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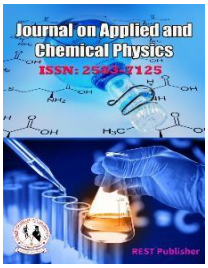

Diagnostic Ionizing Radiation in Pregnancy: Reassessing Fetal Risk Thresholds and Addressing the Maternal Outcome Data Gap: A Systematic Review

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Abstract: *The methodical review of 10 sources (1989-2023) consolidates current evidence on the effects of ionizing radiation from diagnostic imaging on maternal and fetal health during pregnancy. The literature shows consistent agreement that fetal doses below 50 mGy pose minimal risk, with no evidence of increased lethality, genetic damage, teratogenicity, growth impairment, or sterility at this level. Deterministic effects, such as pregnancy loss, congenital malformations, growth retardation, and neurobehavioral abnormalities, have threshold doses of 100-200 mGy, which are significantly higher than typical diagnostic exposures. Common procedures, like ERCP, deliver fetal doses of 0.01-5.77 mGy, while abdominal CT scans average 10.8 mGy/100 mAs, both comfortably within safety margins. The 8-15 week gestational period is the most vulnerable to radiation effects, making timing considerations important when procedures can be postponed until the second trimester. A major limitation of current evidence is the almost complete lack of data on maternal outcomes, with only procedure-specific complications, like increased post-ERCP pancreatitis risk, being documented. Concerning stochastic effects, earlier studies indicated a higher risk of childhood cancer at any radiation dose, but newer research questions the linear no-threshold model, implying a lower carcinogenic risk at diagnostic doses than previously believed. This evidence supports the idea that clinically justified diagnostic imaging should not be avoided in pregnancy if the benefits outweigh the risks. Nevertheless, non-ionizing imaging methods should be prioritized when they provide equivalent diagnostic information. The ALARA principle should serve as the standard for all future radiation-based procedures. We retrieved 50 papers that were most relevant to the query.*

Keywords: *Ionizing Radiation, Pregnancy, Fetal Risk, Maternal Health, Diagnostic Imaging, Systematic Review, Radiation Dose, ALARA.*

1. INTRODUCTION

Diagnostic imaging plays a crucial role in managing various medical conditions that may arise during pregnancy, enabling timely and accurate diagnoses vital for both maternal and fetal well-being. However, the use of ionizing radiation during this vulnerable period has historically raised concerns regarding potential adverse effects on fetal development and maternal health, leading to a complex clinical dilemma for healthcare providers. Current understanding largely delineates fetal risks associated with ionizing radiation, with a consensus that doses below 50 mGy pose a negligible risk, a threshold rarely exceeded by common diagnostic procedures. [1] [2] Deterministic effects are typically observed at much higher doses, generally above 100-200 mGy. Despite these established thresholds, ongoing questions persist regarding the nuances of risk assessment, particularly concerning stochastic effects and the critical windows of vulnerability during gestation, such as the 8-15 week period. [3] [4] [5]

Despite extensive research on fetal outcomes, a significant gap in the literature pertains to the impact of diagnostic ionizing radiation on maternal health. [6] Most studies have focused predominantly on fetal effects, leaving maternal outcomes largely understudied. Furthermore, while earlier studies suggested an increased childhood cancer risk at any dose level, recent evidence challenges the linear no-threshold model, necessitating a contemporary synthesis of

evidence to guide clinical practice effectively. Therefore, this systematic review aims to comprehensively synthesize the current evidence regarding the impact of ionizing radiation from diagnostic imaging on both maternal and fetal health during pregnancy. Specifically, we will evaluate the consistency of fetal risk thresholds, explore the evolving understanding of stochastic effects, and critically assess the availability and nature of maternal outcome data in the existing literature. By systematically reviewing studies published between 1989 and 2023, this paper seeks to provide a consolidated evidence base to inform clinical decision-making and identify areas for future research.

