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Refresher Course 516

‘DIAGNOSTIC X-RAYS AND PREGNANCY’

J. Damilakis, PhD
University of Crete,
Faculty of Medicine,
Department of Medical Physics,
P.O. Box 2208
71003 Iraklion, Crete
Greece
damilaki@med.uoc.gr
• **Main objectives of the presentation**

1. To provide guidelines to manage and counsel pregnant patients in case of (a) intentional exposure and (b) accidental exposure to diagnostic x-rays

2. To learn dose limits, regulations and recommendations concerning (a) exposure of pregnant patients to diagnostic x-rays and (b) occupational exposure of pregnant women employed in diagnostic radiology

3. To provide a methodology for establishing a program to calculate and monitor conceptus radiation dose as a result of the occupational exposure of the pregnant worker

• **Terminology**

The terms embryo, fetus, unborn child, conceptus and others have been proposed for various stages of development of a child. In the current presentation, the term ‘**conceptus**’ will be used. Wagner et al take the following position regarding the above terms: ‘**conceptus** refers to all products of conception at any stage of prenatal development whereas fetus, embryo are temporally restricted terms’ (1).
X-RAY EXPOSURES AND THE PREGNANT PATIENT
• **Intentional exposures:** Exposure of a pregnant patient to ionizing radiation for her benefit. Although the pregnancy is known, exposure of the woman is unavoidable for medical reasons.

• **Accidental exposures:** Exposure of a woman who is not aware that she is pregnant. Accidental irradiation occurs during the early post-conception weeks.

A. **GUIDELINES TO MANAGE AND COUNSEL PREGNANT PATIENTS IN CASE OF INTENTIONAL EXPOSURES**

• **STEP 1: JUSTIFICATION OF EXPOSURE**
When pregnancy is known, the use of procedures leading to lower radiation dose or even no radiation dose to the conceptus, for example magnetic resonance imaging or ultrasound, should be carefully considered. When an x-ray examination is being considered during pregnancy, the benefits of that study should be weighed against the conceptus risks.

- Radiation conceptus risk is a function of two parameters:
  A. Conception age
B. Conceptus dose

- Several methods may be used to determine the conception age (e.g. ultrasonography). Many methods have also been developed for the estimation of conceptus dose. However, a detailed dose assessment is not always needed.

- The dose received during the first 2 weeks postconception will either terminate the pregnancy, or the conceptus will recover completely. In that situation, conceptus dose assessment is not needed. Moreover, detailed estimation of conceptus doses is not necessary if conceptus doses are suspected of being lower than 10 mGy (2).

- ICRP states that installation specific measurements and detailed conceptus dose assessment is needed if conceptus doses are suspected of exceeding 10 mGy (2). **Below 100 mSv, abortion because of radiation exposure is not justified** (2, 3). When the dose to the conceptus exceeds 100 mGy, individual circumstances should be taken into account (3). However, it is relatively uncommon for doses to conceptus from diagnostic radiology procedures to exceed 100 mGy.

- Under normal operating conditions, most x ray diagnostic extra-abdominal examinations result in very low dose to the conceptus (<1 mGy). However, sub-standard equipment performance may contribute to unnecessary conceptus dose. Conceptus doses from radiodiagnostic examinations reported in the
literature are valid only for x-ray systems that are subject to quality assurance programs.

- The conceptus dose from a chest radiograph is less than 0.1 mGy in all periods of gestation (4). For a typical cardiac ablation procedure requiring 0.58, 2.3, 5.3 and 10.2 minutes for groin to heart PA, PA, RAO and LAO exposures respectively the dose to the conceptus is less than 1 mGy in all periods of gestation (5). The conceptus dose from a CT examination of the thorax is less than 1 mGy during the first trimester, less than 2 mGy at the second trimester and less than 6 mSv at the third trimester (6). The dose to the unborn child associated with spinal and hip dual X-ray absorptiometry scans carried out in pregnant patients is at least 700 times lower compared to that from a thoracolumbar or pelvic radiograph (7).

- Examinations involving the abdomen or pelvis may deliver higher doses to the unborn child (>10 mGy). In these cases the conceptus dose should be evaluated by a radiological physicist.

