Pregnant women management at the Radiology Department: Informed Consent

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Purpose

To present our models of informed consent (IC) for pregnant women that require an imaging study with ionizing radiation.

To show our experience referred to concrete clinical situations using them.

To make known the detailed casuistry of the different examinations with the use of ionizing radiation in pregnant women performed at our institution in the period of time between January 2009 and December 2011.
Methods and Materials

We performed a retrospective study with the review of IC of pregnant women that require an ionizing radiation examination in the Radiology Department of our institution in the period of time between January 2009 and December 2011.

Models of informed consent

We have two models of IC to use according to the probable fetal dose depending on the examination, less or higher than 1 mGy.

IC for low dose examination are those in which the predictable fetal dose is less than 1mGy, among them are included all the plain radiography examinations (cranium, chest, cervical and dorsal spines, limbs and hip), mammogram, complex examination (barium swallow) and CT in which the examination does not include the abdomen or pelvis (as the head, neck, chest and limbs) in which the fetus is out of the radiation field.

IC for high dose examinations are those in which the predictable fetal dose is higher than 1mGy in which usually the pelvis and abdomen are within the exposed area, as plain radiography of the abdomen and pelvis, lumbar spine, bowel enema, intravenous urography, and CT of the abdomen, lumbar spine or pelvic area.

Both were written up in 2007 following the current legislation (article 5 of RD 815/2001 and article 9 of RD 1976/1999) and the recommendations of the ICRP 84 that refer to the effects of ionizing radiation on the fetus.

Besides the obligatory fields common to all IC forms, our specific models for pregnant women include:

Information of the possible stochastic and determinists effects of ionizing radiation in each fetus stage, the least grouped according to the gestational age (GE) as it is referred to in the ICRP 84 adapting them according to if it is a IC for low or high dose.

Gestational age data. In the special case of unknown or not controlled pregnancies we include in both models a section for the gynecologic evaluation, if necessary, where the gestational age and fetus condition are evaluated.

Type of examination performed.

Technical parameters (kilovoltage and miliamperage).
Measures for optimization of dose (ALARA criteria) and radioprotection used (absence of antiscatter grid and use of lead apron) that the in charge radiologist should supervise and complete.

And the last, there is a section reserved for the Radiophysics and Radiological protection Department (RPRPD) to calculate the dose and the fetal risk.

ACTUATION PROTOCOLS IN THE USE OF IC MODELS

We established two propositions depending on if the fetus was included or not in the examination field.

In the cases in which it was not included, the fetal dose could be assumed to be lower than 1 mSv, with the use of IC for low fetal dose examinations.

In the cases in which the fetus was included in the examination field, the predictable fetal dose would be higher than 1 mSv, with the use of IC for high fetal dose examinations.

For each of them, we performed an individualized estimation of the fetal dose by the RPRPD.

FETAL DOSE ESTIMATION

The fetal dose estimation was performed with two possible entry values:

a) From DSE or PDA values or in the case that we do not have them.

b) From the tube performance (in Gy/mAs) measured previously by the radiological protection department.

We required two additional entry values:

a) Acquisition technical parameters of the study

Skin-beam length (SBL), kv and beam filtration (if we have de SBL or PDA data, we do not need mAs). In the cases in which we didn´t have those parameters we used miliamperage for the determination of the SBL value from the tube performance (SBL=performance x mAs x RSF retro scattering factor).

b) Data related to the patient: gestational age, abdomen thickness, beam impact (direct or not).
In the first case (predictable dose lower than 1 mSv), once the study is justified and completed all the required data, we sent the IC form to RPRPD that made an estimation of the fetal dose with the available data. In this case, the RPRPD report consisted of recording in the IC the estimated fetal dose value and the estimated risk that practically was despicable.

In the second case (predictable dose higher than 1 mSv) we performed in situ measures with thermoluminescent dosimetry on the patient’s skin.

To do this, previous to the examination, we notify the RPRPD that proceeded to the placement of TLD on the patients’ skin.

