SCAI Consensus Document on Occupational Radiation Exposure to the Pregnant Cardiologist and Technical Personnel

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Concerns regarding radiation exposure and its effects during pregnancy are often quoted as an important barrier preventing many women from pursuing a career in Interventional Cardiology. Finding the true risk of radiation exposure from performing cardiac catheterisation procedures can be challenging and guidelines for pregnancy exposure have been inadequate. The Women in Innovations group of Cardiologists with endorsement of the Society for Cardiovascular Angiography and Interventions aim to provide guidance in this publication by describing the risk of radiation exposure to pregnant physicians and cardiac catheterisation personnel, to educate on appropriate radiation monitoring and to encourage mechanisms to reduce radiation exposure. Current data do not suggest a significant increased risk to the foetus of pregnant women in the cardiac catheterisation laboratory and thus do not justify precluding pregnant physicians from performing procedures in the cardiac catheterisation laboratory. However, radiation exposure amongst pregnant physicians should be properly monitored and adequate radiation safety measures are still warranted.

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Introduction

Over the past decade, percutaneous coronary intervention (PCI) has increased by 58%, with an estimated 1.3 million PCI procedures now performed annually in the United States [1]. These procedures continue to increase in anatomic and technical complexity requiring greater fluoroscopy time and subsequent radiation exposure to the patient and catheterisation laboratory personnel [2]. Occupational radiation exposure is of importance to all members of the cardiac catheterisation team as this has the potential to increase the risk of malignancies and other health hazards [3].
Women find this risk of even greater concern during child-bearing years as radiation exposure is listed as a reason for altering a career plan in cardiology to a minimally exposed field in 24% of women [4]. According to the American Association of Medical Colleges women now account for 49% of all medical students and 44% of all internal medicine residents [5]. However, only 18% of cardiology fellows are women, with only 8.7% in interventional cardiology fellowships [4]. The proportion of women who choose interventional cardiology as a career is less than half of the rate of women going into general surgery, and currently only 5.9% of board certified interventional cardiologists are women [6]. Even when women do not choose a career in interventional cardiology, radiation exposure during pregnancy may be an issue whilst completing fellowship. Additionally, female cardiac laboratory nurses and radiology technicians may have concerns regarding their risk with pregnancy. For women to make informed decisions, a clear understanding of the risk of radiation exposure during pregnancy including risk to the foetus is required. Understanding the magnitude of the risk and mechanisms to limit radiation exposure are critical.

Risks and Concerns Specific to the Foetus

Radiation exposure to the embryo or foetus could lead to two types of adverse effects: deterministic and stochastic effects. Deterministic effects result from damage to a number of cells for which there is a threshold before any clinical effects happen. The main deterministic effects in the developing embryo or foetus consist of intra-uterine growth retardation, pregnancy loss, mental retardation, small head size, reduced intelligence quotient (IQ) and congenital malformations. Stochastic (random) effects result from damage to single cells for which there is no threshold but there is an increased probability of these effects as the radiation dose increases. The main stochastic effects from radiation exposure to the embryo consist of childhood risk of cancer and hereditary diseases in the descendants [7,8]. The development of these effects depends on the age of the conceptus when the radiation exposure occurs and the amount or the dose of radiation to which it is exposed.

The biological effects of radiation are at the deoxyribonucleic acid (DNA) level which may result in three outcomes: (1) injured or damaged cells repair themselves resulting in no residual damage; (2) cells die; or (3) cells incorrectly repair themselves resulting in biological changes that could lead to the development of cancer and genetic defects amongst children of parents exposed to ionizing radiation [9,10]. Biomarkers, such as the test of chromosomal aberrations in peripheral blood lymphocytes, demonstrate that high frequency of chromosomal breakage is a strong predictor of cancer risk in healthy subjects [11,12].

Probability of Healthy Children Being Born

The primary risk for a pregnant woman’s child is cancer induction. Wagner and colleagues estimated the overall probability that a child will suffer a malformation or cancer assuming a normal incidence of childhood cancer is approximately 0.07% (Table 1) [13,14]. The predicted probability of a live birth without malformation or cancer is reduced from 95.93% to 95.928% following conceptus exposure of 0.5 mSv using a conservative estimate from the NCRP. Exposures above 10 mSv were predicted to increase the risk by 0.1%. However, it is possible that there is no added risk at all.

