Radiation exposure and pregnancy

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Introduction: **The effect of radiation on the fetus has been derived primarily from animal studies and human exposures to diagnostic and therapeutic radiation as well as atomic bomb exposure. Given the variety of sources, there is controversy over the dose of radiation in addition to the other environmental conditions that surrounded these events and their relationship to exposure today.**

Methods: **The effects of ionizing radiation on the fetus, the prenatal period, parental exposure, the pregnant clinician, and the pregnant patient are discussed in the context of their exposure to radiation.**

Results: **The fetus is most sensitive to radiation effects between 8 and 15 weeks of pregnancy. Stepping away from the table and using movable shields help reduce the exposure by a factor of four for every doubling of the distance between the operator and the radiation source.**

Conclusion: **Proposed guidelines for pregnancy during vascular residency training involving fluoroscopic procedures can help bring about awareness, clarify maximal exposure, and better delineate the role of the pregnant resident. (J Vasc Surg 2011;53:28S-34S.)**

RADIATION EFFECTS ON THE FETUS

The effect of radiation on the fetus has been derived from animal studies, human exposures to diagnostic and therapeutic radiation, to atomic bomb radiation at Hiroshima and Nagasaki in 1945, and to the fallout of the Chernobyl nuclear power plant explosion in April 1986. It is important to appreciate that much of the information is taken from the exposure of large populations at Hiroshima and Nagasaki. Of the >2800 pregnant women exposed, 500 of their fetuses received >10 mGy (1 rad) of radiation. The offspring of these women were assessed in the context of the amount of radiation received and the timing of the exposure during their development. Multiple factors have raised questions of whether the effects were solely due to the radiation. Those factors include controversy over the dose of radiation, the influence of neutron radiation, and other environmental conditions surrounding this event.[1-9]

Effects of ionizing radiation on the fetus. Radiation risks throughout pregnancy are related to the stage of pregnancy and the absorbed dose. Potential radiation effects vary, depending on the fetal stage of development and the magnitude of the doses.[10] These risks are more significant during organogenesis and in the early fetal period, somewhat less in the second trimester, and least in the third trimester. Malformations have a threshold of 100 to 200 mGy or higher and are typically associated with central nervous system problems. For example, fetal doses of 100 mGy are not reached even with 3 pelvic computed tomography (CT) scans or 20 conventional diagnostic x-ray examinations; however, these levels can be reached with fluoroscopically guided interventional procedures of the pelvis and with radiotherapy.[11]

Osei et al[12] performed a retrospective study assessing the radiation exposure in 50 pregnant women who underwent radiologic examinations of the lower abdomen and pelvis with the fetus near or in the field. The follow-up data spanned 10 years. The radiation-absorbed dose was estimated and varied between <0.01 μGy and 117 mGy. Gestational ages were between 2 and 24 weeks, with 68% at <8 weeks, and 18% in the period of gestation (8 to 15 weeks), a point at which the concern for mental retardation is raised. Two fetuses received total doses >100 mGy.

The authors used risk coefficients to estimate risks after in utero exposure to diagnostic x-rays. At 8 to 15 weeks after conception, the decline in intelligence quotient (IQ) was estimated to be 30 IQ points/Gy.[13] The estimate for hereditary effects in all future generations was assumed to be 2.4×10^{-2} per Gy. Total risk of fatal childhood cancer at age ≤15 years as the result of prenatal exposure was 3.0×10^{-2} per Gy. The natural risk of fatal childhood cancers in this geographic area to age 15 years was 7.7×10^{-4}.[14] These authors concluded that for the risk of death, malformation, and mental retardation, diagnostic radiologic studies pose very small risk to the fetus.

