The physician should benefit, not harm the patient

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Abstract

Six hundred years before Christ, Hippocrates said that physicians on exercising their medical duties, should benefit but not harm their patients. Seventy years ago increased medical radiation caused radiologists in the US an excess risk of leukemia, lymphoma and multiple myeloma. Now medical radiation is rather safe for the physician but the question remains if proper prophylactic measures are being taken to make it safe for the subjects examined. Roughly, first trimester of pregnancy radiography has a much greater fatal cancer risk than that of exposures taken later in pregnancy. It is suggested that women should be administered the minimum activity consistent with achieving the desired clinical information, whether or not they are known to be pregnant. The best available risk estimates suggest that pediatric CT diagnostic procedures will induce significantly increased lifetime radiation risk in children. Professor Roger Clarke wrote that there may be a need to reduce or prevent doses of medical radiation up to 3 mSv if there is no benefit to the individual. 30 mSv is described as "a dose which should not be exceeded" and can be approached only if there is a benefit to individuals and the dose is difficult to reduce or prevent. In WHO Category III a) Static brain imaging with technetium-99m pertechnetate, b) Gated cardiac imaging c) Bone imaging with technetium-99m MDP, d) Quantitative haemodynamics with technetium-99m pertechnetate, e) Myocardial imaging with thallous-201 chloride and f) Abscess imaging with gallium-67 citrate, induce an effective dose equivalent of 5-9 mSv. A CT scan commonly gives 25 mSv to the subject examined. BEIR VI indicated that a 10 mSv single population dose is associated with a lifetime attributable risk for developing a solid cancer or leukemia in 1:1000. Multiple CT examinations have administered to some patients with renal colic a dose of 19.5-153.7 mSv. One may suggest that there should be "justification" and informed written patients' consent for nuclear medicine examinations administering to the patient doses greater than 5 mSv, especially doses around or above 30 mSv/year.

Keywords: Medical radiation – Justification of doses – Informed consent – Biological effects

Six hundred years before Christ, Hippocrates said that physicians on exercising their medical duties, should benefit but not harm their patients. He expressed this laconically: "Ωφελέειν ή μη βλάπτειν". "To benefit not harm". Today, 2600 years later, the question remains as for the possible harmful effects of medical radiation exposure. Medical radiation exposure constitutes about 20% of the overall average annual dose we receive from natural radioactivity, derived from earth, radon, cosmic rays, food, water etc and is increased throughout the years [1,2]. Seventy years ago increased medical radiation caused radiologists in the US an excess risk of leukemia, lymphoma and multiple myeloma [3]. It was proposed that the above risk was related to immunologic changes induced by radiation [3]. Now medical radiation is rather safe for the physician but the question remains if proper prophylactic measures are being taken to make it safe for the subjects examined.

The first study documenting cancer and leukemia in children whose mothers had been exposed to in-utero X-rays of only 1-2 mGy, appeared in 1958 [4]. During the first two weeks after conception, irradiation of the foetus due to diagnostic or therapeutic procedures can result in prenatal death and miscarriage. If pregnancy continues the embryo can be considered as healthy [5,6]. In the periods from 0-7 weeks and beyond 15 weeks after conception, no risk of severe mental retardation was found. There were fetal risks following antenatal radionuclide administration during the 8th-15th week after conception with a maximum likely threshold value above 250 mGy and during the 16-25 weeks after conception, with a maximum likely threshold value above 700 mGy [7]. Roughly, first trimester radiography has a much greater fatal cancer risk than that of exposures taken later in pregnancy [8]. As well as considering alternative methods of investigation, the Administration of Radioactive Substances Advisory Committee (ARSAC) has recommended that women should be administered the minimum activity consistent with achieving the desired clinical information, whether or not they are known to be pregnant [7,9]. Total uterine dose estimate greater than the 0.5 mGy should be avoided. Of course nowadays, fetal diagnostic X-ray doses have been reduced and the cure rate for childhood leukemia – the most common form of these radiation induced cancers – has been increased [8].

Another related subject is medical radiation administered to children. It has been strongly indicated that there exists a dose-response relationship between absorbed dose in the brain and the subsequent risk of developing an intracranial tumor and that this risk is higher among infants exposed to ionizing radiation at younger ages [10]. Low doses of ionizing radiation to the brain given in infancy to treat local haemangiomas or other skin diseases, influence cognitive abilities in adulthood [10,11]. According to another study, the best available risk estimates suggest that pediatric CT diagnostic procedures will induce significantly increased lifetime radiation risk in children [12]. Radiation exposure to the paediatric patient from cardiac catheterization and angiocardiography is

also considerable. The dose to the thyroid gland in paediatric patients in cases of cardiac catheterization and angiocardiography was reported to be on average 77 mGy [13].

