatment to avoid serious side effects

If we could select the patient group that is expected to be most responsive to the treatment in this way, it would also enable us to shorten the development period of new drugs. This would be done by conducting clinical studies in a smaller number of patients and providing the most appropriate drug to the most appropriate patient group more safely.



As its name suggests, companion diagnosis is used from the initial stage of drug discovery, and unified development with a therapeutic drug is said to be advisable. Compared to drugs already available on the market, these drugs, including diagnostic drugs developed in a retrofitted manner, are called companion diagnostic drugs.

(Text by Michi Arakawa, Roche Diagnostics K.K.)

AMDD Holds the 26th Media Lecture

– The Influence of Radiation on the Medical Frontline and the Latest Technology for Reducing Radiation Exposure

The American Medical Devices and Diagnostics Manufacturers' Association (AMDD) held the 26th Media Lecture on July 21st in Tokyo. Under the title "The Influence of Radiation on the Medical Frontline and the Latest Technology for Reducing Radiation Exposure," the second lecture in the "Safety of Medical Practitioners" series, three doctors presented lectures on the occupational exposure of healthcare professionals who handle radiation.

First, Dr. Toshiaki Nitatori, Chief Professor of the Department of Radiology, Kyorin University, delivered a lecture on cutting-edge technology to protect against radiation exposure along with the history of and an introduction of radiation.

Next, Dr. Takashi Miyamoto, Senior Assistant Professor of the Trauma Center of Nagasaki University Hospital Emergency Medical Center, delivered a lecture on the reality of irradiation at the Department of Orthopedic Surgery and the need for doctors to recognize themselves that they are exposed to radiation.

Finally, Dr. Takashi Moritake, Associate Professor of the Department of Radiological Health Science, University of Occupational and Environmental Health, described how doctors need to understand and manage their radiation dose, and how the education of young doctors is essential.

At the back of the venue, medical devices which are actually used in medical settings were exhibited. Many reporters who participated in the media lecture commented that they "learned a lot about the radiation exposure of healthcare professionals, a topic seldom touched upon" and that they were "very satisfied" with the event.

(Please see the article on page 1 and inserted articles for summaries of the lectures by the three doctors)

Dr. Toshiaki Nitatori　Dr. Takashi Miyamoto　Dr. Takashi Moritake

Radiation Exposure, Risks, and Cutting-edge Technologies in Orthopedic Surgery

About Radiation Exposure

Radiation exists in our own backyard and, in fact, we are constantly exposed to radiation in our daily lives. For example, I got on an airplane from Nagasaki for this lecture. During the flight, I was exposed to radiation from space (cosmic radiation). When the altitude gets higher, the air becomes thinner and the exposure to radiation coming from space increases. When you fly from Japan to New York, for example, it is said that you are exposed to a radiation dose of 0.19 mSv. You are also exposed to radiation from food.

The annual radiation dose is 2.3 mSv as a global average, 1.1 mSv in Japan, and about 0.8 mSv in Kanagawa Prefecture. There are areas with a high radiation dose such as Ramsar in India at 30 mSv and Guarapari in Brazil at 35 mSv. The radiation dose varies depending on location.

When a pregnant woman gets injured and undergoes an X-ray in an examination, people often make a noise, saying that she was "exposed to radiation." The radiation dose for one chest X-ray is 0.2 mSv. If you are concerned about such a small dose, you should be concerned about getting on an airplane for your overseas trip. You should undergo the necessary examination by considering its advantages.

Since we cannot actually see radiation, many people tend to be blindly scared of it. But, it is important that we should be "correctly scared of" radiation with accurate knowledge.

Risks of Medical Exposure

The most frequent radiation exposure in Japan is medical exposure which accounts for 60% of all types of exposure. In particular, we, orthopedic surgeons, have an inseparable relationship with exposure. The reason is, while we primarily treat bones in the field of orthopedic surgery, X-ray photography is indispensable for a diagnosis.

The number of hospitals in Japan is 3.7 times the number of hospitals in the United States, and therefore there are more examinations/tests for patients. I sometimes enter a CT room with patients. Even with a protector attached to my body, there is always the risk of radiation exposure.

However, we are more susceptible to exposure when we perform surgery with IVR (interventional radiology) than during examinations. We used to perform surgery by broadly cutting the skin or muscle and directly looking at the bone. But now, a minimally invasive surgery which is performed by making a small incision and inserting an instrument through the hole along with radiographic guidance of images has become the mainstream. While such a technique is minimally invasive, since it uses radiation, the risk of exposure is increasing for both patients and doctors.

