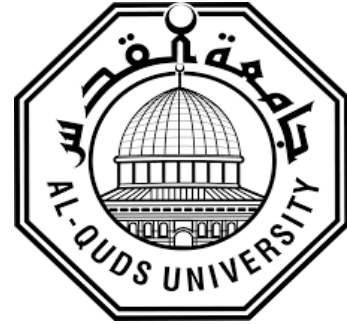


**Deanship of Graduate Studies**

**Al-Quds University**



**A Comparative Study of Six Software Tools Used for  
Estimating Fetal Radiation Dose from CT Examinations**

**By: Huda Husni Mahmoud Nasser**

**M.Sc. Thesis**

**Jerusalem- Palestine**

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A Comparative Study of Six Software Tools Used for  
Estimating Fetal Radiation Dose from CT Examinations

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1446/2024

Al-Quds University  
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## Thesis Approval

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Jerusalem-Palestine

1446/2024

## **Dedication**

This research is dedicated to  
Family, Professors and Colleagues.

## **Declaration**

I certify that this thesis submitted for the degree of master's is the result of my research, except where otherwise acknowledged, and that the thesis has not been submitted for a higher degree to any other university or institution.

Signed *Huda Nasser*

Huda Husni Mahmoud Nasser

Date: 4/Nov/2024

## **ACKNOWLEDGEMENT**

I am deeply thankful to God for guiding me with strength throughout this journey. My sincerest thanks go to Prof. Adnan Lahham for his invaluable support and guidance. I also extend my gratitude to my beloved family and friends for their unwavering support and encouragement through every step of my journey.

Huda Husni Mahmoud Nasser

## Abstract

The assessment of fetal radiation dose during computed tomography (CT) examinations is crucial for ensuring the safety of the pregnant women and their fetuses. This study aimed to perform a comparative analysis of six MC-based software tools (VirtualDose CT, FetalDose.org, CODE, Waza-ari, ImPACT, and CT-Expo) for fetal dose estimation in various CT examinations, assessing their reliability and performance. The analysis involved estimating fetal radiation doses for pregnant women in our sample set using these tools. The six software tools were used to estimate fetal radiation doses for twenty-six pregnant participants undergoing twenty-seven different CT examinations, including head, cervical spine, chest, abdomen-pelvis, lumbar spine, and ankle scans. Single measures and average measures Intraclass Correlation Coefficient (ICC) values at 95% Confidence Interval (CI) were calculated, to assess the reliability of the six software tools together, and the pairs of software tools separately as well. Bland-Altman plots were also utilized to assess the agreement between some pairs of software tools. A comparative analysis for the six software tools' performance in estimating fetal dose from CT examinations was also conducted. Total performance score was calculated for each tool based on the established criteria in this study, which are considered critical in performing dose estimates to fetus, including availability of pregnant phantoms, required inputs, availability of CT procedures, availability of CT scanner models, details of resulting fetal and maternal doses, number of available phantoms, cost, ease of use, and compatibility with mobile systems. The resulting fetal dose estimates were all within the ICRP-recommended threshold for deterministic effects, specifically below 100 milligray (mGy). Average measures ICC value for the six software tools was found to be 0.96 (95% CI: 0.91 – 0.98), indicating excellent reliability, whereas single measures ICC value for the six software tools was found to be 0.80 (95% CI: 0.63 – 0.90), indicating moderate to excellent reliability of an individual software tool with the others. VirtualDose CT and FetalDose.org showed the highest single measures ICC value across all pairs of software tools at 0.98 (95% CI: 0.96 – 0.99), indicating excellent reliability of both tools. Whereas CODE software showed the lowest single measures ICC values with all other software tools, indicating a low reliability of this software tool. Bland-Altman plot showed a mean difference of 0.79 for VirtualDose CT and FetalDose.org software tools, with limits of agreement ranged from – 2.45 to 4.03, indicating a good agreement between both tools, and confirming their reliability as well. For the comparative analysis of the software tools' performance in calculating fetal dose from CT examinations, VirtualDose CT was identified as the best performer according to the predefined criteria evaluated in this study with a total performance score of 485.25. Ultimately, VirtualDose CT, with its superior performance and high reliability, was recommended as a standout tool for fetal dose estimates from CT examinations.

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## Definitions

**Adaptive Filtration:** A technique that dynamically adjusts filtering to enhance image quality and reduce noise in CT images while maintaining sharp edges.

**Automatic Exposure Control:** Is a system that automatically adjusts the amount of radiation used during a CT scan based on the density and size of the area being imaged.

**Beam Filtration:** Placing a filter material (often aluminum or a mix of metals) prior to the patient in the path of the X-ray beam, in order to absorb low-energy photons which contribute less to image formation.

**Beam Shapers:** A physical device, named 'bowtie filter' placed in the X-ray beam that modulates the spatial distribution of the beam, thereby matching the patient's anatomy to be imaged.

**Beam Width:** Is the nominal scanning slice thickness multiplied by the number of slices scanned per rotation.

**CTDI<sub>free-in-air</sub>:** The measurement of radiation dose produced by a CT scanner in an open air environment, without any absorbing material like a phantom.

**Milliamperere-Second:** A measure of the total X-ray tube current (in milliamperes) multiplied by the exposure time (in seconds). This parameter controls the amount of X-ray energy used to create an image.

**Milligray:** A unit of absorbed radiation dose, equivalent to one-thousandth of a gray, used to quantify the energy deposited in tissue by ionizing radiation.

**Millisievert:** A unit of effective radiation dose that measures the biological effect of ionizing radiation on human tissue, with 1 millisievert equal to one-thousandth of a Sievert.

**Overranging:** Is the increase in dose length product as a result of extra rotations in a spiral scan's beginning and end which are essential to reconstruct the initial and the last slice of the scanned body region.

**Pencil Ionization Chamber:** A pencil-shaped detector with a 10 centimeters active length, composed of a small container filled with air, where the collision of the high energy photons occurs which in turn ionize some air molecules and emit electrons as a result, that are detected as electric charge with an instrument named electrometer.

**Pitch:** The ratio of table feed in one 360° gantry rotation to the beam width.

**Scan Length:** The distance between the selected first and last slices of the scan.

**Tube Current Modulation:** The adjustment of the tube current (the amount of milliamperere used by the CT scanner's X-ray tube) during the scan. It modulates the tube current based on the density of different organs within the scan region.

**Tube Potential:** Is the X-ray beam energy (tube voltage).

## Abbreviations

<b>3D</b>	Three Dimensional
<b>ACOG</b>	American College of Obstetricians and Gynecologists
<b>ACR</b>	American College of Radiology
<b>ALARA</b>	As Low as Reasonably Achievable
<b>CI</b>	Confidence Interval
<b>cm</b>	Centimeter
<b>CODE</b>	COncceptus Dose Estimation
<b>CT</b>	Computed Tomography
<b>CTDI</b>	Computed Tomography Dose Index
<b>CTDI<sub>vol</sub></b>	Volume Computed Tomography Dose Index
<b>CTDI<sub>w</sub></b>	Weighted Computed Tomography Dose Index
<b>DLP</b>	Dose Length Product
<b>E</b>	Effective Dose
<b>GATE</b>	Geant4 Application for Tomographic Emission
<b>H<sub>T</sub></b>	Equivalent Dose to Tissue
<b>ICC</b>	Intraclass Correlation Coefficient
<b>ICRP</b>	International Commission on Radiological Protection
<b>kVp</b>	Kilovolt Peak
<b>L</b>	Scan Length
<b>mA</b>	Milliampere
<b>mAs</b>	Milliampere Second
<b>MC</b>	Monte Carlo
<b>mGy</b>	Milligray
<b>MIRD</b>	Medical Internal Radiation Board
<b>mm</b>	Millimeter
<b>MS</b>	Microsoft
<b>mSv</b>	Millisievert
<b>NCAP</b>	Neck, Chest, Abdomen and Pelvis
<b>NCRP</b>	National Council on Radiation Protection
<b>P</b>	Pitch
<b>RESC</b>	Research Ethics Subcommittee
<b>s</b>	Second
<b>SSDE</b>	Size-Specific Dose Estimate
<b>TLD</b>	Thermoluminescent Dosimeters
<b>t<sub>rot</sub></b>	Rotation Time
<b>W<sub>T</sub></b>	Tissue-Weighting Factor

## **Chapter 1: Introduction**

---

Radiological imaging is crucial in providing accurate diagnosis noninvasively, but some imaging modalities may expose patients to harmful ionizing radiation e.g. radiography, fluoroscopy, and computed tomography (CT) examinations. However, for pregnant patients, it is common to start the diagnosis analysis with modalities that utilize non-ionizing radiation such as ultrasound and magnetic resonance imaging. While these modalities may not yield to clear and accurate diagnosis in some cases, CT scan would be the modality of choice. Then, the scan should be performed safely after making a balance between the necessity of diagnosis and potential risks to the fetus and maternal organs (Goldberg-Stein et al. 2012). CT examinations might also be performed to a pregnant woman erroneously without being aware of her pregnancy (Sensakovic et al. 2020). For instance, a total of 0.8% of pregnant women in the United States and 0.4% in Orinato underwent CT scans between 1996 and 2016 as reported by (Kwan et al. 2019).

CT imaging was the first of the contemporary slice-imaging modalities, which was initially used in clinical practice in 1972. CT modality utilizes ionizing X-radiation to create cross-sectional images (slices) of the body with high resolution, detail and clarity. Data is acquired from the rotation of the X-ray tube and detector around the patient. Slices are mathematically reconstructed from a large number of projections originating from discrete angles. X-ray attenuation values of different tissues allow for the differentiation between structures with different densities within one slice. The collected data is digitized and transferred to a computer for image processing and archiving purposes. CT angiography, CT fluoroscopy, three

dimensional (3D) imaging, cardiac CT imaging and others are all CT applications, in addition to its applications in nuclear medicine technology and radiation therapy fields (Seeram 2015a).

Common clinical conditions during pregnancy that necessitate CT imaging for a precise and sufficient diagnosis include at first polytrauma, which is broad in scope, varying in severity from minor to major. There is a 40% to 50% chance of fetal death following a major trauma (Krywko et al. 2019). Coronavirus which may result in pneumonia is a pathological condition, where chest CT imaging is more sensitive compared to chest X-rays (Liu et al. 2020). Furthermore, acute pulmonary embolism, as it tends to be one of the main causes of maternal mortality (Hobohm et al. 2022). In addition to abdominal pathologies which involve acute appendicitis (Poletti et al. 2019), and acute urolithiasis that occur during pregnancy (Chan et al. 2023). Aortic dissection is also implied, where the increased cardiac output may result in vascular structural abnormalities, placing pregnant women at significant risk (Patel et al. 2019).

## **1.1 Radiation-induced Bioeffects on Fetus**

The bioeffects of ionizing radiation are generally categorized into deterministic and stochastic effects. Deterministic effects are related to direct cell damage as a result of exposure to radiation dose above a threshold value. Deterministic effects become more severe with the increase in the dose and frequency of scans. Currently, according to the International Professional Societies (National Council on Radiation Protection (NCRP), International Commission on Radiological Protection (ICRP), American College of Obstetricians and Gynecologists (ACOG) and American College of Radiology (ACR)), the risk of serious malformations and spontaneous abortion is considered to be minimal for fetal exposure to radiation doses <50 milligray (mGy). However, 100 mGy is the fetal absorbed dose threshold of deterministic effects recommended by ICRP (Vodovatov et al. 2023). United States Nuclear Regulatory Commission further states that the overall amount of radiation exposure to the fetus throughout pregnancy ought to remain below 5 millisievert (mSv) (Yoon and Slesinger 2020).

Stochastic effects are radiation-induced alterations in cells which may give rise to malignant neoplasms. Stochastic effects have no absolute dose threshold, so that 20 mGy fetal absorbed dose may correspond to a cancerogenesis risk of 1 in 125 in accordance with the clinical practical guidelines of the ACR. Whereas the cancer risk to the fetus is lower with reference to ICRP and is 1 in 500 at 30 mGy fetal absorbed dose (Vodovatov et al. 2023).

There are various radiation-induced effects on the fetus, including mental retardation, growth retardation, organ malformation, prenatal death, spontaneous abortion, and increased risk in childhood cancer. Some risks tend to peak and exhibit in specific gestational stages. Table (1.1) presents the bioeffects that are associated with different gestational ages, in addition to the absorbed fetal dose threshold values for each bioeffect (Sensakovic et al. 2020).

Table 1.1: The bioeffects on fetus associated with specific gestational ages and threshold values of fetal absorbed dose (Sensakovic et al. 2020).