For the induction of deterministic effects per radiographic examination, the reported threshold doses are approached by CT pelvis examination with mean fetal dose of 89 mGy. They noted that increased genetic risk of 2×10^{-3} for an individual fetus was associated with the highest dose from diagnostic procedures, and this is small compared with the natural risk of genetic disease. The risk of death from cancer for an individual fetus ranged from $<4 \times 10^{-6}$ to 15×10^{-4} for leukemia and 35×10^{-4} for solid cancers. Approximately 20% of fetuses carry a risk above the

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natural cumulative risk of fatal childhood cancer in England and Wales, the region assessed.[12]

Prenatal period. The prenatal period is the most sensitive and includes the 0 to 8 days before implantation. This is also the time when about 50% to 75% of all human pregnancies abort[15] and has been attributed to abnormal development.[16] Because there is such a high incidence of spontaneous abortion at this time, evaluation of the influence of radiation as a causative factor is difficult. Multiple authors have suggested that in animals, radiation-induced prenatal death might occur at doses of 50 to 100 mGy (5 to 10 rad) and above if delivered before implantation.[17-20]

Brent suggested in 1989 that radiation-induced prenatal death in humans occurs at other stages of gestation but at higher levels >250 mGy (25 rad). The observed effects include growth retardation, malignancies, and neurologic effects such as small head size, severe mental retardation, intellectual deficit, and seizures. Periods have been identified when the fetus is vulnerable to these effects as follows: growth retardation, embryonic at 8 to 56 days postconception (PC); small head size or microcephaly at 2 to 15 weeks PC (14-105 days); severe mental retardation at 8 to 15 weeks PC (56-105 days); intellectual deficit at 8 to 15 weeks PC (56-105 days); and seizures at 8 to 15 weeks PC (56-105 days). A correlation between an increased incidence of childhood cancer and in utero doses of approximately 20 mGy (2 rad) has been demonstrated by several authors.[21-24] An estimated 1 to 2 cases of childhood cancer occur per 3000 children exposed to 10 mGy (1 rad) of in utero irradiation. Although there is some debate, Doll and Wakeford,[25] who have done a review of 40 years of research on this topic, believe there is compelling evidence to support in utero radiation as a causative factor inducing childhood cancer, even at doses of 10 mGy (1 rad).

Paternal and maternal exposure in year prior to conception. Case-control studies have been performed to try to assess radiation effects on maturing reproductive cells by studying children conceived shortly after population exposure. Although some authors, such as Gardner,[26] have noted an unusual correlation between paternal exposure and childhood cancer for workers in a nuclear facility, the data presented by Gardner and several other authors are hard to interpret. Thus, there are a variety of hypotheses that need further investigation. There is no evidence that a child will be at a greater risk for birth defects from parental exposure to x-rays or radionuclide medical tests. In the last century, the number of women exposed to medical radiation has increased, while the rate of birth defects and miscarriages is unchanged.[10]

Dose equivalent to the embryo/fetus. The Massachusetts Department of Health has released recommendations[27] regarding the "Dose Equivalent to an Embryo/Fetus" that state the following:

"A.) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed five millisieverts (0.5 rems).

B.) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 105 CMR 120.218 (A).

C.) The dose equivalent to the embryo/fetus is the sum of:
  1.) the deep dose equivalent to the declared pregnant woman
  2.) the dose equivalent resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

D.) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 millisieverts (0.5 rem) of this dose by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with 105 CMR 120.218(A), if additional dose to the embryo/fetus does not exceed 0.5 millisievert (0.05 rem) during the remainder of the pregnancy."

General requirements regarding administrative controls. The fetal dose received during fluoroscopic examinations is influenced by operational factors such as the settings used on the automatic dose rate control system. Magnification will reduce the field of view of the intensifier, and the dose rate to the patient will increase because the automatic dose rate control compensates for the decrease in minification gain of the image intensifier. Additional factors that affect the amount of radiation used in the examination include the quality of the tube, electronic gain controls, and the methods used by the manufacturer to control image clarity and dose rates.[12]

THE PREGNANT OPERATOR

Careful planning, understanding of the risks, and minimization of radiation dose can address many concerns regarding the pregnant operator. The International Commission on Radiological Protection (ICRP) considers the unborn child a member of the public when considering the occupational exposure of the pregnant worker.[28,29] Embryos in the earliest stages are most susceptible to radiation. For example, an exposure of 100 mGy (10 rads or 10,000 mrem) <2 weeks' gestation may lead to death of the embryo before clinical pregnancy is even suspected.[30,31] Therefore, education regarding the pregnant operator should be readily available to every female operator of child-bearing potential. In most cases, pregnant operators may safely perform procedures without the risk of fetal injury or death. In general, malformations only occur above a threshold dose of 100 to 200 mGy (10,000-20,000 mrem) during a pregnancy.[32] Between 8 and 15 weeks after conception, fetal exposure of 1000 mGy may reduce IQ by about 30 points and potentially cause mental retardation. Fetal exposure at a rate of 6% per Gy may also cause an increase in childhood (age 0 to 15) cancer risk. Fortunately, no risk of fetal or childhood effects has been found after preconception irradiation of either parent's gonads.[32]

