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Endovascular Repair: Radiation Risks

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1. Introduction

Abdominal aortic aneurysms (AAA) occur when weakened areas of the abdominal aortic wall result in a ballooning of the vessel. Endovascular repair of AAA (EVAR) has rapidly been integrated into clinical care worldwide as an alternative to open surgical repair. However, such a management is coupled with extended exposure to X-rays for intervention planning, manipulations of catheters and endovascular devices and documentation of the repair, as well as for long-term postoperative surveillance. The energy absorbed in the human body by X-rays causes ionizations triggering biochemical changes that may lead to death or modification of cells. Although many patients derive great benefit from such repairs, some may suffer radiation - induced harm (e.g. skin injuries and increased risk for future cancer), mainly due to the use of inappropriate equipment and, more often, due to poor operational practices (International Commission on Radiological Protection [ICRP], 2000). The three key principles of radiological protection, justification and optimization and application of dose limits, have to be applied in AAA management, as in any practice related to use of ionizing radiations. The radiological burden to both patient and staff has to be assessed at each facility, and if required, the employed practice has to be modified, to keep the risks as low as reasonably achievable, commensurate with the medical purpose.

2. Dosimetric quantities

The medical use of ionizing radiations has the potential to cause harm, as well as provide benefit. Most of the energy emitted from of the X-ray unit during aorta imaging is absorbed non-uniformly in the imaged sections of the patient's body. The patient's bed and the image receptor absorb another fraction of the emitted energy. An additional fraction, usually of the order of 20%, is scattered towards other directions, such as non imaged sections of the patient's body and the staff present in the operation room.

The estimation of the probability of induction of radiobiological effects, either acute or delayed, requires the assessment of quantity absorbed dose, D, at any point in the human body, i.e., the quotient of the energy imparted by ionizing radiation to a volume to the mass in the volume. This quantity is measured in grays, Gy (J/kg). Direct dose measurements at any point are impractical for most organs and tissues. Therefore, simulations of clinical practices are often carried out using physical or mathematical anthropometric phantoms coupled with the following quantities that are assessed in real-time during AAA repair:

- dose at the interventional reference point, D_o , i.e., the procedure cumulative absorbed dose in air at a specific point in space along the central beam axis, with no patient in place, i.e., this quantity, sometimes also referred as cumulative air kerma. does not include backscattering from the human body
- dose area product, i.e., the cumulative product of the absorbed dose in air with the beam cross sectional area (this quantity is often referred as kerma area product, KAP, due to the marginal differences between the physical quantities kerma and absorbed dose in low energy X-ray radiation fields). This distance invariant quantity is related to the entire amount of energy delivered to the patient during the procedure.

C-arm units used for fluoroscopically guided vascular interventions should to be equipped with a device called DAP (or KAP) meter, that tracks and displays dosimetric quantities on or near the operator's imaging monitors both in real-time and cumulatively (FDA regulations enacted on June 2006, require all new fluoroscopic equipment to be equipped with a DAP meter, that is integrated into the unit, Conference of Radiation Control Directors [CRCPD], 2010). The meter consists of a large parallel plate ionization chamber located close to the exit window of the fluoroscopic head and connected with an electrometer. A rough estimation of D_o and DAP can be obtained alternatively in some units using a build-in software (in practice, the software does not take into account possible temporal changes in the X-ray tube output per mA during its working life). The thus obtained dosimetric data as well as procedural and anatomical data, are often introduced off-line to software that allows the assessment of the mean value of absorbed dose in the various organs and tissues of the human body, but not on the spatial distribution of the dose in each of them.

3. Radiobiological aspects

The various biological effects that can be induced by ionizing radiations are divided in two groups, stochastic and deterministic. The former can be induced even after irradiations at low doses of irradiation; on the contrary, the latter can be induced only by high doses (International Commission of Radiological Protection [ICRP], 2007). However, controversy exists today regarding the risk of exposure to X-ray doses less than 100 mGy. Many mechanisms operated in cells and tissues are still evasive in this dose range. Some radiobiologists claim that extrapolation of high-dose to the low-dose region of the dose-effect relationship may overestimate the risk (Feinendegen, el al, 2011). However, the current strategy to quantify the radiological risks in daily practice, assumes that both radiogenic cancer induction in exposed individuals attributed to mutations of somatic cells and heritable effects in their offspring attributed to mutations of reproductive cells, may occur at low doses. Risks of other non-cancer diseases following low dose irradiations, such cardiovascular disorders and vision impairment, still remain uncertain (ICRP, 2007).

3.1 Stochastic effects

Stochastic effects are those for which the probability of induction, but not their severity, is regarded as a function of dose without threshold. More specifically, epidemiological data on subjects irradiated with –X of –γ rays at doses >100 mGy indicate a linear relationship without threshold between the mean absorbed dose in a number of irradiated organs and tissues and the probability of cancer induction to them. Therefore, an increment of absorbed dose induces a proportional increment in risk at low doses. So far only two effects are considered to be stochastic, induction of malignant disease and heritable effects. In radiation

protection the quantity called effective dose, E, expressed in Sv (J/kg), is widely used as an estimator of the health detriment at low doses.

The probability of induction of stochastic effects is related to the quantity effective dose, i.e., the weighted sum of the doses absorbed in a number of organs and tissues specified by ICRP, that their exposure may induce cancer or heritable effects. This quantity takes into account the fact that the induction probability and severity of radiobiological effects per unit dose are not identical in various parts of the body by weighting individual organs and tissues by the relative detriments. Nowadays, most countries base their legislation on the 1990 ICRP recommendations (ICRP, 1990), that take into account the absorbed doses to gonads and to 21 organs or tissues. More specifically, a 0.20 organ weighting factor was assigned to gonads (testes or ovaries), 0.12 to red bone marrow, lung, stomach and colon, 0.05 to five organs (urinary bladder, breast, liver, esophagus and thyroid), 0.01 to bone surface and skin, and 0.005 to ten organs or tissues (adrenals, brain, upper large intestine, small intestine, kidney, pancreas, spleen, thymus, uterus or prostate and muscle). ICRP assigned a nominal risk coefficient of 7.3% per Sv for the whole population and 5.6% per Sv for adult workers (18-64 years old).

According to 1990 ICRP recommendations, the detriment-adjusted risk to patients that undergo a CT examination of the aorta, that results to a 14 mSv effective dose, is about 0.1% ($=14 \cdot 10^{-3} \times 7.3\%$). Let's assume that the examination has to be repeated three times. Taking into account that the fact that the risk increases linearly with dose and the hypothesis often made that that the time period over which the dose is given does not modify the risk, the three examinations result in a 0.3% risk. Similarly, the occupational radiological risk of an interventionist that gets an effective dose of 100 mSv due to his occupation over a 25 year period (4 mSv annually on the average) is estimated to be almost 0.6% ($\sim100 \cdot 10^{-3} \times 5.6\%$).

Recently ICRP updated its recommendations (ICRP, 2007). Among others, the number of organs/tissues that are taken into consideration for cancer induction was increased from 21 to 27, the weighting factors were modified (for example, the nominal risk for heritable effects in adult workers up to second generation was reduced by a factor of eight) and the nominal risk coefficients for the whole population and for adult workers were reduced to 5.7 % and 4.2% per Sv, respectively. Taking into account that most EVAR patients are past reproductive age and have serious underlying health problems, i.e., with life expectancy shortened as compared to whole population, deterministic injuries in patients are usually of greater concern than those of stochastic effects.

3.2 Deterministic effects

Deterministic effects, or tissue reactions, can be induced by X-ray doses of a few Gy from X-rays to ovaries, testes, red bone marrow, skin, carotid arteries, brain and the eye lens (ICRP, 1984, 2007). However, recently ICRP stated that "although uncertainty remains, medical practitioners should be made aware that the absorbed dose threshold for circulatory disease may be as low as 0.5 Gy to the heart or brain". Doses higher than few Gy are required to induce deterministic effects to other organs, such as lungs, intestine and kidneys.

The incidence of radiation induced injuries in patients is small when compared with the large number of fluoroscopy – guided procedures carried out world-wide, but their consequences can be devastating (Balter & Moses, 2007; ICRP, 2000). Therefore, practitioners should apply methods to avoid the induction of such effects and know how to recognize their signs. In addition, they have to communicate the radiation risk information to patients and provide them the opportunity to ask questions, whenever they deliver doses that could potentially induce them.

Early tissue reactions (on time scale less than about two months after irradiation) usually are the result of either inflammatory type reactions occurring as a result of cell permeability changes or sterilization of stem and progenitor cells. On the contrary, late tissue reactions (on time scale from months to many decades) may occur as a result of either the direct injury to the target tissue, or as a result of severe of early reactions (e.g., dermal necrosis as a result of epidermal denudation) or/and chronic infection. Late tissue reactions, such as excess cardiovascular disease that becomes clinically apparent only 10 to 20 years post-irradiation, have a long and dose-dependent latency period before their clinical expression, reducing thus the probability of induction in elderly patients.

Although deterministic effects may appear in all body areas, the various tissues and organs have different tolerances. Once a threshold dose has been exceeded, the probability of induction and the severity of the effect increases with increasing dose. The threshold dose, TD_1, i.e. the amount of radiation that is required to cause a specific observable effect in 1% of the exposed individuals, depends on a number of factors, such the irradiated tissue or organ, the type of response and the time over which the dose was given. TD_1 usually increases with increase of the time over which the dose is given, or by dose fractionation, due to cellular repair and even repopulation. Therefore, increase of the interval between medical procedures that require "heavy" exposure of the same body region, if clinically acceptable, modifies the dose response relationship.

The TD_1 currently used values, such as those on skin reactions (Table 1) refer to healthy adults. No specific data have been proposed to be used for children and subjects with mutations in important DNA damage sensing or repairing genes (the homozygous form of ataxia telangiectasia gene, Fanconi anemia, and Bloom syndrome are typical examples), patients with diabetes, active connective tissue diseases (scleroderma, lupus erythematosus, etc), autoimmune disorders, and patients with disrupted skin due to surgery or burns.

In most tissues and organs, responses are greater when the irradiated volumes are greater. This volume effect means that the threshold dose increases as the volume of the irradiated organ/tissue decreases. Cell migration, proliferation and differentiation of progenitor cells from the margins to the heavily irradiated tissue volume may explain this effect (Dilmanian et al., 2007). Paired organ, such as the kidneys, and organs with functional subunits arranged in parallel, such as elements in the liver, rather in series, such as elements in the spinal cord, can sustain partial inactivation without clinical signs of injury.