Bioeffect	Period of Highest Risk (Week)	Fetal Absorbed Dose (mGy)
Prenatal death	0-1	50
Growth retardation	1-8	200
Organ malformation	2-8	250
Microcephaly	2-15	100
Loss of intelligence quotient	8-15	100
Cancer induction	2-full term	-

## 1.2 Factors Influencing Radiation-Related Risks to Fetus

The extent of ionizing radiation impact on the fetus mainly depends on radiation dose, gestational stage, and the scanned region. These factors should be taken into consideration while performing CT imaging to a pregnant patient, in order to be able to appropriately minimize the radiation-related risks. This could be achieved by building a complete understanding of each factor, and how it could be modified (when possible) to serve in the process of managing the radiation risks on the fetus (Yoon and Slesinger 2020).

Imaging with ionizing radiation, and so does CT imaging, during pregnancy typically follows the same general principle as imaging for the general public, with the aim of keeping radiation exposure as low as reasonably achievable (ALARA). If a pregnant patient undergoes numerous necessary diagnostic studies, the total radiation exposure to the fetus during pregnancy should be known, and should not exceed the threshold value mentioned earlier (100 mGy). Therefore, radiation dose reduction should be a primary purpose when performing CT imaging to a pregnant patient (Picone et al. 2023). The exposure to radiation received by patients undergoing CT scans is mainly determined by equipment-related factors, application-related factors (Nagel 2007), and patient-related factors (Seeram 2023).

Several factors that are related to the CT scanner's design in terms of dose efficiency affect the amount of radiation dose delivered during the scan, these factors include the use of beam filtration and beam shapers that lowers the overall dose to the patient, and the use of a wide beam collimation which also reduces the dose (Seeram 2023), additionally, the number of detectors that also influences the radiation dose inversely, where a decrease in radiation dose is delivered to the patient with the use of scanners that comprise an increased number of detectors (Khoramian, Sistani, and Firouzjah 2019). Furthermore, automatic exposure control and tube current modulation systems (Goo 2012), adaptive filtration, noise-reduction image reconstruction algorithms including filtered back projection and iterative reconstruction all contribute to reduction in patient radiation dose (Nagpal et al. 2020; Chang et al. 2017). Whereas the use of overranging contributes to unnecessary increase in patient dose (Dimitroukas et al. 2023).

The manner in which the technologist operates on the CT scanner and makes use of the scan parameters plays a crucial role in the dose optimization process. The scan parameters that significantly influence radiation dose include the milliamperere second (mAs) product which is

made of tube current (mA) and rotation time ( $t_{rot}$ ), the radiation dose is significantly correlated with the mAs, since doubling the mAs also doubles the CT dose. This also means that increasing mA,  $t_{rot}$  or the total scan time results in an increase in the radiation dose. Tube potential or tube voltage (kilovolt peak (kVp)) which has an exponential relationship with the radiation dose i.e. the dose is directly proportional to the square of kVp. Furthermore, wider beam width (total collimation), increase in pitch (P), and short scan length (L) all contribute to reduction in patient radiation dose (Raman et al. 2013).

Patient characteristics and other factors that are related to the patient are also involved in influencing the absorbed CT radiation dose. Such as, patient size (weight) which is a reliable indicator of radiation dose, where an increase in body weight is correlated with higher levels of radiation dose (Nagpal et al. 2020), tissue composition, where body parts with more dense material such as bone and some pathological tissue types are associated with higher radiation dose levels (AlShurbaji et al. 2024), in addition to the accurate positioning, that is considered an essential task, which contributes to dose and noise reduction, since incorrect centering results in a patient dose increase because of the poor performance of the bowtie filter (Seeram 2023).

The radiation effect on the fetus is also influenced by the gestational age. As previously explained, each effect is associated with a specific period during pregnancy, according to the growth stages that the fetus goes through, as shown in (Table 1.1). Consequently, radiation exposure during the first two weeks after fertilization causes an “all or nothing” event that could result in either spontaneous abortion or normal growth of the fetus with no effects. In the first trimester, the fetus is most vulnerable to radiation, especially between week 2 and 7 of gestation where organogenesis occurs. Following that, the fetus becomes more radiation-resistant throughout the second and third trimesters (Kumar and De Jesus 2024).

The uterus is generally located within the female pelvis, situated particularly on the superior and anterior aspects of the pelvis during pregnancy. The fetal radiation dose can be easily classified based on the location of the fetus relative to the scan range (whether the fetus is inside or outside the scan range). In turn, the maximum fetal dose is delivered from pelvic CT scans where the fetus is directly irradiated, which is caused by both the primary radiation beam and scatter. While scanning body parts outside the pelvic region where the fetus is indirectly irradiated contributes minimal scattered radiation exposure to the fetus (Eastwood and Mohan 2019).

### **1.3 CT Dosimetry Concepts**

The instrumentation and methods utilized to make measurements for the patient dose from CT scan is referred to as CT dosimetry. The nature of CT dosimetry is somewhat complex and challenging due to the continuous technological advances in CT scanners. Types of dosimeters utilized to measure CT dose, CT dosimetry phantoms, and CT descriptors (quantities and units) are the main compositions of the CT dosimetry field (Seeram 2015b).

Several types of dosimeters are utilized to measure the ionizing radiation exposure in CT imaging. In the past, film dosimeters, specially designed ionization chambers, and

thermoluminescent dosimeters (TLDs) were used to achieve CT dose measurements (Sarhan et al. 2023). Pencil ionization chambers, optically stimulated luminescence, and solid-state real-time dosimeters were developed later (Bauhs et al. 2008). The pencil ionization chamber has been the standard for reporting dose index in CT imaging (Anam et al. 2019).

The standard CT dosimetry phantoms are two cylindrical Plexiglas phantoms recommended by the American Association of Physicists in Medicine, used to standardize the dose measurements in CT imaging. Both phantoms are 14 centimeters (cm) long, but have different diameters that represent the geometry of head and body regions. The first phantom diameter is 16 cm which represents the adult head geometry known as head phantom. The other phantom is 32 cm in diameter, which is used to represent the adult patient in body examinations, named as body phantom. Five holes are drilled through each phantom to accommodate the 10-cm pencil ionization chamber, as shown in (Figure 1.1). The dose measurement procedure is performed by placing the pencil ionization chamber within one of the phantom's holes, taking a scan, and recording the amount of charge detected by the dosimeter. Then, repeating the same procedure for each of the remaining holes individually (Akpochafor et al. 2019).

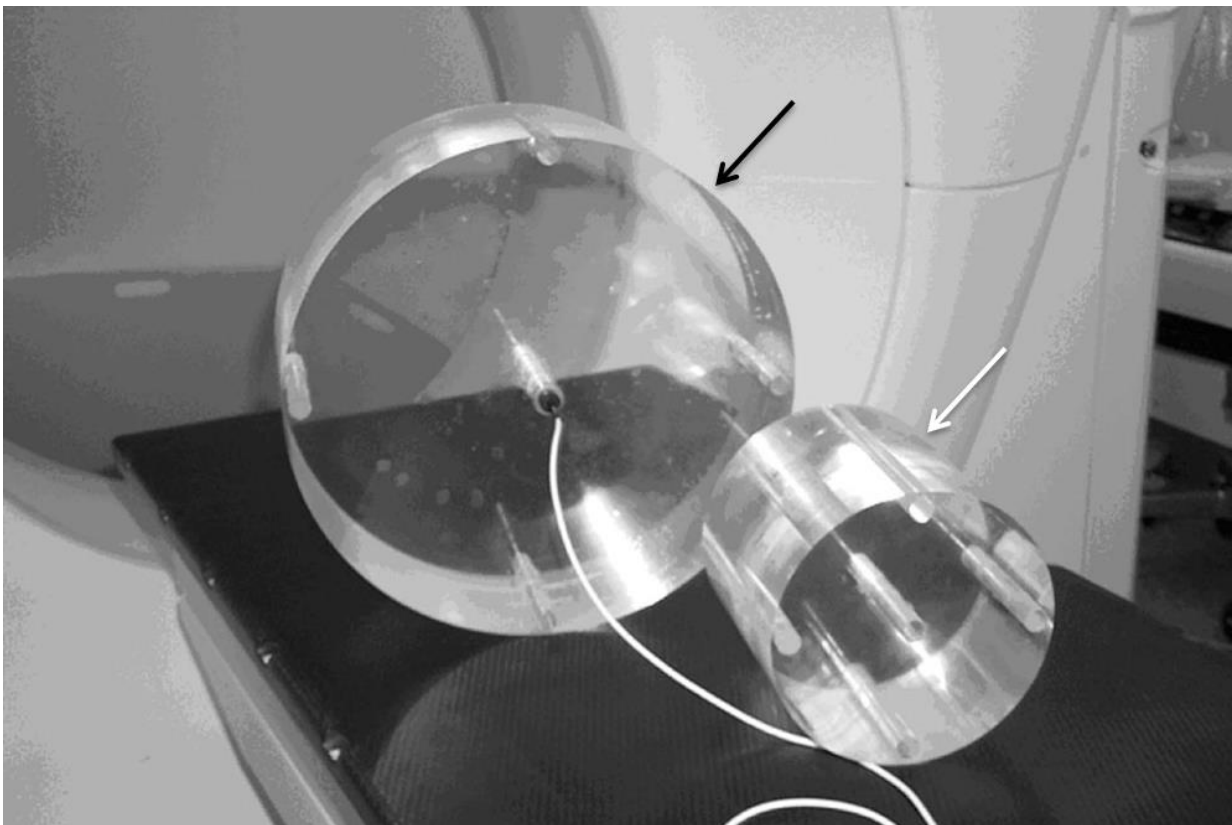


Figure 1.1: A head phantom (white arrow) and a body phantom (black arrow) for dose measurement from CT scans. A pencil ionization chamber is placed in the center of the body phantom (Mitic et al. 2003).

Basically, there are three main dose descriptors commonly utilized in CT imaging to represent the radiation dose, including the CT dose index (CTDI), the dose length product (DLP) that are limited to the CT scanner output, and the effective dose (E) that is crucial in CT scanning and in each imaging modality uses ionizing radiation as well (Roslee et al. 2020). Below is an explanation of the dose descriptors:

- CTDI is the primary CT dose quantity, which is equivalent to the radiation dose value for a specific slice. It is obtained from the dose distribution recorded for a single source rotation along a line parallel to the scanner's rotational axis (Z axis). Several common CT dose indices are worthy of mention, CTDI<sub>100</sub> (a linear dose distribution measurement over a 10 cm long pencil ionization chamber), weighted CTDI (CTDI<sub>w</sub>), which represents the weighted average dose over a single slice that accounts for the CTDI values at the center and the periphery of the phantom, and volume CTDI (CTDI<sub>vol</sub>) is the pitch-corrected CTDI<sub>w</sub> which provides a measurement of dose per slice of tissue. CTDI<sub>vol</sub> is the most common index used currently. It is calculated by dividing the CTDI<sub>w</sub> by the P in helical scans (Khan, Srivastava, and Khan Ullah 2023).

A modification of the CTDI<sub>vol</sub> value known as the size-specific dose estimate (SSDE) enhances the absorbed dose estimation, where correction factors are applied to the CTDI<sub>vol</sub> to take different patients' sizes into consideration (Martin, Abuhaimed, and Lee 2021).

- DLP represents the total dose delivered along the scanned distance. It considers the intensity which is represented by the CTDI<sub>vol</sub>, as well as the extension which is represented by scan length. In sequential scanning, L is the same as the distance between the start of the first slice and the end of the last. While for spiral scanning, L includes the overranging in addition to the net length of the distance scanned. DLP is usually calculated by multiplying CTDI<sub>vol</sub> by L, and measured in mGy.cm (Aliasgharzadeh, Mihandoost, and Mohseni 2018).
- E, the quantity that is used to relate the exposure to risk. It accounts for the different radiosensitivities of various tissues i.e. tissue-weighting factor ( $W_T$ ) and the average equivalent dose to tissue ( $H_T$ ) as well. The tissue-weighting factors are available in reports provided by the ICRP and the NCRP (Martin, Harrison, and Rehani 2020).

CTDI and DLP are CT dose-specific quantities that cannot be compared with radiation exposure from other modalities; both are expressed in mGy. E is an estimate based on different  $W_T$ , thereby it is considered the best method available for stochastic radiation risk estimate, and is expressed in mSv. E can be used to provide a meaningful comparison between CT scan dose and the radiation doses from different sources and modalities, by converting organ doses to an equivalent uniform dose to the body (Trattner et al. 2018).

## 1.4 Fetal Dose Estimation

Fetal radiation dose estimation from CT scan procedures is currently performed by various approaches that are basically based on direct phantom measurements, Monte Carlo (MC) i.e. statistical computer simulations, or a combination of both (Hardy et al. 2019).