All institutions are required to publish radiation safety standard operating procedures concerning pregnant operators, but these may vary significantly and may be influenced by state-to-state difference in laws. An institutional policy in Minnesota, for example, may state that declaration of pregnancy is not required to work with radiation, but if such declaration is done, it must be in writing. Other states or institutions may require confirmatory pregnancy test results or physician letter to accompany the declaration. The institutions have an obligation to publish or make their policies known regardless of the employee's pregnancy status at the time of the request.

Once a pregnancy declaration is made, or even before in some cases, the employee can request an additional badge to monitor fetal radiation. This abdominal badge (or fetal badge) is worn in addition to the standard badge and is secured to the lower abdomen under a lead apron to estimate the dose received by the fetus when protected by lead. The employee has the option to request and wear an abdominal badge regardless of whether a pregnancy declaration has been made. The fetus is most sensitive to radiation effects between 8 and 15 weeks of pregnancy.[32] This period is often before the pregnant worker may announce her pregnancy to coworkers or supervisors, and therefore she may request a fetal badge before actually declaring pregnancy. The purpose of the fetal badge is to assure that the maximum radiation dose to the fetus of 500 mrem over the entire gestational period is not reached. This radiation monitoring is done in addition to the standard collar badge, and the dose should be reported monthly during pregnancy.

Because radiation dose is cumulative, every effort to reduce exposure should be taken in the pregnant operator. This includes minimizing fluoroscopy time, possibly by limiting less experienced operators from using the fluoroscopy pedal or controls. Careful planning to reduce unnecessary imaging or using ultrasound guidance when possible may be used as long as it does not affect patient care or interventional outcomes. The pregnant interventionalist may consider stepping away (ideally >6 feet) away from the table, or even into the anteroom, during imaging runs. Doubling the distance between the operator and the radiation source will reduce the exposure by four. If the pregnant operator cannot step away from the table, movable lead shields should be used and placed between the x-ray beam and the operator. In addition, collimation of the radiographic beam by using metal tubes, cones, or diaphragms interposed in the path of the beam may reduce the peripheral portion that reaches the operator.

The extent of exposure of the pregnant operator may also be dictated by institutional or state mandates. For example, the radiation policy from an Arizona institution states that holding or manipulating the patient during radiographic or fluoroscopic procedures *is not* permitted and that declared pregnant individuals *are not* to approach ≤2 feet of the primary beam during diagnostic fluoroscopic procedures. This may prohibit a declared pregnant individual from working in interventional radiology, cardiac catheterization laboratory, gastroenterology endoscopy, or operating a C-arm in surgery.

The principle of "as low as reasonably achievable" (ALARA) is an important practice in both pregnant and nonpregnant operators. As discussed, reducing time and distance from the radiation source is important. Also critical is the use of protective aprons. The lead equivalence in the apron varies, as will the transmission of radiation through the apron. For example, if the lead equivalence in the apron is 0.75 mm, the transmission through the apron is about 1.1%; if it is 0.5 mm, transmission is about 2.0% to 3.8%; if it is 0.25 mm, transmission is about 10.4%.[33] Most states have criteria requiring 0.50-mm lead equivalent coverage, although some states may allow 0.25 mm.

The pregnant operator should be aware of the degree of apron protection and may consider additional coverage. For example, wearing wraparound aprons may allow reduction of exposure from the side or back.[34] "Pregnancy" or "maternity" lead is a commercially available apron that wraps around or has additional 0.5- to 1.0-mm protection in the fetal area. If these options are not available, the pregnant operator may consider wearing an additional protective skirt, particularly if the standard lead equivalent is 0.25 mm.

