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Research Article

Exposure to Ionizing Radiation in the Endovascular Era in a Secondary Care Center

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Introduction

The use of ionizing radiation (IR) for medical use has been increasing over the decades. In 1977 the International Commission for Radiation Protection [1] established fundamental guidelines for estimating the features of stochastic or non-stochastic damage caused by IIn fact, IRs cause tissue damage through two effects. The deterministic effect (better defined non-stochastic tissue damage) is dose-correlated, so it has a threshold value below which there is no tissue damage, and vice versa the more the dose increases and the greater the damage is. Its effects are verifiable in a short-medium time interval (e.g. radiodermatitis and non-tumour skin diseases, cataracts, infertility). The stochastic effect, on the other hand, is not dose-correlated, does not present a threshold value and is related to the mutagenic effect and to the risk of inherited transmission of the mutations induced by IR. The stochastic effect can occur even decades after the exposure, and therefore in the medium to long term.

Dosimetric quantities

When a biologically significant medium is exposed in a field of ionizing radiation it becomes the seat of a series of processes, originating from the transfer of energy from the ionizing particles to the medium, which can lead to a certain effect. The main problem of the different branches (such as radiobiology, radiotherapy, radioprotection, radiochemistry) is to relate the effect produced with the physical characteristics of the radiation field. Since all the effects - biological, physical, chemical induced by the IRs occur only when there is a transfer of energy to the substrate, physicists use the “absorbed dose” (D) that coincides, substantially, with the energy absorbed by the irradiated medium per unit of mass.

Sizes used in radioprotection dosimetry

The unit of measurement of the absorbed dose in SI is Gray (1 Gy=1 Joule/kg). Rad special unit is however still in use, although rarely. By definition 1 rad=10-2 Gy. In the absence of specific information on the irradiation conditions, the absorbed dose D alone is not sufficient to predict the extent of the damaging health effects in radiation protection, since it does not completely interpret the processes of energy transfer from IR to living matter. It was therefore necessary to introduce other "radioprotection" quantities that better express the probability of the occurrence of the stochastic effects. This quantity is the equivalent dose (or equivalent of Dose), H=D x Q, where D is the absorbed dose, expressed in Gray, and Q is a dimensionless factor, called the radiation quality factor, which takes into account the type of radiation field (photonic, corpuscular, directly or indirectly ionizing). The quantity H is that by which the ICRP recommends the limits for exposed individuals. In the international system of measurement units, the dose equivalent is expressed in Sievert (Sv). The dimensions of the Sv, being dimensionless Q, are the same as those of Gray, i.e. J/ kg-1.

The risk related to the stochastic effects must be the same both in the case of uniform irradiation of the entire human body and in the case of non-uniform or partial irradiations, the effective dose quantity E is equal to the sum weighed on all organs and tissues of the dose equivalent received from the individual organ or tissue. The weight factors tend to consider the different radio sensitivity of the various organs and tissues. They are based on the evolving results of epidemiological studies.

The effective dose E allows to consider the biological risk of the whole body due to the irradiation of all the various organs of the individual, with the aim of reducing stochastic effects. The effective dose is also expressed in Sievert (Sv). Since we are concerned not so much by the amount of IR absorbed, but rather from the overall risk associated with them, the values calculated by the dosimetric plates worn by the staff are precisely expressed in terms of equivalent dose H and the dose attributed to the staff exposed in terms of effective dose E.The evolution of materials, of endovascular techniques and of medical technology has generally led to face an ever-increasing number of endovascular procedures, often of greater complexity than in the past, and these have now outpaced that of traditional surgical procedures. Such numbers are constantly increasing. About 25 years ago, the number of interventional procedures performed was around 350,000; a number that tripled after only 7 years. later [2].

The exposure of the medical and paramedical operating room staff to the IRs has also progressively increased. The absorbed doses of IR among the personnel involved, especially in the cardiac and vascular fields, are among the highest recorded if we consider those of all the staff working in contact with IR sources [3]. An interventional procedure for peripheral arterial disease involves a load of IR for the patient comparable to about 1500-2500 chest radiograph [4]. To have a comparison, a standard chest radiograph involves a load of about 0.01 mSv; a brain CT scan 2 mSv; an abdominal-pelvic CT scan 10 mSv, a coronary CT scan 12 mSv, while exposure to the natural background radioactivity in Italy is about 3 mSv/year, with variability between different areas.

In the absence of large and prospective registers on the effect of low doses/protracted exposures over time IR, it is not possible to establish with certainty a causal link between exposure of the operators and risk of cancer onset. However, it is well known that the use of IR in the diagnostic and therapeutic field is the largest artificial source of radiation exposure, even though interventional procedures are only 12% of all radiological procedures [5]. Basically, the question is that interventional procedures are evolving at a rate that exceeds the growth of our knowledge in the field of the safety of exposed personnel, especially given the long or very long latency times on the potential health damage caused by exposures.