3.2.1 Skin reactions

Since the early 1990s reports of radiation-induced skin injuries to patients due to fluoroscopically guided medical procedures have steadily increased. The skin is the only organ, which is always exposed to primary radiation during X-ray imaging (the skin region of beam entrance is the region that gets the highest dose). Relative to other organs, skin is less liable to develop fatal cancer after irradiation (ICRP 1991, 1992, 2007). However, the thresholds for mild deterministic effects are relatively low compared other organs (International Atomic Energy Agency [IAEA], 1998). Therefore, only five months after the discovery of X-rays, serious skin damage was documented, three weeks after imaging the head of a child (Daniel, 1896; Tarbell et al., 1981). Since then, a vast literature has been published on skin injuries that may evolve slowly over time, extending from hours to years after irradiation, often with periods between them of none or few symptoms (Table 1).

A minimum number of adjacent cells must be damaged by radiation to elicit skin injury (Peel & Hopwell, 1984; Dilmanian, et al., 2003). The dose-response relationship for each type

of skin damage due to X-ray irradiation (Table 1), as well as the kinetics of healing, depend on a large number of factors, such as protraction of irradiation or dose fractionation (potential of partial or full repair between fractions), size and location of the exposed area (the skin in the back of the trunk is considered to be of medium radiosensitivity), obesity, skin hydration status and coloration (light-colored skin is regarded to be most sensitive). The dose-response relationship is often modified in patients given some medications that may modify skin response, before, during, or even years post irradiation (Burris & Hurtig, 2010; Camidge et al., 2001; Hymes et al., 2006).

In general, the earlier the onset of clinical changes (Table 2) the more severe the pathology of the skin lesion (Muller & Meineke, 2010). Following skin irradiation some basal cells are destroyed. The remaining cells shed more quickly. Mitotic inhibition appears about 30 minutes after a single 4 to 5 Gy X-ray irradiation, followed by decrease in the proliferation of the germinal layer of the endothelium. No clinically observable skin reactions are expected to be induced following a single acute dose up to 2 Gy of X-rays (higher total doses can be tolerated following prolonged or fractionated irradiations). Pain, if occurs, does not occur immediate (as in thermal burns), but when it appears, it is sever and resistant to drugs (its evolution is regarded as a good indicator for the prognosis and prediction of local skin atrophy and even necrosis (Rojas-Palma, et al., 2009). Therefore, although skin injuries are not usually life threatening, the more severe lesions may result among others in chronic intractable pain and permanent disability, such as that related to amputation (IAEA, 1998, 2002).

The earliest visible skin response that may appear is a transient skin erythema, (reddening), at the entrance site of the X-ray beam. It resembles to sunburn with no hair loss at this stage, in contrast to thermal burns, where early hair and tissue loss is observed (Table 2). The first wave of erythema may be accompanied by sensation of heat and itching. It may be seen from a few hours up to 48 h after irradiation at single X-ray doses above 2 Gy, when the exposed skin area is relatively large (as in EVAR where ~250 cm^2 is a typical field area), and fades after few hours to two days. This injury is attributed to inflammation due cytokine activation and capillary dilation, thus increasing blood volume beneath epidermis and vascular permeability. This stage is followed by a latent one during which there are no apparent skin reactions, despite the subcellular processes that may take place. In daily clinical practice, the isolated or confluent prodromal patches in the skin of EVAR patients that received high local doses may go unnoticed, because they are anticipated to occur at the patient's back, an area that patients could no easily see. However, if observed, they can serve as an alarm for possible more serious radiation reactions. In this case, the use of dermatoprotector creams is recommended (IAEA, 2002).

effect	TD_1 (Gy)	effect	TD_1(Gy)
early transient eryrhema	2	dry desquemation	14
temporary epilation	3	late erythema	15
main erythema	6	dermal necrosis	>15
permanant epilation	7	moist desquamation	18
dermal atrophy	10	ischemic dermal necrosis	18
telangiectasia	10	secondary ulceration	24

Table 1. Threshold acute X-ray doses (ED) for skin reactions in 1% of the subjects (protraction of dose over a period of 1-3 weeks results in higher TD_1).

stage	latency	persistence	symptoms
prodromal	minutes-hours	0.5 – 36 h	erythema, pruritus
manifestation	3 weeks	1- 2 weeks	erythema, pruritus, bullae, ulcer
subacute	16 weeks	months	erythema, ulcer
chronic	years	unlimited	ulcer, keratosis, fibrosis, epidermal atrophy, teleangiectasia, angioma, alterations in pigmentation
late	>10 years	unlimited	angioma, basal and squamous, cell carcinoma

Table 2. Clinical stages of skin reactions (IAEA, 2002).

If the dose is sufficient, inflammatory processes prevail and a second hyperemic phase of more sustained erythema (second wave of erythema), may appear at two to four weeks after dosing of at least 3 to 6 Gy in adults, usually lasting 20 to 30 days (ICPR, 2007). The severity of erythema and the latent period are dose dependent. This erythema phase may appear even one week after an acute dose above 15 Gy, often accompanied by subepidermal blister formation due to apoptosis and necrotic destruction of the epidermis (Muller & Meineke, 2010), heat sensation, itching, tenderness in the irradiated skin area and changes in pigmentation. However, if the dose is not much a greater than the threshold, the erythema fades after about 4 weeks (Koening et al., 2001). The third phase of erythema (third wave of erythema) may also be seen with an onset of about 8 to 20 weeks post-irradiation following a single irradiation of at least 15 Gy. This phase may vary in severity, but at its maximum is characterized with a dusky / mauve appearance. Recently, Rahimi et al. (2011) associated to radiation damage a square shaped burn observed in the back of a patient with abdominal aortic aneurysm during the second post-repair visit to the hospital.

Two to three weeks after an acute X-ray dose exceeding the 4 Gy threshold (ICRP, 2007), epilation may occur due to damage in the base of the hair follicles (in some anatomic locations the TD_1 could be higher than 4 Gy). Single acute doses from X-rays in excess of 7 to 10 Gy may irreversibly reproductively sterilize or lead to apoptotic death the stem cells in hair follicles, resulting in permanent epilation (Koening et al., 2001; Kim et al., 2003). However, epilation is temporary following low radiation doses. Survival of basal and germinal matrix cells in the hair follicles may allow for hair re-growth (Geleijns et al., 2005) about 1.5 to 4 months post-irradiation. At the initial stage of re-growth, hair may be thinner (up to 30% reduction in diameter) and sparse, differing occasionally in pigmentation and structure from that before irradiation.

Alopecia has been reported in literature to be induced in patients who underwent endovascular treatments for various clinical conditions, such as aneurysm (Foroozan et al., 2008; Lee et al., 2004; Marti et al., 2008) and arteriovenous malformations (Fellman, 2011; Wen, et al., 2003) mainly in the skull, as well as in practitioners, such as hair loss reported at the lower legs of cardiologists (Wipper et al., 2005). Taking into account the locations of the X-ray entrance ports used in patients with aortic aneurysm and their age distribution, radiation induced hair loss is not as stressful as in other patients, such as those in young patients with malformations in the head or those with radiotherapy.

The rate of gradual decline in cell density in the basal layer depends on the rate of epidermal turnover at the irradiated site. A 50% reduction of the normal basal cell density appears to

provide a stimulus to the remaining viable colonogenic stem cells to proliferate starting about 3 weeks post irradiation in pig skin, the model historically assumed to be the best one for human skin *(*Van de Aardeg et al., 1988*)*. At relatively low doses the number of developing colonies will be adequate to unite into a single group, thus leading 3 to 6 weeks to dry desquamation, an atypical keratination of the skin (ICRP, 1992). If the X-ray dose exceeds 18 Gy, the reduced number of developing colonies may not cover the entire damaged area and cell loss will continue, leading to moist desquamation, i.e., loss of the epidermis. At this stage dermis is denuded, allowing serum from the deep cutaneous layers to be excreted (Koening et al., 2001) often responding with marked inflammation (the use of glucocorticoids and hydrocolloid dressings might be considered, as well as local infection prophylaxis and treatment). When the area of the irradiated skin is completely denuded of clonogenic epithelial cells, healing must occur totally as a result of division and migration of epithelial cells from the edges of the irradiated skin area. For all, but the very small radiation fields, the repopulation progresses slowly, thus exposing the skin to risk of secondary ulceration, at least 6 weeks post-irradiation (ICRP, 1992; Balter et al., 2010). Some radiation ulcers that were healed over time have a tendency to recur in the following months and years (Koenig et al., 2001). Other ulcers never heal completely even years after fluoroscopically guided interventions.

In general, dermis presents clinically its response at a later stage than epidermis and may not reach its peak even after some years (Geleijns et al., 2005). Cutaneous reactions are attributed to complex interactions between antiproliferative and proinflammatory processes, involving a variety of cytokines, adhesion molecules, growth factors and their receptors (IAEA, 2002). Dermal ischaemia and necrosis may appear 6 to 8 weeks post-irradiation at doses of at least 20 to 25 Gy. These effects were preceded by loss of endothelial cells, microvascular damage, reduction in capillary density, edema and impaired lymphatic clearance (ICRP, 1992). Late skin damage is characterized by dermal atrophy, dermal tissue thinning, long-lasting telangioectasia (it appears at least 1 year after an acute X-ray dose of at least 10 Gy), cutaneous fibrosis characterized by an increase of collagen fibers, keratosis, and often by reduction in the linear dimensions of the irradiated area. The use of interferon gamma as an inhibitor of collagen can be considered.

The various techniques for diagnosis and medical management of localized radiation injuries were reviewed by various organizations and investigators (IAEA, 2002; Rojas-Palmas et al., 2009; Muller et al., 2010). For example, moist desquamation may require surgical intervention to remove irradiated dermal and subcutaneous tissue (Rojas-Palmas et al., 2009).

3.2.2 Eye reactions

The eye lens is one of the most radiosensitive tissues of the human body, not with respect to cancer induction but mainly to the induction of lens opacity. The potential of X-rays to produce cataracts was suggested only two years after their discovery (Merriam & Worgul, 1983). Lens transparency depends on proper differentiation of fibre cells from a layer of epithelial cells in the lens anterior surface near its equator. The earliest lens change is the visualization of granular opalescent on the posterior lens capsule observed by slit lap examination followed by the appearance of small vocuoles (ICRP, 2007; Merriam & Worgul, 1983), which, over time, aggregate to form larger opacities of great impact in vision. The time between irradiation and the clinical manifestation of eye damage varies from half a year after "heavy" exposures to many decades.