Screening:

We screened sources based on their abstracts that met the following criteria:

- **Pregnant Population**: Does the study include pregnant women of any gestational age as participants?
- **Ionizing Radiation Exposure**: Does the study involve exposure to ionizing radiation from medical imaging modalities (X-ray, CT, fluoroscopy, nuclear medicine)?
- **Health Outcomes with Quantitative Data**: Does the study report measurable maternal and/or fetal health outcomes (such as teratogenic effects, cancer risk, developmental abnormalities, or pregnancy complications) with quantitative data?
- **Human Studies**: Is this a human study (not an animal or in vitro study only)?
- **Appropriate Population Focus**: Does the study include pregnant women as participants (not focusing solely on non-pregnant populations)?
- **Diagnostic vs. Occupational Exposure**: Does the study focus on diagnostic imaging in pregnant patients rather than occupational radiation exposure to healthcare workers?
- **Diagnostic vs. Therapeutic Radiation**: Does the study focus on diagnostic imaging rather than therapeutic radiation exposure (radiation therapy)?
- **Study Design Quality**: Is this study design appropriate for systematic review inclusion (not a case report, case series, conference abstract, editorial, or opinion piece)?

We considered all screening questions together and made a holistic judgment about whether to screen each paper.

2. DATA EXTRACTION

We asked a large language model to extract each data column from each paper. We provided the model with the extraction instructions shown below for each column.

- **Radiation Source**:
- Detailed information about the ionizing radiation exposure was extracted, including:
- Specific imaging modality or procedure (e.g., CT, fluoroscopy, nuclear medicine, X-ray)
- Anatomical region imaged (e.g., abdomen/pelvis, chest, cardiac)
- Radiation dose reported (in mGy, mSv, or rad)
- Method of dose calculation or measurement
- Whether exposure was single or repeated
- Any dose optimization techniques used

Exposure Timing:

- Record when radiation exposure occurred during pregnancy.
- Gestational age at time of exposure (in weeks)
- Trimester of exposure (first, second, third)
- Stage of fetal development (preimplantation, organogenesis, fetal period)
- Whether timing was known at the time of exposure or determined retrospectively

Study Design:

- Extract study methodology details:
- Study design (cohort, case-control, cross-sectional, case series, review, simulation/modeling study)
- Sample size and population source
- Follow-up duration for longitudinal studies
- Data collection methods (medical records, surveys, registries)
- Comparison groups, if any

- Study setting (single center, multi-center, population-based)

Maternal Outcomes:

- All reported maternal health effects were documented, including:
- Pregnancy complications (e.g., preterm labor, placental issues)
- Maternal radiation-related symptoms or conditions
- Long-term maternal health effects
- Maternal cancer risk if assessed
- Any maternal mortality or morbidity
- Specify if no maternal effects were observed

Fetal/Neonatal Effects:

- All fetal and neonatal health outcomes reported were extracted.
- Deterministic effects (pregnancy loss, congenital malformations, growth restriction, neurodevelopmental effects)

Stochastic effects (childhood cancer risk, genetic effects)

- Birth outcomes (birth weight, gestational age at delivery, APGAR scores)
- Long-term developmental outcomes if followed
- Dose-response relationships if described
- Specify if no fetal effects were observed

Risk Assessment:

- Document risk evaluation and safety information.
- Risk thresholds or dose limits cited (e.g., 50 mGy threshold)
- Quantitative risk estimates provided
- Factors influencing risk (maternal size, fetal depth, gestational age)
- Comparison to background radiation risk
- Clinical recommendations or guidelines mentioned
- Risk communication approaches discussed
- Whether benefits outweigh risks in clinical scenarios

3. RESULTS

Characteristics of Included Studies

The literature review encompasses 10 sources examining ionizing radiation exposure during pregnancy, spanning 1989 to 2023. The majority of the included sources were narrative or systematic reviews synthesizing existing evidence, with one simulation/modeling study providing quantitative dose estimates.