We used TLD-100 dosimeters from the Harsaw brand previously calibrated (Fig. 1 on page 7). The dose reading was performed in a Harsaw 3500 reader; the dosimeters belonged to the same lot and all had the same erasing process and reset of the information using an oven (Fig. 2 on page 7).

As a minimum in each examination we placed

-2 control dosimeters, placed in a non exposed to radiation point.
-2 dosimeters placed at the beam’s entry (Fig. 3 on page 8 and Fig. 4 on page 9).
-2 dosimeters placed at the beam’s exit.

With the obtained values we determined the dose at the entrance surface, that with the technical data of the examination and the patient’s data (GE and abdomen’s thickness) allowed the calculation of the estimated fetal dose.

Equally as in the low dose studies, the RPRPD made a report addressed to the clinician with the estimation of the fetal dose and an interpretation of the results (fetal risk estimation).

In some cases for the fetal dose calculation, we used the FETDOSE software version 2 that use the parameters of acquisition values with the patient’s data to estimate a NUD (normalized uterus dose) value that converts the patient’s absorbed dose values, SBL or dose area product (DAP), in dose received by the fetus. In our case we used the SBL value determined by TLD.

We created a database in which it was included patient’s age, gestational age, reason and type of examination, abdominopelvic exposure or not under the X ray beam, technical data of the examination (kv and mAs), use or not of the lead apron and withdrawal of the antiscatter grid as radioprotection measures, estimated fetal dose, estimated fetal risk,
and presence of complications during pregnancy and/or newborn alterations related to
the radiation exposure.
Images for this section:

Fig. 1: TLD-100 Harsaw Dosimeters.

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Fig. 2: Harsaw 3500 reader (image "a") and oven (image "b").

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Fig. 3: Placement of the TLD (white arrow) on the patient’s skin. We place minimum 2 TLD in the region of the beam’s entry, two at the exit and the other two in a place not exposed to radiation.

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**Fig. 4:** Simulation of a fetal dose study using thermoluminescence dosimetry in a lumbar spine examination in a 36 weeks pregnant woman. Take notice that for the projection, the TLD location (beam’s entry) is different.

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Results

In the period between January 2009 and December 2011 we performed a total of 54 radiological examinations to 24 pregnant women (2 examinations/patients) from an age ranging from 17 to 41 years old (mean age of 31 years old). 50 of them were low dose (92.5%) and four (7.5%) high dose. The gestational mean age was 23.5 weeks in a range between 7 and 41 weeks respectively.

Low dose examinations (<1mGy).

We performed 50 low dose examinations in which none of them included the abdominopelvic region, 48 of them were plain digital radiograph examinations with a distribution of 21 chest X rays (17 PA, 1 PA and 3 lateral projections), 26 limb examinations.

We performed a CT scan and a continuous fluoroscopy in the lower limb during 4.8 seconds at the operating room with four PA and two lateral projections of the ankle (surgical arch Philips BV Libra) (Fig. 5 on page 13 and Fig. 6 on page 13).

In 96% of these studies (48) we used radiological protection measures (Fig. 7 on page 14). The exception (4%) was a study of a plain chest radiography (PA and L) in a patient with an unknown pregnancy.

In 49 examinations (98%) the estimated risk and fetal dose was calculated based on the technical parameters of the study acquisition and tube performance. The mean value for kilovoltage and miliamperage for these studies were 79 kv and 11 mAs respectively. The mean estimated fetal dose was 0.01 mSv with a risk for the fetus very low, practically despicable according to ICRP 84 considerations.

In orthopedic surgery with use of Xray the calculation of the received dose was performed by the positioning of 6 dosimeters: two for control, two at the entry of the beam and two at the exit of the beam. According to these values, the estimated fetal dose was about 0.1 mSv, with a risk for the fetus very low/practically despicable.

High dose examinations (>1 mGy).

