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Is the 28-Day Rule Safe for Use in Abdominal Radiography?

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ABSTRACT

Introduction: The 28-day rule is utilized as a precautionary measure for irradiating the fetus at an early stage of conception for abdominal and pelvic radiography. There is a probability of the women being pregnant if the 28-day rule is applied for this examination and thus irradiating the conceptus. It is difficult to convince people that low radiation doses during early pregnancy will not cause any harm to the conceptus. As such this study was to ascertain whether the 28-day rule can be used safely for abdominal radiography in women of reproductive age.

Material and Methods: The experimental study was conducted at the Radiography Laboratory, International Islamic University Malaysia, Kuantan using an anthropomorphic PBU-50 phantom. The entrance surface dose (ESD), organ dose and effective dose (ED) were estimated using CALDose_X 5.0 software, based on the exposure parameters and tube output of the x-ray unit.

Results: The mean ESD for AP abdominal radiographic examination of 3.162 mGy is within that recommended by radiation protection regulatory bodies. Additionally, the mean organ dose of 0.468 mGy is lower than the threshold value of 100 mSv for the "all-or-none" phenomenon to happen. Further, the mean ED of 0.73 mSv is within the recommendation of the International Atomic Energy Agency (IAEA) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

Conclusion: This study indicated that the 28-day rule is safe to be used for abdominal radiography for a woman of reproductive age.

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Introduction

The 28-day rule is one of the radiation protection measures taken for women of childbearing age in which the examination should not be performed if the first day of the last menstrual period exceeds 28 days [1]. The 28-day rule is used for low dose examination like plain radiography which includes abdomen and pelvis x-ray examinations [2]. Usually, a radiographer or staff-in charge in the radiology department will ask the patient about her last menstrual period. If the date exceeds the normal menstrual cycle and there is uncertainty whether the patient is pregnant, the radiological procedure is normally postponed unless there is an urgency for the examination to be carried out [3]. Thus, the 28-day rule is utilized as a precautionary measure from irradiating the fetus at an early stage of conception [1]. This because 100 mGy is the lowest threshold value for implantation to fail [4] resulting in either spontaneous abortion or the embryo is completely unaffected [5].

Abdominal radiography involves x-radiation to image the abdomen of the patient. This examination is to diagnose any pathology or for ruling out clinical abnormality of the abdomen [6] to see small or large bowel obstruction, any calcification or bowel pattern. Thus, abdominal radiography is the primary imaging procedure that is conducted when the patient in with the pain of the abdomen. When performing the abdominal x-ray, the pelvic region will be included, and shielding cannot be afforded especially in women as it will obscure the region of interest. To an extent, there is a probability of the patient being pregnant if the 28 day-rule is applied for this examination and thus irradiating the fetus. As such, imaging of the abdomen in women of childbearing age needs extra precaution so that no irradiation of the fetus could occur [7]. Many reports have mentioned that exposure of the fetus to x-radiation in early pregnancy will unlikely cause any effect from the low exposure factors utilized [5,8]. As stated by the International Atomic Energy Agency (IAEA) [9], malformations or termination of pregnancy is very rare or unlikely to occur at early pregnancy or conception because the radiation dose given is very minimal for a routine x-ray examination. The risk from radiation during x-ray examination is low and does not cause harm to the uterus and malformations towards the fetus [3]. However, many people still doubt and worry about the radiation dose they received when they undergo the x-ray examination due to insufficient knowledge of x-radiation and its risk [10].

