Evidence-based Guidelines Needed on the Use of CT Scanning in Japan

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Abstract

The increasing use of medical radiation, especially in diagnostic computed tomography (CT) scanning, has raised many concerns over the possible adverse effects of procedures performed without a serious risk versus benefit consideration, particularly in children. The growth in the number of CT scanning installations and usage, some new and unprecedented applications, the relatively wide variation of radiation doses applied by different radiological facilities, and the worrisome estimations of increased cancer incidence in more susceptible organs of children all point to the need for a clear specification of evidence-based guidelines to help limit and control the amount of radiation doses the Japanese population is being exposed to through medical diagnostic imaging technologies. Recommendations have already been issued on how to reduce the exposure dose to the minimum required especially in pediatric CT but more work is needed to establish good practice principles by the medical community through determination of more reasonable indications to request CT scanning.

Key words Computed tomography (CT) scanning, Evidence-based guidelines, Medical radiation, Pediatric CT, Radiation induced cancer

Introduction

The average annual collective doses of ionizing radiation exposure to the UK population from all sources have been summarized in a recent review[1] that depicts a good example of the latest situation of radiation exposure in developed countries. Radon as one of the natural sources of radiation, is responsible for 50% of the total annual dose (Fig. 1a) and next to it diagnostic radiology becomes the largest source of radiation exposure to the general population. The use of diagnostic X-rays also comprises more than 93% of all man-made sources of such exposure. On the other hand, the latest available data in Japan point to a much larger role of medical radiation in the average annual collective radiation doses (Fig. 1b).

The risk of cancer induction by medical radiation is not a recent issue but a long-standing one.[2] Fortunately, the radiation doses of all common diagnostic radiological examinations have generally been decreasing, except for computed tomography (CT) and interventional radiology (particularly angiography), which have increased. It is also worth noting that on an individual basis, the radiation dose a person receives during a CT examination is much higher than the expected dose of annual natural background radiation. Most of the recent increase in medical radiation dose has been ascribed to the higher frequency of use as well as higher radiation doses of CT scanning (Fig. 2).

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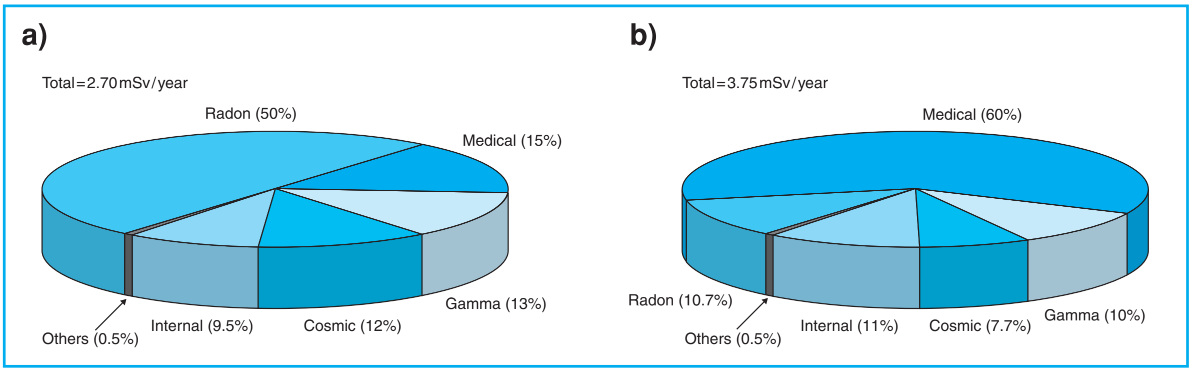

Fig. 1a) The most recent (2005) estimation of the average annual dose to the general population from all sources of ionizing radiation in UK is about 2.7 mSv, divided into five major & "other" sources (based on HPA-RPD-001 Report)

b) The 1992 estimation of the average annual dose to the general population from all sources of ionizing radiation in Japan was about 3.75 mSv, divided into five major & "other" sources (based on data of the Japanese Nuclear Safety Research Association)