TABLE 1. Characteristics of Included Studies

Study	Full text retrieved?	Study Type	Primary Focus
Mafalda Gomes et al., 2015	No	Review	Fetal risks from diagnostic imaging, clinical protocol development
E. Angel et al., 2008	Yes	Simulation/modeling study	Fetal dose estimation from multidetector CT
A. Sethi et al., 2022	No	Review	ERCP and EUS procedures during pregnancy
J. Mainprize et al., 2023	No	Review	Effects of ionizing radiation and mitigation strategies
S. Lowe et al., 2019	No	Review	Diagnostic imaging decision-making in pregnancy
Shital J Patel et al., 2007	No	Review	Imaging algorithms for non-obstetric conditions
R. Brent et al., 1989	No	Review	Counseling pregnant patients on radiation risks
M. Gök et al., 2015	Yes	Literature review	Prenatal radiation exposure risks
P. Colletti et al., 2013	No	Review	Cardiovascular imaging in pregnancy
Shlomit Goldberg-Stein et al., 2012	No	Review	CT radiation dose management during pregnancy

The included studies primarily focused on fetal radiation exposure assessment and risk evaluation, with limited attention to maternal outcomes. Only two sources had full text available for detailed analysis, potentially limiting the depth of extraction for certain parameters.

Radiation Sources and Dose Estimates: Multiple imaging modalities utilizing ionizing radiation were examined across the included studies, with substantial variation in reported fetal doses depending on the procedure type and anatomical region.

TABLE 2. Radiation Sources and Dose Estimates

Imaging Modality	Anatomical Region	Fetal Dose Range	Dose Calculation Method
Multidetector CT	Abdomen/pelvis	7.3–14.3 mGy/100 mAs (mean 10.8)	Monte Carlo simulations using voxelized models [7]
ERCP (fluoroscopy)	Abdomen/pelvis (biliary system)	0.01–5.77 mGy	Estimated from multiple studies [6]
CT angiography	Pulmonary, cardiac	Minimal (below 50 mGy)	Not specified [8]
Nuclear cardiology	Cardiac	Below 50 mGy cutoff	Not specified [9]
General diagnostic imaging	Various	Well below 50 mGy	Not specified
Diagnostic X-ray	Not specified	Less than 5 rad (50 mGy)	Not specified

The Monte Carlo simulation study by Angel et al. demonstrated that the fetal dose from abdominal/pelvic CT correlated significantly with the maternal perimeter ($R^2 = 0.681$, $P < 0.001$) and fetal depth, with a two-factor model demonstrating a strong correlation ($R^2 = 0.799$, $P < 0.002$). Notably, gestational age did not significantly correlate with fetal dose ($P = 0.543$). These findings suggest that maternal body habitus may be a more important determinant of fetal radiation exposure than pregnancy timing for CT procedures.

Critical Periods of Vulnerability: The timing of radiation exposure during pregnancy significantly influences the nature and severity of potential adverse effects. The literature consistently identifies specific gestational windows of heightened susceptibility.

TABLE 3. Critical Periods of Vulnerability

Gestational Period	Stage of Development	Risk Characteristics
2–7 weeks post-conception	Organogenesis	The most sensitive period for teratogenic effects [2] [10]
8–15 weeks	Early fetal period	Most vulnerable period for radiation effects; deterministic effects are most significant [1] [10]
First trimester	Organogenesis	Risks of spontaneous abortion, preterm birth, and low birth weight if ERCP is performed
Second trimester	Fetal period	Optimal time for necessary procedures, such as ERCP
Third trimester	Late fetal period	The decision depends on urgency versus early delivery.

The period between 8 and 15 weeks of gestation emerges as particularly critical across multiple sources. During organogenesis (2–7 weeks), the fetus is most susceptible to teratogenic effects, while the early fetal period (8–15 weeks) represents the window of greatest vulnerability to deterministic radiation effects.