### 1.4.1 Direct Phantom Measurement

Physical phantoms can be constructed from uncomplicated materials such as water, or new tissue substitutes that allow the creation of realistic anthropomorphic phantoms. The primary goal of physical phantoms is to imitate the scattering and attenuation properties of the human organs, by simulating the human geometries i.e. shape and size closely and resembling tissue compositions as well. Multiple dosimeters can be accommodated within the phantom to provide a thorough dose map throughout its structure. Anthropomorphic phantoms can be constructed in-house for particular research purposes, or they can be commercially available in several series (Stratakis and Papadakis 2019). The anthropomorphic phantoms are usually designed to mimic the average nonpregnant patient due to the high cost involved in their manufacturing (Hardy et al. 2019), unless some modifications are made to the standard phantom to represent gestational ages, such as using fabricated gelatin boluses to increase the circumference of the maternal abdomen, as shown in (Figure 1.2) (Saeed 2021).

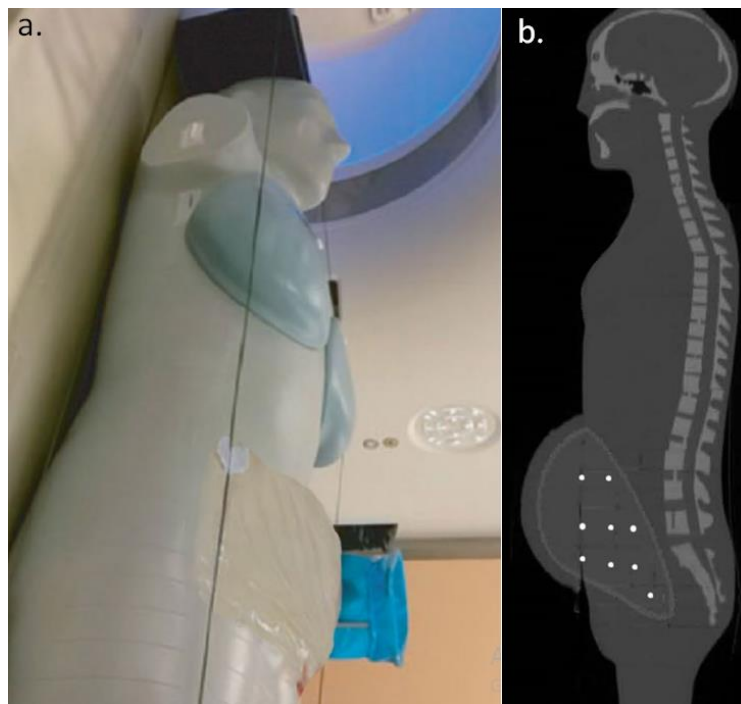


Figure 1.2: (a) Anthropomorphic phantom represents a pregnant woman at sixth month of pregnancy. (b) CT image of the anthropomorphic phantom in sagittal view. White dots represent the dosimeters distributed in the uterus position (Saeed 2021).

## 1.4.2 Monte Carlo Simulation

MC methods are computational algorithms that rely on random numerical simulation to model complex physical processes. This is mainly applied by modeling the radiation source and computational phantoms that represent patients, followed by tracking the transmission of photons and their interactions in matter, as well as computing the deposition of energy in tissues i.e. calculation of radiation doses (Bert and Sarrut 2022).

Virtual computational phantoms are modeled to closely simulate human anatomy. They are available in different three format types and four morphometric categories as well. Stylized, voxelized, and hybrid are the format types, whereas the morphometric categories encompass reference (a limited set of phantoms defined by age), patient-dependent (a more extensive set of phantoms with various weights and heights), patient-sculpted (phantom modified to represent an individual's body shape with corresponding changes to internal anatomy), and patient-specific (an exact model of patient's body shape and internal anatomy). Variations in the phantom's characteristics have a significant impact on the calculated doses (Stepusin et al. 2017).

Stylized or mathematical equation-based phantoms use simple 3D volumes to create body organs. They are presented in a few body sizes and age groups. This simple anatomical structure may decrease the accuracy of dose calculations. This format type was used with first generation software tools made to calculate radiation dose (Lawson et al. 2022). Figure (1.3) show stylized phantoms with external vision and internal organs representation.

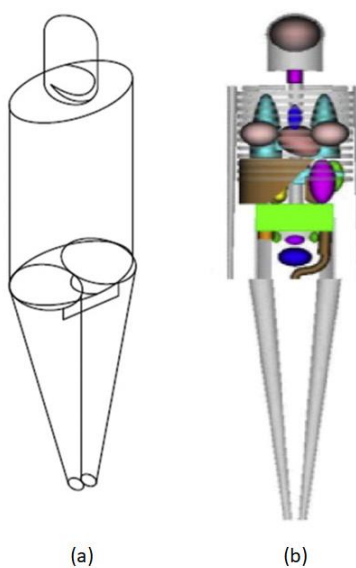


Figure 1.3: Stylized phantoms: (a) External vision of an adult. (b) Internal organs and skeleton (Taleb, Khadour, and Bitar 2015).

Voxelized or tomographic phantoms represent anatomical structures through the segmentation of CT images. Thus, a set of CT images for the entire body are utilized to segment body organs by assigning identification number for each pixel, where chemical compositions and densities are determined for different tissues. A 3D volume that is registered from the segmented slices is generated with visualized anatomical structures. Fig (1.4) illustrates the creation steps of a voxelized phantom using visible human image dataset (Peng et al. 2022).

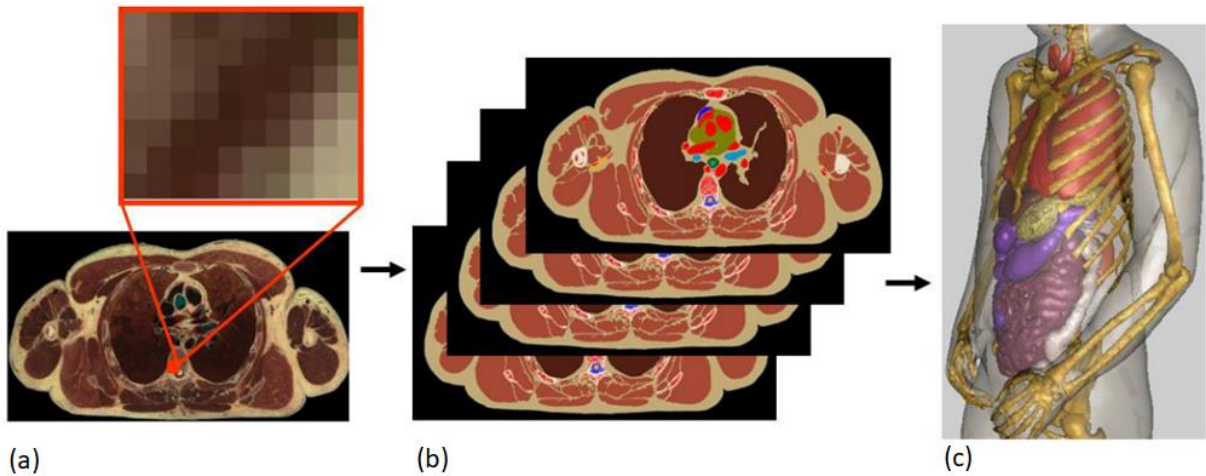


Figure 1.4: Steps to create a voxelized phantom utilizing visible human image dataset as an example. (a) Identification of organs in each slice. (b) Registration of slices. (c) Finalized 3D voxelized phantom (Peng et al. 2022).

Hybrid phantoms integrate the stylized phantoms with the voxelized phantoms, resulting in highly detailed phantom models that precisely represent the surface of the body and the internal organ boundaries. They provide anatomically realistic views and smooth surfaces within the phantom models, as well as patient-specific models for accurate dose calculations. Fig (1.5) shows pregnant hybrid phantoms at 20, 31, and 35 weeks of gestation (Makkia et al. 2022).

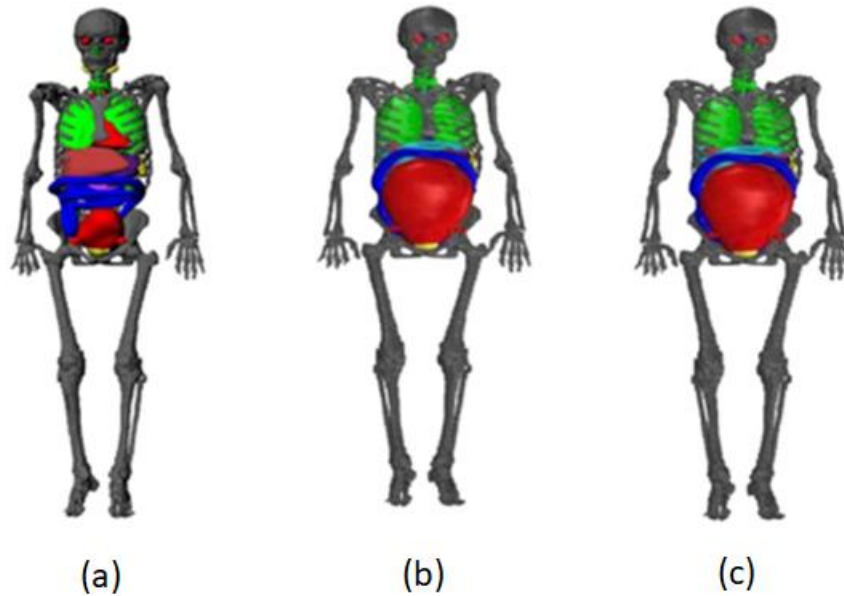


Figure 1.5: Hybrid phantoms of pregnant females at (a) 20, (b) 31, and (c) 35 weeks of gestation (Makkia et al. 2022).

In MC-based fetal dose calculation, precise modeling of radiation source involves simulating the photons generated by the X-Ray tube of the CT scanner. Then, stochastic solutions to the Linear Boltzmann Transport Equation that governs the transport and interactions of photons with matter are provided by tracking a plenty of photons. The behavior of photons in a small volume is described by the Linear Boltzmann Transport Equation, where photon's position, direction of photon transmission, photon energy, fluence of photons, and cross-sections of materials are considered by this equation. For a given set of computational phantoms, CT device, photons, and physics data, MC methods sample interactions between photons and media randomly based on cross-section data, considering the type of interactions, scattering angle, secondary particle generation, and energy loss. Types of interactions include scattering (Compton effect), absorption (photoelectric effect) and transmission of photons (H. Lee 2024).

The average of dose deposited by all simulated photons within a volume is calculated in MC simulation. The absorbed dose is derived from the energy loss along a photon track segment. MC algorithms are used to find dosimetric quantities crucial to determine the absorbed dose in a medium. Dosimetric key quantities are adopted according to the factors influencing the radiation dose (Andreo 2018). The accumulated dose distribution is calculated across the phantoms, providing detailed organ doses. Effective dose might also be calculated by applying its specific equation recommended by the ICRP i.e.  $E = \sum W_T \cdot \sum H_T$  (Xie et al. 2018).

Monte Carlo simulations in medical imaging research are available as codes or as ready-made software packages. User-friendly general purpose codes, general-purpose MC codes for expert, and GPU-based accelerated MC codes are all available for imaging modality modeling. Geant4 application for tomographic emission (GATE) code is mainly used to simulate medical imaging systems including CT, which is a user-friendly general purpose code (H. Lee 2024).

### 1.4.2.1 Monte Carlo Software Tools

Several software tools supporting MC-based fetal dose calculations from CT imaging are available for end-users. Some computational dosimetry software tools use phantom models with a standard size, and do not account for gestational variations. In this instance, the radiation dose is not estimated directly for the fetus, but rather, for the uterus alternatively. One example is ImPACT which stands for Imaging Performance Assessment of CT scanners, is a Microsoft (MS) Excel spreadsheet performed by the National Radiological Protection Board in the United Kingdom, based on a stylized phantom (Stratakis and Papadakis 2019). Additionally, CT-Expo is also an MS Excel application performed at the German National Research Center that uses stylized phantoms (Angel et al. 2008). Another tool which is a web-based CT dose calculator known as Waza-ari which is based on voxelized phantoms (Ban et al. 2011). Since all those software tools and many others use standard-size patient phantoms, the uterus dose is utilized as an alternative to fetal dose estimate, particularly at an early gestational age (Stratakis and Papadakis 2019). However, uterine doses may be misleading during gestational ages (Badawy et al. 2024).

Other software tools were developed to report maternal organ doses and fetal dose as well, as they account for the natural variations throughout gestational ages. As an example, VirtualDose CT, is web-based software developed by Virtual Phantom Inc. Company, where voxelized phantoms are used (Ding et al. 2015). Another web-based tool is CONceptus Dose Estimation (CODE), which was developed in the Department of Medical Physics, University of Crete, Greece (Stratakis and Papadakis 2019). FetalDose.org that is based on hybrid phantoms, is another web-based tool developed in the Institute of Diagnostic and Interventional Radiology, University of Zurich, Germany (Saltybaeva et al. 2020). More other software packages that can directly calculate the dose to the fetus are available such as NCICT (C. Lee et al. 2015).