As such, imaging a woman of child-bearing age with the use of radiation has become a great challenge

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to the physicians and medical imaging technologists. This is due to the increase in the anxiety level of the woman, her family and her doctors because of the concern regarding the radiation risk to the embryo or fetus [7]. However, the possibility of irradiating the fetus during early pregnancy because of diagnosis purposes in certain situations is necessary and unavoidable [11]. Due to this reason, it remains a concern for mothers and physicians regarding the stochastic effect and biological harm towards the fetus when conducting diagnostic examinations [7]. However, the threshold value for malformation that could occur in the fetus is 100 mGy, while the radiation dose for medical imaging is generally below this value [10]. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2010 report [12], only radiation dose more than 100 mGy can give potential biological effects to the fetus. Various studies have been done to estimate the fetal dose from radiographic examinations. The study by McCollough [7], estimated conceptus dose on AP abdominal radiography for 21 cm and 33 cm patient thickness to be at 1 mGy and 3 mGy respectively. While Nguyen and Goodman [5] in their study stated that the estimated fetal dose for AP abdominal radiography is 1.4 mGy. A study carried out by Lowe [11] reported the same estimated fetal dose as that of Nguyen and Goodman [5]. As such, the study was undertaken to ascertain whether the 28-day rule is safe to use in women of reproductive capacity for abdominal radiography.

Table 1. Imaging parameters used for AP abdominal radiography

Imaging Parameters	Details
Imaging plate size (cm)/ Orientation	35 x 43/ Lengthwise
Focal-film distance (FFD) (cm)	100
Kilo voltage peak (kVp)	60, 66, 70, 75, 81, 85
Milliampere-seconds (mAs)	43.4, 29.4, 23.8, 18.7, 14.5, 12.4
Central beam position	Iliac crest
Tube angle	Perpendicular to the image receptor
AEC	Yes (Center detector)
Filter	2.5 mm Aluminium (Al)

Figure 1. Equipment setup for the experimental study

Materials and Methods

Instrumentation and Procedure

The x-ray unit used in this study is a ceiling-mounted x-ray tube, Siemens AXIOM ARISTOS (Siemens, Germany). A torso of an anthropomorphic phantom; PBU-50 (Kyoto Kagaku, Japan) was placed in the supine position on the x-ray examination table for the AP abdominal examination. The central ray was directed perpendicularly at the level of the iliac crest with a beam collimation size of 42 x 32.5 cm to include the region of interest. The tube potentials for the projection were set at 60, 66, 70, 75, 81 and 85 kVp while the tube current exposure time (mAs) were governed by the automatic exposure control (AEC) unit. Table 1 shows the imaging parameters used for this study. The setup of the experimental study is as shown in Figure 1.

CALDose_X5 Software

CALDose_X version 5.0 was then used to calculate the entrance surface dose (ESD), organ dose and effective dose (ED) of the examination. CALDose_X is a software tool that enables the calculations of incident air kerma (INAK) and entrance surface air kerma (ESAK), based on the output of the x-ray equipment [13]. ESAK or the older term ESD is the absorbed dose to air (or the air kerma) measured on the central axis of the x-ray beam at the point where the x-ray beam enters the patient or phantom [14-15]. ESAK is the INAK multiplied by the backscatter factor (BSF), where BSF is evaluated by the software itself based on the tube potential and total filtration devices [13, 16].

CALDose_X5 uses conversion coefficients (CCs) to assess the absorbed dose to organs and tissues of the human body as well as the effective dose. The CCs, which are the ratios between organ or tissue absorbed doses and measurable quantities, have been calculated with the male (MASH) and female (FASH) adult reference phantoms in standing and supine position [13]. The software also determines the risks of cancer incidence and cancer mortality for the radiographic examination selected by the user [13, 17]. In measuring the ED, the following formula was used:

$$ED\ (mSv) = ESD\ (mGy) \times CC_{ESD}\ (mSv/mGy)$$

Where CC_{ESD} is the conversion coefficient estimated by the NRPB-262 [18-19].

Dose Measurements and Calculations

For dose measurement using the software, the tube potential, mAs, FFD, field position, type of examination and other patient's detail such as name, age and gender were manually entered in the data input page. The output curve (air kerma versus potential) was obtained with INAK, ESAK and BSF calculated by the software. By using the option of dose calculation, organ and tissue absorbed doses were acquired. The female weighted dose (FASH) was used to obtain the ED.

