

## Fetal radiation exposure: Is monitoring really needed?

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**Core tip:** The effects of endoscopic retrograde cholangiopancreatography (ERCP) on pregnant women, addressed in the recent article by Smith *et al*, is an interesting topic. Despite the large sample of patients investigated by the authors, strong experimental evidence on this topic is still lacking. ERCP should be performed only with a therapeutic purpose and by experienced ERCP endoscopists, preferably during the second trimester of pregnancy.

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### Abstract

The effect of fetal radiation during endoscopic retrograde cholangiopancreatography (ERCP) on pregnant women is a very interesting topic. Smith *et al* recently estimated the fetal radiation exposure in pregnant women undergoing ERCPs using thermoluminescent dosimeters (TLDs). The authors concluded that TLDs are unnecessary during ERCP with modified techniques. We believe that an extreme caution is needed in clinical practice before drawing such conclusions when they are not strongly supported by enough experimental evidence. Therefore, we recommend that fetal radiation exposure be monitored in clinical practice by using dosimeters, bearing in mind that all relevant techniques to control and minimize the exposure must be applied.

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### COMMENTARY ON HOT TOPICS

The effects of endoscopic retrograde cholangiopancreatography (ERCP) on pregnant women, addressed in the recent article by Smith *et al*<sup>[1]</sup>, is an interesting topic. It is estimated that 3%-12% of pregnancies are complicated by gallstone disease. In pregnant women weight increase and hormonal changes are responsible for an increase in the prevalence of cholelithiasis or gallbladder sludge. Uncomplicated cholelithiasis should preferably be treated before planning the pregnancy or during the postpartum phase. Fortunately, a pregnancy does not increase the frequency or the severity of complicated gallstone disease. However, when pancreatobiliary disease comes in an acute form, such as acute pancreatitis or cholangitis, there are increased rates of the morbidity and mortality for both the mother and the fetus<sup>[2-4]</sup>. Since 1990, ERCP has been used in biliary stone disease during pregnancy, although this technique could increase the risk of maternal complications (such as bleeding, perforation, pancreatitis), as in non-pregnant women. Moreover, fetal teratogenicity or tumorigenesis is an additional risk factor for pregnant patients. For these reasons, ERCP is

nowadays only used for therapeutic purposes.

The irradiation risk for the fetus depends on both deterministic and stochastic effects. Deterministic effects are dose-correlated, can affect the growth and development of the fetus, and are most probable between the second and fifteenth week of gestation. According to the consensus statements from the relevant major national organizations, in particular the American Congress of Obstetricians and Gynecologists, the risk of malignancy, miscarriage, or major malformations is negligible in fetuses exposed to 50 mGy or less<sup>[5]</sup>. The risk of developing cancer following irradiation, although characterized by a small probability, is a stochastic effect and does not have any threshold level. In fact, the probability of stochastic effects shows a monotonic increase as a function of the absorbed dose and follows a “no-threshold” model. According to this model, the carcinogenesis risk has a linear dependence with the radiation doses, and even the smallest dose can potentially increase the risk of cancer occurrence<sup>[6]</sup>.

Numerous studies have addressed the estimation of the radiation exposure levels for the fetus. Cappell<sup>[7]</sup> performed a comprehensive analysis of 46 previous studies including 296 pregnant women. He observed that the rate of complications after therapeutic ERCP is similar for both pregnant and not-pregnant patients. Cappell identified the most common maternal complications to be pancreatitis, with a rate of 6.4% (only one case was severe and no cases required surgical intervention), and post-sphincterotomy bleeding with an incidence of 1%. Among the 254 cases examined in the Cappell’s review the most common fetal complications were: (1) prematurely born infants with a low birth weight (4.3%); (2) late spontaneous abortion (1.2%); (3) infant death right after the birth (0.8%); and (4) voluntary abortion (0.4%).

It is important to mention that the teratogenic effects of radiation on the fetus have a stochastic nature and are essentially unknown. The reason for this may be related to the lack of follow-up after birth in most of the studies on ERCP in pregnancy, potentially underestimating eventual complications. To the best of our knowledge, only Gupta *et al.*<sup>[8]</sup> performed a long term follow up, which revealed that after a median time of 6 years all the babies were healthy.