Kicken et al[35] evaluated the dosimetry of occupationally exposed persons with 0.5-mm lead and compared different procedures, particularly cerebral angiograms and percutaneous transluminal angioplasties. The authors calculated that the fetal dose limit would be reached after 208 percutaneous transluminal angioplasty procedures.[35] The evaluation of staff at two cardiac catheterization units wearing torso shielding with 0.25-mm lead equivalent indicated that the fetal dose limit would be reached after 34 cardiac catheterizations by a cardiologist or 87 procedures by the laboratory nurse.[36]

In the rare circumstance that a woman operator has a significant exposure during pregnancy, the amount of exposure is critical to decision making. Most protection agencies agree that termination of pregnancy at fetal doses of <100 mGy (10,000 mrad) is *not* justified based on radiation risk.[37] If the fetal dose is between 100 and 500 mGy, the operator and support staff must make decisions based on individual circumstances. If fetal doses are >500 mGy, however, significant fetal damage may have already occurred, and decisions regarding pregnancy termination must be made based on the stage of pregnancy.

PROGRAM GUIDELINES FOR PREGNANT VASCULAR SURGEONS, FELLOWS, AND RESIDENTS

Standard guidelines are important for a variety of reasons. In 2011, more than half of the medical students are women. This is very different from 1849, when Elizabeth Blackwell, the first woman to graduate from a medical school, failed to gain acceptance into a training program.[38,39] Fortunately, many things have changed in medicine for female medical students and residents; currently, women account for at least half of the medical school

matriculants and are trained in all medical and surgical specialties.

Although women comprise approximately 50% of the average graduates, they still occupy <25% of training positions in general surgery and <20% of the vascular fellowship positions.[40,41] In the last 8 years, the leadership in vascular surgery training has made an effort to attract more qualified women to consider training in vascular surgery.[41,42] Some concerns regarding prolonged training have led to changes in the structure and length of training as well as the encouragement of role modeling for both men and women. Thus, the vascular societies recognize the need to increase the number of female vascular residents or fellows, developing a new paradigm of training in vascular surgery.

The integrated 5-year vascular residency program has been adopted by many vascular institutions and welcomed with significant enthusiasm by medical students. This vascular residency program is geared to be more efficient in instructing the vascular and endovascular surgery of today. This will hopefully be more attractive to women and men as it considerably shortens the years of training. Only 18 women applied for the vascular residency in 2008; however, this number almost doubled in 2009 with 33 women applicants.

Meanwhile, the type of procedures performed by vascular surgeons has changed dramatically. Numerous reports have shown that endovascular procedures requiring prolonged exposure to radiation comprise >75% of all vascular procedures performed in current academic or private practices. Therefore, the new vascular residents in their training are expected to undergo routine exposure to radiation for up to 5 years during endovascular procedures. This is during the prime of their childbearing age, and it is quite possible that they may contemplate pregnancy during these years. A discrepancy in the ability to start a family while in training between men and women becomes increasingly evident in our vascular and surgical societies. In recent reports, 64% of male surgical graduating residents had a family at graduation vs only 15% of their female counterparts. The difference persisted after graduation, with 95% of men and 40% of women having children.[40,43] This is a real concern among female students and must be addressed by the surgical societies.

Although prolonged working hours during training has been considered the main hindrance in starting a family, exposure to radiation is also a significant concern. In a recent survey among female medical students, 31% expressed concerns regarding exposure to radiation that might affect their health and their childbearing potential. This percentage will probably be higher among vascular residents and fellows participating daily in long endovascular procedures.

A lack of written policies regarding pregnancy causes confusion and frustration among candidates applying for and those already participating in a residency program. Standardized policies to protect pregnant residents, at least during the crucial weeks of gestation, and written information regarding pregnancy and radiation can address concerns up front and prevent loss of potential candidates who are qualified to enter vascular residencies. A female applicant is likely to be reticent to ask about the existence of such a policy within the program, fearing that her particular interest in such policies and pregnancy would affect her ranking in this already competitive field. A program that is viewed by women and men as "family friendly" and sensitive to work-family issues would be more attractive to the current generation of candidates. Furthermore, a program with clearly written guidelines detailing safety guidelines regarding the amount of radiation permissible during pregnancy and options for fair redistribution of duties and rotations during pregnancy will guide residents throughout these years. There exists a certain amount of anxiety regarding consequences of becoming pregnant as a partner in practice or trainee. A mutual understanding can prevent animosity and tension amongst co-residents or partners. A clear acceptance of this type of policy by vascular surgery leadership will send a strong message to others.