Results

Entrance Surface Dose, Organ Dose and Effective Dose

Table 2 summarizes the exposure factors used for the AP abdominal examination in the study. Backscatter factor (BSF), entrance surface dose (ESD), organ dose for the uterus and weighted FASH dose obtained from CALDose_X software were recorded as well. Effective dose (ED) derived from the calculation were also presented.

Mean ESD of the Study Compared To Radiation Protection Regulatory Bodies and Other Studies

The estimated mean ESD for AP abdominal examination from this study is 3.16 mGy. This value is lower compared to the recommended value of 3.64 from IAEA [9], 7.4 mGy from the Ministry of Health Malaysia (MOH) [20] and 3.64 mGy from UNSCEAR [21]. Table 3 compares the patients' characteristics, technical parameters and mean ESD of this study and other studies.

Mean Organ Dose of the Study and Other Studies

Table 4 shows the patients' characteristics, technical parameters and uterus dose for the study and other studies.

Conceptus (Early Age of Embryo/ Fetus) Effects from Low-Level Radiation Exposures

Table 5 summarizes the effects of low-level radiation exposure towards the conceptus at a very early age**.**

Mean ED of the Study, Other Studies and Recommendations of Radiation Protection Regulatory Bodies

The mean ED for AP abdominal examination from this study is 0.73 mSv. This value is lower than the recommended value of 0.80 mSv from IAEA [9] and UNSCEAR [21] but slightly higher than 0.53 mSv recommended by the International Commission on Radiological Protection (ICRP) [29]. Table 6 shows the comparison of patients' characteristics, technical parameters and ED for this study and other studies.

Table 2. The exposure factors and measured doses for abdominal radiography

Tube Potentials (kVp)	Tube Current Exposure Time (mAs)	Backscatter Factor (BSF)	Entrance Surface Dose (mGy)	Organ Dose (uterus) (mGy)	Weighted FASH Dose (wt)	Effective Dose (mSv)
60	43.4	1.36	4.340	0.495	0.256	1.11
66	29.4	1.38	3.520	0.472	0.232	0.82
70	23.8	1.39	3.180	0.467	0.226	0.72
75	18.7	1.41	2.880	0.461	0.219	0.63
81	14.5	1.44	2.610	0.457	0.214	0.56
85	12.4	1.45	2.440	0.456	0.212	0.52

Table 3. Patient's characteristics, technical parameters and the mean ESD of the study compared with other studies

Variables	This study	Other studies			
		Hart et al., 2012 [22]	Osei & Darko, 2012 [23]	Aliasgharzadeh et al., 2015 [24]	Nikzad et al., 2018 [25]
	Mean (Range)	Mean (Range)	Mean (Range)	Mean (Range)	Mean (Range)
Age	NA	57 (16-106)	60.5 (25-89)	NA	(25-70)
Weight (kg)	50	70 (36-114)	NA	(60-80)	59
kVp	72.83 (60-85)	76 (60-94)	87.6 (65-90)	73	(65-75)
mAs	23.7 (12-43)	41 (1-440)	34.4 (10-121)	24	(20-30)
Total Filtration	2.5 mm Al	3.1 (2.6-3.6) mm Al	NA	(2-3.5 mm) Al	NA
System	CR	CR/DR/SF	SF	SF	NA
Types of Patient	Phantom (PBU-50)	Ambulatory Patient	Ambulatory Patient	Ambulatory Patient	Ambulatory Patient
FFD (cm)	100	NA	NA	NA	(105-120)
Dosimetry	CALDose_X5	DAP meter/TLD	OrgDose	UNIDOSE	TLD
Mean ESD (mGy)	3.16	3.60	1.82	2.01	2.51

CR: computed radiography, DR: direct radiography, SF: screen-film, DAP: dose area product, TLD: thermoluminescent dosimeter

Table 4. Patient's characteristics, technical parameters and the mean uterus dose of this study compared with other studies

