Radiation Safety

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1. Introduction

The topic of radiation safety has become increasingly important in a world of medicine where reliance upon radiation modalities has increased as part of today's practice patterns. Up to 50% of the radiation dose received by the United States population is attributable to medically related imaging.[1] When one considers the circumstances during the practice of Urology where radiation exposure is possible, the most common scenarios which come to mind involve the use of diagnostic studies or during procedures, with exposure most likely during endourological treatments such as shock wave lithotripsy (SWL), ureteroscopy (URS), and percutaneous nephrolithotomy (PNL). Today's urologists must be cognizant about the amount of radiation exposure that they and their patients are exposed to and be prepared to take appropriate steps to minimize exposure when possible.

The major source of radiation exposure during procedures is from scattered radiation. The best way to reduce exposure is protective aprons, lead screens, and distancing as much as possible. Additionally, the principles of ALARA should be practiced.

2. Radiation Dosing

Appreciation for radiation safety must begin with a foundation of understanding the established radiation exposure measures. [2] The term *absorbed dose* refers to the amount of radiation energy that is deposited into a certain mass of material. It is typically measured as joules per kilogram, which is equivalent to the Gray (Gy) in the International System of Units (SI). One Gray is equal to 100 rads. The term *equivalent dose* refers to the assessment of a specific type of radiation's biologic effect, in this case specifically upon tissue. The *equivalent dose* is measured in Sieverts (Sv) and represents the absorbed dose multiplied by a radiation-weighting factor (Wr) depending upon the type of radiation utilized. One Sievert is equivalent to 100 rems. **For the vast majority of practically utilized diagnostic x-rays, Gray and Sieverts can be considered numerically equivalent since x-rays, and less often, gamma rays, are the forms of ionizing radiation liberated and the Wr is 1.**[3] Effects from radiation are classified as either stochastic or deterministic. Deterministic effects are non-cancer consequences (eg. cataracts, skin injury, hair loss) and happen after exceeding a specific radiation dose.[4] Stochastic effects include malignancies and, according to the linear nonthreshold model, risk rises in a linear fashion with increasing radiation doses and varies based on age and gender.[5] The *effective dose,* also measured in Sieverts, is specifically a measure of cancer risk to an organism as a whole, assuming non-uniform distribution of delivered ionizing radiation during diagnostic testing. Effective dose is the equivalent dose multiplied by a tissue-weighting factor, which varies according to the nature of the particular organ being radiated. Effective doses are not meant to measure deterministic (non-cancer) effects of ionizing radiation.

There are many factors that influence an individual's overall risk from radiation exposure other than simply equivalent dose measurements. These include genetic factors, age at the time of exposure, gender, and the fractionation and protraction of the radiation itself.[6] Typical radiation effective doses delivered by the most common radiographic studies

utilized in Urology are listed in **Table 1**. As expected, computed tomography (CT) scans tend to deliver the highest radiation doses. More recently, use of low dose CT protocols has shown promise to reduce the amount of delivered radiation during scanning. Another modality that can potentially deliver higher amounts of radiation than needed is fluoroscopy. This is because of a number of variables that are involved with fluoroscopic use, including total fluoroscopy time, number of frames per second, size of patient (as many c-arms automatically increase amperes delivered with larger patients), beam trajectory, proximity to the imaging source, desired image quality (as higher resolution requires higher dose), use of beam filters, and degree of operator training and experience. By using appropriate modifications of the aforementioned variables, radiation exposure can be minimized.

Table 1: Typical Radiation Effective Doses

Study	Effective Dose (mSv)
KUB	Male 0.2 – 0.4 Female 0.7
IVP/Retrograde Pylography	Male 1.33 – 1.6 Female 2.3 – 2.8
Abdominal/Pelvic multi-detector CT	7-8
Low dose protocol multi-detector CT (70 mA, 120 KVp, pitch 2, 5 mm slices)	Male 0.98 Female 1.5
CT urogram (triphasic)	14-16
adapted from Andonian and Atalla[2]	

3. Principles of ALARA or As Low as Reasonably Achievable

ALARA principles include minimizing time of fluoroscopy, maximizing distance from the source of radiation and always wearing shields. Let's review each of these principles and determine how they could be applied to our practice.