## 1.5 Problem Statement

In cases where pregnant women undergo CT examinations, knowing the radiation dose value received by the fetus is critical, and has a significant role in clinical decision-making. However, as dose estimation methods have recently moved towards MC-based approaches, it is crucial to investigate the reliability and performance of multiple software tools that are available and used for fetal dose estimation from CT examinations. Thus, maintaining the safety of pregnant women and their fetuses, along with making correct clinical decisions.

## 1.6 Study Justification

1. **Patient safety concerns:** pregnant patients represent a vulnerable population, therefore minimizing fetal radiation dose is paramount to prevent bioeffects as much as possible.

Uncertainty in dose calculations raises concerns about over- or underestimation of radiation risk, potentially compromising patient safety.

2. **Current knowledge gap:** there is a considerable lack of comparative studies that assessing the performance and reliability of more than three software tools for fetal dose estimation.
3. **Need for reliable and effective tool:** there is a need for a reliable tool that also performs well to evaluate fetal radiation doses from CT in Palestinian healthcare institutions.
4. **Potential for future research:** this study will lay the groundwork for future research initiatives aimed at enhancing dose calculation algorithms and exploring technologies to further improve the accuracy in fetal dose calculations.

## **1.7 Main Goal and Specific Objectives**

### **Main Goal:**

The main goal of this study is to perform a comparative analysis of six MC-based software tools (VirtualDose CT, FetalDose.org, CODE, Waza-ari, ImPACT, and CT-Expo), that are used for fetal dose estimation from various CT examinations, assessing their reliability and performance as well. This involves estimating fetal radiation doses for pregnant women in our sample set using the six software tools.

### **Specific Objectives:**

1. To assess the reliability and performance of the previously mentioned six MC software tools in fetal dose estimation from CT examinations.
2. To recommend a reliable software tool with a high performance to be adopted by Palestinian healthcare institutions.
3. To clinically apply the six software tools to estimate fetal doses for pregnant participants in our sample set.
4. To compare the resulting fetal dose estimations in this study with previous literature.

## **1.8 Research Questions**

1. How reliable are the six MC software tools employed in this study?
2. Which software tools demonstrate a high reliability in dose estimations across the six MC software tools?

3. Which software tool provides the best performance in fetal dose estimations?
4. Do the estimated fetal radiation doses for pregnant women in our sample set exceed the threshold value of developing radiation deterministic effects (i.e. 100 mGy, as recommended by the ICRP)?

## **1.9 Hypothesis**

1. The six MC software tools will demonstrate adequate reliability across dose estimations.
2. The software tools that estimate the fetal dose will demonstrate high reliability among themselves, as will the software tools that calculate the uterine dose. However, the reliability between fetal dose software tools and uterine dose tools will be lower.
3. The resulting fetal dose estimations for pregnant women in our sample set will be below the threshold value of developing radiation deterministic effects.

## Chapter 2: Literature Review

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The literature related to the use of MC-based software tools in estimating fetal radiation dose field is both wide and critical for medical safety purposes. Previous studies have diligently worked on previous methodologies and scopes using those software tools, and demonstrated various findings, some of which showed agreements, while others disagreed with each other. MC-based software tools were utilized differently in previous studies, and this section aims to delve into the methodologies, key findings, and gaps highlighted in the existing literature.

### 2.1 Comparative Studies of Software Tools

Two studies explored the use of various dosimetric estimation methods, including VirtualDose CT, CODE, CT-Expo, and others, providing valuable perspectives into the fetal dose estimation during CT imaging, along with highlighting the reliability and accuracy of various software tools.

Carlstein (2020) has conducted a comparative study using CT-Expo, CODE and VirtualDose CT to estimate fetal dose for twenty-six female pregnant patients who underwent abdomen and pelvis CT scans. Phantom measurements were also performed, which enhances the reliability of findings. Her results showed that there was a minimal difference between the software tools, with the highest estimated doses recorded by C-Expo for most pregnant patients and all phantom measurements as well. Whereas VirtualDose CT estimations were the lowest for all phantoms and patients (Carlstein 2020).

Dimitroukas et al. (2023) utilized CODE and VirtualDose CT to calculate fetal dose and organs' doses for six pregnant patients who underwent CT pulmonary angiography. The resulting calculations showed a decrease in dose values that reported by VirtualDose CT compared with CODE in all cases. The mean total fetal dose for CODE and VirtualDose CT (including overranging) were 0.20 mGy and 0.16 mGy, respectively (DIMITROUKAS et al. 2023).

Both studies evaluated multiple software tools for fetal dose estimation from CT imaging and concluded that all those tools can provide reliable results (fetal doses). Additionally, both confirmed that the resulting fetal doses from the evaluated CT scans were below deterministic thresholds. Another point to consider, Carlstein (2020) found minimal differences between software tools but noted that CT-Expo reported the highest dose estimations, whereas VirtualDose CT provided the lowest dose values. Dimitroukas et al. (2023) also found that VirtualDose CT reported lower fetal dose values than CODE, which agreed with Carlstein's findings.

However, the use of a single type of imaging protocol in both studies limits the ability to generalize the findings to a broader range of CT protocols and body regions. Furthermore, the very small sample size (six patients) in Dimitroukas's study represents a significant limitation, particularly in terms of enhancing statistical significance and validating their findings. Additionally, the use of only two and three software tools, despite the availability of other options, restricts the comparison of a wider variety of MC-based software tools.

## **2.2 Assessment of Software Tools Validity**

The validation of fetal dose estimations was assessed using phantom measurements in two studies, exploring the accuracy level of some MC software tools (VirtualDose CT and ImPACT) in estimating fetal doses from CT examinations.

Saeed (2021) used VirtualDose CT software tool to perform fetal and uterine dose estimations using six female phantoms and three pregnant phantoms representing multiple gestational stages, which are available in the software tool. Phantom measurements were also conducted as a validation step. The estimated doses agreed to within  $\pm 10.8\%$  of the measured values (Saeed 2021).

Similarly, Matsunaga et al. (2017) examined the accuracy of dose estimates to the fetus and maternal organs using ImPACT software tool, comparing calculated doses with measurements obtained by TLDs in phantoms. This study focused on pregnant women in their late gestation, and found that calculated and measured doses differed by less than 23% when the fetus was located within the scanned region (Matsunaga et al. 2017).

Both studies underscore the necessity of validation of MC-based software tools for fetal dose estimation through the inclusion of a real-world validation (phantom measurements), which also enhances the methodological accuracy and reliability of their measures. However, the exclusive use of a single software tool in both studies is considered one limitation. Given the availability of multiple software tools, a comparative analysis of those tools under similar conditions is essential to evaluate their relative accuracy and reliability. Moreover, Matsunaga et al. (2017) only addressed late-stage pregnancy which limits its applicability to earlier gestational stages.

### **2.3 Analysis of Uterine Dose as a Proxy for Fetal Dose**

Some studies utilized MC software tools and focused on estimating uterine and fetal doses during CT examinations using different methodologies, allowing for more precise fetal dose estimations in clinical settings where direct measurements of fetal radiation exposure might not be practical or possible.

Two studies used NCICT software tool, demonstrating similar methodologies. Vodovatov et al. (2021) applied parameters of a standard chest protocol on phantoms with different gestational ages available in the software tool. Fetal and uterine doses were measured by the software and it was found that there were no significant differences between uterine doses and fetal doses, since the uterus is located outside the primary beam (Vodovatov et al. 2021).

Badawy et al. (2024) extended the application of NCICT software tool by evaluating fetal and uterine doses using standard CT protocols from Facility Reference Level audits. They assessed various examinations and observed that fetal and uterine doses were almost the same for protocols that do not expose the fetus directly. Whereas for protocols that expose the fetus directly, the uterine dose calculations resulted in underestimations of fetal doses (Badawy et al. 2024).

Similar findings regarding fetal and uterine doses were observed in Saeed's (2021) study, where VirtualDose CT software tool was utilized to assess doses during various CT examinations. The findings in this study showed that there were no significant differences between fetal and uterine doses when the uterus is located outside the primary beam. In protocols involving direct exposure to the fetus, more difference between fetal and uterine doses was observed. Fetal doses were higher than uterine dose values, with underestimations up to eight times depending on gestational age (Saeed 2021).

All three studies found no significant differences between uterine and fetal doses when the uterus is outside the primary radiation beam. Whereas in protocols where the fetus is directly exposed to radiation, these studies demonstrated that uterine dose calculations underestimate fetal doses.

An unresolved issue across all three studies is the lack of comparative analysis between multiple MC software tools for assessing uterine dose and fetal dose, rather than the use of a single software tool. Additionally, none of the studies fully account for patient-specific anatomical and gestational variations or differences in scanning parameters, which could also influence dose estimation.

### **2.4 Evaluation of Fetal Dose from CT Procedures Using MC Software Tools**

Some studies collectively demonstrate the utility of multiple MC software tools in evaluating fetal radiation dose from CT examinations during pregnancy, using different dose estimation tools and methodologies.

Dabli et al. (2022) utilized CT-Expo software tool to estimate uterine doses (as an alternative to fetal doses) for 256 pregnant women who underwent CT examinations for various body parts. Their results showed that uterine doses for head, neck, and chest CT scans were all below 1 mGy. Conversely, for CT scans directly exposing the uterus, the mean uterine doses ranged from 9.79 mGy to 18.5 mGy, with the highest dose value (31.2 mGy) reported for a pelvic scan (Dabli et al. 2022).

Mokubangele et al. (2022) utilized FetalDose.org to evaluate the absorbed fetal doses for 194 CT pelvimetry examinations performed to pregnant patients. All calculations were very low comparable to deterministic thresholds, with a mean value of fetal dose 1.5 mGy (Mokubangele et al. 2022).

Whereas Demir and Işikci (2023) utilized FetDose V4 to calculate embryo doses from chest and chest-abdomen CT scans for 22 pregnant patients. The calculated mean fetal doses for CT covering chest and chest-abdomen were 1.54 mGy and 5.31 mGy, respectively. The resulting fetal dose calculations were much lower than the threshold value of deterministic effects (Demir and Işikci 2023).

All three studies confirm that fetal dose estimates are generally low in CT scans where the fetus is not directly exposed. Whereas when direct exposure occurs, fetal dose estimates increase but remain below the deterministic threshold, ensuring fetal safety. However, the studies differ in their areas of focus; Dabli et al. (2022) concentrated on fetal doses in a wide range of CT examinations, involving a large sample size, which adds considerable strength to the study's findings. On the other hand, while Mokubangele et al. (2022) exclusively studies only CT pelvimetry, Demir and Işikci (2023) focused on fetal doses from chest and chest-abdomen CT scans. The studies of Dabli et al. (2022) and Demir and Işikci (2023) were limited to one and two types of CT procedures, which restricts the generalizability to other CT examinations. Furthermore, the relatively small sample size (22 patients) used by Demir and Işikci (2023) limits the study's ability to draw robust, confident conclusions about the fetal dose for chest and chest-abdomen CT scans.

## **2.5 Application of Software Tools for Dose-Scan Parameter Correlation**

MC software tools were used in some literature to investigate the correlations between fetal radiation dose from CT examinations and some scanning parameters, emphasizing the importance of optimizing scanning parameters to minimize fetal dose in CT imaging.

Ye et al. (2023) utilized VirtualDose CT software tool, where standard scan parameters were applied to three pregnant phantoms (with three gestational stages) available in the software tool. Collimation width and kVp were used as variables, enabling systematic analysis of dose variability. Their results showed a negative correlation with collimation width and a positive correlation with kVp (Ye et al. 2023). Whereas Demir and Işikci (2023) investigated the correlation between scan length and dose during their assessment of fetal doses in chest CT examinations. Their results demonstrated that fetal dose increases with increasing the scan length (Demir and Işikci 2023).

Ye et al. (2023) conducted a controlled computational phantom-based study, manipulating collimation width and kVp, whereas Demir and Işikci (2023) focused on clinical cases involving real pregnant patients, providing practical insights into dose variability based on scan length (chest vs. chest and abdomen CT scans).

However, neither study examined enough scan parameters and assessed their impact on fetal dose, which might help in effective dose reduction without compromising image quality. Additionally, offering standardized protocols (for balancing dose reduction with diagnostic efficacy) in future research can further optimize CT imaging practice during pregnancy.

## **Chapter 3: Materials and Methods**

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### **3.1 Study Design**

This research is a comparative simulation-based study, conducted on six different MC-based software tools for estimating fetal radiation doses from CT, among pregnant women who underwent different CT examinations in radiology departments across some governmental hospitals in Palestine (only CT scans with the available data required to conduct this study).

Six software tools were fully accessible and ready to be used for applying fetal CT dose estimations. Two of them were downloaded as MS Excel spreadsheets, registration was done for four online software tools, and the last one was available online with no need for registration.

### **3.2 Study Sample**

A sample of twenty-six pregnant participants who underwent various CT examinations was selected from the Palestinian governmental hospitals. The sample size was based on the availability of the pregnant participants and the entire data required for conducting the dose estimates.