Actual Radiation Exposure to the Foetus

No data are currently available which adequately demonstrate the actual radiation exposure to the foetus in women working in the cardiac catheterisation laboratory. However, to analyse the risk we evaluated the data from the Mayo Clinic, Rochester, MN in all women regardless of profession and in any clinical area who wore a pregnancy radiation badge. Of the 68 women where we had matching collar and waist radiation badges, 56 (82.4%) had an undetectable radiation measurement from the badge under the lead at waist level including one interventional cardiologist and an interventional cardiology fellow (unpublished data obtained from personal communication, Glenn M. Sturchio, Ph.D.). Of the remaining 12 women who did not have undetectable radiation levels, 9 were nuclear medicine technicians or nurses, 2 were X-ray technicians, and another worked in anaesthesiology. The increased radiation exposure could be explained by the fact that nuclear medicine technicians and nurses do not routinely wear lead aprons for protection.

Dose Monitoring and Radiation Dose Assessment

Dose Limits

To understand dose limits, one must understand what is meant by dose (absorbed dose) which is expressed as Gray (Gy) or effective dose which is expressed as Sievert (Sv). Modern X-ray systems commonly report the procedure-cumulative kerma-area product (KAP, Gy cm²). KAP is the literal product of air kerma (kinetic energy released in material which is the sum of the initial kinetic energies of all charged particles liberated by uncharged ionizing radiation in a sample of matter, divided by the mass of the sample) and the X-ray field area at the location of the interventional reference point and describes the total X-ray energy incident upon a patient. With appropriate conversion factors, KAP values can be used to estimate skin dose-area product (DAF, GY cm²) and patient effective dose. The effective dose is an estimate of the uniform, whole-body equivalent dose that would produce the same level of risk for adverse effects that results from the non-uniform partial body irradiation and is a calculated dose. In general, the foetal dose of radiation is often described as a tissue dose, although this is not always uniform. The National Council on Radiation Protection and Measurements (NCRP) recommends limiting occupational radiation exposure of the foetus to a value as low as is reasonably achievable (ALARA) but not to exceed 5 mSv (500 mrem) during the entire pregnancy and 0.5 mSv per month of the pregnancy [15]. The risk of
Radiation exposure is ubiquitous and background radiation is 0.23 mSv per year [28,29]. Airline travel is another radiation source, which varies based on the length of the flight, the altitude and the latitude. Long flights in studies varied in radiation from 0.003 to 0.0097 mSv/h (0.3–0.97 mrem/h) [30]. Airline personnel flying 600–800 h/year are exposed to 2–5 mSv/year [31]. Another potential source of radiation exposure to the foetus is medical imaging. Estimations of foetal doses for common X-rays are <0.03 mGy for upper or lower extremity X-rays but increase to as high as 0.51–3.7 mGy for a hip and femur series of X-rays (Table 3) [26]. Foetal dose from helical computed tomography (CT) scans of the abdomen and pelvis has been estimated by simulation studies to be 7.3–14.3 mGy/100 mA s [32]. Radiation exposure to the foetus from CT scans also vary based on the imaging field and length of the study, but are as high as 1.52–1.68 mGy at 0 months and 2–4 mGy at 3 months for an abdominal CT on an appendix protocol [33].

Monitoring Radiation Exposure During Pregnancy
To adequately comply with the National Council for Radiation Protection and to ensure the limiting of occupational radiation exposure of the foetus to a value ≤5 mSv (500 mrem) during pregnancy, monthly monitoring of the radiation exposure under the lead at waist level is typically recommended. Using a personal monitoring dosimeter, radiation exposure down to 0.01 mSv (1 mrem) can be determined. Under lead badge measurements of radiation exposure may also be utilised prior to pregnancy for a woman in order to evaluate her own individual risk and the risks to her future children. This would allow a woman to determine if any changes in her practice would be necessary during pregnancy. However, it would be unusual for a pregnant cardiologist to receive more than the maximum 1 mSv allowed under a protective lead apron especially if the woman is also behind a table shield [34,35].