Awareness in other societies. The American Association of Program Directors in Radiology identified the problem early on and in 2006 presented proposed guidelines for pregnancy during radiology residency.[44] In doing so, the association initiated surveys to training programs to assess the degree to which these issues have been addressed in various programs. In 1987, the lack of policy became clear when only 14 radiology programs from all the academic departments and private practices submitted such written policies.[45]

From these surveys, they have proposed guidelines to support trainees and set a standard for those programs. In 2004, however, despite significant encouragement by the society, only 50% of the radiology resident's programs had developed and implemented a written policy or offered special accommodations for pregnant residents. Furthermore, only 35% of the available policies were distributed to the applicants during interviews. Interestingly, the specialty of radiology, despite more flexible work hours, is another profession that attracts few women. Although half of the medical school graduates were women in 2005, only 27.5% of the radiology residents were women.

A proposal for development of guidelines. The development of guidelines is something that can potentially be initiated through the Program Directors of Vascular Surgery. Contribution from the directors of the training programs is critical to developing fair and balanced guidelines and eventual implementation by the society of vascular surgery. The following principles should be considered:

1. Clear definition of occupational radiation dose limits during the 9 months of pregnancy: Most agree that 500 mrem during the entire pregnancy or 50 mrem/mon is a safe dose. This translates to 100 to 1000 fluoroscopic examinations of 5 minutes each per gestational month.
2. Strict measures to decrease exposure during fluoroscopic procedure/exam include:

- availability of maternity aprons to pregnant residents (1.00 mm lead equivalent with double-lead inserts over the pelvis), which decrease dose by a factor of nearly 100 compared to standard aprons);
- encouragement of low magnification use during the procedures and collimation; and
- strict dosimetry and monitoring using a fetal monitoring badge and a badge under lead in accordance with ALARA principles.

3. Delineation of resident role when pregnant and redistribution of responsibilities: pregnant residents should be reassigned to rotations not exposed to significant radiation at least for the crucial gestational weeks.
4. Pregnant residents should be expected to participate fully in the residency; however, adjustments in rotation schedule should be possible with an effort made to not detract from their experience or that of their co-residents.

THE PREGNANT PATIENT AND RADIATION EXPOSURE

Radiation doses have been studied and are well known for typical diagnostic examinations.[46] Therefore, in patients who are pregnant or potentially pregnant, it is imperative that special considerations be given. Most diagnostic x-ray studies that are performed looking at structures other than the pelvis, ovaries, uterus, and lumbar spine do not lead to measurable exposure of radiation to the fetus. Those studies that have a higher risk of exposure include x-rays of the lumbar spine, intravenous pyelogram, and upper and lower gastrointestinal series; studies of the gallbladder and gallbladder function, pelvic, hip, and abdominal x-rays; and specific x-rays of the uterus and fallopian tubes, such as a hysterosalpingogram. The Health Physics Society suggests that if any question exists about the amount of radiation exposure, the radiation safety officer and the physicist associated with the department performing the study can calculate the dosage to the fetus.

It is accepted practice to protect the patient and the fetus by shielding areas most susceptible to the effects of radiation, limiting the time of exposure, and using alternative modalities to study areas closest to the developing fetus whenever possible.[47] Companies that manufacture equipment have continually improved the equipment that concentrates the radiation dose to limited areas. Software has been improved to produce better imaging to allow for less radiation to be administered. Reduction in kilo voltage and milliampere/second setting was shown recently to reduce the radiation dosage in pregnant patients undergoing computed tomographic angiography for suspected pulmonary embolism while maintaining image quality.[48]