### 3.3 Inclusion and Exclusion Criteria

#### Inclusion criteria:

- Pregnant patients who were referred to hospitals existed for CT scans of any body part.

#### Exclusion criteria:

- Pregnant patients who underwent CT examinations, but did not have available recorded radiation doses.
- Pregnant patients who underwent CT examinations, but did not have available scan data i.e. scan parameters.

### 3.4 Data Collection

Data were retrospectively collected from Departments of Radiology in four governmental hospitals (Palestinian Medical Complex/ Ramallah, Darwish Nazzal Hospital/ Qalqilya, Jericho Governmental Hospital/ Jericho, Beit Jala Governmental Hospital (Al-Hussein)/ Bethlehem).

Participant demographics (participant's age and gestational age of pregnancy), scan protocol and scan parameters (kVp, mAs, beam collimation (width), pitch, scan length, mA, rotation time and table feed), dose report ( $CTDI_{vol}$ ), in addition to manufacturer CT and scanner model used to perform the scan were all collected for each participant. The collected scan parameters and participants' demographics were inserted into each of the six software tools separately to estimate the absorbed fetal and uterine doses. Then the estimated dose values from each software tool were recorded for each participant.

### 3.5 Study Tools

The six MC-based software tools that were used to estimate fetal and uterine radiation doses were:

- VirtualDose CT, a paid web-based software tool developed by Virtual Phantoms Inc, New York, supported with a comprehensive organ dose database derived from MC simulations, including a library of twenty-five anatomically realistic patient phantoms that represent patients of various body sizes, ages, and pregnancy stages. It enables users to assess organ doses and total effective dose as well. Total dose to fetus is estimated by this software, in addition to the fetal brain, soft tissue and skeleton dose values. Gestational age (3, 6 and 9 months), scan protocol, CT manufacturer and scanner model, bowtie filter, beam collimation (in millimeters (mm)), kVp, mAs, P, and  $CTDI_w$  (mGy/100 mAs) are the required input data for this software.  $CTDI_w$  was calculated as:  $CTDI_w = CTDI_{vol} \times Pitch$ . Figure (3.1) shows the user interface of VirtualDose CT and a phantom for a pregnant woman in the ninth month of pregnancy.

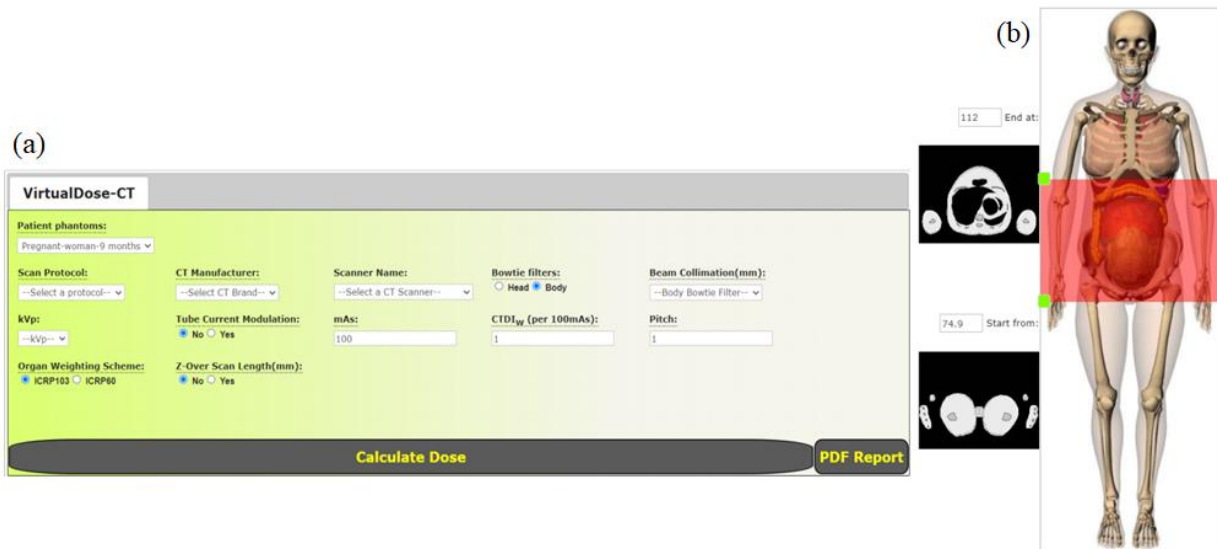


Figure 3.1: (a) The user interface of VirtualDose CT software. (b) A phantom for a pregnant woman in the ninth month of pregnancy.

- COnceptus Dose Estimation (CODE) developed by the University of Crete, Greece. It is a free web-based tool that estimates radiation doses to a fetus during medical imaging procedures (radiography, fluoroscopy, and CT) for pregnant patients and workers exposed to fluoroscopy. The required input data are gestational age (weeks), mAs, kVp, P, beam collimation (mm),  $CTDI_w$  (mGy/100mAs),  $CTDI_{free-in-air}$  (mGy/100mAs), and scan range.  $CTDI_{free-in-air}$  is included in the technical specifications for each CT scanner model. Patient circumference is optional and can be left blank if not available. The phantoms used in this tool represent only the trunk and do not encompass all body parts. Four phantoms are available with four gestational ages defined as 0-7 weeks, 8-12 weeks, 13-25 weeks, and 26-40 weeks. Embryo dose (mGy) and risk for radiation-induced childhood cancer (%) are the provided calculations. Registration was required for the use of this software tool. Figure (3.2) presents the user interface of CODE software. This tool uses Monte Carlo N-Particle transport code (“CODE User Manual,” n.d.) that provides highly sensitive dose calculations, considering all potential interactions between radiation and tissues, which may lead to higher dose levels compared to other tools (Lazarine 2006).

## Computed Tomography (CT)

The interface includes a dropdown menu for gestational age (13-25 week) and a 'Clear' button. Below are input fields for Tube Load (mAs), Tube Voltage (kV) with a 'Click to select' dropdown, Pitch, Beam Collimation (mm), Patient Circumference (cm), CTDI<sub>free-in-air</sub> (mGy/100 mAs), and CTDI<sub>w</sub> (mGy / 100 mAs). A central window shows a CT scan of a phantom with two vertical red lines indicating the scan range. Below the scan is a slider for 'Start of scan' and 'End of scan' in cm. At the bottom are 'Calculate' and 'Save' buttons.

Figure 3.2: CODE software tool's user interface, shows the required input data and the phantom used as well.

- FetalDose.org developed by University Hospital Zurich, Switzerland. A free web-based tool that estimates the radiation dose received by the fetus from CT scans. This software employs an MC simulation based algorithm performed on real data of pregnant patients at different gestational ages (0-3 months, 3-6 months, and 6-9 months) and computational phantoms (Saltybaeva et al. 2020). Gestational age, kVp, CTDI<sub>vol</sub> (mGy), maternal perimeter (optional), and scan range are the required input data to estimate the radiation dose to the fetus (mGy). The interface of this tool is presented in (Figure 3.3).

The interface features input fields for Gestational age, month (0-3), Tube voltage, kVp (100kVp), CTDI<sub>vol</sub>, mGy, and Maternal perimeter, mm (optional). A central window displays a 3D anatomical phantom of a pregnant woman. To the right are input fields for Upper position, mm (1350) and Lower position, mm (690), along with a Patient ID (optional) field. A blue 'Calculate' button is at the bottom left.

Figure 3.3: The user interface of FetalDose.org software tool, showing the required inputs and the phantom.

- Waza-ari II developed through a collaborative effort between the National Institute of Radiological Sciences, Japan Atomic Energy Agency, and Oita University of Nursing and Health Sciences, Japan. A free online platform that is based on voxelized phantoms of Japanese male and female models with various sizes and ages to estimate organ doses (mGy) and total effective doses referred to ICRP 60 and 103 (mSv). Manufacturer and scanner model, bowtie filter, kVp,  $t_{rot}$  (in seconds (s)), P, beam width (mm), phantom (size and age), scan type and protocol, scan range, and mA are the required input parameters. CT scanner models that are not available in this software can be registered by inserting the source data,  $CTDI_{free-in-air}$ , CTDI phantom size (16 cm or 32 cm), and  $CTDI_w$  specific for the scanner model in the “register your user model” screen. The dose to fetus is not available by this tool, therefore the uterine dose is estimated instead. Registration is required for the use of this software tool. Figure (3.4) presents the user interface of Waza-ari, the required input parameters, and a female phantom with a standard size.

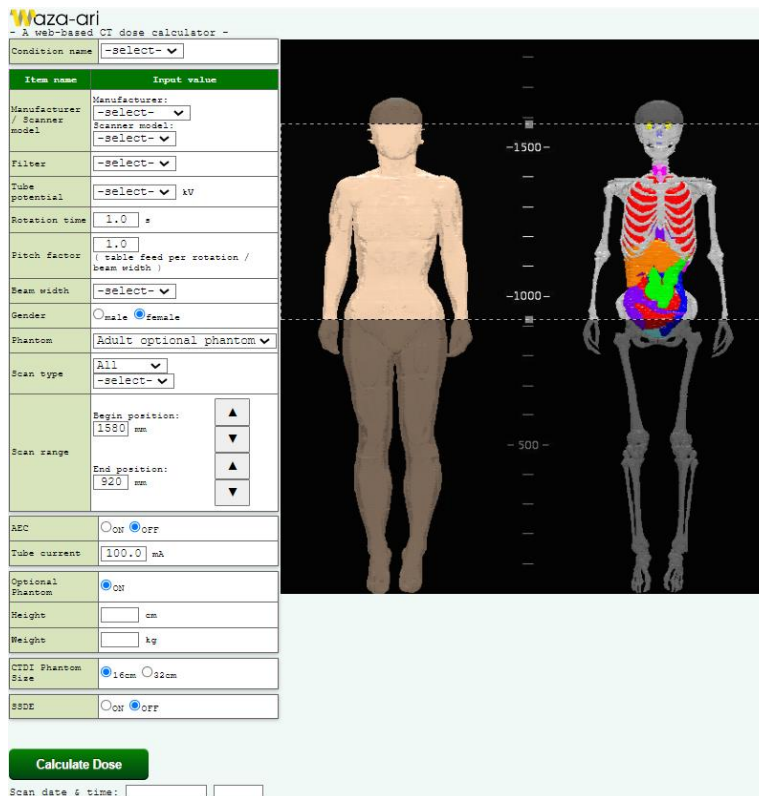


Figure 3.4: The user interface of Waza-ari software tool, showing the required inputs and a phantom represents an adult female with a standard size.

- CT-Expo version 2.5 developed by the German National Research Center, Germany. An MS Excel application that is based on mathematical phantoms derived from MIRD-type ‘Adam’, ‘Eva’, ‘child’ and ‘baby’ with standard sizes. The mode (spiral/axial), age group, gender, L (cm), scanner type, kVp, mA,  $t_{rot}$  (s), collimation (mm), table feed (mm), P, reconstructed slice thickness, and number of scan series are the required input parameters to calculate equivalent tissue organ doses (mSv) and total effective dose referred to ICRP 103 (mSv). The equivalent doses for the uterus were converted into organ doses using this equation:

*Equivalent dose (Sv) =  $\sum$  Radiation weighting factor  $\times$  Organ dose (Gy).* Where the tissue weighting factor of X-Ray is 1 (Commission 2007). Table feed (mm) was calculated by multiplying the beam width (mm) by P. It is worth mentioning that this software tool provides a free version that has a limitation, where the option of selecting scanner model is not available. However, the paid version offers multiple scanner models that could be selected. Figure (3.5) presents the spreadsheet of this tool, the required inputs, and ADAM and EVA phantoms with standard sizes.