The aim of the article by Smith *et al.*<sup>[1]</sup> was to estimate the fetal radiation exposure in pregnant women undergoing ERCPs using thermoluminescent dosimeters (TLDs). This is the largest prospective study of ERCP during pregnancy ever published: 35 patients were subjected to ERCP performed by expert endoscopists. In order to minimize the amount of maternal and fetal exposure, the authors suggest performing a modified ERCP technique where colangiography is used only to detect the presence and position of stones after blind common bile duct cannulation and sphincterotomy. Complications occurred in 6 patients (17%): 2 post-sphincterotomy bleeding (5.7%), 2 post-ERCP pancreatitis (5.7%), 1 fatal acute respiratory distress syndrome (2.8%), 1 cholecysti-

tis (2.8%). Four of these patients were carrying a term-fetus, while only two were pre-term, and no data were available regarding the outcome of the uncomplicated pregnancies. In this paper, the authors reported that the fetal irradiation, supposedly due to ERCP, was less than 0.2 mGy in 88.6% of the patient population, concluding that TLDs are actually unnecessary during ERCP with modified techniques since the radiation exposure of the fetus was well below the threshold established by the International Commission of Radiological Protections (10 mGy)<sup>[9]</sup>.

However, this very strong statement it seems not to be strongly supported by sufficient experimental evidence. We strongly disagree with the authors as we believe that extreme caution should always be advocated before drawing such conclusions in clinical practice. We will now critically address all the unclear points and inconsistencies present in the paper. Firstly, we wish to repeat the main message of the paper as reported by the authors themselves: “for a routine ERCP with modified techniques, estimating the fetal radiation exposure from the fluoroscopy time and measuring it with the use of TLDs is unnecessary”. This is in apparent contradiction with the statement which appears in the following paragraph of their manuscript: “The threshold may be exceeded in complicated long-lasting ERCPs and in these complicated long-lasting ERCPs, dosimeters may be used to estimate the fetal radiation exposure”. In these situations a clear decision cannot be taken, since there are no objective clinical and imaging parameters that can be evaluated prior to ERCP, which are able to predict the duration of the procedure and its difficulty. Furthermore, continued monitoring offers a quality benchmark or an opportunity to keep doses “as low as reasonably attainable”.

An additional weak point of the paper is the lack of a proper discussion of age and physical issues. The authors affirmed that the 10% of the dose recorded by TLDs on the upper back could be considered to be the fetal dose. However, different gestation ages and different physical and demographic features of the mother could dramatically influence these parameters, considerably modifying their value.

We suggest using a more empirical approach to the problem. In order to verify the real need for radiation dose monitoring, a mathematic model correlating the estimated fetal exposure with physical observables associated with the treatment of the patient should be developed and tested. These parameters could include fluoroscopy exposure time, the procedure time, the gestation age, maternal features, and could vary in number according to the complexity of the model. In this framework, we suggest that entrance skin exposure of the mother could be used as the input variable in an appropriate algorithm able to derive the absolute value of the fetal exposure. This approach would have the advantage of being selective and specific to each patient.

Despite the findings from Smith *et al.*<sup>[1]</sup> and any pos-

sible analytical model, many studies have shown that repeated exposures to low levels of ionizing radiation can cause cancer. In fact, stochastic effects of radiation do not exhibit any threshold dose. For this reason, ESGE Guidelines<sup>[10]</sup> recommend that the kerma-area product should be monitored, and its cumulative value should be recorded for every ERCP.

In conclusion, we have discussed disease occurrence, radiation risks and fetal exposure during ERCP on pregnant women. In particular we closely evaluated the results obtained by Smith *et al.*<sup>[11]</sup> who estimated the fetal radiation exposure in pregnant women undergoing ERCPs using TLDs, and claimed that TLDs are unnecessary when ERCP is performed with modified techniques. Despite the large sample of patients investigated by these authors, strong experimental evidence is still lacking on this topic. Therefore, until other prospective studies show that TLD monitoring is not necessary, fetal radiation exposure should be always monitored in clinical practice by dosimeters, bearing in mind that all relevant techniques to control and minimize exposure should be applied. Moreover, ERCP should be performed only with a therapeutic purpose and by experienced ERCP endoscopists, preferably during the second trimester of pregnancy.

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