A) Time: The most effective method of reducing radiation exposure is to shorten the fluoroscopy time. This means controlling the foot pedal for snap shots at critical moments during endourological procedures and using last-image hold technology.[2,7,8] Another effective method of reducing radiation exposure during endourological procedures is to use pulsed fluoroscopy with low dose feature. Several investigators have found that by reducing pulsed rate down to 4 or even 1 frame per second in addition to using the low dose feature resulted in significant reduction in fluoroscopy time and radiation exposure to patients and surgeons.[9,10] Fluoroscopy time could be further reduced during ureteroscopy using a laser guided c-arm combined with visual and tactile cues for guidewire placement.[11] It is also important to keep track of fluoroscopy time during procedures. Ngo et al found that by when surgeons were given feedback, fluoroscopy time was reduced by 24% over a 3-year period.[12] Additionally, reduced radiation fluoroscopy protocols can reduce fluoroscopy time by 82%.[11] The third application of minimizing time is to limit the number of imaging studies that use ionizing radiation. In addition, when it is necessary to obtain imaging studies that use radiation, it is important to choose lower dose options. According to the AUA's Imaging Guidelines, when patients with BMI<30 present with renal colic, the most appropriate imaging study would be low dose non-contrast CT Abdomen and Pelvis.[13] When we follow patients with radio-opaque stones, instead of repeating the CT scan, we obtain KUB and renal ultrasound to minimize radiation.[13]

B) Distance: Radiation exposure is inversely proportional to the square of the distance. Therefore, by doubling the distance we reduce radiation exposure by a quarter. One way of applying this principle is to use lens-mounted cameras to distance ourselves from the radiation source and the patient (source of scatter radiation).[2] (**Figure 1**). This also means that if we are not directly involved in the procedure, we can step away from the source. If we stand 12 feet away from the c-arm, radiation levels are down to background level[2]

C) Shielding: We always need to use shields to protect radiation sensitive organs. This is the third line of defense when time and distance could not be optimized[2] (**Figure 1**). Shielding is made of heavy metals such as lead. It comes in the form of lead-impregnated glasses, gloves in addition to thyroid, chest and pelvic shields.[2]

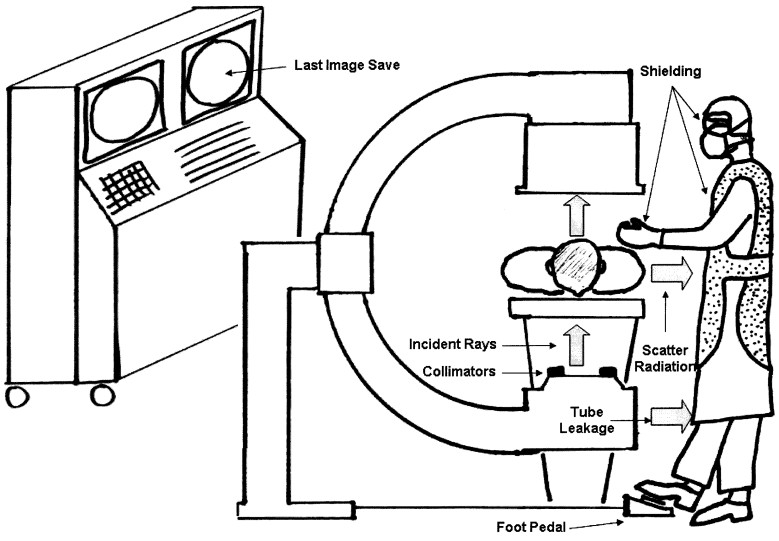

Figure 1: Demonstrates the urologist wearing appropriate shielding and controlling the foot pedal. (Adopted from Andonian and Atalla, AUA Update Series 2009).

4. Minimizing Radiation Exposure

Traditionally, annual occupational radiation dose limits have been set at 5 rem (50 mSv) to the entire body and 50 rem (500 mSv) to a single organ.[2] An increasing amount of attention has focused upon the potential detrimental effects of cumulative radiation exposure to patients and urologists. The most ominous of these risks is the potential of radiation to contribute to future malignancies. Although it is difficult to assess the true incidence of cancer directly resulting from radiation exposure, risk models combined with age and gender specific CT scan frequencies in 2007 estimated that 29,000 future cancer cases could be attributed to the use of CT scanning in 2007 in the United States alone. [14]

Patients with nephrolithiasis are particularly prone to potential overexposure to radiation due to the need for acute diagnostic information during bouts of colic, the use of fluoroscopy during surgical stone treatment and the need for radiographic follow-up given the generally high rate of stone recurrence.[15,7] Increasing use of CT scan is believed to be the largest contributor to a dramatic increase in per capita radiation exposure from medical sources in the United States over the last 20 – 30 years.[16] In the UK, John et al found that the median expected effective dose of radiation encountered by a patient for a single episode of renal colic, from presentation to ultimate resolution (stone passage or surgery), was 5.3 mSv. The median total effective dose in those patients that received a CT scan was significantly higher at 14.46 mSv versus 4.25 mSv is those who did not.[17] In the USA, where CT scans are ordered much more frequently to assess renal colic, radiation exposure has been found to be greater. Ferrandino and colleagues looked at patient radiation exposure at two tertiary care centers both during an acute stone event and the year following this event.[18] The investigators found that the median exposure during this year's time was 29.7 mSv and that 20% of the cohort of 108 patients had more than 50 mSv of exposure over the same time period. The average number of CT scans performed per patient over the 12 month span was 1.7, but was 3.5 in the patients receiving over 50 mSv of effective dose, the same as the annual occupational radiation dose limit!