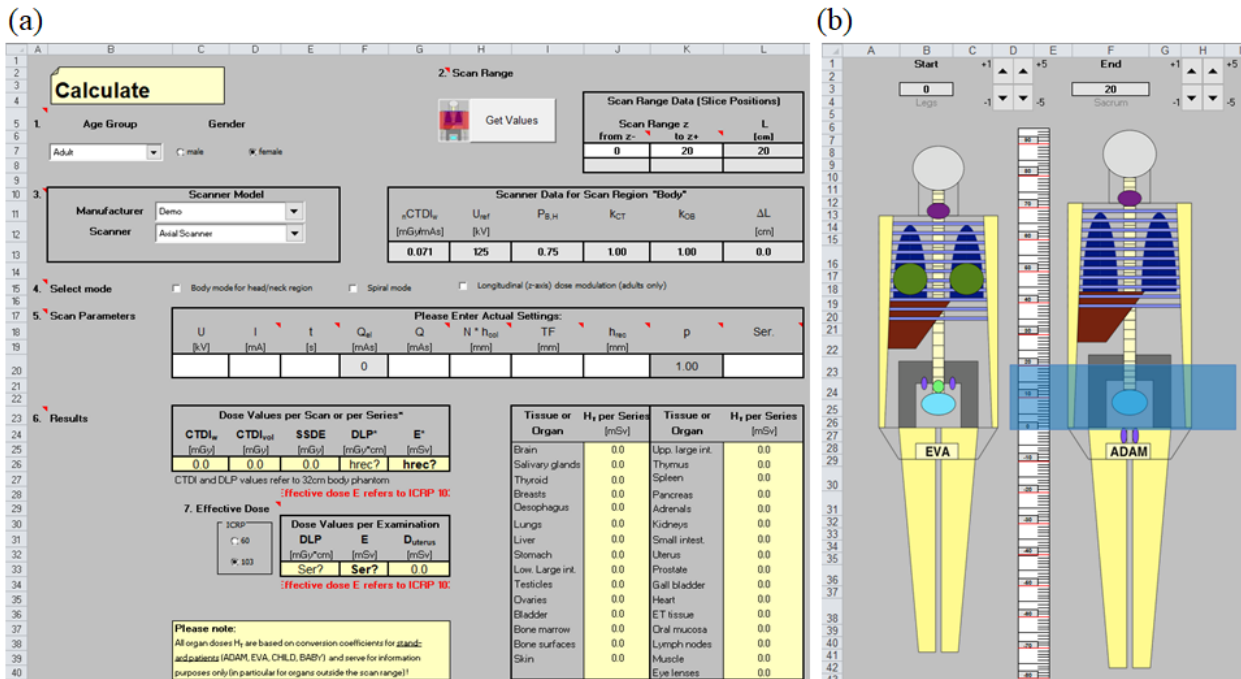


Figure 3.5: The spreadsheet of CT-Expo, showing (a) the required input parameters, and (b) EVA and ADAM phantoms with standard sizes.

- ImPACT CT Patient Dosimetry Calculator (version 1.0.4) developed by the National Radiological Protection Board in the United Kingdom. It is an MS Excel spreadsheet that is based on a geometric Medical Internal Radiation Board (MIRD) phantom to estimate the organ doses and the effective dose for individual exams. Monte Carlo dose data sets should be downloaded along with this tool, so that normalized organ dose data

for irradiation of phantoms by a range of CT scanner models is provided. One phantom is only available, which represents head and trunk body regions, where the lower limbs are not encompassed. The required input parameters are CT manufacturer and scanner model, kVp, scan region, scan range, mA,  $t_{rot}$  (s), P, and collimation (mm). CTDI values are recommended by the software according to the input parameters. The dose to uterus is estimated by this tool since the fetal dose is not offered. Figure (3.6) presents the spreadsheet of ImPACT, the required parameters, and the phantom used.

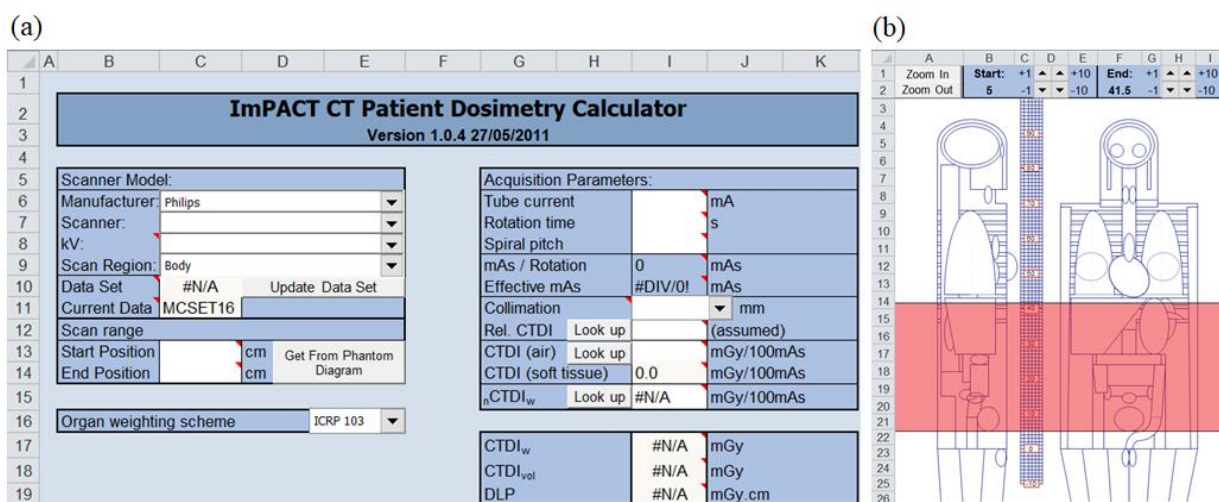


Figure 3.6: The spreadsheet of ImPACT CT Patient Dosimetry Calculator, showing (a) the required parameters, and (b) the phantom used in this tool.

Radiation fetal doses (mGy) were estimated directly using VirtualDose CT, CODE, and FetalDose.org. Whereas Waza-ari, ImPACT, and CT-Expo do not estimate the radiation dose to the fetus as their phantoms do not account for the gestational variations, hence the uterine radiation doses were estimated and used as alternatives to fetal doses.

### 3.6 Data Analysis

SPSS Statistics version 27 was utilized to calculate descriptive statistics, including measures such as mean and range, to summarize the distribution of fetal radiation dose estimations across the six software tools, offering an overview of the resulting fetal dose values from different CT examinations, allowing for comparison with findings from previous studies and with deterministic thresholds recommended by the ICRP.

The reliability of the software tools in estimating fetal dose from CT examinations was assessed by conducting Intraclass Correlation Coefficient (ICC) analysis using SPSS Statistics version 27. ICC is a statistical measure calculated by mean squares obtained through analysis of variance which reflects both, degree of agreement and correlation between measurements i.e.

the resulting fetal dose estimations from software tools. Selecting the appropriate form of ICC for this study was done based on the guideline established in Koo and Li study (Koo and Li 2016). The type of reliability that was assessed in this study is the inter-rater reliability which reflects the variation between two or more raters (software tools) that measures the same subject group (participants). Along with employing Two-Way Mixed-Effects model since the selected raters were specifically selected (only tools of interest), and absolute agreement definition as well, that concerns the degree to which different raters assign the same measurements to the same subject. Two ICC values at 95% confidence interval (CI) were obtained; single measures and average measures. Single measures ICC reflects the reliability of each individual rater's measurements related to the other raters, whereas average measures ICC which reflects the reliability of multiple raters based on averaging the measurements from all raters.

First, ICC was conducted to assess the reliability of the six software tools together, providing the reliability of individual software tool's dose estimations related to the others (single measures ICC), and the overall reliability when averaging the results from all software tools (average measures ICC). Then, single measures ICC values were conducted for each pair of tools separately, to determine which pair offers the most reliable estimations across the six software tools.

Bland-Altman plots were generated using QI Marcos, a statistical add-in for MS Excel (2010 in this study). Bland-Altman plot is a graph that compares two techniques performing the same type of measures by assessing the agreement between the measurements. These graphs were used in this study to evaluate the agreement between fetal dose estimations from pairs of software tools with different ICC values. This method involves plotting the difference between measurements from two tools against the mean of both tools. This analysis includes the calculation of the mean difference and the limits of agreement ( $\pm 1.96$  times the standard deviation of the differences), in addition to identification of any outliers (Mansournia et al. 2021).

### **3.7 Performance Comparative Analysis**

A comparative analysis was conducted to evaluate and compare the performance of the six MC-based software tools across a range of criteria to determine which software tool provides the best performance for estimating fetal radiation doses from different CT examinations. Specific performance metrics (criteria) were used for evaluation, with weight assigned to each one based on its relative performance in this analysis. Table (3.1) presents the selected criteria and their assigned weights.

Table 3.1: The selected criteria for the comparative analysis of the software tools' performance in estimating fetal dose from CT examinations, along with the weight assigned to each criterion.

<b>Criterion</b>	<b>Weight</b>
Availability of phantom models for pregnant women	10
Number of required input scan parameters	9
Availability of CT procedures	8
Number of CT scanner models available	7
Details of resulting fetal radiation doses	6
Details of resulting maternal doses	5
Number of phantoms available	4
Cost	3
User interface usability	2
Compatibility with mobile systems	1

The weights assigned to each criterion were based on its importance in providing more accurate dose estimations from CT scans specifically for the fetus, fetal and maternal safety, and eventually accessibility and flexibility. Regarding the accuracy of estimating fetal dose, the availability of pregnant phantoms with an accurate representation of the anatomy is a top priority since they take into account a different dose distribution when the fetus is modeled within the phantom across different gestational ages. A weight of 10 assigned for this criterion as it directly impacts the accuracy of the resulting fetal dose (Badawy et al. 2024; Saeed 2021). Number of required parameters followed with a weight of 9, as CT scan parameters have a significant impact on the resulting radiation dose (Raman et al. 2013). Availability of specific CT procedures within the software contributes to more accurately dose estimations. It is additionally related to availability of all body parts within the phantom; however it had a lower weight as accuracy may be achieved by lower number of procedures as long as the required input parameters have more influence on the radiation dose. Moreover, availability of CT scanner models within the software also contributes to more accurate CT dose estimations since each scanner type has its specific CTDI values, where a weight of 7 assigned to this criterion (Seeram 2023). Since the tools may function more effectively with fewer scanner models as long as all required procedures are available.

Regarding the fetal safety, details of the resulting fetal doses may enhance the understanding of the fetal dose values and how they affect fetal safety (McLean et al. 2024); therefore a weight of 6 was assigned. Whereas the maternal safety is more apprehensible by providing more details of maternal organ doses (weight of 5), as well as the number of phantoms used in the software (weight of 4) which participates in determining more accurate maternal organ doses (rather than fetal doses) by selecting the phantom that mostly represents the maternal size.

The criteria used to determine the accessibility and flexibility are the cost, the user interface usability, and the compatibility with mobile systems. The cost is critical in healthcare settings as budget constraints may influence tool adoption, where a weight of 3 was assigned. The uncomplicated interface can reduce the probability of user error, though it is important, it had a weight of 2 which is lower than the cost, because high costs may obstruct the adoption of even the most user-friendly software. The least weight was assigned to the compatibility with mobile

systems which enhances accessibility and flexibility of a tool, it is less essential than cost and user interface usability in clinical practice.

A consistent framework was applied to evaluate how well each software tool met the pre-defined criteria. The tools' performance in each criterion was scored on a numeric scale of 1 to 10, where 1 represented poor performance and 10 represented excellent performance. Weighted scores were calculated for each software tool by multiplying the score for each criterion by its assigned weight ( $\text{Weighted Score}_{\text{tool}} = \text{Score}_{\text{criterion}} \times \text{Weight}_{\text{criterion}}$ ). Then, the total weighted score for each software tool was obtained by summing the weighted scores across all criteria ( $\text{Total Weighted Score}_{\text{tool}} = \sum (\text{Weighted Score}_{\text{criterion}})$ ). The total weighted scores (total performance scores) were directly compared.

### **3.8 Ethical Consideration**

A letter of approval was granted from the Research Ethics Subcommittee (RESC) of Faculty of Health Professions at Al-Quds University (Appendix A). Ethical approval from the Palestinian Ministry of Health was also obtained (Appendix B). To protect patient confidentiality, all medical records were anonymized.

## Chapter 4: Results and Discussion

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A total of twenty-six pregnant women aged 20 to 38 years were included in this study. Eleven of them were in the first trimester, eight were in the second trimester, and seven were in the third trimester of pregnancy. They underwent various CT examinations, with Participant 26 having two separate examinations—one for the head and the other for the neck, chest, abdomen, and pelvis (NCAP). Therefore, two dose estimations were reported for this participant, resulting in a total of twenty-seven dose estimations. The fetus was located within the scanned region in seventeen examinations but not in the other ten. Three CT scanner models were used in the hospitals from which data were collected: Philips Brilliance 64 CT, Philips Brilliance 16 CT, and Hitachi Supria 16 CT.

The scan parameters were variable for each participant and each protocol. Eleven abdomen-pelvis CT scans, six chest CT scans, four lumbar spine CT scans, two head CT scans, one cervical spine CT scan, one ankle CT scan, one chest-abdomen-pelvis CT scan, and one CT scan for NCAP were the twenty-seven CT examinations included in this study. Chest CT scan was repeated twice for Participant 12 with the same scan parameters. 120 kVp was used for all examinations except for the lumbar spine scan of Participant 15, where it was 140 kVp. The mAs ranged from 56 and 350 across all examinations. Furthermore, the scan length varied among participants with the maximum L being 75 cm for Participant 26 (NCAP scan), and the shortest L being 11 cm for Participant 8 (head scan). L was also relatively long for Participant 24 who underwent chest-abdomen-pelvis scan (65 cm). The utilized beam width for the examinations ranged from 12 mm to 40 mm. Pitch and rotation time had ranges of 0.4 - 1.06 and 0.5 s - 0.75 s, respectively.  $CTDI_{vol}$  values ranged from 4.8 mGy to 26.25 mGy.