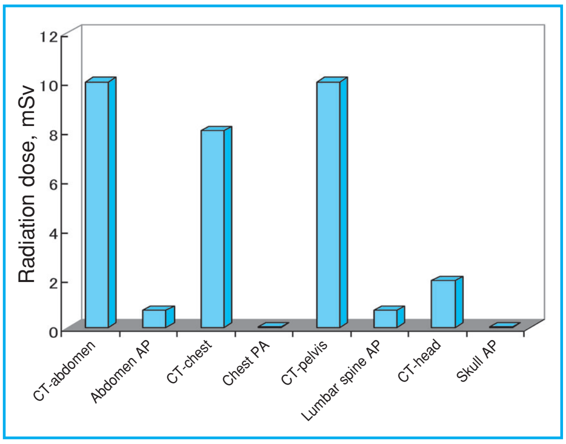

Fig. 2 Average effective radiation doses from diagnostic CT and the corresponding plain X-ray examinations to adults

Many physicians are unaware that CT examinations expose their patients to significantly higher radiation doses; dose of an abdominal CT is 400 times higher than a chest X-ray. (from Wall BF, Hart D. Revised radiation doses for typical X-ray examinations. BJR. 1997;70:437–439).

The growth of the radiation dosage ascribed to CT usage is mainly due to the increasing use of techniques such as contrast and multiphase enhancement, and multi-slice CT[3]; also the development of new helical CT has played a large role in the increase of pediatric CT usage because the fast spiral (helical) CT systems eliminated the need for sedation in most cases.[4,5] By the year 2000, US researchers reported an increase in the frequency of CT examinations to about 11% of all radiological examinations, accounting for 67% of the total effective dose from diagnostic radiology.[6]

In spite of several precautionary advisories that have already been published,[7–10] the increasing number of annually performed CT scans has moved far beyond control and has raised serious concerns over radiation safety, particularly induction of cancer. Radiation exposure through medical radiological devices has been blamed for 0.6% up to 1% (more than 3% for Japan) of total cancer incidence in many countries,[11,12] and specifically the risk of cancer induction through CT scans performed on children has received particular attention.[13–15] The extra concern over pediatric use of radiation is due to the fact that many organs in children are more sensitive to cancer induction. Also children receive a higher absorbed dose due to the small size of their body and with more years of life ahead for such a complication to appear, the lifetime risk of cancer is higher for them.[14,16]

There have been many attempts to lower the exposure dose of medical radiation,[17,18] either through guidelines for the radiological facilities to set dose parameters of their machines to the lowest needed range, or recommendations to physicians not to request high-dose diagnostic radiological examinations for their patients without a clear indication for its necessity and only after consideration of other diagnostic

Table 1 Mean effective dose to patients per procedure, from common CT scan examinations in some developed countries

Country	Year	Head CT	Chest CT	Abdomen CT
Japan	1994	—	4.6–10.8	6.7–13.3
Germany	1993	2.6	20.5	27.4
Australia	1995	2.6	10.4	16.7
United Kingdom	1994	1.6	9.7	12.0

(from UNSCEAR 2000 Medical radiation exposures, Annex D)

alternatives, such as ultrasound and MRI.

Unfortunately the number of peer-reviewed papers on the subjects of efficacy, dose and image quality criteria, especially for CT usage in children, is still limited; the lack of internationally approved indices for image quality and exposure among X-ray equipment manufactures is partly responsible for this problem. Still many radiological facilities purchase equipment on the basis of higher image quality, and/or operate their equipment in a high-dose, high-image quality mode.

In this paper, we will focus our attention on special precautions for CT scanning, especially in children, and will discuss the specific situation in Japan with regard to medico-radiological practice.