In the past, induction of vision-impairing cataract was considered as a deterministic effect with threshold of 5.0 Gy following a single brief exposure to X-rays and higher than 8 Gy following highly fractionated exposures (ICRP, 2000). Based on knowledge available on 2007, ICRP reduced the TD_1 for cataract formation to 1.5 Gy, stating, however, that "the Committee can not ultimately exclude cataract induction at even lower doses". Recent studies indicated a significant association between exposure to lower doses and increased risk of cataract formation (Ainsbury et al., 2009; Chodick et al .,2008; Ciraj-Bjelac et al., 2010; Jacob, et al.; Shore et al., 2010, Worgul et al., 2007). For example, some investigators reported on increased cataract rate even after ~0.5 Gy, acute or fractionated; others found detectable lens changes even after only 0.1 Gy doses and some even proposed the use of a linear non-threshold model (Chodick et al., 2008; Nakashima et al., 2006). Based on evidence available on April 2011, ICRP further reduced the threshold dose for the eye lens to 0.5 Gy.

Those occupationally exposed during fluoroscopically guided procedures are at a risk of radiation-induced eye damage. For example, Vano et al. (2010) found a 3.2 relative risk of posterior subcapsular opacities in 116 interventional cardiologists versus unexposed individuals. Ciraj- Bjelac et al. (2010) found a 5.7 relative risk of posterior subcapsular opacities in 56 interventional cardiologists of average age 42 y, that received a mean cumulative dose to the lens 3.7 Gy versus unexposed matched individuals (prevalence 52% vs 9%). Therefore, precautions, such as protective glasses and X-ray tube positioning, have to be taken to protect the eyes of staff heavily involved in fluoroscopically guided interventional procedures, delaying thus opacity propagation and limiting future cumulative lens dose (Vano et al., 2008).

3.2.3 Effects of antenatal exposure

Embryo and fetus are highly radiosensitive during the entire gestation period. The possible biological effects due to prenatal irradiation were reviewed in ICRP Publication 90 (ICRP, 2003). The type and the severity of the damage depend on the time of exposure relative to conception (ICRP, 2003, 2007; Brent, 2007). Chronic or fractionated irradiations to X-rays at a specific total dose are usually assumed to be four to ten times less risky than single acute doses.

The life-time cancer risk after prenatal irradiation is assumed to be at most few times that of the population as a whole and not greater than that following exposure in early childhood (ICRP, 2007). For example, following an 100 mGy fetal dose there is a 99% chance that the exposed fetus will not develop childhood cancer or leukaemia. Animal experiments indicate higher radiosensitivy for cancer induction in females than in males and at late than early gestation periods (ICRP, 2003). However, it is not clear if these findings hold for humans. In addition, it is not possible to determine tissue/organ weighting factors of the conceptus, based on the currently available data.

The risk for lethality of the developing organism is assumed to be highest during the first post-conception days (pre-implantation period). At this period the number of cells in humans increases from one, the zygote, to about 200. No observations are available at this gestational period in humans, as conception in not noticed at that time. Therefore, the current knowledge is based on animal models. At doses of few tens of mGy lethal effects are very infrequent. However, lethality reaches 50% for 1 Gy X-ray doses given at stages from the zygote to expanded blastocyte (ICRP, 2003). The currently available data provide no reason to believe that, if death does not occur at this stage, significant health effects may occur after birth, except if there is genetic predisposition for malformations (ICRP, 2007).

Human epidemiological studies and animal studies indicate that the *in utero* radiosensitivity for malformations (defects visible at birth) depends on gestation age and that the regenerative capacity decreases as differentiation of tissues and cells progresses It is currently believed that there is a dose threshold of about 100 mGy for malformation during the most radiosensitive period for such an effect, the period of major organogenesis (3 to 7 weeks post-conception). Studies on rodents indicated the existence of a dose threshold for induction of intrauterine growth retardation of about 0.25 Gy following an X ray irradiation within a short time period during the most sensitive period that is advanced stages of organogenesis and 0.5 Gy during the less sensitive stages (ICRP, 2003). Therefore, for stage of peak sensitivity for fetal underweight differs from those for lethality and malformations. Nakasima, et al (1994) analyzing body habitus of age 18 years of *in utero* exposed atomic-bomb survivors found a clear radiation effect on standing height, however in a later study (Nakashima, et al., 2005) they failed to find dependence of the effect on the gestational period at exposure, particularly among males. Neurobehavioral studies of animals exposed *in utero* demonstrate a threshold for behavioral effects at the same dose as for other teratological effects, i.e. 0.2 Gy (Brent, 2007).

High radiation doses (1 to 2 Gy) of ionizing radiation to the developing human fetus may induce mental retardation and microcephaly (Brent, 2007). The susceptibility of the developing human to injury from prenatal exposure was clearly shown by Schull and Otake (1984, 1999). The human data related mainly to those exposed to radiation from the use nuclear weapons in Hiroshima and Nagasaki are in good agreement with data on animal models. Severe mental retardation may occur following prenatal irradiation. When the cases assumed to have non-radiation aetiology at the two Japanese towns were excluded (e.g. Down's syndrome), threshold dose values of 0.55 Gy (95% confidence interval 0.3 to 0.6 Gy) and 0.87 Gy (95% confidence interval 0.3 to 1.1 Gy) were proposed for irradiations 8-15 and 16-25 weeks post-conception, respectively, i.e. the major neuronogenetic periods of the developing human neocortex during which the developing brain expands very fast (ICRP, 2000; Nowoakowski & Haeys, 2008). In addition, a decline in IQ values of about 25 IQ points per Gy was observed due to irradiation 8 to 15 weeks post-conception, resulting in very small detriment at X-ray doses less than 0.1 Gy. Irradiations 16 to 25 weeks pos-conception resulted in lower IQ decrement, 13 IQ points per Gy. From the other hand, there is no data supporting a similar damage, when the dose is given at a later gestation stage (ICRP, 2003, 2007).

4. Radiation protection in aneurysm repair

Radiation dose and image quality strategies are important for ensuring a balance between cost and benefit. The question to ask in daily clinical practice is not "is this radiation-related procedure safe?" but "is this procedure needed to help the physicians provide the best medical treatment?" The practitioner has the responsibility to order / carry out the appropriate tests and interventions when justified by the presenting symptoms or concerns with the lowest cost consistent with the medical aim.

In EVAR, as in any other type of fluoroscopy guided vascular intervention, both patient and staff radiation exposures are related to the dose at the interventional reference point (D_o) or/and the dose area product (DAP) value. Patient data related to over AAA 1000 repairs are summarized in Table 3. The corresponding studies indicated that the vast majority of the patients were male with mean age 70 to 75 years and that the mean fluoroscopic time

reference	n	mean age (years)	mean fluoroscopy time (min)	mean DAP (Gy cm^2)	median DAP (Gy cm^2)	Dose (mGy)	PSD (mGy)	type of fluoroscopic unit
Geijer, et al., 2005	24	72	28	72$\pm$45	60.1		390	mobile
Kalef-Ezra et al., 2009	62	74	23	42.5$\pm$25.6	37.4		227	mobile I
Lipsitz, et al., 2000	47		39				360	mobile
Present study	142	70	22	30$\pm$24	24.4		205	mobile II
Weerakkody, et al., 2008	96*	73	21*,++		150*		850*,++	mobile
Weiss, et al., 2008	12		21	152			750	mobile
Farrar, et al., 2005	121	74	24++					not specified
Jones, et al., 2010	64	75	23	54$\pm$34				not specified
Jones, et al., 2010	320	75	29	47 $\pm$28		1187		not specified
Bannazadeh, et al., 2009							729	stationary
Blaszak, et al., 2009	61	71.5	23	381$\pm$285	355			stationary
Geijer, et al., 2005	24+				600 +	2900+		stationary
Kalef-Ezra, in press	6	72	12	192	205		1050	stationary
Kuhelj, et al., 2010	152	71	21		154		440**	stationary
Panuccio, et al., 2011++	47	75	83	782	697	6300	2590	stationary

* excluding data on seven patients, ** median rather than mean value,
PSD: peak skin dose, + simulated procedures, ++ thoracoabdominal aneurysms

Table 3. Demographic data, fluoroscopy time and dosimetric quantities related to AAA repairs.

per repair was about 20 min, with two exceptions, the studies by Lipsitz er al, and by Panuccio et al. (2011) who treated thoracoabdominal aneurysms. On the other hand, the spread of the DAP and the mean peak skin dose, (D_{peak}) values were also large, even excluding the study by Pannuccio, et al. In addition, as in other types of vascular interventions, the spread of values at each facility was also large (65% is a typical value of the coefficient of variation) and their distributions were not Gaussian (the median is typically about 15% lower than the mean value). In the following paragraphs some of the factors related to the spread of the mean DAP values between facilities and between repairs carried out at each facility are discussed, as well as, some means to control the radiation burden.

The currently acceptable errors in D_o and DAP measurements are quite large, $\pm$35% by the Food and Drug Administration (FDA) and $\pm$50% by International Electrochemical Commission (IEC). In addition, there is no unique definition on the place of the interventional reference point along the central beam line. IEC defines it to be at 15 cm distance on the X-ray tube side (IEC, 2000), while FDA defines it at 30 cm distance from the image receptor, leading a factor of four difference in the displayed D_o values in systems with 100 cm focus to distance. An additional source of error is the angular dependence of the X-ray beam attenuation on the patient's bed (the calibration of the DAP meter is often

carried out at a geometry that differs from that used during AAA repair). Therefore, spatial attention is required when comparing values presented in various studies and/or correlating the displayed quantities with the mean or the peak doses in an organ or a tissue.

4.1 Assessment of stochastic risk to patient

The assessment of the effective dose related to AAA management is required to weigh the potential stochastic risks against the anticipated medical benefits. However, direct dose measurements are impractical for most organs and tissues. Thus, the assessment of mean doses absorbed by the organs and tissues of interest is usually made by introducing to a software some repair-related parameters (DAP, field size, data on patient's body habitus, the anatomic location of the lesion, X-ray tube high voltage and filtration, etc.). The dose corresponding to each radiation field has to be assessed separately and then summed-up to calculate E (most investigators so far assumed that the location and the size of the X-ray beam and spectral distribution remained unchanged throughout repair, and neglected the influence of body shape and composition on dose distribution). Various investigators reported mean E to DAP ratios ranging between 0.14 and 0.25 mSv/Gy cm² (Table 4) using the 1990 definition of E by ICRP. On the other hand, the mean E values shown in Table 4 differ up to two orders of magnitude, with the lower ones being comparable to the effective dose resulting from three years of exposure to natural background radiation.