Materials and methods

The monthly dosimetric surveys were compared in the last 6 years (2012-2017), in a Division of Vascular Surgery within a secondary care center, where endovascular interventional procedures are regularly performed. The surveys allowed to document the exposure of the operators over the years, and to verify if there has been an increase in average exposure over time, according to database of the Hospital Health Medical Service.

The personal dosimeters used are of the film-badge type for the whole body, and TLD for the ends (bracelets/rings). For the most radio-exposed operators, a dosimeter was also provided to estimate the crystalline dose. The dosimeters for the whole body, as instructed by the Qualified Expert in charge of physical surveillance, are worn over the anti-X coat (typically 0.50 mmPB Ant/0.25 mmPb Post), in order to increase sensitivity to low exposures and evaluate the mode of exposure to the diffused beam. The effective dose attributed to exposed personnel is corrected to take into account the protection of PPE (gown, collar), which is always mandatory.

In accordance with the recommendations of the ICRP and Directive 96/29/EURATOM [6, 7], the radiation dose of the operators is expressed through the radiometric quantities Efficace Dose (E) and Equivalent Dose (H) expressed in milliSievert (mSv) for the verification of the annual exposure limits of the exposed personnel (20 mSv for the whole body, 500 mSv for the extremities, 150 mSv for the crystalline lens). The European Directive 59/2013, which should have been implemented in the Law by February 2018, provides for the reduction of the annual dose limit to the crystalline at 20 mSv. This norm, which should have been implemented in the national legal system, has yet to be approved by the Italian Government.

Results

The annual dose, measured over the anti-X overalls, of the entire team (composed of 10 surgeons in the years 2012-2013 and 9 surgeons in the years 2014-2017) is expressed in table 1. The minimum dose was found in 2012, with a global exposure of 23.12 mSv. The maximum dose in 2015, with a global exposure of 61.77 mSv (Figure 1). If we take into account only the two temporal extremes (2012 and 2017), we note that the increase in exposure is about 100% in 6 years (from 23.1 mSv to 43.9 mSv), with a peak of increase 200% in 2015 (61 mSv).

The IR dose above reported refers to exposure over the gown. Based on the attenuation factors estimated by the Health Physics Service, which take into account the quality of radiation and the presence of collective and individual shields, the measured dose value is reduced of ¼ (correction factor=0.250). Therefore, the average individual effective dose attributed to the members of the team was between 0.57 mSv (2012) and 1.71 mSv (2015), with a range of interpersonal variability, which is better highlighted in bracelet surveys (Figure 2).

For what concerns the doses at the extremities, they were obviously higher than the body doses, with an increasing trend between 2012 (15.1 mSv) up to a peak of

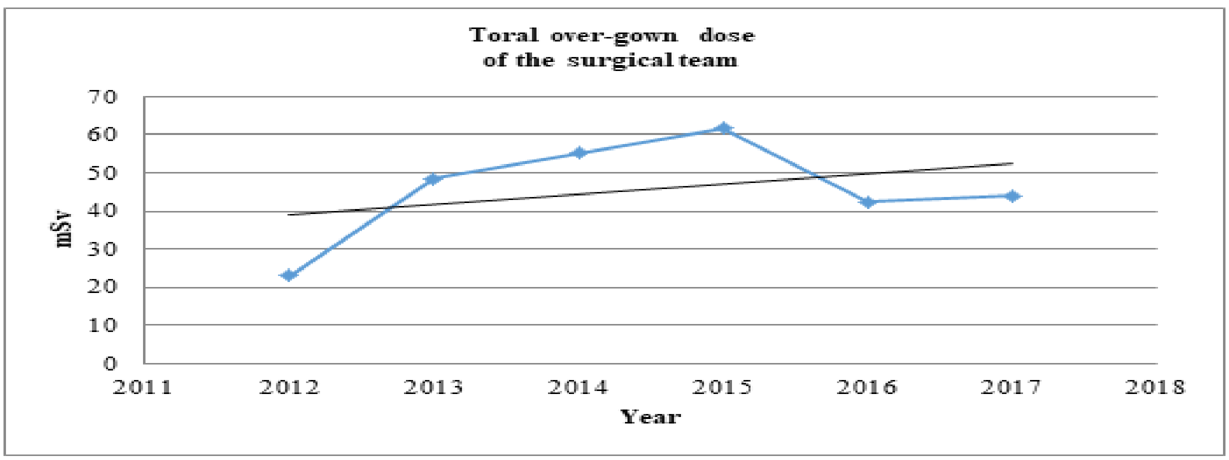

Figure 1: Global over-gown dose for the whole surgical team during the considered time(2012-2017).