The Use of Diagnostic Radiology & CT Scanning in Japan

In Japan, according to UNSCEAR survey,[19] the annual frequency of diagnostic medical radiological examinations increased from 830 per 1,000 population in 1979, to 1,160 per 1,000 in 1990, and then to 1,477 per 1,000 population in 1996. However, a relatively significant part, namely 42% of the last figure, was related to chest X-rays which is a very low dose examination. This large share of chest X-rays in the number of annual radiological examinations in Japan, which is two times higher than in Germany at the same period (chest X-rays, 21%) can be explained by the Japanese anti-tuberculosis law that requires annual X-rays of students and employees over 16 years of age in the form of Mass Miniature Radiography (MMR).

Publication of guidelines, regulations and reference dosimetry for CT by European and international authorities cited earlier,[8–10] led the Japan Industry Association of Radiological Systems (JIRA) to respond by issuing some guidance and countermeasure recommendations to reduce the CT exposure dose.[20] Accordingly, CT manufacturers in Japan now provide data related to X-ray exposure dose including the weighted CT dose index (CTDIw) for adjusting CT exposure parameters as well as a CT infant protocol to reduce the dose for children. Moreover, the Japan Association of Radiological Technologists (JART) recently published a set of recommendations referred to as "pediatric CT guidelines to lower the dose of radiation" (http://www.jart.jp, in Japanese).

However, the observation of such standards of radio-diagnostic practice in Japan has not been mandatory or under the control of an agency (such as FDA in USA) and there are concerns that standards are not fully observed in some centers in order to achieve higher image resolution; the presence of a wide gap in the range of CT exposure doses in Japan (Table 1) raises the possibility that different facilities are not following the same standards. The publication of a paper that estimated the risk of cancer induced by diagnostic radiology in 15 countries and cited the highest risk for Japan,[11] reverberated through the Japanese radiological community. Although the basic assumption in this paper, namely the extension of the linear non-threshold (LNT) dose-effect relation to very low dose radiation, is still controversial[21–23] and the lowest doses of X-rays for which reasonably reliable evidence of increased cancer risk exists range from 10 to 50 mGy,[24] CT is not considered a low dose procedure (in 1998, the European Community classified CT as a high-dose procedure). Recently the in vivo formation

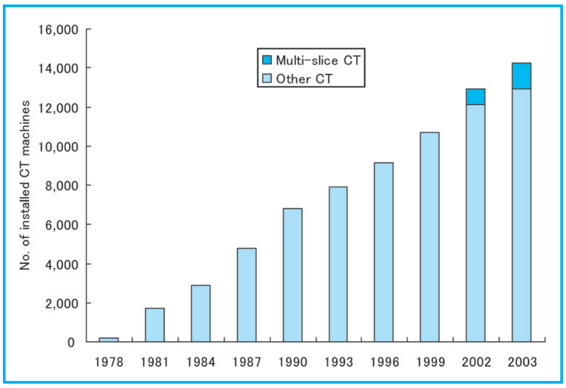

Fig. 3 Changes in the number of CT equipment installations in Japan through recent years

The number of Multi-slice CT machines in Japan reached 1,361 units in 2003. (from data presented by Nishizawa)

(and normally, repair) of DNA double strand breaks has been demonstrated after radiation doses in typical CT examinations.[25]

Some of the Japanese CT scan usage data are quite alarming. In Japan, there are no restrictions for CT use in cancer screening and routine health medical check-ups. Currently some medical imaging facilities are promoting new and unprecedented applications for CT scanning such as whole body CT scans combined with a PET examination, especially for cancer screening of asymptomatic individuals. With private radiological facilities openly advertising CT-PET full body screening to healthy people, and the only barrier being the cost of approximately US$1,100 which is not covered by health insurance, the commercialization of part of the medico-radiological sector has become a reality.

On the other hand, egalitarian public health policies to equip rural medical facilities with high-tech equipment such as CT machines in order to secure equal access to medical technologies all around Japan, have also been implicated.[26] These and other factors have been responsible for the growth of CT equipment installations in Japan (Fig. 3) such that the number of CT machines per million population of Japan was reported as 87.8 in 2000,[27] while Canada had only 10.3 CT machines per million population at the same period (CIHI report). The newer multi-slice CT machines expose the patients to about 40% higher radiation doses and in some applications a double dose or even higher.[28]

Our own survey on CT scanning usage in Nagasaki University Hospital (unpublished data) suggests that factors other than private economic gains may be responsible for overuse of CT in Japan, such as a lack of guidelines on clinical management and decision making, patients' expectations and physicians' over-reliance on high-tech imagery rather than clinical observation, which will be discussed further in our example of management of minor head trauma in children.