Reference	E / DAP (mSv/Gy cm²)	mean E (mSv)	median E (mSv)
Badger, et al., 2010	0.25	12	
Bannazadeh, et al., 2009	0.14		109
Ho, et al., 2007		12.7	
Geijer, et al., 2005	0.14	10.5	8.7
Kalef-Ezra, et al., in press	0.23	5.8 *	4.6
Kalef-Ezra, et al., in press	0.23	6.6 **	
Kalef-Ezra, et al., in press	0.21	40 ***	
Weerakody, et al., 2008	0.18		27

* mobile C-arm unit I, ** mobile unit II, *** stationary C-arm unit

Table 4. Repair related effective dose.

The excess life mortality after exposure to ionizing radiations at low doses decreases with increasing age (ICRP, 1991). It is about 4.8% per Sv in men exposed at age of 65 years, 2.6% and 1.1% per Sv in men exposed at 75 and 85 years, respectively, and slightly lower in women (3.9%, 2.9% and 0.9%, respectively). In case of uniform irradiation, leukemia is anticipated to be the main cause of death (almost 50% in men exposed at age of 70 years). Taking into account the age and sex distribution of EVAR patients (Table 3), an excess life mortality of 3.5% per Sv can be assumed. Therefore, the radiological health detriment of a repair requiring an effective dose of 10 mSv is about 3.5 10⁻⁴.

Combining dosimetric data on 91 repairs carried out at Ioannina University Hospital (IUH) using a Pulsera mobile C-arm unit with a PC-based Monte Carlo software (Kalef-Ezra in press), it was found in that:

-      the mean E/DAP ratio was 0.23 mSv/Gy cm² (range 0.17 to 0.31 mSv/Gy cm²),

- the red bone marrow and colon were the main contributors to E in male patients,
- the image registration contribution to E was only 20%,
- the effective dose was linearly correlated with fluoroscopy time, t_{fl}, and body mass index (BMI), i.e.,

$$E \text{ (mSv)} = -7.24 + 0.298\ t_{fl} \text{ (min)} + 0.237\ \text{BMI (kg/m}^2)$$

The effective dose related to the repair itself is often lower than that related with the other aspects of AAA management. For example, a typical two-phase CT abdominal/pelvic angiography often requires about 20 mSv, i.e. few times higher than that of a repair itself carried out using a mobile unit. Therefore, various protocols for diagnostic / planning and postoperative follow-up imaging have been proposed to reduce both radiological and renal function deterioration risks. Dose reducing protocols related to post-operative imaging can be divided in three main groups:

- application of less intensive follow-up procedures, including an optimized temporal spacing between CT scans (Dias, et al., 2009; Go, et al, 2008; Verhoeven, et al., 2011; White & McDonald, 2010; Zhou, 2011),
- optimization of the CT scanning parameters (Diehm et al., 2008; Iezi et al, 2006,2009; Kalef-Ezra et al., in press; Kirby et al., 2007; Macari et al., 2006; Nakayama, et al., 2006; Sommer, et al., 2010; Wintersperger, et al., 2005),
- replacement of CT imaging with alternative imaging / assessment techniques, that require lower or even no radiation dose, such as ultrasound or MRI imaging (Elkouri et al.; 2004, Manning, et al, 2008.; Sternbergh, et al., 2008; Ten Bosch, et al.; 2010; Tomlinson, et al, 2007, 2009; Truijers, et al., 2009).

The application of the life-long protocol for AAA management at IUH with optimized post-operative CT parameters resulted in a cumulative effective dose of almost 60 mSv (Kalef-Ezra, in press), which leads to a 0.2% excess life-time mortality, using the 3.5% per Sv risk factor. However this value has be divided by a factor of two according to the current ICRP recommendations (ICRP, 2007) due to dose fractionation over many years, resulting in a life-time mortality of 0.1%.

4.2 Assessment of deterministic effects to patient

On contrast to radiation-induced cancer that can be observed clinically after many years, deterministic reactions are often near-term radiation effects. In CT imaging the X-ray spectrum is harder than that used in AAA repair and the X-ray source rotates around the human body, dispersing thus the imparted energy to the body more uniformly and over larger volumes. Therefore, the induction of deterministic effects in AAA patients is mainly related to the repair itself and not to CT.

If such effects occur, the most probable location is the skin at the patients' back (Table 3). Damaging skin levels can be reached in a short time especially when obese patients are treated using short focus-skin distance, non-optimized fluoroscopic units and/or high image magnification factors. Therefore, each medical facility has to develop techniques to assess peak skin dose, PSD, and control it at levels below the threshold for induction of deterministic effects (Tables 1 and 2), taking into account that the same skin area may absorb additional doses due to other imaging procedures made within a relatively short time period.

Skin dose mapping shows the overlapping fields and allows the accurate determination of PSD. Recently some manufactures of stationary fluoroscopic units introduced the use of software to calculate PSD combining the readings of the DAP meter with geometrical data

related to bed movements during the procedures, focus to table distances, beam angulations, etc. High sensitivity self-developing radiochromic films, such as reflective-type dosimetric gafchromic XR type films and arrays of thermoluminescent dosimeters (TLDs) have been used for direct 2D dose skin mapping by placing them between the surgical bed and patient's back (Table 5). The extent of polymerization of the films, and thus the changes in their optical properties, are influenced by their dosing. TLDs emit light upon heating at any time after irradiation. Other types of dosimeters could be used, such as the scintillating ZnCd dosimeters and diodes. Slow photographic film, such as those use in radiation therapy, do not allow accurate determination of the dose distribution due to the large dependence of their response to X-ray spectrum. Currently there is no perfect dose mapping system available and each facility should use the best available indicator.

TLD handling and processing are complex and time consuming and the cost of the equipment to process is high. In addition, there is a risk to miss with TLDs the region with the peak skin dose. On the other hand, one has to consider the cost of the radiochromic films, that can be used only once, the substantial dependence of their response on the X-ray spectrum and the fact that they cannot be read accurately until after their use, because they must undergo a time-consuming stabilization process (Kalef-Ezra et al., 2008, 2010). However, if concern is raised over skin dose, the radiochromic film can be removed from the bed during repair and examined by bare eye in normal light at the operation room for a rough dose assessment.

Kuhelj, et al. (2010) analyzing the dosimetric data on 179 patients treated using a suboptimal mobile C-arm unit found a 0.44 Gy median PSD (range 0.12 to 2.7 Gy). Investigators at Cabridge reported a 0.85 Gy median PSD on 96 repairs (Weerakkody, et al. 2008; Walsh, et al., 2008). About 1/4 of their patients received PSD higher than 3.75 Gy and the maximum dose was 8.8 Gy (the authors excluded from the analysis data on seven additional repairs because the "values were orders of magnitude greater than typical values recorded"). Pannuccio, et al. (2011) reported on 47 patients that undergone thoracoabdominal aneurysm repair a 2.5 Gy mean PSD (in ten patients the dose was higher than 4.0 Gy, and the maximum value was 6.5 Gy). The most heavily irradiated areas were of 4 cm² size and located at the central part of the back close to the kidneys. Despite the high PSDs found, no skin reactions were reported. On the contrary, Rahimi et al. (2011) related to radiation the acute gastrointestinal complications (nausea, diarrhea and abdominal pain) reported by an EVAR patient during the first post-repair visit. These symptoms were coupled with skin color alterations observed during the second visit. According to the authors "the procedure required about 56 min of fluoroscopic imaging time resulting in 6.8 Gy total radiation exposure".

Lower mean PSD values were reported by other investigators (Table 3). For example, Weiss et al. (2008) measured a 0.75 median value (range 0.27 to 1.25 Gy) in twelve repairs. Geijer, et al. (2005) analyzing data on 24 procedures calculated a 0.33 Gy median value (range 0.08 to 1.1 Gy). Among the 204 patients treated with EVAR at IUH using mobile C-arm units, no patient received a peak dose exceeding 1.1 Gy. Therefore, in none of the repairs presented in these studies using mobile fluoroscopic units, PSD approached the threshold for any skin reaction.

In daily clinical practice direct 2D dose skin mapping in all patients is considered to be a time and money consuming procedure. In addition, it does not provide real-time guidance to the operator on accumulated dose to adjust the employed techniques during repair, such as the use of dose spreading techniques, i.e. change of the X-source angle, while the intervention site is kept in the centre of the field of view (Johnson et al., 2001).

An empirically determined relationship between indications of meter and PSD obtained by direct measurements in a subgroup of patients in each facility can be used for this purpose (Kalef-Ezra, et al., 2009, 2010). This approach bypasses the accuracy limitations of the DAP indicators and many of the differences in employed imaging strategies. If no direct data is available at a facility, data from other facilities could be used as a rough estimation, keeping in mind that the relationship depends on a larger number of factors. The currently available data on the PSD to DAP ratio for AAA repairs vary between 3 and 7 mGy per Gy cm² (Table 5). Assuming a 6 mGy / Gy cm² value, the restriction of the DAP below 333, 667 Gy cm² keeps PSD below the threshold for temporary erythema and epilation (Tables 1 and 2), 1.0, 1.15 and 2.3 kGy cm² below the threshold of main erythema reaction, permanent epilation and dry desquamation respectively, provided that no other imaging with X-rays is carried out within a short time period. Based on such findings a warning level (called also as triggering level) of 250 Gy cm² can be used for the operator to consider modification of the imaging strategy during the repair of the specific patient. In practice the operator could be notified by the technical staff present in the room when the 150, 250, 350, 650 and 1000 Gy cm² levels were reached. However, it is up the interventionist in charge to decide how to proceed, when a significant dose level has been crossed.

To avoid the induction of skin injuries, practitioners should always seek to establish before repair whether the patients had previous imaging procedures or radiotherapy sessions, together with the estimated skin doses and the beam entrance sites (ICRP, 2000). In addition, monitoring and tracking of radiation doses in endovascular AAA management should to be carried out after repair (CRCPD, 2010). More specifically, the dose indications should to be recorded in the machine's log book (physical or electronic) and reviewed immediately after repair to determine if the patient is at risk to develop skin injuries. The dosimetric data have to be recorded to the patient's medical record, indicating the beam entry site. If some threshold is exceeded, such as 150 Gy cm² (the level depends on national legislation and the local rules), the medical (or health) physicist in charge of the unit has to assess more accurately the doses and the associated risks. The facility radiation safety committee/ officer should periodically check the distribution of the dosimetric parameters, compare them over time and review one by one all repairs that exceeded some dose value, such as a PSD of 3.0 Gy. In departments with "heavy" duty, the data have to be also analyzed according to the interventionist in charge.