The upper limit of exposure for healthcare professionals is 50 mSv/year. If we are exposed to radiation of 0.2 mSv per surgery, it means that we can perform surgery only for about 250 patients a year. However, we actually perform surgery for 700 to 800 patients per year at Nagasaki University.

With IVR, we take advantage of C-arm (surgical X-ray equipment). This equipment acts as our eyes but has 10% to 20% scattered radiation. Scattered radiation refers to secondary radiation which is produced when it hits an absorber. It flies in every direction, such as into the eyes, thyroid gland, and chest. The radiation dose is small compared to the direct radiation that patients are exposed to. But since healthcare professionals are repeatedly exposed to scattered radiation, the risk increases.

In the case of orthopedic surgery, the exposure rate is higher for assistants than for operators because of the position they are in and it is said that assistants are exposed to five times more the amount of radiation than operators.

Countermeasures are necessary for the use of C-arm. Because we are exposed to scattered radiation squarely if we irradiate patients from directly above, it is ideal to irradiate from below. If we irradiate from below, radiation is scattered under the feet.

The NCRP (National Council on Radiation Protection and Measurements) sets three concepts for patients: "Block," "Keep a distance," and "Shorten time." These concepts can be applied to healthcare professionals, too.

For blocking, though we wear a protector or goggles, our hands are most susceptible to exposure. While protective gloves are available, since they are heavy, we cannot wear them for a long time. Therefore, it is important to shorten surgery time as much as possible.

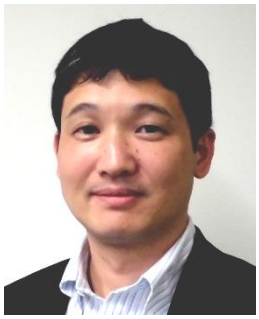
Cutting-Edge Equipment and Training Trends

With people's increasing awareness of exposure, a system that does not irradiate has been introduced. It is a surgical navigation called a distal targeting system. It navigates the location and direction of a drill to insert a locking screw from the side after inserting a femoral interlocking nail. It allows us to operate while looking at a monitor and, like a shooting game, it emits a sound when the target is locked on and a hole is opened up when the drill is applied to it. Young doctors of the gaming generation are good at operating it compared to elderly doctors.

Across the country, the time of irradiation was shortened at hospitals which introduced this distal targeting system and the awareness about exposure among the doctors grew significantly. This had a profound effect and was a groundbreaking event. Unfortunately, however, statistically no significant difference was found at our university. As one of the causes, it is considered that the surgical time at our university was short from the beginning.

Aiming to shorten the irradiation time, the Orthopaedic Trauma Association in the United States is also taking the initiative. It has developed a surgical simulator and is promoting the standardization of surgical procedures so that only those who passed a test related to this simulator can perform surgery for patients. There is a report showing that those who were trained with the simulator could shorten the surgical time by 75% by becoming more aware of the irradiation time.

The key words to reducing the risk of exposure are blocking, distance, and time but the most significant key word is the doctor's high level of awareness.



Dr. Takashi Miyamoto
Senior Assistant Professor
Nagasaki University Hospital Trauma Center

Graduated from Kagoshima University School of Medicine in 1996 and joined the Department of Orthopedic Surgery of Nagasaki University in the same year. Studied abroad at University Tennessee Cambell Clinic in 2006 and Massachusetts General Hospital in 2008. Dr. Miyamoto has been in his current position since 2015.

Measurements of Medical Exposure and Protection for Intravascular Treatment

The Radiation Exposure of Patients and Doctors

Speaking of "radiation exposure," we can see that it differs between patients and healthcare professionals. Let's list differences and similarities of exposure between the two. More accurately, patients call it "medical exposure" and healthcare professionals "occupational exposure." The measuring method, protection, etc. also differ.

However, the largest difference between the two may be the purpose of radiation control. While patients cannot get tested or treated unless they are exposed to radiation, healthcare professionals do not need to be exposed to even 1 mSv of radiation. Healthcare professionals must not be exposed to unnecessary radiation. Although there are such contradictory purposes, we must confront the issue of radiation exposure.