Liberal utilization of CT scans for acute assessment of renal colic has justifiably come into question in the USA recently. Although providing high sensitivity and specificity for diagnosing urolithiasis, CT scans not only lead to increasing amounts of accumulated radiation exposure but also, by themselves are expensive, and can lead to incidental findings which may trigger inappropriate follow-up and/or treatments. Smith-Bindman et al have published a multicenter comparative effectiveness trial that examined outcomes of patients presenting to the emergency department (ED) for renal colic and having randomly been assigned to receive either initial point of care ultrasound (US), formal US performed in the radiology department, or CT scan of the abdomen and pelvis. Among the three groups there were no differences in return ED visits, hospitalizations, or serious adverse events. Six-month cumulative radiation exposure was lower in both US groups compared to those receiving initial CT scan. [19]

The use of US has important limitations however in both the acute setting of renal colic and in follow-up of patients with urolithiasis. While Smith-Bindman et al has demonstrated safety in the use of US as a first line diagnostic modality, one must consider the care of the patient suffering from stone disease beyond the acute setting. Many groups, in well-designed studies comparing stone presence and size, have demonstrated the tendency of US to be less sensitive in stone detection and size estimation. Sheafor et al demonstrated using a prospective study in 2000 that NCCT had 96% sensitivity for ureteral stone detection compared to 61% with US.[20] In 2010, Ray et al provided a review of the literature, which revealed US having a pooled sensitivity of only 45% for detection of ureteral calculi and renal calculi when compared to CT scan alone or CT with clinical follow-up.[21] Sternberg et al compared low dose NCCT to renal US both performed within 24 hours of each other for patients with nephrolithiasis. They noted that 37% of the patients with a stone seen on low dose NCCT did not have the stone detected on US and the average size of the missed stone by US was 4.5 mm. Furthermore, when stones were detected by both modalities, for stones $\leq$ 5mm on NCCT, there was overestimation by US of stone size by an average of 3.3 mm in 82%.[22] Ray et al reported US overestimates renal stone size by 1.9 mm compared to NCCT in stones $\leq$ 5 mm.[21] Viprakasit et al have reported similar findings when comparing stones $\leq$ 4 mm seen on both NCCT and US. In that report, 33% of these small stones seen on NCCT were estimated to be larger by US. [23] Given the well-known, inverse relationship between ureteral stone size on NCCT and the frequency of spontaneous stone passage,[24] using US data alone when counseling nephrolithiasis patients beyond the acute setting,

can be unreliable.

Given the above limitations, US is still very valuable given that it delivers no ionizing radiation. US can be an excellent method to follow non-obstructing stones over time especially if combined with prior NCCT data or KUB x-rays. In addition, even though US may frequently not detect ureteral stones directly, a recent study has shown that US used in the setting of renal colic has a 77% positive predictive value for ureteral stone detection when hydronephrosis is present. Conversely, US has a negative predictive value of 71%, such that no ureteral stone is present in those patients with renal colic when hydronephrosis is absent. This was observed when comparing NCCT to US done within 24 hours of each other in the setting of acute renal colic.[25] Thus US remains valuable in the assessment of urolithiasis, keeping in mind that it often relies on indirect evidence instead of direct evidence for ureteral stone detection and it frequently overestimates stone size. It is important to share these limitations with patients in order to maintain realistic expectations.

In the case of CT scanning, thoughtful use of low dose protocols is certainly appropriate where applicable. Low dose CT scanning is felt to be the preferred modality for diagnosis of potential ureteral calculi in patients with a body mass index ≤ 30 kg/m^2 as it maintains high sensitivity and specificity levels.[26,27,13] Zilberman, *et al* attempted to answer the question of using low dose CT for detection of stones as a follow-up modality. The investigators looked at a cohort of 62 patients that underwent a standard tube current of 160 mA and then applied a dose reduction simulation model which added a random Gaussian noise distribution to the previously obtained images to achieve image appearances consistent with 70, 100, and 130 mA current levels. [28] This study concluded that low dose CT may be reliable for the identification of stones in the outpatient setting for follow-up of stone patients, but cautions that the bony pelvis may compromise diagnostic confidence for stones localized in this region.