Physician Issues in Procedure Type and Radiation Dose Management
Radial Arterial Access
Routine use of the transradial access for diagnostic coronary angiograms and PCI has gained popularity because of the potential to reduce bleeding and vascular complications and improve patient comfort [36,37]. However, procedures which utilise radial access historically have not shown an increase in radiation exposure with the radial arterial access technique [45]. Some non-randomised studies have not shown an increase in radiation exposure with radial arterial access [44,45] but a subsequent randomised study demonstrated an increase in operator radiation exposure with the radial arterial access technique [45]. Radial access has been associated with an increase in air kerma, used as an indicator of skin radiation dose, compared to femoral procedures and remained a strong predictor of increased radiation in the multivariate model [46]. In a more recent randomised study, the procedure duration was longer with the radial approach and the radiation exposure was modestly increased [median DAP 38.2 GY cm² vs. 41.9 GY cm²] [41]. The increase in radiation exposure occurs not only from the increased procedure time, but also from the operator standing closer to the image intensifier during the
procedure. It is also difficult to adequately use radiation safety devices in the radial approach [39]. In addition, the learning curve for radial procedures is quite steep and may significantly add to the procedure time and increase radiation exposure [47–49]. Minimising radiation through maximising the distance of the operator to the radiation field and proper shielding techniques are always important but take on greater importance when using the radial technique [50]. Thus, because of the learning curve, pregnancy would not be an ideal time to initiate routine use of radial arterial procedures.

Peripheral Vascular Interventions
Peripheral vascular interventions may have increased operator radiation exposure compared to coronary interventions done from a femoral access site because of longer procedure times, greater challenges with shielding, and closer location of the operator to the radiation. There is considerable variability to the radiation exposure reported in the literature from all catheterisation procedures. In peripheral procedures the DAP ranges from 4.7 to 103 Gy cm² compared to a reported range of 6.2–109 Gy cm² for coronary angiography [51]. Approximately 90% of the total procedural radiation exposure for peripheral procedures comes from manual-injection digital subtraction angiography (DSA), and therefore the use of a power-injector that allows for distancing of the operator from the radiation source can be a useful technique to reduce operator radiation [52].

Other Potential Exposure in the Cardiac Catheterisation Laboratory
Some cardiac catheterisation laboratories have added a Stereotaxis magnetic navigation system to their equipment to assist in the ability to guide a wire in tortuous vessels [53,54]. The use of this system does not obviate the need for radiation, and additionally adds the exposure of a magnetic field. Exposure to magnetic fields including magnetic resonance imaging (MRI) and the Stereotaxis system are generally considered safer than radiation. Currently the FDA states that the safety of MRI to the foetus has not been established. However, the currently available human data has failed to demonstrate any adverse effects [55–57]. Occupational exposure in the catheterisation laboratory is somewhat different. Stereotaxis has a smaller magnetic field than MRI, but chronic exposure such as might be seen with a health care employee has not been adequately studied.

Ways to Reduce Radiation Exposure
The key ways of reducing radiation to pregnant personnel in the catheterisation laboratory are consistent with patient safety goals of minimising patient radiation [58]. The National Council on Radiation Protection requires that occupational radiation exposure is kept at a level as low as reasonably achievable [22]. Formal education and training in radiation protection is essential to create awareness of the hazards of radiation amongst interventional cardiologists [58–63]. In other countries, such as the United Kingdom it is mandatory that all interventional cardiologists working in the catheter laboratory receive adequate training and obtain a certificate from the Ionizing Radiation Medical Exposure Regulations (IRMER) before using radiation imaging equipment in the cardiac catheterisation laboratory. These guidelines and regulations were developed to adequately protect employees from medical radiation exposure. A similar policy is now in place in most, if not all, US hospitals. The majority of occupational radiation exposure is from radiation scatter. The optimal use of radiation safety techniques should be used in all cases regardless of the operator’s pregnancy status (Table 4) [64,65].

The key protection factors are under the control of the operator using the imaging equipment. The use of these techniques along with optimised lead shields and personal protective equipment can reduce the radiation exposure to 0.8% of unprotected levels [66]. Lead shields can attenuate at least 99% of the scatter radiation and in studies reduced overall radiation exposure by 50–75% [35]. Maintaining working views which areposteroanterior (PA) and right anterior oblique (RAO) are preferred to the left anterior oblique (LAO) views as they reduce radiation exposure to the operator standing on the right side of the table [67]. Increasing the distance of the operator from the X-ray source is important due to the inverse square relationship of dose and distance. It has been demonstrated that increasing the working distance from 80 cm to 80 cm decreases scattered radiation to around one fourth of the original dose [68]. Likewise, frame rate reduction can significantly impact radiation exposure resulting in a reduction of 40–60% of occupational exposure [69,70]. This must be balanced however, by the need to obtain adequate, high quality images. Equipment choices, such as digital flat panel systems are also associated with reduced radiation exposure to patients and operators compared with the conventional system [71,72]. Future innovations, including robotic assisted interventions may lead to dramatic reductions in operator radiation exposure [73].