References	C-arm unit	operation bed	D_{peak}/DAP (mGy/ Gy cm²)	dosimetric method
Geiger, et al., 2005	mobile	angiographic	5.5	calculated
Kalef-Ezra, et al., 2009	mobile I	surgical	5.0	LiF:Mg,Ti TLD
Kalef-Ezra, et al., 2011	mobile II	angiographic	6.8	LiF:Mg,Ti TLD
Kalef-Ezra, et al., 2011	mobile II	angiographic	6.7	gafchromic XR-RV2
Kuhelj, et al., 2010	stationary	angiographic	3.5	gafchromic XR
Panuccio, et al., 2011	stationary	angiographic	~3	gafchromic
Weiss, et al., 2008	mobile	-	~5	gafchromic
Weerakkody, et al., 2008	mobile	surgical	~6	calculated

Table 5. Skin peak dose and its relationship with DAP.

All patients who potentially received a skin dose higher than some predetermined value, usually set at 3.0 Gy, should be closely monitored for potential serious skin injuries. The practitioner should arrange for the patient to be reviewed about two weeks after repair. The patient and family should to be informed of the possible symptoms and signs and instructed to check the patient's skin during the first 48 h procedure (in case of out-patients) and once a week over the following five weeks. If radiation cannot be ruled out as the cause of skin lesion, the patient has to be referred to either a dermatologist or a radiation therapist, experienced in managing radiation injuries. In addition, patient's personal physician should be informed to avoid procedures during subsequent two months, which could result in a substantial dose to the same skin area. Such actions are important because radiation injuries are often misdiagnosed and treated inappropriately.

4.3 Determinants of patient's radiation risks

The potential risks of medical exposures to ionizing radiation must be balanced against the potential medical benefits of the procedures. Limiting potential radiological risk is essential, remembering the currently applied working hypothesis that there is no dose below which there is zero risk. In general radiation burden, besides the age and general clinical conditions of the patient, is influenced by a number of anatomical and technical factors, as well as to the education and training of the interventional team. Radiation protection can be ensured by appropriate design, procurement and commissioning of equipment, optimal operational technique and quality assurance backed by quality audit. In particular, the choice of the fluoroscopic unit to be used and the irradiation modes to be selected, have to be based primarily on the required level of image quality, ergonomic factors, financial costs, and associated radiological risks. The analysis of the influence of the various factors and the analysis of the accumulated experience may allow the selection of the optimum repair strategy.

4.3.1 Equipment related factors

Repairs can be carried out using angiographic units equipped with either low power generators, such as mobile C-arm fluoroscopic units widely used in operation theaters, or with high power stationary generators, such as those designed primarily for guidance in coronary artery interventions and located at radiology / cardiology suites. According to data shown in Table 3, the mean DAP per repair carried out using mobile units ranged between 30 and 152 Gy cm². On the other hand, higher mean (192 to 782 Gy cm²) and median values (154 to 697 Gy cm²) were reported on repairs carried out using stationary units.

To exclude the possible influence of the use of different protocols, few AAA repairs were carried out at IUH using a stationary 100 kW unit, an Allura 9C by Philips, at the lowest available mode (12.5 p/s fluoroscopy and registration rate 12.5 images/s and 11 mm Al equivalent filtration). The dosimetric data of these repairs was compared with those of repairs carried using a much cheaper mobile unit, a 7.5 kW Pulsera unit by the same manufacturer, selecting a registration rate of 3 images/s, and 50% of its maximum power during fluoroscopy in the majority of the patients, and avoiding magnified views. The repairs carried out with the stationary unit required on the average lower fluoroscopic time than those using the mobile one (Table 3). However, the use of the stationary unit resulted in an increase in both patient and personnel dose by a factor of about seven (this finding

dictated the early stop of repairs using the stationary unit). The increase was related in large part to the five-fold higher mean DAP rate during fluoroscopic imaging with the stationary unit and to the fact that registration contributed about 50% to total DAP, rather than only 20% when the mobile unit was used, indicating the importance of the rate of registered images. Similarly to the present study (Table 3), Geijer et al. (2005) simulating a typical repair using a stationary high-power unit, reported that the replacement of the mobile unit with a stationary resulted in an eight-fold increase in DAP.

Radiological burden, purchase and operation costs are not the only factors against the use of high power stationary units. AAA repairs performed at surgical theaters with mobile angiographic units are carried out in a more sterile environment, do not require the transfer of surgery and anesthesia equipment as well as staff to an often remote location in the hospital. In addition, repairs carried out under such conditions, could be easily changed during the procedure from enovascular to open repair, if required. Taking into account that AAA repairs are often time consuming, when such procedures are carried out in angiographic suite, an extra suite has to be kept free to carry out urgent cardiac procedures. Therefore, AAA repairs carried out using units designed for interventions in vessels of small diameter, such as the coronary arteries, have to be avoided. Hybrid units designed for interventions in both cardiac and non-cardiac vessels could be used, only if it is possible to adapt the operating parameters to the needs of AAA repair.

Some mobile units may not meet the required criteria (e.g. adequate anode cooling rate, image quality, image processing capabilities). For example, two units made by the same manufacturer were tested at IUH under clinical conditions, a 3.15 kW Libra unit equipped with a stationary anode made of tungsten (W), two foci (0.6 and 1.4 mm, respectively), and a 9" CsI/CCD image intensifier and a Pulsera unit equipped with a rotating W/Rh anode, foci 0.3 and 0.6 mm in diameter and a 12" CsI/CCD image intensifier (Kalef-Ezra, et al., in press). The mean fluoroscopic times per AAA repair were similar (Table 3), however, the superior image quality of the Pulsera unit allowed its operation at lower mean power during fluoroscopy (120 versus 250 W on the average) leading to a mean skin dose reduction by a factor of about two and to a 15% reduction in the mean effective dose. In addition, most of the procedures carried out in obese patients with the Libra unit, had to be interrupted for few minutes to let the non-rotating anode to cool down, increasing thus the overall procedure time. The machine output depends on the mode selected by the operator. For example, Vano et al. (2008) simulating PA projection found in eight C-arm units that the use of the low dose fluoroscopy mode rather the high dose one, decreases the dose rate by a factor of about 2.5 on the average (range of values 1.5 to 4.5), while the image registration increased the rate by a factor of 4 on the average (range 2 to 8). In addition, the high voltage and the X-ray tube current are automatically selected according to the distance between the focus and the image receptor, and the X-ray beam attenuation (in the patient's body and in any supporting material, such as the bed).

In general EVAR is carried out with the X- ray tube located below the bed. In this geometry, beam attenuation in the bed is anticipated to have a marginal influence on the patient's dose, but not on the staff. Scattered radiation to staff is proportional to the X-ray machine output. To test the influence of bed attenuation thirty AAA repairs were carried out at IUH using a conventional surgical bed (Marquett Alphamaxx) and sixty with an angiographic table with carbon table-top and bed-suspended side shielding. The use of the latter reduced the mean DAP per repair by ~30% and personnel dose at chest level by about 40%.

4.3.2 Patient related factors

Analyzing data on 140 patients treated at IUH over a 3 year period using a mobile unit, it was found that DAP values were positively correlated fluoroscopy time (r=0.78), a parameter that is related with the complexity of the repair. Similar correlations were observed by Blaszak, et al. (2009), Jones, et al. (2010), and Kuhelj, et al. (2010), but not by Pannucio (2011). Badger (2010) found that the radiation burden is also influenced by the operative strategy chosen by the surgeon, that depends on the clinical presentation. Studies at Belfast City Hospital on possible correlations between the DAP values of 320 elective AAA repairs and lesion-related morphological parameters, revealed weak positive correlations between DAP and proximal neck, sac and distal diameters, but no statistically significant correlation with neck length, and sagittal or coronal neck angles (Badger, et al.; 2010, Jones, et al., 2010). In addition, they failed to find a statistically significant difference in the DAP values of urgent and those of elective repairs (Table 3). Panuccio, et al. found that type II or II thoracoabdominal repairs require higher mean DAP values than those of type IV repairs (1006 and 642 Gy cm², respectively).

Obese patients appear in particular to benefit from EVAR over open repair (Johnson 2010). However, DAP was found be positively correlated with the patient's body mass index (BMI) (Kalef-Ezra, et al.; 2009, Panuccio, et al., 2011). Therefore, the risks for induction of radiobiological effects are increased in obese patients. In addition, higher mean DAP values are anticipated in male than in female patients, mainly due to differences in body built and body composition.

4.3.3 Staff related factors

Aneurysm repairs are complex and demanding procedures performed according to the operator's education, training and practical skills. The number of initial repairs required to achieve the optimal surgical result was the subject of a number of studies (Forbes, et al., 2007). Another factor to be considered is the potential for radiation-induced damage to patients and clinical staff. Therefore, medical and non-medical staff related to AAA management should receive appropriate theoretical and practical training in both clinical technique and radiation protection.

All medical students should receive basic training on radiation physics, radiation biology, instrumentation, and radiation protection with emphasis on justification and optimization as part of the basic curriculum. Additional training on the span and impact of all factors that modify the radiological risks is required for those who intend to perform fluoroscopically guided vascular interventions (EC, 2000; Hirshfeld, et al, 2005; ICRP, 2011). For example, according to the European Union guidelines and the International Commission on Radiological Protection, medical doctors involved in interventional cardiology should get an accredited 20 to 30 h – long training program on radiation protection, which should include among other things, practical exercises and practical sessions (EC, 2000; ICRP, 2011). Specific additional training on the safe use of new radiation-related equipment / techniques should be provided at each medical facility before commissioning and during the initial stages of use and to all new personnel before the initiation of the clinical work (Dimitriou, et al., 2011). Such programs of initial and continuing education and training should be established at national, regional or institutional level, approved by the Regulatory Authority of the country/state, and carried out in collaboration with academic institutions and appropriate professional bodies.