Fluoroscopy during URS has clearly been shown to be a source of significant radiation exposure. In a manuscript examining radiation dose during URS using a anthropomorphic male model, Lipkin and colleagues included clinical data from 30 non-obese male patients and found that the median fluoroscopy time for these patients was 46.95 seconds.[29] Using the equivalent dose rates derived from their model, the investigators were able to extrapolate that one patient in the actual clinical cohort who had bilateral ureteral and renal stones treated ureteroscopically received 7.17 mSv of radiation exposure. This certainly highlights the fact that limiting radiation use during URS is a critical goal. To prove that this is a readily achievable goal, Hsi and Harper recently published a retrospective review of a cohort of URS patients who were able to be treated with either no or very minimal use of fluoroscopy. [30] When utilizing this protocol, 75% of 156 renal units with fluoroscopic usage data did not require any fluoroscopy and 85% required 2 seconds or less of fluoroscopy time. Deters et al described a series of strictly ultrasound guided ureteroscopic laser lithotripsy procedures performed in previously stented patients with ureteral stones of about 6 mm average size. [31] In this randomized trial, 50 patients were assigned to either conventional ureteroscopy with fluoroscopy or to ureteroscopy with exclusive ultrasound guidance. Stone free rates, OR time and complication rates were statistically similar. In this population of previously stented patients, fluoroscopy can be minimized or omitted given the high likelihood of ureteral dilation and previous knowledge of appropriate stent length based on prior operative report.

Radiation exposure during PNL typically occurs during establishment of access and also during the case to help localize stones and also appropriate placement of nephrostomy tubes or stents. Bush, et al found that the average fluoroscopy time utilized for 102 procedures was 25 minutes.[32] To help minimize the use of radiation, ultrasound imaging can be used for establishment of access. However, ultrasound imaging often requires some degree of renal collecting system dilation to allow for optimal visualization of the peripheral calices. When fluoroscopic access is utilized, the fluoroscopic triangulation technique can help to minimize surgeon exposure by allowing the radiation source and image intensifier to be brought out of direct antero-posterior alignment. [33] A recently published study has shown that a lower dose radiation protocol during PNL can significantly reduce exposure.[34] This study did not look at the radiation dose from percutaneous access establishment of access as all patients had access established by the interventional radiology prior to stone treatment.

A timely American Urological Association Technology Assessment was recently published that attempts to address questions about appropriate imaging modalities specifically for the topic of ureteral stones. This resource serves as an

excellent summary of imaging protocols that should be considered with attempting to diagnose, observe, or follow patients following treatment of ureteral calculi with either SWL or URS.[35]

In summary, radiation safety has become an important topic in Urology. Urologists must play an active role to protect themselves and their patients from radiation exposure and be prepared to utilize the appropriate imaging studies in their practice to optimize patient outcomes while also maximizing safety from a radiation standpoint. Although attention to radiation safety is increasing, much work still needs to be done in order to increase awareness. Soylemez et al exposed a knowledge gap among European urology residents concerning the safe usage of ionizing radiation in endourological procedures.[36] In a survey of 124 trainees from 20 different European nations, only about 55% had attended a course on radiation safety. Only 75% reported routine use of a lead apron during procedures involving fluoroscopy while 22% never wore thyroid shields and 48% admit to never wearing a dosimeter! In an effort to improve radiation safety measures among urology residents in the endourology suite, Weld et al described SMART (Safety, Minimization, and Awareness Radiation Training) implementation.[37] With this resident training program, they demonstrated a 56% decrease in fluoroscopy time during relatively straightforward ureteroscopic laser lithotripsy procedures performed by urology residents.

See **Radiation Safety for Urologists** (Mohamed A. Elkoushy, Abdullah Alkhayal, and Sero Andonian)

5. Radiation Safety and Pregnancy

Urological problems during pregnancy such as renal colic, nephrolithiasis, urinary tract trauma or malignancies can mandate the use of diagnostic imaging. In fact, renal colic is the leading non-obstetric diagnosis for hospital admission for pregnant women.[38] The estimated incidence of symptomatic upper urinary tract calculi during pregnancy is 0.07%[39] and is not significantly different compared to the incidence of symptomatic stones in non-pregnant women of similar age.[40] Every urologist will be required to choose imaging modalities, which offer high diagnostic yield with minimal negative effects to the mother or fetus. A sound understanding by the physician of the potential fetal risks is necessary for appropriate patient counseling and management.