Variables	This study	Other studies			
		Helmrot et al., 2007 (1) [26]	Helmrot et al., 2007 (2) [26]	Nahangi & Chaparian, 2015 [27]	Ko & Kim, 2018 [28]
	Mean (Range)	Mean (Range)	Mean (Range)	Mean (Range)	Mean (Range)
Age	NA	NA	NA	30	NA
Weight (kg)	50	55	55	73.2	54
kVp	72.83 (60-85)	(50-150)	(50-150)	67.3 (64-70)	80 (40–150)
mAs	23.7 (12-43)	NA	NA	55.0 (50-60)	20
Total Filtration	2.5 mm Al	NA	NA	(1.5-2.5) mm Al	2.2 mm Al
System	CR	SF	SF	SF	NA
Types of Patient	Phantom (PBU-50)	Phantom (CIRS ATOM)	Phantom (CIRS ATOM)	Ambulatory Patient	Phantom (Rando)
FFD (cm)	100	NA	NA	100	100
Dosimetry	CALDose_X5	PCXMC	PCXMC	PCXMC	Glass dosimeter
Mean Uterus Dose (mGy)	0.468	0.40	0.84	0.938	0.879

PCXMC: PC program for x-ray Monte Carlo, (1): study conducted at University Hospital in Linköping, (2): study conducted at County Hospital in Jönköping

Table 5. Summary of conceptus effects from low- level radiation exposures

Effects	Most Sensitive Period after Conception (days)	Threshold Dose at Which an Effect was Observed (mSv)
*Prenatal death	0-8	No Available Data
*Growth retardation	8-56	200
*Organ malformation	14-56	250
#Spontaneous abortion/ completely unaffected embryo	0-14	100

* Mccollough et al. [7]
# Nguyen and Goodmann [5]

Table 6. Patient's characteristics, technical parameters and the mean ED of this study compared with other studies

Variables	This study	Other Study			
		Nahangi & Chaparian, 2015 [27]	Aliasgharzadeh et al., 2015 [24]	Nikzad et al., 2018 [25]	Ko & Kim, 2018 [28]
	Mean (Range)	Mean (Range)	Mean (Range)	Mean (Range)	Mean (Range)
Age	NA	30	NA	(25-70)	NA
Weight (kg)	50	73.2	(60-80)	59	54
kVp	72.83 (60-85)	67.3 (64-70)	73	(65-75)	80 (40–150)
mAs	23.7 (12-43)	55.0 (50-60)	24	20-30	20
Total Filtration	2.5 mm Al	(1.5-2.5) mm Al	(2-3.5 mm Al)	NA	2.2 mm Al
System	CR	SF	SF	NA	NA
Types of Patient	Phantom (PBU-50)	Ambulatory Patient	Ambulatory Patient	Ambulatory Patient	Phantom (Rando)
FFD (cm)	100	100	NA	(105-120)	100
Dosimetry	CALDose_X5	PCXMC	UNIDOSE	TLD	Glass dosimeter
Mean ED (mSv)	0.73	0.52	0.28	0.33	0.94

Discussion

The mean ESD obtained for AP abdominal radiographic examination for this study was lower compared to that recommended by the radiation protection regulatory bodies. The mean ESD value was also lower when compared to the study by Hart et al. [22]. However, the mean ESD of the current study was found to be higher compared to the studies by Osei and Darko [23], Aliasgharzadeh et al. [24] and also study by Nikzad et al. [25]. Basically, patient size is associated with the magnitude of ESD received. Thicker patients will result in more of the x-ray beam being absorbed or scattered, which eventually increase the ESD value [30-31]. This is reflected in the study conducted by Hart et al. [22] in which the high ESD attained could be due to the higher mean weight of the patient compared to other studies. Generally, the usage of a higher tube potential will result in a lower tube current-time being utilized which then resulted in a lower ESD. This is indisputable because the magnitude of ESD in diagnostic radiography is directly proportional to the tube current, the length of exposure and the square of tube voltage [32-33]. However, in the study conducted by Hart et al. [22], even though a high tube potential has been utilized, a higher mAs was employed, possibly due to larger patient size.