- The conceptus dose from a CT examination of the abdomen is 25-46 mGy (6). Low dose CT techniques have been developed for conceptus dose reduction (8). Conceptus doses from intravenous urography examinations have been measured in 4 institutions (9). The range of doses was 5.77 – 35.2 mGy. In case of accidental irradiation, conceptus doses from barium enema examinations can exceed 50 mGy, especially if the total time of fluoroscopy exceeds 7 minutes (10). Kyphoplasty and vertebroplasty procedures may deliver high doses to the patient (11). Conceptus dose from
fluoroscopically assisted surgical treatment of spinal disorders may be up to 105 mGy when the conceptus is primarily irradiated (12).

- Several methods have been developed to estimate conceptus dose from radiographic and fluoroscopic examinations (13-17).

- Several methods for the estimation of conceptus dose from Computed Tomography (CT) examinations have been developed. Depth-dose data for estimating conceptus radiation dose from CT studies in late pregnancy have been provided by Damilakis et al (6). Other methods estimate conceptus dose from CT studies performed at the first postconception weeks. Felmlee et al (18) estimated the conceptus dose from individual CT scans at various distances from the conceptus. Dose values were normalized to the CTDI. These data can be used to estimate conceptus dose from CT studies. A method based on the results of Monte Carlo calculations was developed by Panzer and Zankl (19). They presented factors to convert dose free in air on the axis of rotation into uterus dose for single slices of 1 cm width across a female mathematical phantom. Adams et al (20) developed a computer model to facilitate conceptus dose estimations. This model combines empirical beam data with anatomical information.

- The biological effects of ionizing radiation on humans can be divided in two categories. For cancer and hereditary effects the probability of their occurring is a function of dose without threshold. These effects are called stochastic. Radiation-induced changes in a single cell may be enough to cause a stochastic effect.
For some effects (organ malformations, growth retardation, mental impairment) a threshold of dose exists below which no damage can be detected. Above the threshold the severity of harm increases with dose. These effects are called deterministic or non-stochastic.

The dose received during the first 2 weeks postconception will either terminate the pregnancy, or the conceptus may recover completely.

Exposure of the conceptus to irradiation during organogenesis may cause malformations with a threshold of about 0.1 Gy. At 0.1 Gy, no detectable decrease in IQ is seen over the general distribution. When higher doses are absorbed by the conceptus, a shift of about 30 IQ points per Gy has been estimated to be valid in the period from the 8th to 15th postconception.

The number of excess cancer cases up to age 15 years following irradiation in utero can be taken as $6 \times 10^{-2}$ (6%) per Gy. The risk factor for induction of hereditary effects is assumed equal to $10^{-2}$ per Gy (2).

If the conceptus dose from a diagnostic examination is 5 mGy, the risk of excess childhood fatal cancer is 0.03%. For conceptus dose 100 mGy, the corresponding risk of excess childhood fatal cancer is 0.6%. The natural risk of fatal childhood cancer is about 0.2%. Therefore, when the conceptus dose is 100 mGy, the probability that the child will not develop fatal cancer is about 99.2%.
• **STEP 2**
  - When the conceptus dose has been anticipated by a radiation physicist, the results should be reported to the woman’s physician.
  - The report should contain all relevant data required for conceptus dose estimation, brief description of the method used for the calculation of dose, results and recommendations from the literature and references. The risks should be explained to the patient so that she can realize the situation and take her decisions.
  - For high-dose examinations, the patient should be asked to sign a consent form.

• **STEP 3**
  - Once a decision has been made that irradiation of a pregnant woman is necessary, the exposure must be optimized. Main actions for minimization of conceptus radiation dose include
    A. Radiography: Selection of the most efficient equipment, adjustment of the bladder volume, careful collimation of the beam and use of fast screens and film
    B. Fluoroscopy: Reduction of fluoroscopy time, careful collimation of the beam and use of fast screens and film
    C. Computed Tomography: Reduction of mAs, reduction of the number of slices and non contiguous slices. For MDCT scanners, the effect of z-overscannig should also be taken into account (21).
D. Angiography / Fluoroscopically Assisted Rf Cardiac Ablation: Insertion of the catheter from the subclavian route, adjustment of
the bladder volume and limitation of the fluoroscopic time.

Especially for cardiac ablation procedures, a recent study has shown
that more than 50% of the total radiation dose to the conceptus is
due to the groin-to-heart posterior-anterior exposure (5). Insertion of
the catheter by the subclavian route instead of the femoral
eliminates direct conceptus irradiation.