Diagnostic imaging usually makes use of either nonionizing or ionizing radiation. Nonionizing radiation is of relatively low frequency and theoretically disperses energy through heat without any alterations in cellular structure or chromosomes. US and Magnetic Resonance Imaging (MRI) are examples of nonionizing radiation imaging modalities. Multiple studies have failed to detect any substantial fetal risks with in utero exposure to nonionizing radiation including US and MRI.[41]

5.1 Ultrasound

Ultrasound is the first line choice for imaging in pregnant patients with renal colic when urolithiasis is suspected. US is widely available, relatively inexpensive and has a favorable safety profile with no fetal exposure to ionizing radiation. Similar to the situation in non-pregnant patients, US tends to rely on indirect evidence to make a diagnosis of urolithiasis especially in the case of ureteral stones. The sensitivity and specificity of US in detecting upper urinary tract stones in pregnant patients is 54% and 79%, respectively,[42] far inferior compared to detection rates with CT scan. Transvaginal US has improved detection rates for distal ureteral calculi.[43] Furthermore, although US is very effective for demonstrating hydronephrosis, many have described the presence of hydronephrosis as a normal physiologic variant seen in pregnancy thought to be secondary to ureteral smooth muscle relaxation due to elevated progesterone levels and mechanical compression. This “gestational” hydronephrosis is thought to exist in almost 90% of right kidneys and 67% of left kidneys.[44] Some modifications to US have been described in an effort to improve diagnostic accuracy for nephrolithiasis and to further characterize the very commonly seen hydronephrosis during pregnancy as obstructive or non-obstructive. Doppler ultrasound can evaluate for the motion of urine streaming out of the ureteral orifices. The presence of these “ureteral jets” can assure physicians that complete ureteral obstruction does not exist.[45] Multiple studies[46,47] have demonstrated the value of resistive index (RI) measurements using US to better discriminate obstructive hydronephrosis in pregnancy. The difference in RI’s between two kidneys in the same patient of 0.06 or more was highly associated with obstruction when correlated with intravenous pyelogram.[46] The utility of RI to detect ureteral obstruction however is limited in cases of partial obstruction, in those with medical renal disease and those presenting with colic for duration of less than

six hours.

5.2 Magnetic Resonance Imaging (MRI)

MRI has been advocated as a second line modality in pregnant patients with renal colic in which US has not proven diagnostic and there is persistence of symptoms. MRI has a well-recorded safety profile during pregnancy. Clements et al reported no overt impairments in infants evaluated at nine months of age when previously exposed to MRI as early as 20 weeks gestation.[48] In another series, no adverse effects were reported in children up to nine years old when MRI had been performed during the third trimester.[49]

Spencer et al[50] were among the first to demonstrate the utility of MRI in the evaluation of pregnant patients with renal colic. They studied 24 consecutive pregnant patients with colic and hydronephrosis on US over a 4-year period during which about 11,000 deliveries were performed at their institution. They instituted a relatively elaborate protocol starting with fast T2-weighted images of the abdomen and pelvis and thick section (50 mm) heavily weighted T2 MRU images. These initial images visualize water-containing structures very well, such as the intrarenal collecting system, ureter and bladder. Using this preliminary data, the level of ureteral caliber change was then closely re-examined with high-resolution T2-weighted views in the axial and coronal planes. The authors described three patterns seen on MRI correlating with urological situations found during pregnancy and correlated these with stone passage, surgical findings or postpartum imaging. In 63% of the patients studied, a smooth tapering of the ureter to the its middle third below which was normal caliber or collapsed ureter was found to represent physiological urinary tract dilation thought to be secondary to compression by the gravid uterus. Seven other patients studied were diagnosed with calculi. The patients with distal ureteral stones were described as having a “double kink sign” in which the above mentioned expected tapering at the mid ureter was found but below this a column of urine was noted which would then abruptly stop at the level of the distal stone, signifying obstruction. Furthermore, stones on MRI were described as signal voids surrounded by urine in more than one plane, thus representing filling defects, sometimes noted to have surrounding periureteral wall edema.

Generally, MRI shows some benefit given its ability to provide anatomic detail and in certain cases distinguish between hydronephrosis from calculi versus physiological hydronephrosis of pregnancy. This is possible without ionizing radiation and gadolinium is not required. The limitations with MRI however continue to be cost, limited availability, and relatively lengthy time of exam. Furthermore, given MRI’s inability to directly identify stones, there still remains some reliance on secondary signs that are nonspecific. Thus, this modality has its place as a second line procedure when US is not definitive, or the patient’s symptoms are persistent and the results may alter management given the individual situation.