4.4 Assessment of staff radiological risk

Staff exposure has to be assessed on a regular basis. In busy facilities trunk dosimeters may be combined with extremity dosimeters, such as ring and eye dosimeters. They can be of either passive or active type, such as solid state electronic dosimeters. Passive dosimeters, such as thermoluminescent badges, are typically used for one month before submitted for processing. On the other hand, active personal dosimeters (APDs) that often provide real-time readings, may introduce substantial errors when used in fluoroscopy. Most of the currently commercially available APDs may not have appropriate characteristics for use in pulsed X-ray fields, such as those observed in EVAR, due to the dependence of their response on dose rate, X-ray pulse frequency and duration, as well as on angle of incidence (Clairand, et al., 2011). For example, APDs of the type used by surgeons that carried out EVAR (Panuccio, et al., 2011) were found to have substantial energy dependent response, that varies up to a factor of two in the spectral region of interest and saturates at dose rates above 30 mGy/min. Irrespective of the type of dosimeter used, the readings have to be analyzed by an experience medical (health) physicist.

If a single personal trunk dosimeter is used, it can be located either above or below the protective apron, usually at the waist level, the chest or the base of the neck, depending on local regulations The effective dose to professionals due to fluoroscopically guided interventions will be numerically much lower than the dose registered by their dosimeter, if worn below the apron, and higher, if worn above. Therefore, in some departments, two dosimeters are routinely used, one above and the other below the apron. For example, the doses registered by personnel dosimeters worn above the protective apron at IUH catheterization laboratories, are 15 times higher than the doses registered by dosimeters worn below the apron.

Various algorithms have been developed to correlate the readings of the trunk dosimeters with the worker's effective dose. However, quite often these algorithms provide very different results for the same configuration. In those countries, that a specific algorithm is not posed by legislation, one may estimate the effective dose simply by dividing the reading of a dosimeter worn above an apron of lead equivalence of at least 0.35 mm (section 4.4) by the factor of 12 and 8, depending on the use or no use of a protective collar. Therefore, if the dose registered by such dosimeters during a single year is 24 mSv, the occupational effective dose is 2 mSv, if the worker used a protective collar and 3 mSv, if he does not use it, irrespective of the exact type of the apron used.

The probability of induction of stochastic effects to staff present in an operation room during AAA repair is related to the collective effective dose (staff presence is required, as far as robotic techniques are not used). The collective dose increases with increasing DAP and kV, and decreases with increasing distance between staff and the centre of the irradiation port. The mean collective dose registered by TLD badges worn by the IUH staff outside the apron at chest level per to DAP ranged between 2.1 and 2.5 µGy per Gy cm², depending on the type of the C-arm unit used (Kalef-Ezra, in press). About 58% of the collective dose from repairs carried out using a mobile unit. Corresponded to the chief surgeon, 24% to the surgeon that stood at the opposite side of the bed and 18% in the remaining staff present in the room. The relative contribution of the chief surgeon decreased by a factor of two in procedures carried using a stationary unit. This difference was mainly attributed mainly to a ceiling-suspended radiation shield available only in the room equipped with the stationary unit. The replacement of the surgical bed used with an angiographic table with a table suspended radiation shield reduced the collective dose by about 40% (Section 4.3.1).

Assuming a 0.1 ratio between personnel effective dose and the dose registered by a badges worn at chest level outside apron for the IUH staff, that used 0.5 mm Pb equivalent wrap-around aprons and thyroid collars, the mean collective effective dose per repair carried out with the mobile and the stationary units coupled with angiographic beds (Table 3) were about 6 and 48 µSv, respectively. These values were lower than the 170 µSv value calculated by Panuccio, et al. (2011), i.e., 130 and 230 µSv per type IV thoracoabdominal repairs and type II or III repairs, respectively.

The mean "chest" dose to the chief surgeon at IUH that used a mobile Pulsera unit was ~35 µGy per AAA repair using an angiographic table with table-suspended side protection. The registered mean dose per repair increased to 50 µGy by the use of a surgical bed and to almost 200 µGy by the use of a stationary unit. Liptsiz et al. (2000) and Panuccio et al. (2011) reported mean "chest" doses 300 and 560 µGy per repair, respectively. Ho et al. (2007) measured eye and left index finger doses to the first surgeon 6 and 33 µGy, respectively. However, Liptsiz at al. measured 165 and 380 µGy mean eye and finger doses per repair. Similarly, Saether, et al. (2005) analyzing data on fifteen repairs, found a mean dose at the middle phalanx of the middle finger of the first surgeon of 350 µGy per repair (the maximum value was 1.18 mGy). The main reason for such a large spread of values is attributed in large part to the interrelationship between staff and patient exposures.

The number of repairs that a surgeon may perform to reach a predetermined radiation level is related to the mean DAP per repair and the means used to control personnel exposure. According to ICRP recommendations (ICRP, 1990, 2007) any of the following annual limits must not be exceeded in those exposed to low energy X-rays due to their occupation (additional limits refer to pregnant worker)

- effective dose: 20 mSv,
- eye lens dose: 150 mGy,
- dose to any skin area that exceeds 1 cm^2: 500 mGy.

The 20 mSv annual effective dose could be reached at IUH by the first surgeon in case that he was carrying out annually repairs with a total DAP of ~160 kGy cm^2 (20 mSv divided by the experimentally determined 0.125 µSv / Gy cm^2 factor), under that assumption that he is not occupationally exposed to any other radiation source. This value corresponds to about 5330 AAA repairs using the Pulsera mobile unit and the angiographic table and 830 repairs using the Alura stationary unit (Table 3, Section 4). However, one has to consider also the other two limits. The dose to the lens of the eye is closely related to the dose registered by the badge worn out side the apron (Lie et al., 2008). In case that no eye protection is used, the maximum number of AAA repairs has to be reduced by 25% (3800 and 580, respectively) assuming an eye lens dose equal to the one measured above apron (Kim, et al., 2008). Early in 2011 ICRP modified its recommendations and reduced eye lens dose limit from X-rays from 150 to 20 mSv, averaged over defined periods of 5 years, with no single year exceeding 50 mSv. The application of the new limit restricts the maximum number of AAA repairs down to 533 and 83 respectively, if no eye protection is used.

In the case that adequate eye protection is used and one of the surgeon's legs is close to the imaged region, the maximum annual number of repairs could be dictated by skin dose. Simulations of repairs carried out at IUH were made to assess the absorbed dose at 35 cm horizontal distance from the central beam axis of the X-ray tube operated at 83 kV and located below the angiographic table. The dose to DAP ratio increased with increasing height from the floor, from 10 µGy/Gy cm^2 at ~3 cm height, up to 50 µGy/Gy cm^2 at ~80 height (~15 cm below the lower surface the bed), and reduced at higher heights, (e.g., ~20

Gy cm² at 110 cm height, i.e., at the horizontal level of the centre of the patient's body). Assuming the operator's leg is unprotected by his apron up to a 60 cm height from the floor, i.e. at a height where the dose to DAP ratio is ~40 µGy/ Gy cm², an annual total DAP of only 12.5 kGy cm² results in 500 mGy skin dose, thus reducing the maximum annual number of repairs to about 415 or 65, depending on the type of fluoroscopic unit used. This example indicates the need to increase the distance of the operator's leg from the X-ray source and the importance in the use of bed mounted drapes (Section 4.5). In case that a member of the operating team is a pregnant woman specific measures have to be carried not to exceed the limits related to the conceptus dose (section 4.6).

4.5 Determinants of personnel radiation risks

Those present in the room during AAA repair are irradiated from scattering radiation from the patient's body and the operation table, and to a lower extent from radiation leaking from the X-ray head. Staff exposure can be limited by using various techniques. The most obvious techniques to reduce patient radiation burden are the reduction of the number of workers present in the room to minimum required for the procedure, shielding, and the appropriate positioning of the workers relative to the X-ray tube and the area of the patient's body where the beam enters his body.

The ratio of the scattered dose to the incident dose decreases with increasing distance from the center of the area where the beam enters the scattering material, increases with increasing beam area and kV and depends on the scattering angle. Therefore, one has to increase the staff distance from the location where the beam enters in the patient's body and reduce the radiation field to the needs of the repair, i.e., "collimate tightly and view only what has to be seen, not more". In addition, the higher the photon energy, the higher is the transmission of the primary X-ray beam. However, the increase of the mean photon energy by either kV increase or beam hardening (e.g. addition of a 0.2 mm Cu filter), usually reduces staff exposure. Forward scattering ratio is less than the backwards scattering ratio (the maximum value of the ratio in AAA repairs occurs usually at ~120° scattering angle). Therefore, if the X-ray beam has to be vertical, or near vertical it is preferable to keep the X-ray tube under the patient. On the other hand, if the beam has to be horizontal or almost horizontal, staff should stand close to the detector and not close to X-ray tube.

The interposition of a suitable barrier between the source of radiation and staff reduces the exposure by an amount that depends on its nature and its thickness, the photon spectrum and the angle of incidence of the photons to the barrier. Shielding requirements depend among other things on the type and location of the equipment in the room, the types of procedures performed, room design work habits and workload. Lead is the most widely used shielding material in rooms where fluoroscopically guided procedures are carried out. Shielding properties are often expressed by the thickness of lead that provides the same protection when irradiated with an X-ray beam (usually a 100 kV broad x-ray beam). The types and thickness of the barriers to be used are specified by the radiation protection adviser during the design or the re-design of the room, bearing also in mind ergonomic factors and the anticipated workload. The various types of shielding can be divided to structural stationary shields, or movable shields inside the room and personal protective equipment.

Structural shielding, usually made of lead sheets of total thickness 0.25 to 2.0 mm with no gaps or holes, is built into the walls and doors of the room (the concrete thickness of the

floor and the ceiling usually provide adequate shielding). Optically clear lead glass windows of adequate dimensions are often used to protect those outside the room, who may have to observe the procedure. In rooms with heavy fluoroscopic load, it may be advisable to provide a separate protected area inside the room for anesthesiologists in the form of protective cubicles.

As a "golden rule" mobile barriers used in the room should be placed as close to the radiation source as practicable, casting the biggest shadow. Free-standing mobile radiation shields with or without visible screens, which rest on the floor are particularly well suited for the protection of the nurses, the technicians and the anesthesia personnel as well as other medical staff possibly present in rooms with heavy work load. Protective drapes suspended from the operation bed and ergonomically designed optically clear shields suspended from the ceiling are often used to protect the lower and the upper body of the practitioners respectively. For example, in the framework of collaborative project sponsored by EU, it was found that when drapes and ceiling mounted screens were used, the dose to the eyes of the first operator was reduced by a factor of five (Dommienick, et al, 2011).