The Risks of Radiation Doses Used in CT

The lifetime cancer mortality risk from a single full-body CT examination has been estimated around 0.08% (about 1 in 1,250) for a 45-year-old adult,[29] but as mentioned earlier, the pediatric population is particularly susceptible to CT radiation doses. The thyroid gland, breasts and gonads in growing children are more sensitive to radiation meaning that the same radiation dose per unit weight of tissue is more prone to cancer in a child, compared with an adult.[14] Also, the smaller size of a child leads to the exposure of many nearby organs by CT slices of a nearby regional section, to a higher degree than an adult.[30] For example, the thyroid may be exposed in CT scan of the chest as well as the cervical and thoracic spines, the neck, and facial bones, and gonads in girls may be included in CT scans of abdomen as well as pelvis.

Calculations of Brenner et al. for "head" CT scans, show the risk of brain cancer to be the highest, with thyroid cancer posing a smaller risk of about 10% almost irrespective of sex, while in "abdominal" CT scans, stomach, liver and colon cancer dominate the risk profile which is higher for females. They estimated the lifetime cancer mortality risk attributable to radiation exposure from a single abdominal CT scan in a 1 year old child as about 1 in 550, and for a single head CT scan, 1 in 1,500.[13] These estimates are based on analyses of mortality data among Japanese atomic bomb survivors who were exposed to intermediate levels of radiation doses and therefore theoretically must be more applicable to the Japanese population. However, it must be emphasized that such a small increase over the background risk of cancer is still too small to be detected in an epidemiologic study.

It is not only the risk of cancer, but also the possible effects of CT scans on the development

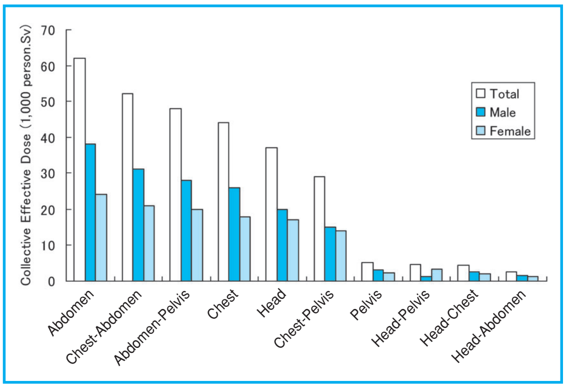

Fig. 4 Annual collective effective dose by the body regions CT scanned in Japan
(from Nishizawa et al. Nippon Acta Radialogica. 2004;64)

of cognitive capabilities of children,[31] that requires a reasonable risk versus benefit balance when ordering CT scans.

Overall, the raising of these concerns has caused many researchers and health care authorities to recommend strategies to minimize CT radiation exposure for children. The ALARA (As Low As Reasonably Achievable) principle is the basis of such strategies that aim to limit the CT examinations performed to only necessary ones, to limit the region of coverage, and to adjust individual CT dose settings based on indication, the region imaged, and size of the child.[32]

As for the scales of CT scanning practice in Japan, according to Nishizawa et al.,[27] the number of CT examinations per 1,000 population in Japan in the year 2000 was 290 and the average annual effective dose per caput was estimated as 2.3 mSv. About 3% (1.140.000) of all CT scans were performed on children (14 years old or less) 62% of which were performed on males; in comparison in those 15 years old and more, 54% were done on males. Eighty two percent of these examinations were head CT scans, compared with only 39% in the age group ≥15. Although "head" CT scans were the most common CT procedure, abdominal organs received the highest total collective doses in CT scans (Fig. 4). In the United States, according to the 2000–2001 NEXT survey[33] the total number of CT exams annually was about 58 million and the average effective dose per CT examination was approximately 6.2 mSv, so the average annual effective dose per caput was 1.2 mSv. The number of CT scans on children less than 15 years of age was estimated to be 2.7 million in the year 2000, about 4.8% of the total.[34]