5.3 Computerized Tomography (CT)

Computerized Tomography (CT) scans are considered the gold standard imaging modality for assessing acute flank pain with sensitivities of 95-100% and specificities of 92 -100% for detecting urolithiasis.[51] Effective radiation doses can vary significantly depending on the CT scanner specifications such as pitch, kilovoltage (kVp), milliampere/sec (mAs) and slice width (mm). **Estimated fetal radiation doses from CT scanning will depend on these above variables and the gestational age but are estimated at 0.00240 – 0.0260 Gy (0.240 – 2.60 rads)**[37] (**Table 2**). The effective radiation dose produced by CT scan can be adjusted by altering the pitch. Hamm et al and others have demonstrated that low dose CT scans can provide 50% less radiation dose and still provide sensitivity and specificity well over 90%. In a study performed in 2007, White et al reported on 20 pregnant patients who had low dose CT scan performed between 18 – 40 weeks gestation (average 26.5) for acute renal colic with an average of 705 mrads (0.705 rads). [52] All 20 patients had initial US demonstrating no direct evidence of stone but 19/20 demonstrated hydronephrosis. Stones were diagnosed in 13/20 (65%), some of which required management with ureteroscopic laser lithotripsy or stent placement. The remaining 7/20 showed no significant findings on low dose CT and were treated conservatively with analgesics and anti-emetics. Of these, 6/7 showed hydronephrosis on US and 4/7 had significant hematuria at some point during their course. The authors comment that unnecessary empiric surgical interventions were avoided in these seven patients with either stones that had passed or physiologic hydronephrosis of pregnancy. Although not to be considered a first line modality, low dose CT scan can be considered for pregnant patients in the second or third trimester when US is equivocal and decision

making may be affected. [35] In this situation, the urologist should consult with the radiologist to ensure CT scanner specifications are used to keep estimated fetal radiation doses well below the suggested 50 mSv (5.0 rad) limit.

Table 2: Estimated Fetal Radiation Doses From Common Diagnostic Imaging Tests*

Test	Fetal Dose (GY [Rad])
Computed Tomography Abdomen	0.00240 – 0.0260 (0.240 – 2.60)
Computed Tomography Pelvis	0.00730 – 0.0460 (0.730 – 4.60)
KUB	0.001 – 0.003 (0.1 – 0.3)
Intravenous Pyelography (IVP)	0.00358 – 0.01398 (0.358 – 1.398)

* Adapted from Williams[41]

5.4 Intravenous Urogram (IVU)

Intravenous Urograms (IVU) have historically played a role in diagnosing calculus disease in the pregnant patient when US has been equivocal. The disadvantages include exposure to ionizing radiation and intravenous contrast. Advantages of this approach include gaining perspective of the patient's anatomy and defining the site and degree of obstruction. Advocates of IVU during pregnancy suggest a limited protocol IVU consisting of a scout film, a 30 second film and a 20-minute film. [53] Fetal shielding can limit dose exposure. Estimated fetal doses for IVU range between 0.00358 – 0.01398 Gy (0.358 – 1.398 rad) [41] (**Table 2**). With the advent of low dose CT scan protocols, IVU has been utilized progressively less and is not recommended in pregnancy as per a recent AUA technology assessment on diagnosing and following ureteral stones.[35]

5.5 Potential Fetal Health Effects of Ionizing Radiation

Broadly speaking, fetal exposure to ionizing radiation may have teratogenic, carcinogenic or mutagenic effects. Teratogenic consequences may include growth retardation, malformations, impaired brain function/nervous system dysfunction. Carcinogenic effects may take form as childhood cancer or increased risk of lifetime cancer development. Mutagenic effects involve mutation in germ cells.

The fetal health effects of ionizing radiation are classified according to the observation that a threshold dose may or may not be required for a detrimental outcome. **Deterministic** effects on an organism result from ionizing radiation causing cell damage or death and are dose dependent. Typically, a threshold dose exists above which changes can be expected and the chances of this happening increase with larger doses. Below the threshold dose, detrimental changes are not thought to occur. These changes result from radiation causing loss of tissue or organ functionality, which may lead to pregnancy loss, congenital malformations, fetal growth restriction or neurological deficits including loss of IQ points. These are also known as non-cancer health effects of prenatal radiation exposure.

Stochastic effects do not require a threshold and are thought to be possible even at low radiation doses. With these effects, which tend to be cancer risks, a linear relationship exists in which the individual cancer risk increases with the radiation dose but no threshold value is believed to exist. Thus, even at low doses of radiation, estimated cancer incidence is thought to slightly increase compared to baseline for childhood cancer risk and lifetime cancer risk.

Much information regarding the health effects of individuals exposed to ionizing radiation while in utero was gathered from atomic bomb survivors, early studies involving pregnant patients requiring diagnostic imaging and animal studies. **The most important determinants of potential fetal health effects are the gestational age of the fetus at the time of the exposure and the radiation dose incurred.** Particularly sensitive times during gestation are the periods of blastogenesis (up to 2 weeks post conception), organogenesis (2-7 weeks) and early fetogenesis (8 – 15 weeks). **Ionizing radiation should be avoided whenever possible during the first trimester of pregnancy since fetal tissues are most susceptible during this time of organogenesis and nervous system development.** A recent AUA technology assessment[35] on imaging for ureteral stones recommends renal US as the initial imaging modality in pregnant women with suspected renal colic. MRI without gadolinium is recommended as a second line modality in those with equivocal US results during the first trimester. Pregnant patients in the second or third trimester with equivocal US findings maybe candidates for Low dose CT scans if clinically important for decision-making.