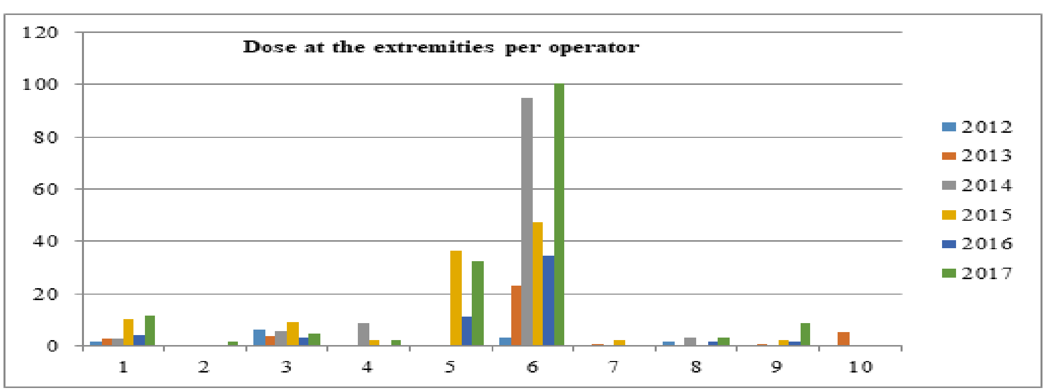

Figure 2: IR Cumulative dose divided by operator in the period considered (2012-2017). The data refer to the doses absorbed to the dose absorbed by the extremity (Bracelet Detection).

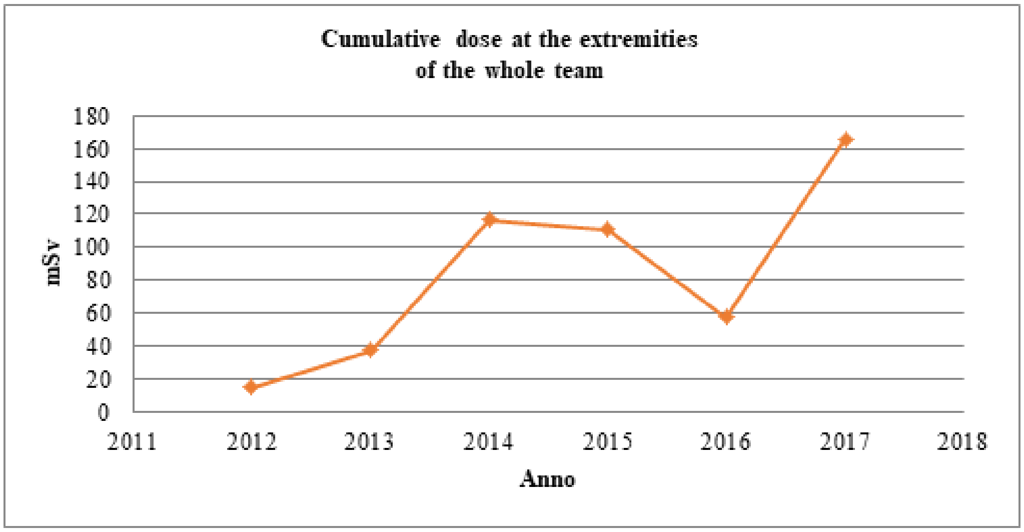

Figure 3: IR Cumulative dose of the team (extremities) in the period considered (2012-2017).

166 mSv in 2017 (Figure 3). Translated into average load per person, this means a IR load comprised between 1.5 mSv in 2012 and 18.44 mSv in 2017 (in this case no correction coefficient of attenuation is applied, being the exposure of unshielded fabrics). The values measured, albeit of an important entity, are within the limits of the law.

From the dosimetric point of view we observed a progressive increase in exposure, linked to a parallel increase in endovascular procedures if compared to traditional surgical procedures performed, in accordance with data merging from literature. This trend is probably destined to increase over the years to come, as the development of endovascular techniques and the evolution of materials and technologies will increasingly allow a minimally invasive and endoluminal approach to vascular pathologies.

Discussion

The standard method of measuring operator exposure employs personal detectors that record cumulative doses in certain areas of the body. The limit doses considered safe for occupational exposure to radiation use a linear model with no minimum threshold according to which the cancer risk in direct proportion to length and features of the exposure.