Additional filtration aids in reducing the ESD received by patients due to the absorption of low energy photons that do not help in the formation of the image [34-35]. This can be seen from the lower ESD received by patients in the studies conducted by Aliasgharzadeh et al. [24] in which the kVp and mAs used was quite similar to that of other studies such as the present study and the study by Nikzad et al. [25] but the ESD received was lower. Further, the difference in imaging systems such as CR, DR and SF with the addition of speed class could contribute to the difference in ESD received in the various studies. Generally, the speed class of CR is equivalent to a fast SF combination of 400-speed class. This is undeniable because the higher the speed class, the less dose is required to make an acceptable exposure [36]. However, it is difficult to compare its' contribution due to insufficient data from other studies. Additionally, types of dosimetry used in the study could contribute to the differences in the ESD values obtained from the various studies. As can be seen from Table 4, the direct method of dosimetry such as the use of TLD and DAP meter resulted in a lower ESD being reported as compared to indirect means such as using estimated software such as CALDose.

The findings of this study further reported that the mean uterus dose was lower than other studies but slightly higher compared to the study conducted by Helmrot et al. [26]. The lower uterus dose attained from the current study could be due to the usage of an appropriate range of kVp for an abdominal x-ray with low mAs compared to the other studies in which even though the mean kVp is higher than the current study, but a higher mAs was also used. This then resulted in higher ESD, due to higher absorbed radiation dose which then resulted in a higher uterus dose. Another possibility for the higher uterus dose is the size of patients used in the study as reflected in the study by Nahangi and Chaparian [27] whereby the mean patients' weight was 73.2 kg. As such, higher exposure factors were utilized which then resulted in a higher uterus dose.

The study of uterus dose is significant as women sometimes are unaware of early pregnancy conception. The "all-or-none" phenomenon could occur if the conceptus is irradiated with radiation dose in the excess of 100 mSv during the first eight days after the conception [4-5, 7]. This dose is considered a threshold value for the phenomenon to happen during the first two weeks after conception [4]. The "all-or-none" phenomenon is likely to result in failed implantation or a completely unaffected embryo [5]. As the mean uterus dose from this study is 0.468 mGy and the minimum threshold dose at which an effect could be observed is 100 mSv, therefore, the application of the 28-day rule in the AP abdominal radiography for a woman of child-bearing age is safe.

Effective dose has been endorsed as the radiological protection for setting and controlling dose limits received by the patient [37]. For this study, the estimated mean ED received by the patient was 0.73 mSv. Even though the value was higher when compared to the recommendation from ICRP [29], however, the value is still within the recommendation of IAEA [9] and UNSCEAR [21]. When comparing to other studies except for the study by Ko and Kim [28], the mean ED values of the current study was higher (Table 6). Multiple factors such as exposure factors, size of patients, the type of dosimetry used, total filtration and the image detection system are amongst the attributes contributing to the ED values obtained. However, it is difficult to ascertain the contribution of each factor specifically. The following limitations warrant consideration when interpreting the findings. First, this study was carried out by using an anthropomorphic phantom, which might not accurately represent that of a human being. Another study limitation is that CALDose_X5 estimation of organ and tissue absorbed dose is dependent on the phantom anatomy. As such the organ and tissue absorbed doses will be underestimated for an underweight patient and overestimated for an overweight patient [38]. Therefore, the findings of this study might differ from that obtained in the clinical setting.

Conclusion

Uterus dose study is important as sometimes women are not aware of early pregnancy conception. As such, uterus dose for abdominal radiography needs to be undertaken to eliminate the anxiety to women as to the effects of x-radiation arising from abdominal radiography to the early conceptus. The mean uterus dose of 0.468 mGy obtained from the study is lower than the recommendations of IAEA and UNSCEAR and is far below the minimum threshold dose of 100 mSv at which an effect could be observed. Therefore, this study indicated that the 28-day rule can be safely utilized for AP abdominal radiography for women of childbearing age.

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