Lead or lead-equivalent protective garments are required for X-ray fluoroscopy operators and are vital for radiation attenuation in the cardiac catheterisation laboratory. In a study of 30 operators, the mean projected yearly radiation dose under the protective garments was 0.9 mSv, but was 1.3 mSv for individuals with 0.5-mm lead coverage and 0.4 mSv for those with 1.0-mm lead coverage (P = 0.002) [74]. A 0.25 mm lead apron attenuates 66% of the primary radiation beam at 75 kVp and 55% of the primary beam at 100 kVp, whereas a 0.5 mm lead apron attenuates 88% of the primary beam at 75 kVp and 75% at 100 kVp and a 1 mm thick lead apron attenuates 99% of the primary beam at 75 kVp and 94% at 100 kVp [28]. However, since the vast majority of radiation exposure to the catheterisation personnel is from scattered radiation, the more relevant information is that a 0.25 mm lead apron absorbs approximately 96% of scatter radiation whilst a 0.5 mm lead apron absorbs about 98% [75]. The NCRP estimates that the conversion from a collar badge reading to the effective dose equivalent under a lead apron can be converted using a factor of 1.5/6 [76]. The wrap around style lead skirts offer 0.5 mm lead protection in the front.
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The Legal Rights of the Pregnant Healthcare Worker

In the United States, the Pregnancy Discrimination Act, an amendment to the sex discrimination section of the Civil Rights Act of 1964 was passed in 1978 and was the first law which protected women from employment discrimination based on pregnancy or fertility status [77,78]. Because of the potential risk of certain occupational exposures, employers continued practices of excluding women who could become pregnant from these occupations [79]. An example is Johnson Controls, a manufacturer of storage batteries where there was occupational exposure to lead. Since voluntary processes failed to prevent pregnant women from the work area with potential risk to an unborn child, the manufacturer made a policy in 1982 of requiring medical confirmation of the inability to bear children for any women in a job where there was lead exposure. In 1984, a lawsuit of UAW vs. Johnson Controls was brought for discrimination, which eventually made its way to the Supreme Court [77]. In 1991 the Court ruled that all foetal protection policies are in violation of title VII, and that all exposure protection policies must be applicable to all employees, regardless of pregnancy or the potential to get pregnant. Despite this ruling some hospitals have continued policies prohibiting women from working near radiation when they declare their pregnancy. This policy discourages an employee from disclosing pregnancy status, which protects the institution from any liability for the radiation exposure as the institution has no liability if the pregnancy is not disclosed [78]. However, this discourages proper monitoring of radiation exposure during pregnancy. Additionally, recent court rulings have prohibited these types of policies.

In 2005, the US Equal Opportunity Commission sued Catholic Healthcare West in California for the prevention of a registered nurse and a radiology technician from working around fluoroscopy equipment in the cardiac catheterisation laboratory when they were pregnant. The US District Court for the Central District of California ruled this policy was discriminatory and the hospital now maintains a policy of abiding by the recommendations of the National Council on Radiation Protection and Measurements which limits occupational radiation exposure of the foetus to <5 mSv (500 mrem) during pregnancy.

There is great disparity in the approach to the pregnant healthcare worker in different countries. Italy has one of the strictest positions towards radiation exposure of the pregnant healthcare worker. In Italy, the national law (DL 25/11/1996 number 645-DLgs 26/03/2001 number 151) requires women working with radiation to communicate her pregnancy to the hospital director or the chief of the practice and then the worker is absolutely forbidden to enter the exposed zone throughout the pregnancy.

In Spain, a specific consensus document on pregnancy and hospital practice was created in 2002 on behalf of Consejo de Seguridad Nuclear (the Spanish Council for nuclear safety) and the Spanish Society of Medical Physics. Based on the law where the foetus is considered a public member, the pregnant worker environment must guar-
The radiation dose to the abdominal regions for pregnant healthcare workers must be less than 2 mSv during pregnancy. Radiation exposure in pregnancy can be significantly reduced by appropriate fit and thickness of lead aprons, radiation shielding, and maximising distance from the radiation source. Thus, based on the available evidence, heritable or developmental risks to the foetus of pregnant interventional cardiology physicians and staff are extremely low provided that good radiation safety practices are used and dose limits are respected. Therefore, concerns over radiation exposure should not be a barrier to choice in pursuing a career in invasive or interventional cardiology, nor should they arbitrarily limit an existing operator’s choices on work environments during pregnancy.

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References