Diagnostic and interventional procedures using fluoroscopy can expose patients to radiation. Fluoroscopy and cine angiography are both used in interventional laboratories. Almost all of the total radiation exposure is caused by fluoroscopy. These beams are administered in a pulsed fashion, which allows for decreased doses. Several practices can be undertaken to minimize the amount of radiation to the patient. Limiting fluoroscopy time, increasing the distance from the beam, the use of collimation, limiting the extent of angling the beam, and lastly, lead shielding can greatly diminish the dose to the patient and the staff in the room. It is imperative that the equipment performance and calibration be tested regularly. Adequate filtration must be present. A timer must terminate the exposure. In most cases an audible signal will alert the operator to become aware of exposure time. Exposure rates cannot exceed regulatory standards. Regulations have been made and facilities have been mandated to follow them to minimize the radiation dose to the treating physician, the staff, and the patients.

Endovascular procedures in the pregnant patient. Fortunately, pregnant women rarely require endovascular procedures; however, there are certain situations when fluoroscopy is required to save the life of the mother or the life of the fetus, or both. Several such case reports have been published. Endovascular techniques used to place balloons in the pelvic circulation for control of uterine hemorrhage have been applied more and more in an attempt to save the mother's life. Generally, emergency cesarean section occurs to save the life of the baby. Studies have shown that intraoperative blood loss is minimized by this technique, reducing risks for both the mother and the baby.[49]

Treatment of pregnant patients with deep venous thrombosis, with or without pulmonary embolism, has been studied.[50] Vena cava filters have been successfully used to treat patients with propagation of clot or pulmonary embolism while on anticoagulation, bleeding complications while anticoagulated, free floating thrombus in the ileofemoral region, patients with heparin-induced thrombocytopenia, and those pregnant patients presenting 1 to 3 weeks before delivery, without any short-term morbidity or mortality to the mother or the baby.[51]

Case reports of maternal life-threatening emergencies have been published. Cerebral arteriovenous malformations that present during pregnancy have the risk of rebleeding. Generally, conservative management is recommended, with intervention planned after delivery, if at all possible. Lesion morphology, surgical risk, and timing of intervention are looked at closely to make the best decision for the patient.[52] Pregnant patients who present with ruptured splenic artery aneurysms or renal artery aneurysms have high incidence of morbidity and mortality regardless of the treatment method. Case studies exist in which emergent endovascular coil embolizations were undertaken to save the patient's life or an endovascular stent was placed in a pregnant patient with malignant hypertension and renal artery occlusion. The total fetal dose was calculated to be 0.002 Gy.[53]

Pregnancy after endovascular treatments. Uterine embolization has been widely used in the management of gynecologic and obstetric problems. Studies have shown that pregnancy is possible after embolization for hemorrhage,[54] gestational trophoblastic tumors,[55] arteriovenous uterine anomalies,[56] and cervical ectopic pregnancy.[57] When uterine artery embolization (UAE) for symptomatic uterine leiomyomata became available, women were coun-

seled against becoming pregnant. Today, studies show that pregnancy can be achieved after UAE.[58]

Walker et al[59] recently published a study looking at pregnancy after UAE. Of 1200 women who had undergone the procedure, 108 patients were attempting to become pregnant, 56 became pregnant, and 33 had successful outcomes. These authors found a significant increase in the numbers of cesarean sections, preterm delivery, postpartum hemorrhage, miscarriage, and lower pregnancy rates. They concluded that pregnancy after UAE is possible. The general consensus in the literature is that those patients wishing to retain their ability to become pregnant should undergo operative intervention. No study exists to date studying the feasibility of pregnancy after surgical myomectomy vs UAE.

How these procedures affect fertility long term has not been studied. What can be deduced from the literature is that there are patients who have undergone UAE and have been able to become pregnant and successfully deliver.

CONCLUSIONS

Pregnancy poses special considerations in regard to radiation exposure. Therefore, decisions to expose the mother must include need for the procedure, consideration of other modalities to evaluate the condition, knowledge of maternal and fetal dosage, and fetal gestational age. The treating physician, assistants, and technologists involved in the cases must use standard radiation safety practices. Regular interaction with companies providing the service contracts for the equipment and software packages should be helpful in keeping the departments updated regarding improvements and patient safety. UAE is no longer a contraindication for future pregnancy. Patients should be counseled before any procedure regarding risks and benefits.

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