Bed-mounted shields, such as drapes made of flexible lead vinyl with attenuation characteristics similar to those of at least a 0.5 mm thick lead layer, measuring at least 60 cm by 80 cm (height), are often used. It is preferable that such drapes be attached to the accessory side rail of the table, with double joins to allow movement along the table side and swiveling away from the patient's body forming two protective wings. Bed shields with an extra removable separate high top shielding section of similar equivalent thickness, were found to be very useful.

Ceiling-suspended shields are usually made of clear leaded plastic with lead thickness equivalence of at least 0.5 mm, mounted either on a ceiling column or in a ceiling track and moved partially over the patient's body. Such pull-down shields can be rotated and tilted until the ideal angle is obtained to protect the upper trunk, the neck and the head of the practitioners (the operator should only see the imaged area by looking through the shield to decrease lens exposure). Larger shielding area allows some degree of movement by the practitioner without having to reposition the shield and even protect more than one worker. In some cases, additional protection can be achieved by attaching a flexible lead-vinyl drape at the lower part of the transparent shield.

Sterile disposable, protective surgical drapes that contain elements of high atomic number, Z, such as bismuth and tungsten, usually attenuate X-rays similar to that of a 0.25 mm thick lead layer and can be placed on the patient to be submitted to EVAR to reduce the dose from scattered radiation (Germano, et al., 2005). However, their use adds some cost to the procedure and in case that during manipulations such drapes are accidentally exposed in the primary beam, the output of the machine is automatically increased dramatically, thus increasing both patient and staff doses.

Personal protective equipment, PPE, protect specific body regions, such as the trunk and the upper legs (aprons), the thyroid (collars), the eyes (protective glasses) and the hands (protective gloves). The typical flexible material for protective clothing is lead-impregnated vinyl or rubber. There is also lead-free clothing, that provides adequate shielding with the use of a combinations of elements with a high Z, such as tungsten (Z=74), barium (Z=56) antimony (Z=51) and tin (Z=50) at slightly reduced weight (Christodoulou et al. 2003; Finnerty & Brennan 2004; Zuguchi et al., 2008).

Maximum protection will only be obtained by ergonomic PPE that fits well to the worker's body and maintained to the standards specified by the manufacturer's tests (IAEA, 2004).

Taking into account that PPE is expensive, it should be kept in good condition. The shielding material can develop cracks and holes over time. Therefore, folding and lying over a pointed object must be avoided. A visual inspection for obvious tears, rips, cuts, thickness variations, etc, should be carried out monthly and fluoroscopic inspection on initial receipt and at least once a year (Lambert & McKeon2001; Stam, et al., 2008). If defects are found, practical rejection criteria have to be applied. For example, if the sum of the areas of the holes or cracks in an apron exceeds about 5 cm² (about 2.5 cm in radius, in case of a circular hole) it should be replaced. However replacement has to be carried out at an earlier stage, if the unprotected area over testes and the thyroid exceeds 0.2 and 0.1 cm², respectively.

Aprons with 0.5 mm nominal Pb equivalent thickness reduce staff effective dose by a factor of about eight, when an 87 kilovolatge is selected (von Boetticher, et al., 2009). Higher kV, such as those used on obese patients, sharply reduces the shielding benefit. When procedures are performed that require individuals to turn away from the radiation beam, wraparound protective aprons should be used. Taking into account that wraparound 0.5 mm Pb aprons weigh about 7 kg, their use in lengthy procedures may result in fatigue, back pain and other more serious orthopedic complications (Klein, et al., 2209). Aprons made of two pieces (vest – skirt) as well as aprons with a belt to transfer the weight to the hips and off the shoulder, help to reduce the mechanical load on the cervical and lumbar spines (Fadl, et al.; 2007). Wraparound aprons with lead equivalent protection of 0.5 mm in the front and the sides of the trunk and 0.25 or 0.35 mm in the back could be also used. Lighter aprons, such as those of 0.25 lead equivalence, reduce the mechanical load on the neck, shoulders and the back of the user, as well as reducing the shielding benefit. However, in general, it is better practice to always use an apron with smaller lead equivalence than using no apron in some procedures. Those having to stand close to the beam entrance area during AAA repair are recommended to use 0.5 mm thick apron, while those at longer distances, such as the anesthesiologist, may wear a lighter PPE. Whatever apron design is selected, it is important to use an apron of appropriate size to body-build falling below the knees with adequate coverage at the armpits, balancing between radiation risk and the risk of induction of orthopedic complications (Klein et al.; 2009). When aprons are not in use, they should be hung vertically by the shoulders, or in approved apron rounded hangers to prevent cracks and holes.

Similar considerations to the use of protective aprons hold true on the use of collars or shields which mainly protect the upper oesophagus and the thyroid; the later organ is of high importance mainly in female workers younger than ~40 years, due increased radiosensitivity (ICRP, 2007; Kuon, et al., 2003). It was found that the use of 0.5 mm Pb thyroid collars in catheterization laboratories in combination with 0.35 mm Pb equivalent aprons, result in an effective dose per procedure lower than that using 0.5 mm Pb equivalent aprons without thyroid protection, despite the 20% reduction in total weight (von Boerricher, 2009).

The protective eyeglasses must have additional side panels and fit properly for both protection and comfort (protective glasses can be worn over traditional prescription glasses, while others can be specially made and worn instead of regular ones). In addition, they have to provide protection equivalent to that of at least a 0.5 mm of lead. For example, the use eyeglasses with lead equivalence of 0.75 mm in interventional radiology suites was found to provide a reduction of the eye lens dose by a factor of 3 to 10 (Challa et al.; 2009; Thornton, et al., 2010).

The physician's hands must often be in close proximity to the X-ray beam during repair. Therefore, in case of heavy duty, radiation ring monitors must be worn, if possible, on the

middle phalanx of the hand likely to get the highest dose with the sensitive element facing the oncoming beam. Disposable protective gloves containing elements of a high Z, such as tungsten and bismuth, that pose less health and environmental problems than lead, could be used for hand protection from scattered radiation. However, the requirement of tactile sensitivity and dexterity restrict drastically the dose reduction (Kesley & Mettler, 1990). For example, 0.2 to 0.3 mm thick gloves with 30 to 40 μm Pb equivalent attenuation reduce the dose rate of the scattered radiation from a 80 kV beam by 35% to 50%. However, the use of such gloves not only increases the financial cost of the procedure, but also poses the risk of false feeling of radiation safety, that may even result to direct exposure of the hand in the primary beam, i.e. at dose rates many orders of magnitude higher than those outside the beam. In addition, the insertion of the "protected" hand in the direct field triggers the Automatic Brightness Control of the X-ray unit to increase the machine output usually by increasing the kV, decreasing the image quality and increasing the patient's dose. In general, if fingers or a hand appear on the monitor, they should always be pulled back from the imaged area unless necessary for the safety of the patient.

4.6 Radiation protection of the pregnant healthworker

Taking into account the age and the sex distribution of patients with AAA, pregnancy is a matter for concern on workers but not on patients. According to ICRP (2000b, 2207), a pregnant worker can continue her work with unnecessary discrimination, as long as there is reasonable assurance that the conceptus dose can be kept below 1 mGy during the remaining pregnancy period after declaration of pregnancy, eirther verbally or in writing, to the radiation protection officer or the management (the 1 mGy dose is similar to the one that all persons receive annually from penetrating natural background radiation). Pregnancy declaration is voluntary in most countries and can be withdrawn by the employee at any time (Schreiner-Karaussou, 2009).

In some countries other limits are used. For example, in USA, the conceptus dose should not exceed 5 mGy due occupational exposure during the 9 months of pregnancy, under condition of exposure uniform in time (US DOE, 1999), i.e., in practice not exceeding monthly the 0.5 mGy limit after pregnancy declaration. In some countries additional limits are used, such as 0.2 mGy and 0.5 mGy between 1-5 weeks and 5-7 weeks respectively, on top of the limit of the 1 mGy during the remaining gestation period after the pregnancy declaration.

The various limits enforced by legislation do not mean that is necessary for pregnant worker to avoid work with radiation completely, or that she must be prevented from entering or working in designated radiation areas. It does, however imply that the employer should carefully review her exposure conditions (ICRP, 2007).

There is great disparity in the polocies on the protection of the conceptus in different countries and even in different regions of the same country (Best, et al, 2011; Schrewiner - Karoussou, 2009). For example, in some countries supervisors are prevented by law from removing an employee from work area simply on the basis of information that the worker is pregnant (Clark, 2003), while in an other country the pregnant worker is automatically placed in another department (Schrewiner-Karoussou, 2009).

Following the confidential pregnacy decalration to the licensee along with the estimated date of conception, preferably in writing, the radiation officer of the facility has to review the radiation history of the worker. In addition, it is desirable to discuss with the pregnant healthworker the associated radiological risks and the options proposed by the management, pointing out that fetal dose for most women who work in fluoroscopy guided

intervantional precedues are extremely low (Best, 2011) and reminding her the contribution of natural background radiation and the risks to the conceptus that are unrelated to her occupation. In other words the radiation expert has to put the radiological risk into prospective with the objective of having the pregnant worker's attitude on neither extreme (Clark, 2003).

In practice there are three options to be considered:

1. change to a job that has essentially no radiation,
2. modification of work assignments,
3. no change in assigned working duties with an upgrade of protective means used, if required.

The first option is sometimes requested by pregnant healthworkers who realize that risks may be small, but do not wish to accept any increased risk (ICRP, 2000b). The employer may arrange for this in order to avoid future difficulties in case the employee delivers a child with a spontaneous congenital abnormality (which occurs at a rate of about 3 in every 100 births). This approach is not required on a radiation protection basis, and it obviously depends on the facility being sufficiently large and flexibility to easily fill the vacated position.

Modification of job assignments and locations relative to radiological hazards is a widely emplpoyed option, ensuring that these recommendations are mutually satisfactory. For example, some intervenionists prefer to avoid to act as the first surgeon during pregnancy, because this assignment is related to the highest exposure in the team of surgeons that perform AAA repairs, as shown in section 4.4. Others prefer to modify the order of the topics to be trained, during their training as vascular surgeons, postponing thus their training on fluoroscopy guided porcedures after delively. Another example, is the change of the position of a radiation technician or a nurse from fluoroscopy suites to another position in the same department, such as the mammography suite, where exposure to ionizing radiations is considered unlike. An extra ethical consideration involved in choosing the most appropriate option for the pregnant healthworker is the fact that if the first two options are chosen, another radiation worker will get higher radiation exposure.