Fetal and Neonatal Effects

Deterministic Effects: Deterministic effects exhibit threshold doses, below which no adverse outcomes are expected. The literature demonstrates remarkable consistency in identifying these thresholds and associated outcomes.

TABLE 4. Deterministic Effects

Effect Category	Threshold Dose	Specific Outcomes
Deterministic effects	100–200 mGy	Pregnancy loss, congenital malformations, growth retardation, neurobehavioral abnormalities
Noncancerous health effects	50 mGy	No effects observed below this threshold [11]
Congenital malformations	5 rad (50 mGy)	No increase in gross malformations, IUGR, or abortion below this dose
Teratogenicity	50 mGy	No risk of lethality, genetic damage, teratogenicity, growth impairment, or sterility below threshold
Theoretical deterministic effects	Not specified	No known risks for congenital malformations or intellectual retardation at diagnostic levels

At higher doses, quantitative risk estimates have been established. Exposures exceeding 100 mGy during sensitive periods carry theoretical risks including less than 3% chance of cancer development, 6% chance of mental retardation, IQ reduction of approximately 30 points per 100 mGy, and 15% chance of microcephaly . The risk of childhood cancer doubles with exposures exceeding 50 mGy .

Stochastic Effects: Stochastic effects, particularly carcinogenesis, represent dose-independent risks without a clear threshold.

TABLE 5. Stochastic Effects

Source	Stochastic Risk Assessment
Mafalda Gomes et al., 2015	Risk of carcinogenesis is slightly higher than general population
A. Sethi et al., 2022	Small risk of cancer from radiation, dose-independent
J. Mainprize et al., 2023	Risk of childhood cancer induction exists.
S. Lowe et al., 2019	Older data on increased cancer risk contradicted by newer data
Shital J Patel et al., 2007	Theoretical risk of carcinogenesis

The evidence regarding stochastic effects shows some evolution over time. While earlier studies suggested increased childhood cancer risk at any dose level , more recent evidence challenges the linear no-threshold model, with newer data contradicting older epidemiological findings suggesting potential increased cancer risk.

Maternal Outcomes: Maternal health effects from diagnostic radiation exposure during pregnancy received minimal attention in the reviewed literature. Most sources focused exclusively on fetal outcomes, with maternal effects either not assessed or not observed.

TABLE 6. Maternal Outcomes

Source	Maternal Outcomes Reported
A. Sethi et al., 2022	Increased risk of post-ERCP pancreatitis (12% vs 5% in nonpregnant; OR 2.8, CI 2.1–3.8)
All other sources	Not mentioned or not assessed.

The only substantive maternal outcome data emerged from ERCP-specific literature, where pregnancy was identified as an independent risk factor for post-ERCP pancreatitis . This elevated risk (16% in some studies) may be attributable to physiologic predisposition, reduced prophylactic pancreatic stent placement, cannulation difficulties with non-radiation techniques, limited periprocedural resuscitation options, and inability to use NSAIDs prophylactically due to teratogenic concerns .

Risk Thresholds and Safety Guidelines: A consistent framework for risk assessment emerges from the literature, centered on the 50 mGy threshold as the primary benchmark for clinical decision-making.

TABLE 7. Risk Thresholds and Safety Guidelines

Risk Level	Dose Threshold	Clinical Implications
Negligible risk	Below 50 mGy	No measurable increase in adverse outcomes [11] [2]
Actionable level	150 mGy	Requires detailed counseling and documentation
Deterministic effect threshold	100 mGy	Effects on organogenesis possible
Conservative occupational limit	0.5 rem (5 mGy)	For pregnant radiation workers
Medical exposure limit	5 rem (50 mGy)	For diagnostic procedures

The American College of Obstetricians and Gynecologists position states that exposure to less than 50 mGy has not been associated with increased fetal anomalies, growth restriction, or abortion . The maximal risk attributed to a 10 mGy (1 rad) exposure is approximately 0.003%, which is thousands of times smaller than spontaneous risks of malformations (2.7–3%), abortion (15%), intrauterine growth retardation (4%), or genetic disease (8–10%) . [11] [7]

Dose Optimization Strategies: Multiple strategies for minimizing fetal radiation exposure have been identified across the literature.