Risk Versus Benefit of CT Examinations

Observation of exposure reduction principles in Japan has been recommended to all radiodiagnostic facilities but it is not mandatory.[35]

On the other hand, the justification of many of the CT scan requests is based on the assumption that the benefits are likely to exceed the risks, even though many physicians do not have a good knowledge of the amount of radiation exposure to the patients during radiological examinations.[36] For a risk versus benefit study, the radiation risks may be estimated from the effective dose using the system recommended by the International Commission on Radiological Protection, but the benefits of investigations in pediatric radiology are currently un-quantified. Benefits of some tests are so large that any further evaluation may be deemed unnecessary while for some others the maximum potential benefit is so low that they can be discarded. For most investigations, however, research into the magnitude of benefit to the patient is required in order to establish that it is greater than the magnitude of the radiation risk.[37] Increasing numbers of publications suggest more widespread use of CT as the primary imaging technique in multiple clinical scenarios, such as the child with abdominal pain, suspected appendicitis, or suspected renal calculi.[38,39]

For cases in which it is decided that the potential benefits from the information obtained on CT are greater than the risk of the radiation dose, technical factors can still be adjusted to minimize the radiation dose; this adjustment will be the responsibility of the radiologist supervising the examination.

The most recent study on the risks of exposure to low levels of radiation is further proof that concerns over CT scanning doses can be taken seriously[40]; this study on protracted exposures on an occupational basis also underscores the necessity of protecting physicians involved in sophisticated diagnostic and interventional radiological procedures,[41] including on how to monitor the exposure in the workplace, particularly in Japan.

Minor head trauma is one of the most

common reasons to refer children for a head CT scan, especially in Japan. Though minor head trauma in children is very common, it has a very low rate of complications which may be severe; and therefore clinical guidelines have been recommended to help with its correct management.[42] Compared with the UK, Canada,[43] and the USA[44] where there are a series of guidelines for the use of CT scanning in the workup of head injuries in both adults and children, such as those of the Royal College of Surgeons of England and the National Institute of Clinical Excellence (NICE) in the UK,[42] medical doctors in Japan rely mainly on their individual clinical judgment.

Although pediatricians should have the primary and pivotal role in the management of minor head trauma in children, in our survey at Nagasaki University Hospital, neurosurgeons commonly take over this responsibility from the beginning. This is while less than 1 in 5,000 patients without a loss of consciousness sustain intracranial injuries and only 2% to 5% of those with loss of consciousness may require neurosurgical intervention. In a relatively large epidemiological study in Germany, it was noted that while on average a CT scan was taken in only 13.4% of pediatric head trauma cases, the children treated by neurosurgeons received a CT in 75% of the cases.[45]

From the standpoint of health policy making, the potential risk calculated with linear extrapolations from higher doses can be justified even if too conservative because they probably represent the best interest of protecting patients.[46] On the other hand, radiation risk issues are still not taken into account in many papers on clinical decision-making. An example is a WHO collaborative study, which takes a more relaxed position on CT requests for minor head trauma in children, stating that clinical factors can hardly predict CT scan abnormalities and the need for intervention.[47]

Conclusions

The role of ionizing radiation in the promotion of human health is very similar to a double-edged sword. The radiation safety and risk-benefit ratio of various interventional radiological procedures, especially those with a higher dose of radiation such as CT scanning, need a fairly critical evaluation.

In developed countries such as Japan, more concrete evidence should be collected and evaluated on the safety and benefits versus the hazards of common CT applications, especially in the field of pediatrics. The increasing number of CT scan examinations has become a source of concern of the risk of cancer and/or deleterious effects on cognitive function in children. New and more comprehensive guidelines are needed to recommend good practice points to radiological facilities and all physicians who perform or request radiological procedures in Japan.

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