There are situations that the anticipated doses are very small (such as the doses of the anesthesiologist that is present during AAA repairs, departments with low workload), situations in which the pregnant worker wishes to continue doing the same job, or the employer may depend on her to continue in the same job in order to maintain the level of patient care. From a radiation protection point of view, this is perfectly acceptable providing the conceptus dose can be reasonably accurately estimated and falls within the recommended limit (ICRP, 2000b). In this case, the radiation protection officer has to evaluate her workplace, watch closely the worker's practices and the dose registered monthly by her personnal dosimeters (a supplementray dosimeter, a "baby's badge", could be issued to be worn at the waist height, under the protective apron - this practice is obligatory in some country).

Sometimes, the conceptus dose can be substantially reduced by wise choise of the position of the worker in the fluoroscopic suite (such as one or two extra steps away from the location where the beam enters the patient), the use of movable radiation shileding and protective aprons of appropriate fit and lead equivalence. For this purpose maternity aprons are commercially available that are adequately wide and have extra lead in the area of the abdomen. However, the use of a heavy apron, especially an wraparound apron that is not divided to two pieces (vest, skirt), in combination with the susbsantial incerase in body

weight during the last trimester of pregnancy, may result in fatigue, back pain and other orthopedic complications. A possible solution is the use an apron with non-uniform lead equivalence arround her trunk. However, in this case the wearer needs to ensure that her patrially or totally unshielded back is not facing the patient (if it happens, not only there is no adequate shileding, but her personal dosimeter is going to measure a dose tens of higher lower than the dose absorbed by the concetpus). Therefore, the type of apron to be used by the pregant healthworker has to been optimized on individual base.

The proposed options for those working in suites where fluoroscopy guided interventional procedures are carried out, have to take into account that the recommended dose limits apply to the conceptus dose and differ from the dose assessed by the worker's personell dosimeter. For example, Osei and Kotre (2001) found that during the first few months of pregnancy, the ratio of the conceptus dose to the dose registered by the dosimeter worn over a 0.33 mm Pb thick protective apron depends on the high voltage used, incerasing from 1% at 74 kV to 5.4% at 112 kV in the undercouch X-ray tube geometry. These values are increased by a factor of about two, when the lead equivalent thickness is reduced from 0.33 to 0.25 mm. In case that the personal dosimeter is worn below the apron, the conceptus to dosimeter dose ratio is slighlty infleunceed by high voltage, ranging between 36% and 40%. In addition, Damilakis, et al. (2005) found that the conceptus dose in pregnant cadiologists that carry out fluoroscopically guided electrophysiological procedures, depends on the gestation period, ranging from 32% of the value of the air kerma during the 1st tremester to 20% during the 3rd tremester, when a 80 kilovlotage is used. These values, as expected, also depend on kV, beeing at 60 kV 26% and 16%, respectively, and 40% and 27% at 110 kV.

Factors other than radiation exposure should be also considered in choosing the optimum options for work assignments. For example, there are often requirements for lifting patients and for stooping or bending below knee level. Non-radiation related guidelines for such activities at various stages of pregnancy have to be applied. Supervisors have often the tendency to be overptotective of the pregnant worker. However, if he moves her from the usual work assignmenents without her permission, this action can be interpreted as discriminatory (Clark, 2003). Therefore, decisions about working in a radiation enviroment during pregnancy is preferable to be made by both the employer and the pregnant healthworker.

In conclusion, a pregnant health worker can continue working in rooms were endovascular AAA repairs are carried out on a voluntary basis, as long as the there is reasonable assurance that the conceptus dose can be kept below the recommended levels and ALARA principles are enforced. Sex discrimination should be avoided based on radiation risks during pregnancy. If the pregnant woman prefers to continue her work, it has be reensured that she is adequately trained on radiation biology and practical methods to reduce her occupational dose and that she is controling her workload in fluoroscopically guided interventions.

5. Conclusions

Radiological risks associated with fluoroscopically guided vascular interventions are related to patient characteristics, the available infrastructure and staff. The practical actions to control radiological risks were given at various national and international guidelines (American Society for Gastrointestinal Endoscopy, 2010; Balter & Moses, 2007; Chambers et al.; 2011, CRPD, 2010; Hirshfeld, et al., 2005; Johnson et al. 2001; IAEA, 2010; ICRP, 2000;

Society of Interventional Radiology Device Forum, 2003). These actions, as exemplified in AAA repairs can be divided in three groups, general, patient and staff related actions.

5.1 General actions
-   Interventions should be carried out by appropriately trained staff taking into account the risks and the benefits to the individual patient.
-   Each facility should include in the local clinical protocol, a statement on the strategy to be followed before, during and after repair including the equipment maintenance and quality assurance programs.
-   A low-power C-arm angiographic unit (10 to 20 kW) equipped with a ~30 cm detector and rotating anode is to be preferred over high power unit units (~100 kW) designed for coronary interventions.
-   The fluoroscopic unit must provide a real-time display of dosimetric quantities (DAP, DAP rate, fluoroscopy time, mode of operation, focus to image receptor distance, etc.) on or near the operator's imaging monitors (duplication of the indications in the control room is advisable).
-   The fluoroscopic unit has to be coupled with an angiographic bed and not with a surgical one.
-   Reduce fluoroscopy time and the number of registered images to the absolute minimum compatible with the task and take the advantages offered by the last image hold and road mapping capabilities, if available.
-   Image size and quality have to be adjusted as low as compatible with the task t (e.g., 3 to 5 pulses or images per second, rather than 12 to 15 per second, avoid - image magnification, beam collimation closely to the area of interest, i.e., "image only the aorta length of interest").
-   High exposure levels can be reached in a short time, when obese patients treated using short focus-skin distance or/and image magnification.
-   Advice should be available on patient and staff dosimetry, equipment selection and commissioning, and quality assurance by a radiation protection adviser, usually by a qualified medical radiation physicist.

5.2 Patient related actions
-   Patient medical file has to be reviewed before procedure, for possible recent "heavy" exposure of the section of the body to be imaged.
-   The patient should be counselled on radiation risks,
-   Keep the detector (image receptor) as close to the patient as possible.
-   Use thick filters to harden the X-ray beam, provided that the power of the fluoroscopic unit and the anode heating allow their use.
-   In complex repairs, consider alternative imaging projections, to avoid the induction of deterministic effects to heavily irradiated skin areas.
-   Record the dosimetric data of each procedure and correlate the indications of the DAP meter to PSD and effective dose. In case of an anticipated dose to a skin region exceeding a predetermined level, inform the patient's personal physician and avoid radiological procedures with high doses at the same skin region for up to 2 months post-exposure. If the anticipated dose to a skin region exceeds a higher limit, such as 3 Gy, the patient should be counselled and his skin followed-up to two weeks after repair.

- The operator should audit and review the outcomes of the repair, including the potential of radiation injuries with the aim of modifying the selection of patients, the method and the operational procedures to improve clinical outcomes and reduce complication rates.

5.3 Staff-related actions

Personnel exposure is in general proportional to DAP. Additional actions that can be made to control radiological risks are:

- Carry out AAA repairs only in rooms with shielding adequate to the task.
- Reduce the staff present in the room to the minimum required for the task and the needs of the individual patient.
- Distribute the staff in an ergonomic and safe way (room dose mapping is a useful tool for optimization).
- Extremities have to be kept far away from the X-ray beam.
- Dose rate during image registration is much higher than that during fluoroscopy. Therefore, take more aggressive measures during image registration, such as increase staff distance from the area of entry of the beam to the patient's body, if practical.
- If the beam is vertical, or near vertical, keep the X-ray tube under the bed.
- Avoid, if possible, horizontal and almost horizontal radiographic projections. However, if carried out, personnel should stand close to the detector and not close to X-ray tube.
- Take into account that the increased kV automatically selected in obese patients, increases the ratio of scattered dose to DAP.
- Use appropriate physical protection (protective aprons, thyroid shields, protective eye-glasses, viewing screens, table-mounted shields, portable personal shields, etc.).
- Monitor personnel doses with passive personnel dosimeters according to local regulations, assuring that staff knows the appropriate position, such as above the protective apron at the chest level. Additional dosimeters may be required in case of institutions with a heavy workload, and/or equipment not-state-of-art.
- The effectiveness of the means applied to control patient and staff radiation burden has to be closely monitored in each medical facility and changes have to be carried out, if needed.

In conclusion, justification and optimization of the methods used for AAA treatment must commensurate with the medical purpose. Radiation dose and image quality strategies are important for ensuring a balance between cost and benefit. The optimum strategy has to be studied and justified in each medical facility, based on solid clinical and radiobiological evidence.

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7. References

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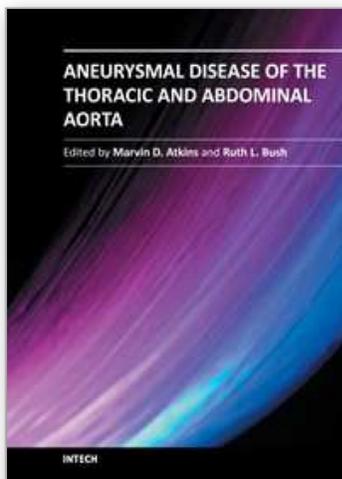
Aneurysmal Disease of the Thoracic and Abdominal Aorta

Edited by Dr. Ruth Bush

The first successful open surgical repair of an abdominal aortic aneurysm was in 1951 by Dubost and represented a tremendous milestone in the care of this challenging disease. The introduction of endovascular repair in 1991 by Parodi furthered the care of these patients by allowing for lower morbidity and mortality rates and also, enabling surgeons to extend surgical treatment to patients traditionally deemed too high of a surgical risk. This new book on Aortic Disease covers many interesting and vital topics necessary for both the practicing surgeon as well as a student of vascular disease. The book starts with background information on the evolution of aortic management from traditional open surgical repair to modern endovascular therapies. There is also a chapter covering the data supporting current treatment modalities and how these data have supported modern management. Also, the use of endovascular means for care of the challenging situation of ruptured aneurysms is discussed. In addition to management of abdominal aneurysm, there is a chapter on treatment of aneurysms of the ascending aorta. Along with surgical treatment, one must also understand the molecular basis for how blood vessels remodel and thus, the role of cathepsins in aortic disease is elucidated. Lastly, chapters discussing the perioperative management of radiation exposure and ultrasound-guided nerve blocks as well as the need for high-quality postoperative nutrition will lend well to a full understanding of how to management patients from presentation to hospital discharge. We hope you enjoy this book, its variety of topics, and gain a fuller knowledge of Aneurysmal Disease of the Thoracic and Abdominal Aorta.

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