Thus, it is deducible that for an actual load of about 100 mSv in an adult, approximately one in 200 individuals will develop a cancer with a fatal outcome, and one in 100 individuals will develop a non-fatal cancer [8]. According to the report of the Biological Effects of Ionizing Radiation Committee VII (BEIR VII), the total incidence of cancers for those receiving yearly 2 mSv of IR for the entire working life of 45 years (18 to 65 years) is about 1 cancer out of 165 exposed subjects and the total tumour-related mortality 1 out of 245 exposed operators. The safety limits adopted are generally extrapolated from the studies on the incidence of cancer developed after exposure to much higher doses among the survivors of the atomic bombs or exposed to nuclear accidents. Very little is known about the biological effects of low intensity exposures but prolonged over time. However, it is interesting to note the probable correlation between exposure to RI and brain tumour's: on a series of 31 brain tumours developed by interventional cardiologists and radiologists with a mean latency time of 23 years, as many as 26 have affected the left hemisphere, more exposed to RI with respect to the contralateral hemisphere [9].

In a recent study [10] the DNA damage of the operators in the preoperative period was quantified, in the immediate postoperative and 24 hours after the procedure, measuring the gamma-H2AX lymphocyte expression, a histone protein that can be used as a marker of DNA damage of lymphocytes (as they are exquisitely radiosensitive cells and therefore ideal for monitoring the biological effects of IR). The measurements showed that the EVAR procedures (Endo Vascular Aneurysm Repair) were associated with a higher level of DNA damage, with a peak in particular in the immediate post-operative period, with the return of the damage in the following 24 hours. Measurements after simple EVAR procedures showed slight increase in DNA damage, whereas traditional surgical procedures showed no signs of damage. In particular, exposure to the lower limbs was significant, and could constitute a potential underestimated danger. In operators without lower limb protection, in particular, the peak of DNA damage in the post-operative period was particularly significant. The direct evaluation of DNA damage has therefore made it possible to measure the direct effects of exposures to ionizing radiation, and to identify the most exposed operators, compared to what is documented by standard dosimeters. Exposure is higher in interventional cardiology department at high workload where trans-radial procedures are preferentially performed with respect to trans-femoral procedures [11], due to the greater average proximity of the operators to the radiant field.

If we take into account only the operators with the greatest volume of interventional work, the radiation load is between 2 and 5 mSv per year, which means an exposure in 15 years of about 50 mSv, i.e. a non-negligible load of IR. The importance can be statistically expressed in a LAR (lifetime attributable risk) of a tumour for every 200 exposed subjects. For subjects exposed to a 5 mSv annual load, the tumour LAR after 20 years of exposure is about 1 over 100.

Expressed in more usable other statistical terms, and always according to the BEIR VII report, if we calculate an average exposure of about 100 microSv per procedure, the risk of developing a tumour by an operator is about 1 in 100,000 for each procedure. This estimate could also increase by a factor of 10 (i.e. 1 in 10,000 procedures) if we take into account that the optimal radioprotection criteria by the operators involved are not always respected.

The peak of risk in chronically exposed operators occurs in the 7th, 8th and 9th decades of life, so many years after the actual exposure [12, 13, and 14].

Currently the scientific community is well aware of the carcinogenic effects of low-dose IR used in the medical field. For example, an operator with a mean exposure of 2-4 mSv per year has twice the number of lymphocytes with chromosomal aberrations and / or with micronuclei, which represent markers of increased tumour risk. We are also aware of the fact that the estimates used could held a source of uncertainty and approximation of a factor 2 or 3 times greater or less than estimated. However, these represent the best estimates currently available, and these must be referred to: a cumulative load of 50 mSv during working life is considered the threshold not to be exceeded. Only some of the most active operators from an interventional point of view are overcoming this threshold of risk.

Conclusion

The exposure of the operators is a risk that should not be underestimated, considering the increasing workload of endovascular work. According some guidelines, we could assist in near future to a reduction of endovascular aortic procedures versus "open" procedures for the treatment of infrared aortic aneurysms [15]. At present, the prevention criteria stress the importance of standing as far as possible from the radiation source, to use available shields, and to limit the total exposure times. Unfortunately, about one third of the personnel exposed is negligent in terms of radiation protection, and it is thus crucial to increase the awareness of the risk in the medical staff.

Hopefully there will soon be better methods to protect operators, especially through the optimization of exposure techniques (use of AEC systems, pulsed fluoroscopy with low pulse rate) and to stratify the risk more precisely. In fact, with the increasing of our knowledge, we will better comprehend the risk of chronic low-dose exposures, above all for what concerns the stochastic risk in the medium / long term.

Based on the data emerging from this work, our group has improved risk awareness and is taking measures to reduce the risk of exposure.

Basically, these measures are the adoption of radio-opaque caps, the maximum possible reduction of the amplifier's frame rate of brilliance in all the phases of the procedure whenever possible, an accurate planning of the procedure and devices to be used, the removal from the operating theatre of all the personnel not indispensable during the phases of fluoroscopy and image acquisition, the use of intra procedural ultrasound devices - when feasible - to reduce the exposition to IR.

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