It is generally accepted by most researchers that a radiation dose of 0.05 Gy (5 rads) or less is not associated with any detectable teratogenic fetal effects no matter the time post conception (**Table 3**).[54] Agreement exists that a practical threshold for congenital effects on the human embryo lies between 0.10 – 0.20 Gy (10-20 rads). Thus the recommended maximal cumulative dose of 0.05 Gy (5 rads) lies well below the accepted threshold for teratogenic effect.[54]

At the earliest gestational age or blastogenesis (up to 2 weeks post conception), radiation doses between 0.05 – 0.50 Gy are thought to result in a slight increase in embryo death or failure to implant. Doses of radiation greater than 0.50 Gy in this period result in a high likelihood of embryo death. If the embryo implants successfully despite the above doses, teratogenic effects are unlikely. Thus, during blastogenesis, an "all or none" effect can be expected from exposure to

ionizing radiation.

Organogenesis (2-7 weeks) and early fetogenesis (8-15 weeks) are the periods during which the fetus is most susceptible to ionizing radiation resulting in teratogenic effects predominantly on the nervous system. Mental retardation, growth restriction and malformations such as microcephaly are seen with exposures during these times and are more likely with increased dose. Studies involving atomic bomb survivors suggest radiation induced mental retardation is most likely if fetal exposure occurs between weeks 8 -15 with threshold doses of 60 – 130 mGy (6 – 13 rads), although the lowest dose documented to clinically result in severe mental retardation is 610 mGy (61 rads).[55] Concerning growth retardation, this finding is most likely to be observed with exposures within the first 13 weeks of gestation. According to the CDC, data derived from atomic bomb survivors indicated a 3-4% reduction in stature at age 18 years when the radiation dose was greater than 1 Gy (100 rads).[54] After 16 weeks gestation, teratogenic effects are generally not observed at exposures less than 0.50 Gy (50 rads). With doses over 0.50 Gy (50 rads), however, even late gestational exposures can result in severe mental retardation, growth retardation, miscarriage and /or neonatal death.

Prenatal radiation exposure has potential carcinogenic effects for the fetus as increased risk for childhood and/or lifetime cancer development, especially for leukemia.[56] Generally, increased radiation dose correlates with increase cancer risk. The effect of radiation exposure on cancer risk based on gestational period is not exactly known but animal studies suggest a stronger susceptibility during later fetal development. The International Commission on Radiation Protection estimates that childhood cancer incidence is up to 6% for those individuals exposed to 0.5 Gy (50 rads) or more during the prenatal period[54] (**Table 4**). This is twenty times higher than the baseline estimate for childhood cancer incidence at 0.3% in those with no prenatal radiation exposure.

Table 3: Potential Health Effects (Other Than Cancer) of Prenatal Radiation Exposure					
	EMBRYONIC/FETAL DEVELOPMENTAL STAGE				
Acute radiation dose**	**Blastogenesis (up to 2 weeks post conception)**	**Organogenesis (2 to 7 weeks post conception)**	**8 to 15 weeks post conception**	**16 to 25 weeks post conception**	**26 to 38 weeks post conception**
< 0.05 Gy (5 rads)^	**Noncancer health effects NOT detectable**				
0.05–0.50 Gy (5–50 rads)	Incidence of failure to implant may increase slightly, but surviving embryos probably will not have substantial noncancer health effects	Incidence of major malformations may increase slightly; growth restriction possible	Growth restriction possible; IQ reduction possible (< 15 points)^^; incidence of mental retardation <20%^^	**Noncancer health effects unlikely**	
> 0.50 Gy~	Incidence of failure to implant is likely large^^`, but surviving embryos probably will not have substantial noncancer health effects	Incidence of miscarriage may increase^^; substantial risk of major malformations (e.g., neurologic and motor deficiencies); growth restriction likely	Incidence of miscarriage probably will increase^^, growth restriction likely; IQ reduction (>15 points)^^, incidence of severe mental retardation >20%^^, incidence of major malformations	Incidence of miscarriage may increase^^, growth restriction, IQ reduction, and severe mental retardation possible^^; incidence of major malformations may increase	Incidence of miscarriage and neonatal death may increase``

			probably will increase		

***** Adapted from Centers for Disease Control and Prevention. Radiation and pregnancy: a fact sheet for clinicians. **http://www.bt.cdc.gov/radiation/prenatalphysician.asp**. Updated October 17, 2014.