In males, fractionated irradiation of the testes may be more harmful than the acute administration of radiation, at least up to total doses of about 600 cGy. Fractionated doses greater than 35 cGy cause aspermia, and after more than 200 cGy aspermia may be permanent. In females, response varies according to age and dose. For example, 400 cGy may cause a 30% incidence of sterility in young women, but in women aged above 40 years it results to 100% sterility [14]. For the absorption of 1 mSv radiation dose, the genetic damage is a risk of 4 in 106 subjects and the fatal cancer or leukaemia a risk of 13 in 106 subjects [1].

Professor Roger Clarke who was Chair of the International Committee for Radiation Protection (ICRP), has published a discussion document on controllable dose [15]. It is argued that there may be a need to reduce or prevent doses of medical radiation up to 3 mSv if there is no benefit to the individual. We would very much agree with this, since in medical procedures the purpose of the test is to benefit the individual [15,16].

The problem of having harmful effects with medical radiation, also appears when we do research in humans. In the discussion document mentioned above, 30 mSv is described as "a dose which should not be exceeded" [13]. This document argues that the limit of 30 mSv can be approached only if there is a benefit to individuals and the dose is difficult to reduce or prevent [13,14]. The decision as to whether ionizing radiation is required (justification) is all important. Of course in everyday medical practice in radiology and in nuclear medicine departments, the limit of 30 mSv would often be exceeded with a number of medical procedures, for instance CT scanning, angiography and therapy with radionuclides [17-19].

The World Health Organization (WHO) categorized all nuclear medicine and radiology procedures according to the effective dose equivalent (EDE) they administer to the individual. We may remind ourselves that EDE is defined as a weighted sum of the dose equivalents to individual tissues. It is a single figure specifying a hypothetical uniform whole body dose equivalent which would involve the same risk as the actual dose distribution [1]. According to WHO Category III, the following procedures of nuclear medicine administer more than 5mSv: a) Static brain imaging with 99mTc-pertechnetate for an injected dose of 500 MBq, b) Gated cardiac imaging with 99mTc red blood cells for an injected dose of 800 MBq, c) Bone imaging with 99mTc-MDP for an injected dose of 550 MBq – today the usual dose is about 700 MBq, d) Quantitative haemodynamics with 99mTc-pertechnetate for a dose of 600 MBq, e) Myocardial imaging with 201Tl thallous chloride for a dose of 75 MBq, f) Abscess imaging with 67Ga gallium citrate for a dose of 80 MBq. The first of these procedures (a) induces an EDE of 5.5 mSv and the last one (f) an EDE of 9 mSv [1]. Others mention that a CT scan commonly gives 25 mSv to the subject examined [17]. Conservative estimates are that in 2002 in USA the radiation dose from all CT examinations was 70% of all medical X-ray exposures [18].

The seventh National Academy of Science report on Biological Effects of Ionizing Radiation (BEIR VI) indicated that a 10 mSv single population dose is associated with a lifetime attributable risk for developing a solid cancer or leukemia in 1:1000 [20]. Multiple CT examinations have administered to some patients with renal colic a dose of 19.5-153.7 mSv [21]. For all medical radiation above a limit i.e. above 3-5 mSv per examination the possible harm to the patient and / or to their relatives should be explained and balanced against the benefit of the examination. Against radiation risks to pregnant women can be balanced a reported incidence of 11 maternal deaths in pregnancy from pulmonary embolism during 1979–1981 [5, 22].

In case of nuclear medicine examinations, the overall information should be given to the patients by the nuclear medicine physician (nmp). If no benefit to the individual is anticipated there may be a need to prevent or reduce doses of medical radiation up to 3mSv [15,16]. For doses between 5-30 mSv per year the patient should be fully informed that the benefit is greater than the radiation risk and give his/her informed consent. This consent should be noted by the nmp in the patients' records. Examinations administering more than 5mSv are those included in the WHO III category as mentioned above. For administering doses above 30 mSv or 20 mSv per year this informed consent of the patient should also be singed by the Director of the Nuclear Medicine Department or his authorized deputy.

It is true that nowadays many clinicians refer their patients for nuclear medicine examinations without knowing the possible radiation effect of medical radiation. Also many nmp do not consider that such a radiation effect exists to some of their patients [19]. Of course the patient should be asked if he or she had undergone in the past other high radiation inducing examinations. Having that in mind, the nmp would consider the benefit and risk from a nuclear medicine test that if performed in the present will add a dose to an already high cumulative dose that the patient had received. As mentioned above, a cumulative medical radiation dose of 100 mSv or more has be administered to patients with renal colic in a short period of time [21]. The justification in performing examinations that give high EDE to the patients is more crucial if patients are children or young age adults, because young ages are more sensitive and they run or will run soon the reproductive age. Radiation effects may not manifest until 5-20 y after the scan [19]. The US Food and Drug Administration has listed medical X-rays as a known carcinogen [19]. As Hippocrates said: "we should benefit not harm the patient" and "the patient" could by chance be one of our cancer patients or one of our own children or one of our children to come.

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