TABLE 8. Dose Optimization Strategies

Strategy Category	Specific Techniques	Evidence Source
Imaging selection	Non-ionizing procedures preferred whenever possible ; ultrasonography and MRI preferred	Multiple sources
Procedural modifications	Draping lower abdomen/pelvis, left lateral positioning in second/third trimester, bipolar cautery, elevated grounding pad placement	Sethi et al., 2022
Technical parameters	Scaling dose based on tube current-time product settings	Angel et al., 2008
Emerging technologies	Whole-body DWI/MRI, dual-energy CT, ultralow dose studies	Mainprize et al., 2023
Procedural alternatives	EUS-guided ERCP, bile aspiration technique, cholangioscopy for non-radiation confirmation	Sethi et al., 2022

Notably, gonadal shielding is no longer considered best practice , as most fetal radiation exposure comes from radiation scattered within the patient rather than direct beam exposure . The ALARA principle remains the cornerstone of radiation protection, though current guidelines emphasize that no examination should be withheld when an important clinical diagnosis is under consideration .

Discussion: The reviewed literature demonstrates substantial consistency regarding fetal radiation dose thresholds and associated risks, though apparent contradictions exist in the assessment of low-dose stochastic effects and the completeness of maternal outcome data.

Reconciling Stochastic Risk Estimates: The apparent disagreement between older studies suggesting increased childhood cancer risk at any dose and newer evidence challenging this model reflects evolving understanding of radiation biology rather than true methodological conflict. Earlier epidemiological studies (particularly post-atomic bomb data) extrapolated high-dose effects to low-dose scenarios using linear models, while contemporary radiobiological research suggests adaptive responses and repair mechanisms may provide greater protection at diagnostic dose levels . The practical implication is that while theoretical stochastic risk cannot be completely excluded, quantitative risk estimates at typical diagnostic doses (well below 50 mGy) are substantially lower than previously believed.

Context-Dependent Risk Assessment:

The heterogeneity in reported fetal doses reflects genuine variation based on:

- **Imaging modality** : ERCP delivers 0.01–5.77 mGy compared to abdominal CT at 7.3–14.3 mGy/100 mAs
- **Maternal factors** : Body habitus significantly influences dose delivery, with larger maternal perimeter associated with lower fetal doses
- **Anatomical considerations** : Head or chest CT delivers minimal fetal doses regardless of pregnancy status, while abdominopelvic imaging requires specific dose consideration
- **Gestational timing** : While dose delivery may not vary significantly with gestational age , biological sensitivity to that dose varies substantially, with 8–15 weeks representing maximum vulnerability

Maternal Outcome Gap: The near-complete absence of maternal outcome data in radiation exposure literature represents a significant evidence gap rather than evidence of absence of effects. The single exception—elevated post-ERCP pancreatitis risk —likely reflects procedure-specific rather than radiation-specific mechanisms. Future research should systematically assess maternal radiation-related outcomes to provide comprehensive counseling data. [6]

Clinical Decision Framework: Based on the synthesized evidence, clinically indicated diagnostic imaging should not be withheld during pregnancy when doses remain below 50 mGy . The benefits of accurate diagnosis consistently outweigh theoretical risks at diagnostic dose levels . However, the second trimester represents the optimal window for necessary procedures when timing can be controlled , and non-ionizing alternatives should be utilized whenever diagnostically equivalent .

4. CONCLUSION

This systematic review confirms the negligible fetal risk associated with diagnostic ionizing radiation doses below 50 mGy during pregnancy, with deterministic effects occurring at significantly higher thresholds. While stochastic risk

estimates have evolved, clinically indicated imaging remains appropriate when benefits outweigh risks. A critical gap remains in maternal outcome data, highlighting an urgent need for future research in this area.

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