****** Acute dose is delivered in a short time (usually minutes), whereas fractionated or chronic doses are delivered over time. The heath effects to the fetus may differ for fractionated or chronic doses.

^ The gray (Gy) and the rad are units of absorbed dose and reflect the amount of energy deposited into a mass of tissue. The absorbed dose is the dose received by the fetus (whole-body fetal dose). Absorbed dose levels are assumed to be from beta, gamma or x-ray radiation. Neutron or proton radiation produces many of the health effects described at lower absorbed dose levels.

^^ Effect is dose dependent.

~ Pregnant women may experience acute radiation syndrome in this range, depending on whole-body dose.

` A fetal dose of 1 Gy (100 rad) will likely kill 50% of embryos. The dose necessary to kill 100% of human embryos before 18 weeks' gestation is about 5 Gy (500 rad).

`` For adults, the LD50/60 (i.e., the dose necessary to kill 50% of the exposed population in 60 days) is about 3 to 5 Gy (300 to 500 rad), and the LD100 (i.e., the dose necessary to kill 100% of the exposed population) is about 10 Gy (1,000 rad).

Table 4: Estimated Risk of Cancer From Prenatal Radiation Exposure*

Radiation dose (Gy [rad])	Estimated childhood cancer incidence (%)
None beyond background	0.3
0 – 0.05 (0 – 5 rads)	0.3 – 1
0.05 – 0.50 (5 – 50 rads)	1 – 6
>0.50 (>50 rads)	> 6

* Adapted from: Centers for Disease Control and Prevention. Radiation and pregnancy: a fact sheet for clinicians. **http://www.bt.cdc.gov/radiation/prenatalphysician.asp**. Updated October 17, 2014.

5.6 Contrast Administration during Pregnancy

In addition to considering the effects of ionizing or nonionizing radiation on the fetus during diagnostic imaging, the prospect of contrast administration during pregnancy deserves mention given the potential concern for drug induced teratogenic or mutagenic effects. In 2005, the members of the contrast media safety committee of the European society of urogenital radiology (ESUR) put forth recommendations for the use of intravenous iodinated contrast and gadolinium during pregnancy.[57] Attention was paid to teratogenic and mutagenic effects of these agents while administered not only during pregnancy but also in the postnatal period during which a lactating mother is undertaking breastfeeding. Multiple in vivo animal studies were cited as demonstrating no overt teratogenic or mutagenic effects to iodinating contrast either in ionic or nonionic forms. Gadolinium based agents also failed to demonstrate any chromosomal or teratogenic changes in animal models and toxicological safety assessments.

The potential for fetal hypothyroidism secondary to exposure of medicines containing iodine is the most important possible harmful effect of iodinated contrast media administration during pregnancy. No published data exists on neonatal thyroid function after maternal exposure to iodinated contrast media. However, indirect evidence suggests that if water-soluble contrast agents are administered to pregnant mothers with normal renal function, the fetus is exposed to only very small amounts of free iodine for relatively short periods. These observations are based on studies measuring thyroid hormone levels in cord blood after amniography[58] as well as iodine concentrations in amniotic fluid after intravenous urography.[59] Furthermore, the administration of high dose intravenous nonionic contrast agents to neonates aged 10 – 28 days does not appear to upset thyroid function.[60] Given the available information, recommendations put forth include the acceptable administration of iodinated contrast agents during pregnancy when absolutely needed for diagnostic imaging. **Following iodinated contrast administration during pregnancy, neonatal thyroid function should be checked within the first week of life.** This is in accordance with pediatric screening for neonatal hypothyroidism in the general population.

Close review of the literature and existing guidelines suggest that use of gadolinium-based contrast enhancement during pregnancy is controversial[55] and routine use of gadolinium in pregnant patients should be avoided.[61] The reason for this statement is that animal models exist which have reported teratogenicity of gadolinium at high and repeated doses, possibly due to the dissociation of gadolinium from its chelated form.[55] The duration of fetal exposure is not known but it is suspected to potentially be prolonged since gadolinium is present in the amniotic fluid and may repeatedly enter the fetal circulation. The decision to administer gadolinium to a pregnant patient should be made on a case-by-case basis by weighing the potential risks and benefits. In general, MRI can many times provide adequate information on soft tissue structures without contrast enhancement, unlike CT, and therefore the true need for gadolinium should be thoroughly discussed among clinicians and radiologists. With regards to intravenous contrast administration during lactation, no alteration in breast-feeding schedules was recommended.[53] It was felt that the amount of either iodinated contrast or gadolinium reaching the neonatal circulation from breast milk ingestion was so small that no significant risk to the neonate exists to justify holding breast-feeding for 24 – 48 hours.

Presentations

Radiation Safety Presentation 1

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