Other required inputs were derived from these primary parameters, such as  $CTDI_w$  and table feed as previously illustrated.  $CTDI_{free-in-air}$  values were: 20 mGy for Hitachi Supria scanner, 17.5 mGy for Philips Brilliance 16 scanner, 7 mGy for head scans performed by Philips Brilliance 64, and 21.5 mGy for body scans at 120 kVp and 31 mGy for body scans at 140 kVp performed by the same scanner model. Table (4.1-a) and Table (4.1-b) presents the primary participants' demographics and the main scan parameters used for each examination and required to perform the fetal dose estimations by MC-based software tools as well.

Table 4.1-a: The collected demographic data and main exam scan parameters for each participant required to perform fetal dose estimations by the software tools.

Participant No.	Participant Age (Yr.)	Gestational Age (Mo.)	Scanner Type	Scan Protocol
Participant 1	26	6	Hitachi Supria 16	Chest
Participant 2	22	1	Hitachi Supria 16	Abdomen-Pelvis
Participant 3	30	1	Brilliance 16	Cervical Spine
Participant 4	28	5	Brilliance 16	Chest
Participant 5	25	1	Brilliance 16	Lumbar Spine
Participant 6	32	1	Brilliance 16	Abdomen-Pelvis
Participant 7	24	7	Brilliance 16	Ankle
Participant 8	33	8	Brilliance 64	Head
Participant 9	21	5	Brilliance 64	Chest
Participant 10	26	4	Brilliance 64	Chest
Participant 11	29	3	Brilliance 64	Chest
Participant 12 <sup>a</sup>	26	7	Brilliance 64	Chest
Participant 13	33	8	Brilliance 64	Lumbar Spine
Participant 14	20	9	Brilliance 64	Lumbar Spine
Participant 15	22	5	Brilliance 64	Lumbar Spine
Participant 16	29	5	Brilliance 64	Abdomen-Pelvis
Participant 17	26	4	Brilliance 64	Abdomen-Pelvis
Participant 18	38	2	Brilliance 64	Abdomen-Pelvis
Participant 19	33	2	Brilliance 64	Abdomen-Pelvis
Participant 20	37	3	Brilliance 64	Abdomen-Pelvis
Participant 21	20	1	Brilliance 64	Abdomen-Pelvis
Participant 22	31	3	Brilliance 64	Abdomen-Pelvis
Participant 23	24	4	Brilliance 64	Abdomen-Pelvis
Participant 24	32	7	Brilliance 64	Abdomen-Pelvis
Participant 25	27	3	Brilliance 64	CAP
Participant 26	22	9	Brilliance 64	Brain
				NCAP

a. Chest CT was repeated twice for Participant 12 using the same scan parameters.

**Abbreviations:** **No.** stands for number, **Yr.** stands for years, and **Mo.** stands for months, **CAP** stands for chest-abdomen-pelvis, and **NCAP** stands for neck-chest-abdomen-pelvis.

Table 4.1-b: The collected demographic data and main exam scan parameters for each participant required to perform fetal dose estimations by the software tools.

Participant No.	kVp	mAs	L (cm)	Beam Width (mm)	P	t <sub>(rot)</sub> (s)	CTDI <sub>vol</sub> (mGy)
Participant 1	120	233.6	23	20	1.06	0.75	17.8
Participant 2	120	206.3	46	20	1.06	0.75	15.8
Participant 3	120	229	28	12	0.5	0.5	23.1
Participant 4	120	200	26	24	1	0.5	11.73
Participant 5	120	223	34	24	0.93	0.75	16.2
Participant 6	120	309	36	24	0.93	0.75	21.29
Participant 7	120	64	18	12	0.93	0.5	10.85
Participant 8	120	105	11	40	0.4	0.5	13.95
Participant 9	120	99	21	40	1	0.5	8.5
Participant 10	120	56	27	40	1	0.5	4.8
Participant 11	120	152	24	40	1	0.5	13.1
Participant 12	120	250	25	40	1	0.5	14.67
Participant 13	120	274	26	40	0.75	0.74	25.48
Participant 14	120	214.6	36	40	0.75	0.74	17.58
Participant 15	140	236	30	40	0.75	0.74	26.25
Participant 16	120	133	48	40	0.75	0.74	10.29
Participant 17	120	210	49	40	0.75	0.74	19.96
Participant 18	120	217	40	40	0.75	0.74	19.7
Participant 19	120	249	45	40	0.75	0.74	21.1
Participant 20	120	200	44	40	0.75	0.74	15.8
Participant 21	120	210	45	40	0.75	0.74	19.5
Participant 22	120	190	47	40	0.75	0.74	19.96
Participant 23	120	168	46	40	0.75	0.74	14.66
Participant 24	120	168	44	40	0.75	0.74	14.66
Participant 25	120	306	65	40	0.75	0.74	22.9
Participant 26	120	350	75	40	0.75	0.74	25.8
	120	200	26	40	0.4	0.5	22.9

**Abbreviations:** No. stands for number, **kVp** stands for kilovolt-peak, **mAs** stands for milliampere-second, **L** stands for scan length, **cm** stands for centimeter, **mm** stands for millimeter, **P** stands for pitch, **t<sub>rot</sub>** stands for rotation time, s stands for second, **CTDI<sub>vol</sub>** stands for volume computed tomography dose index, **mGy** stands for milligray.

#### 4.1 The Resulting Dose Estimates from MC-Based Software Tools

The estimated fetal and uterine doses for CT examinations that do not include the fetus within the scan region from the six software tools are presented in (Table 4.2). This group includes CT examinations of chest, head, cervical spine, and ankle. The uterine dose for Participant 1 was not measureable by ImPACT software since the scanner model (Hitachi Supria 16) is not available in this software tool. Furthermore, the ankle is not available within the phantom used in ImPACT software tool, therefore the dose was not measureable for Participant 7 by

ImPACT. The fetal doses were also not measurable for (Participant 3, 7, 8, and 26b) by CODE software tool, due to the unavailability of head, neck and ankle parts within the phantom.

Table 4.2: Results of fetal and uterine dose estimations (mGy) from the six MC-based software tools for CT examinations where the fetus is located outside the scanned region.

Participant Number	Estimated Fetal Dose (mGy)			Estimated Uterine Dose (mGy)		
	VirtualDose CT	FetalDose.org	CODE	Waza-ari	CT-Expo	ImPACT
Participant 1	0.41	0.27	1.69	0.02	0	N/M
Participant 3	0.22	0.01	N/M	0.01	0	0
Participant 4	0.32	0.46	1.75	0.03	0.1	0.06
Participant 7	0.07	0	N/M	0.01	0	N/M
Participant 8	0.03	0	N/M	0.01	0	0
Participant 9	0.18	0.1	0.83	0.01	0.1	0.01
Participant 10	0.17	0.1	0.68	0.01	0	0.01
Participant 11	0.27	0.11	0.7	0.02	0.1	0.03
Participant 12 <sup>a</sup>	1	0.86	3.52	0.08	0.2	0.11
Participant 26b <sup>b</sup>	0.03	0	N/M	0.01	0	0

**a.** The resulting dose estimations for Participant 12 show the dose from one scan multiplied by two.  
**b.** Participant 26b denotes the head scan for Participant 26.  
**Abbreviations:** mGy stands for milligray, and N/M stands for not-measurable.

The estimated doses for CT examinations that do not include the fetus within the scanned region ranged from about 0 mGy to 3.52 mGy. The highest dose value of 3.52 mGy recorded for Participant 12 (chest scan) by CODE software tool, this was due to doubling the dose value as the scan was repeated twice for this participant. The lowest dose values that were nearly 0 mGy were recorded for CT examinations that are far from the uterus i.e. head, cervical spine, and ankle scans. Whereas the dose values were slightly higher for chest CT scans as the exposed region is nearer to the uterus. The highest estimated fetal doses among the majority of participants included in this group were reported by CODE, followed by VirtualDose CT, FetalDose.org, CT-Expo, ImPACT, and finally Waza-ari, with mean values of 1.53 mGy, 0.27 mGy, 0.19 mGy, 0.05 mGy, 0.03 mGy, and 0.02 mGy, respectively. Figure (4.1) shows the fetal and uterine doses distribution estimated for CT examinations that do not include the fetus within the scanned region by the six software tools.

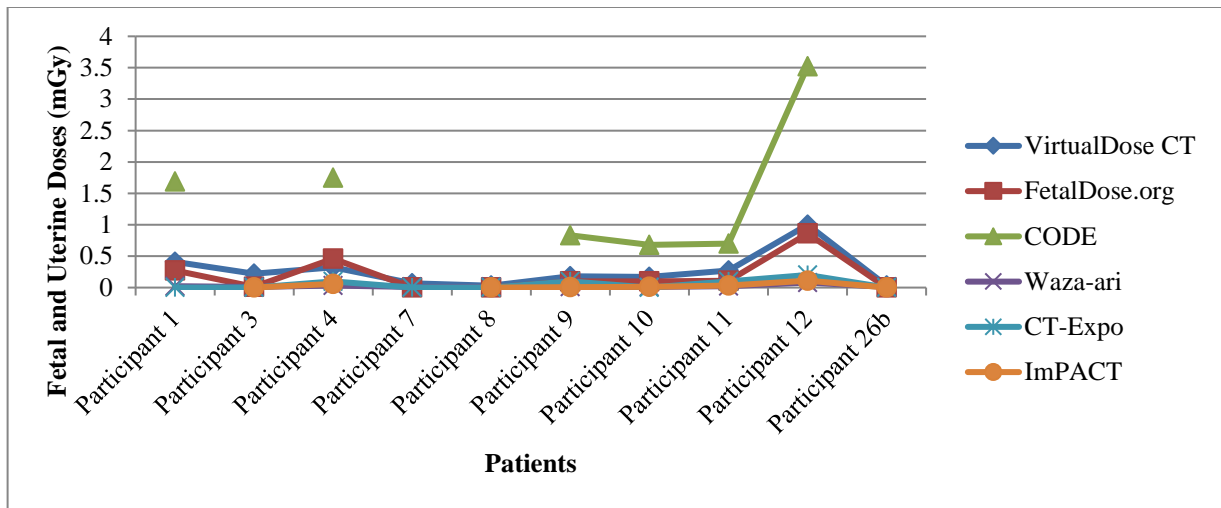


Figure 4.1: Distribution of fetal and uterine dose estimations from the six software tools for CT examinations where the fetus is located outside the scanned region.

CODE software tool reported the highest dose estimations for CT examinations where the fetus is located outside the scanned region. VirtualDose CT and FetalDose.org recorded higher fetal dose estimations than CT-Expo, ImPACT, and Waza-ari. This might be due to a different modeling of scatter radiation within the software tools, since the primary source of radiation to the fetus is scatter radiation (the fetus does not directly expose to radiation exposure), or due to a different modeling of attenuation within the software tools, resulting in lower dose estimations from the software tools that account for attenuation more aggressively.

The estimated fetal and uterine doses for CT examinations that include the fetus within the scan region from the six software tools are presented in (Table 4.3). This group includes CT examinations of abdomen-pelvis, chest-abdomen-pelvis, NCAP, and lumbar spine. The uterine dose for Participant 2 was not measureable by ImPACT software since the scanner model (Hitachi Supria 16) is not available in this software tool.

Table 4.3: Results of fetal and uterine dose estimations (mGy) from the six MC-based software tools for CT examinations involving the fetus within the scanned region.