B. ACCIDENTAL EXPOSURES

• Accidental irradiation of the conceptus is a difficult case (22)
because:
A. Before the examination the pregnancy is unknown, therefore there
is no consideration for an alternative study or a low dose protocol.
B. During the examination, no special radiation protection measures
are taken.
C. After the examination the exact technical parameters (kVp, mAs,
exposure geometry etc) might be unknown.

• Sometimes legal issues may arise. Therefore the crucial question is:
'HOW CAN WE AVOID ACCIDENTAL IRRADIATION?'

• The presence of pregnancy should be evaluated before an x-ray
diagnostic examination. Article 10 of the European Union
97/43/EURATOM – ‘Patient Directive’ – states that in the case of a
female of childbearing age, the referring physician and the radiologist shall inquire whether she is pregnant.

- The referring physician must check a box on the examination request form if the patient is pregnant. For extra-abdominal studies, menstrual history is sufficient to determine if the woman is pregnant. For abdominal x-ray procedures, thorough investigation of the reproductive status of the patient is needed (23). If there are any doubts concerning pregnancy, a pregnancy test should be performed or the patient should be treated as pregnant.

- All radiology departments must have pictorial posters on display in the waiting room with the message ‘Please inform the staff if you think you may be pregnant, before your x-ray examination’.
OCCUPATIONAL EXPOSURE OF PREGNANT WOMEN EMPLOYED IN DIAGNOSTIC RADIOLOGY
• **DOSE LIMITS**

• The US regulations (24) require licensees to ensure that the dose to an embryo/fetus during the entire pregnancy due to occupational exposure of a declared pregnant woman, does not exceed 5 mGy.

• A recommendation of the ICRP is that the conceptus of an occupationally exposed worker should be protected by the application of a supplementary does limit of 2 mSv to the surface of the woman’s abdomen for the remainder of the pregnancy, once it has been declared. ICRP also states that ‘*The working conditions of a pregnant worker, after the declaration of pregnancy, should be as such to make it unlikely that the additional dose to the conceptus will exceed about 1 mGy during the remainder of pregnancy*’ (2). There is no much difference between these two recommendations since it is reasonable to approximate conceptus dose as 50% of the abdominal dose in diagnostic radiology.

• For occupational exposure of pregnant women the 96/29EURATOM Council Directive (25) states that 'the protection of the child to be born shall be comparable with that provided for members of the public. The conditions for the pregnant woman in the context of her employment shall be such that the equivalent dose to the child to be born will be as low as reasonably achievable and that it will be unlikely that this dose will exceed 1 mSv during at least the remainder of the pregnancy'.
• A PROGRAM TO CONTROL CONCEPTUS EXPOSURE

• DECLARATION OF PREGNANCY: The declaration of pregnancy is voluntary. Declaration of pregnancy is the most important element of a program designed to protect the conceptus of an occupationally exposed worker. A pregnancy should be formally declared in writing.

• EVALUATION OF THE WORKING CONDITIONS: Following the submittal of a declaration of pregnancy, the working conditions of the worker should be evaluated. Dose records may provide useful information because they indicate whether the pregnant worker is receiving measurable doses.

• CONCEPTUS DOSE ANTICIPATION: Anticipation of conceptus dose is required for pregnant staff carrying out fluoroscopic and interventional procedures. This is possible by measuring scattered air kerma dose rates separately for each projection involved in the procedure. This method can also provide important information for the dose received by the conceptus prior to pregnancy declaration, when pregnancy is not known. Details are given in recent publications (26-28).

• WORK RESTRICTIONS: Reduction of the number of procedures is the most important work restriction for the pregnant worker. A uniform exposure rate for the weeks remaining in the gestation period (mGy/week) may be calculated by subtracting the dose
received by the conceptus prior to declaration of the pregnancy from the 5 mGy limit and then dividing this difference by the number of weeks remaining in the gestation period. Determination of the maximum workload allowed for each week of the gestation is possible by dividing the calculated uniform exposure rate (mGy/week) with the anticipated conceptus dose per procedure.

- **COUNCILING**: The pregnant employee should understand the factors affecting staff doses and the potential biological effects of radiation. Pregnant staff must use protective devices such as maternity aprons and ceiling-suspended lead acrylic viewing screens.

- **DOSE MONITORING**: Two color-coded personal dosimeters should be worn: the standard dosimeter and a separate personal dosimeter for conceptus dose monitoring.
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