Then, what is the principle of protection from medical exposure? The International Commission on Radiological Protection (ICRP) specifies it as follows. It says that all radiation exposure must be justified from the standpoint of their effects on patients. The biggest goal is to reasonably reduce the stochastic effects. In other words, it means we must reduce the stochastic effects on the carcinogenic rate, etc. but we cannot completely eliminate radiation exposure. Nevertheless, we must avoid deterministic effects, such as skin disorders, as much as possible. However, cancer treatment with radiotherapy is excluded because it is justified.

Understanding Exposure Dose

The ICRP states that doctors are ultimately responsible for exposure, though this is a bit of a home truth for doctors. In order for doctors to fulfill this principle, information is necessary. At first, we must have a scale to properly judge the radiation dose. It is a diagnostic reference level (DRL). The DRL has been introduced to study a standard radiation dose used in IVR (interventional radiology). The radiation dose needed for patients differs depending on their symptoms and we cannot set a limit across the board. Therefore, we often estimate the most appropriate radiation dose (75 percentile value) based on the two values of integral dose and area dose from an IVR standard point. If the mean value (median value) of radiation dose

at your hospital is below the DRL, there is no problem. But you must take appropriate measures if it is above the DRL.

The DRL is effective because it reduces the stochastic effects. Unfortunately, however, it is not effective at all for deterministic effects such as skin peel off or hair loss. In order to avoid the deterministic effects, we must not exceed the threshold dose. It is essential that you know the threshold dose that causes a skin disorder and whether the radiation dose exceeds it or not.

In June 2015, the J-RIME (Japan Network for Research and Information on Medical Exposures) posted the DRL on its website. According to its website, it states that the fluoroscopy radiation dose rate at the IVR standard point is "20 mGy/min," and I felt that there was something slightly wrong with that. The patient's exposure during IVR is considered to be the product of both clinical and radiological elements. Clinical elements refer to doctors' techniques, characteristics of diseases, etc., while radiological elements refer to mechanical things. However, since only the exposure dose rate is shown here, unfortunately, it does not directly lead to reducing patients' exposure. I suppose that more clinical elements should be incorporated into the DRL. Meanwhile, work to revise the DRL by adding clinical elements has already begun.

Risk Management of IVR Exposure That Should be Conducted by Doctors

First, doctors must obtain the patients' informed consent about the risk of exposure. Doctors must provide patients with accurate knowledge to help them understand and accept the risk of exposure.

Next is the management of a radiation dose. Doctors must weigh the risks of exposure against the benefit of a disease getting better if the radiation dose increases. This behavior of thinking about the balance between the risks and benefits itself is a form of management of exposure risks. If you increase the radiation dose, the image quality gets better. If you decrease the radiation dose, the image quality deteriorates. You must always predict the risks by understanding the threshold dose, etc. and consider whether the benefits outweigh or do not justify the risks. This is the behavior of justifying the exposure. Also, optimizing radiation protection means achieving the ideal levels of risks and amount of image data. Justification of exposure and optimization of radiation protection — doctors must perform both but there is a reality here which has not been recognized before.

Education on Radiation at Schools of Medicine

Despite the various efforts we have made, doctors' awareness about radiation exposure is low. It seems to me that there are also problems with medical education. There are no more than 10 universities that have professors who specialize in radiology and some medical schools do not even have basic courses in radiology.

With the publication of the revised version of "Education on Radiation Rays" in the core curriculum in 2010, universities began to step up their education on radiation. However, doctors' awareness about radiation exposure is still low and I think that we need to make further efforts to enlighten them and enhance their understanding.

Dr. Takashi Moritake
Associate Professor
Department of Radiological Health Science
University of Occupational and Environmental Health, Japan,

Graduated from the University of Tsukuba School of Medicine in 1993. Worked as a hospital staff member (Department of Neurosurgery) at the University of Tsukuba Hospital in 1998. Joined the University of Tsukuba Graduate School of Medicine, Division of Medicine in 2000 and completed the doctoral program in 2004. Worked as a Special Researcher at the Japan Society for the Promotion of Science in 2004, a researcher of the Genome Diagnosis Research Group of the National Institute of Radiological Sciences in 2006, and as an Instructor at the University of Tsukuba Hospital Proton Beam Therapy Center in 2009. Dr. Moritake has been in his current position since 2013.

Value of Medical Technology
Our mission is to make more people understand the unlimited potential of advanced medical technology and its contribution to the reformation of the Japanese medical care system

Note: All opinions in this newsletter are the personal opinions of the authors, and do not necessarily represent the opinions and activities of AMDD.