We performed 4 high dose studies, three corresponding to plain radiography (abdomen AP in 8.5 weeks of gestational age (Fig. 8 on page 15)), a pelvis AP-L in the 39th week (Fig. 9 on page 15) and a vascular interventional procedure corresponding to the placement of an inferior vena cava filter in a patient of 26 weeks of gestational age (Fig. 10 on page 16). The mean age of the patients was 28 years.
The three plain radiography studies (75%) included the abdominopelvic region, in two of them (66%) radiological protection measures were taken (inactivation of the antiscatter grid). The fetal risk and dose was calculated through the technical data of the study with an estimated mean fetal dose of 0.3 mGy and the fetal risk was very low.

In the placement of the inferior vena cava (Philips Allura Xper F20 angiographer) the fetus predictably was included or very close to the examination field. The lumbar region was protected (out of the examination field) with a lead apron of 0.35 mm of thickness of lead.

We used 14 dosimeters TLD: 4 for control, 5 in the anterior aspect of the patient (exit of the beam) (Fig. 11 on page 17) and 5 in the posterior aspect of the patient (beam entry).

The readings gave us a mean value at the entry of 10 and 0.04 mSv at the exit respectively. With an abdomen thickness of 24 cm (gestational age between 25 and 29 weeks) and an estimated fetal depth of 9 cm, we estimated a very low fetal dose.

We didn´t need to calculate the accumulated dose.

In no case there were complications during the pregnancy or malformations or newborn alterations derived from the radiation exposure.
Fig. 5: AP and L radiographies of the R ankle with a suprasyndesmosis fracture-dislocation in a 20 weeks pregnant woman, without antiscatter grid and with a lead apron.

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Fig. 6: Postsurgical control with a plain AP and L radiographies of the R ankle in a 26 weeks pregnant woman, without the antiscatter grid and with a lead apron.

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**Fig. 7:** Plain chest PA and L radiographies in a pregnant woman with fever, cough and expectoration that showed a consolidation in the middle lobe. The radiological protection measures applied were an adequate collimation of the study and the utilization of a lead apron (inferior part of the PA projection).

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**Fig. 8:** Plain AP radiography in a patient in which accidentally was discovered an ongoing pregnancy.

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Fig. 9: Pelvimetric study using plain AP and L radiographies for a suspicion of cephalopelvic disproportion.

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**Fig. 10:** Placement of an inferior vena cava filter: 26 week pregnant woman that came to the emergency department at our institution with a premature rupture of membranes; during her admission she started with inflammation and pain in her left lower limb in which it was confirmed an extensive deep vein thrombosis with Doppler ultrasound.

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**Fig. 11:** Placement of the TLD in the anterior aspect of the abdomen previous to the placement of the vena cava filter in a patient with DVT of the LLL.

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Conclusion

The pregnant woman can get sick and require procedures that use ionizing radiations for the diagnosis or treatment of her sickness.

From a medical and legal point of view, the radiologist is in charge of a correct evaluation of the indication of the procedure, with a risk-benefit evaluation for each particular clinical situation.

That is why we need as radiologists to know the possible effects of ionizing radiation in the different stages of pregnancy and the current legislation, with a special attention to expert groups publications about the calculation of the fetal estimated dose for each study and the possible measures of optimization and radioprotection to take in each of them.

Following our IC model adapted to the pregnant woman is possible to systematize the general information offered to the pregnant woman, reducing her anxiety regarding the examination and making easier her choice about giving or not consent for performing the study. In the same way, the systematization recollecting the technical data for performing the examination allow the calculation of the estimated fetal dose and the potential risk derived from the fetal exposition to the radiation.

Most of the examinations with ionizing radiation performed in pregnant women during the last three years at our institution were low fetal dose.

The estimated fetal dose didn´t reach in any case 1.5 mSv, and the fetal risk estimation was very low or practically despicable for all of them. In no case there were complications during pregnancy or malformations or newborn alterations derived from the radiation exposure.
References