Participant Number	Estimated Fetal Dose (mGy)			Estimated Uterine Dose (mGy)		
	VirtualDose CT	FetalDose.org	CODE	Waza-ari	CT-Expo	ImPACT
Participant 2	15.38	17.18	25.36	19.83	18.3	N/M
Participant 5	16.36	15.15	25.95	18.33	18.9	22
Participant 6	25.78	21.37	39.23	29.51	28.2	34
Participant 13	18.89	14.76	39.95	22.96	23.7	28
Participant 14	15.41	11.66	36.24	18.06	20.3	24
Participant 15	24.22	21.87	63.34	26.1	29.3	39
Participant 16	7.62	9.06	19.18	15.43	13.1	15
Participant 17	19.43	17.6	48.86	25.1	20.7	24
Participant 18	21.24	21.41	30.13	25.16	20	25
Participant 19	23.26	23.21	35.7	28.89	24.3	28
Participant 20	17.06	17.37	26.87	23.5	19.5	23
Participant 21	21.14	21.25	33.25	24.36	20.5	24
Participant 22	21.65	21.96	35.09	22.05	19.2	22
Participant 23	14.14	12.9	35.03	19.48	16.6	19
Participant 24	13.31	11.35	31.39	19.49	16.6	19
Participant 25	25.22	25.4	41.98	37.36	32.3	35
Participant 26a <sup>a</sup>	24.36	20.38	58.56	41.83	38.6	40
<p><b>a.</b> Participant 26a denotes the NCAP scan for Participant 26.  <b>Abbreviations:</b> mGy stands for milligray, and N/M stands for not-measurable.</p>						

The estimated fetal doses for CT examinations that include the fetus within the scanned region ranged from 7.62 mGy to 63.34 mGy. The lowest estimated dose value of 7.62 mGy was recorded for Participant 16 (abdomen-pelvis scan) by VirtualDose CT, due to the low mAs value used in this protocol (133 mAs) compared to the mAs values used in other protocols within this group. The highest estimated dose value of 63.34 mGy recorded for Participant 15 (lumbar spine scan) by CODE software, due to the high kVp value used in this protocol (140 kVp). Another high dose value (58.56 mGy) was reported for Participant 26 (NCAP scan) by CODE software, due to the high mAs value used in this protocol (350 mAs) and the large scan length (75 cm) as well. The highest estimated fetal doses for most participants were also reported by CODE, followed by ImPACT, Waza-ari, CT-Expo, VirtualDose CT, and finally FetalDose.org, with mean values of 36.83 mGy, 26.31 mGy, 24.56 mGy, 22.39 mGy, 19.09 mGy, and 17.88 mGy, respectively. Figure (4.2) shows the fetal and uterine doses distribution estimated for CT examinations where the fetus is included within the scanned region by the six software tools.

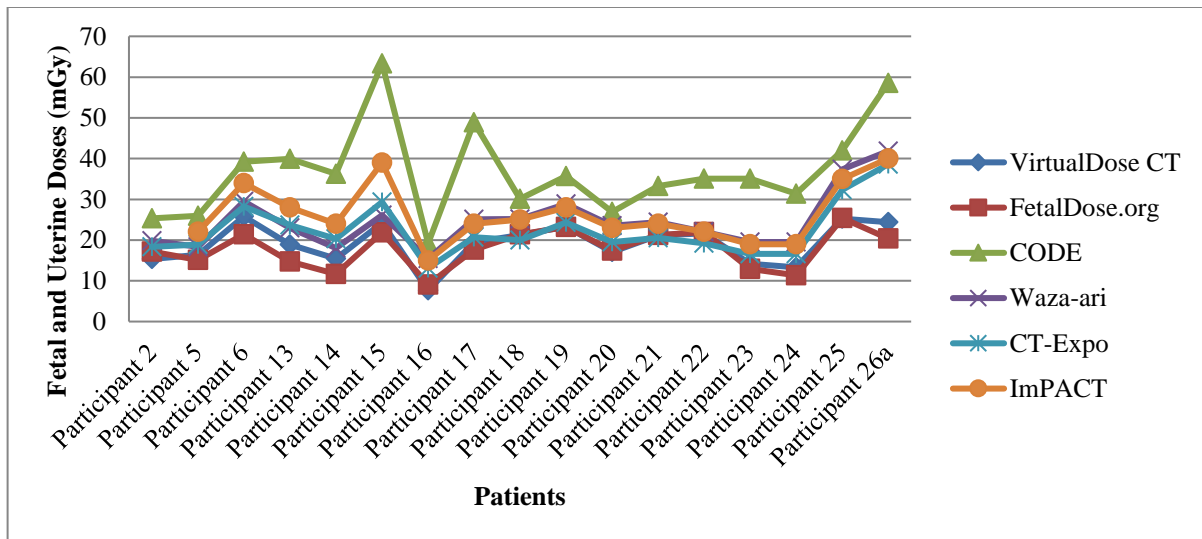


Figure 4.2: Distribution of fetal and uterine dose estimations from the six MC-based software tools for CT examinations involving the fetus within the scanned region.

CODE software reported the highest dose estimations and showed significant differences from all other software tools as well. This might be due to different modeling of phantoms, radiation source, and their interactions with matter from the others. The other software tools showed more similar results, the fetal radiation doses estimated by VirtualDose CT and FetalDose.org (with phantom models for pregnant women) were lower than those estimated by ImPACT, Waza-ari, and CT-Expo that specifically estimate the uterine dose. VirtualDose CT and FetalDose.org use pregnant phantoms where the anatomy of maternal organs is modeled accurately, considering the fetus positioning across various gestational ages. On the contrary, the other software tools that estimate the uterine dose might result in higher fetal dose estimations, as they focus on a more general or more specific anatomical target area rather than the fetus. Furthermore, the non-pregnant uterus is not directly exposed to the same levels of radiation as the fetus.

## 4.2 Reliability Assessment

The Intraclass Correlation Coefficient (ICC) analysis of the six MC-based software tools showed an ICC (average measures) of 0.96 with a 95% CI: 0.91 to 0.98, indicating an excellent reliability for all software tools together when the dose estimates are averaged. This value is considered precise due to the narrow confidence interval. Whereas ICC (single measures) of 0.80 with a 95% CI: 0.63 to 0.90 indicates a level of reliability regarding from moderate (a lower bound of 0.63) to excellent (an upper bound of 0.904). In other words, the ICC value of any individual software tool may fall within this range. This wider confidence interval demonstrates a high variability across individual dose estimates. To determine the reliability for individual software tools, ICC (single measures) values for pairs of software tools were analyzed and presented in (Table 4.4).

Table 4.4: Intraclass Correlation Coefficient (single measures) values with 95% confidence intervals for pairs of MC-based software tools.

Software Tools	ICC (Single Measures)	95% CI	
		Lower Bound	Upper Bound
VirtualDose CT – FetalDose.org	0.98	0.96	0.99
VirtualDose CT – CODE	0.60	0.01	0.84
VirtualDose CT – Waza-ari	0.89	0.62	0.96
VirtualDose CT – CT-Expo	0.94	0.83	0.98
VirtualDose CT – ImPACT	0.88	0.46	0.96
FetalDose.org – CODE	0.54	-0.01	0.80
FetalDose.org – Waza-ari	0.85	0.47	0.95
FetalDose.org – CT-Expo	0.89	0.69	0.95
FetalDose.org – ImPACT	0.81	0.35	0.93
CODE – Waza-ari	0.78	0.25	0.92
CODE – CT-Expo	0.73	0.09	0.91
CODE – ImPACT	0.84	0.29	0.95
Waza-ari – CT-Expo	0.97	0.93	0.99
Waza-ari – ImPACT	0.97	0.94	0.98
CT-Expo – ImPACT	0.97	0.79	0.99

**Abbreviations:** ICC stands for Intraclass Correlation Coefficient, and CI stands for Confidence Interval.

VirtualDose CT and FetalDose.org showed the highest reliability among all software tools with an ICC (single measures) value of 0.98 and a 95% CI of 0.96 to 0.99 indicating an excellent reliability, particularly with the narrow interval which demonstrates the least variability across fetal dose estimations from these software tools. This high reliability might be explained by the common similarities between both software tools, including first the use of patient-specific phantom models with three gestational ages by both tools, additionally, they estimate the dose to the fetus rather than the uterus so they both take the gestational changes into consideration.

Waza-ari also showed excellent reliability with ImPACT and CT-Expo software tools with ICC (single measures) values of 0.97 (CI: 0.94 – 0.98) and 0.97 (CI: 0.93 – 0.99), respectively. CT-Expo and ImPACT showed good to excellent reliability with an ICC (single measures) value of 0.97 (CI: 0.79 – 0.99). However, this wide CI indicates a higher variability across dose values estimated by both tools compared to the previously mentioned software tools pairs. It is worth mentioning that none of these three tools estimate the dose to fetus, they estimate the uterine dose instead. This would explain the high levels of reliability of the pairs of software tools that estimate the absorbed dose to the uterus, which provide consistent dose estimations.

Assessing the reliability among pairs of software tools that combine one software tool that estimates fetal dose and another software tool estimates the uterine dose showed lower levels of reliability. Such as VirtualDose CT and Waza-ari which had an ICC (single measures) value of 0.89 (CI: 0.62 – 0.96), indicating a level of reliability regrading from moderate to excellent

reliability, with a wide CI which demonstrates high variability in dose estimations resulted from both software tools. Another example is the pair of FetalDose.org and ImPACT software with an ICC (single measures) value of 0.81 (CI: 0.35 – 0.93), showing a level of reliability degrading from poor to excellent, with a wide CI which demonstrates a high variability among dose estimations. This low level of reliability showed between software tools that estimate fetal dose and the other tools that estimate uterine dose is explained by the different measurements used to estimate both doses, as taking into account gestational changes, and different degrees of dose absorption by the fetus and uterus, which may lead to high variability among the resulting dose estimates.

CODE software showed the lowest reliability with all other software tools. Where ICC (single measures) value for CODE and VirtualDose CT was 0.60 (CI: 0.01 – 0.84), and for CODE and FetalDose.org was 0.54 (CI: -0.01 – 0.80), indicating a level of reliability regrading from poor to good. ICC (single measures) values for CODE and Waza-ari was 0.78 (CI: 0.25 – 0.92), CODE and CT-Expo was 0.73 (CI: 0.09 – 0.91), and for CODE and ImPACT was 0.84 (CI: 0.29 – 0.95), indicating levels of reliability regrading from poor to excellent for the three pairs of software tools. The extreme wide confidence intervals demonstrate a high variability across dose values estimated by CODE software and the other software tools.

The agreement between some pairs of software tools were assessed by Bland-Altman plots. Figure (4.3) shows the Bland-Altman plot of difference in fetal dose estimates between VirtualDose CT and FetalDose.org software tools, which showed the highest reliability.

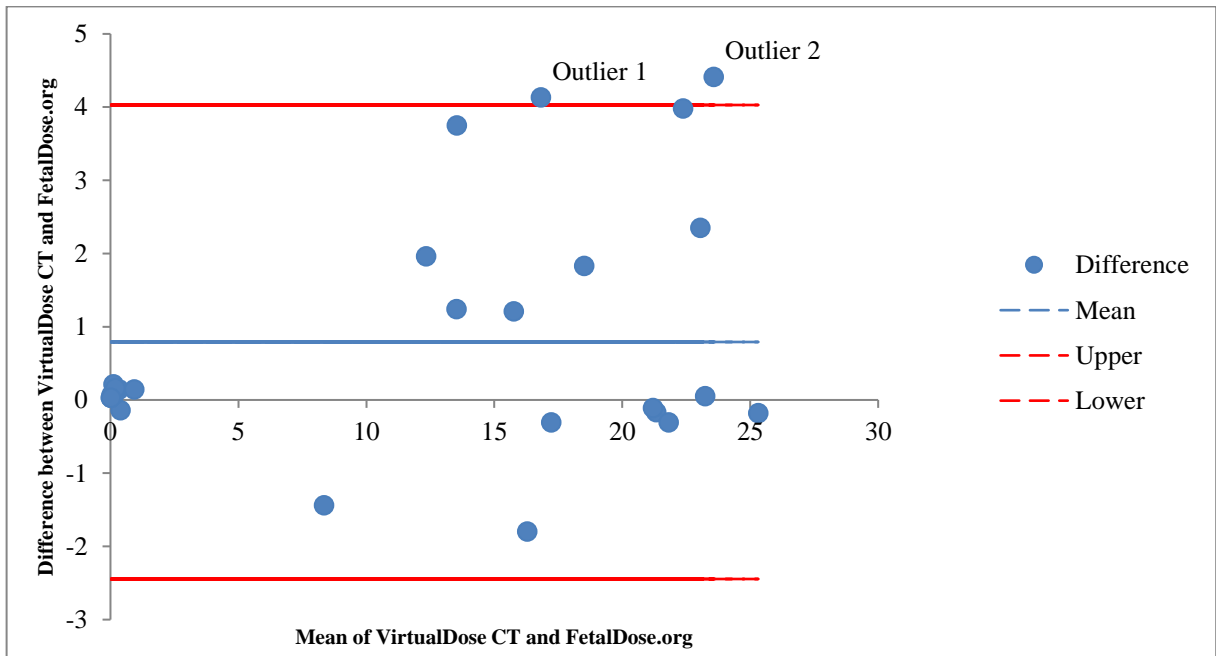


Figure 4.3: Bland-Altman plot of difference in fetal dose estimaitons between VirtualDose CT and FetalDose.org software tools.

Mean difference is 0.79, the lower agreement limit is  $-2.45$ , the upper agreement limit is  $4.03$ . The mean difference indicates a good agreement between these software tools, indicating that, on average, both tools provide almost similar fetal dose estimations. The clustering of more than half of data points around zero is also an evidence of the high agreement between both tools. The majority of the differences between dose estimations from both tools lie within the range of values between upper and lower agreement limits, highlighting the potential for considerable variability with some dose estimations. However, two outliers were identified, with one point showing a difference of  $4.13$  (outlier 1) and another at  $4.41$  (outlier 2), both of which lie outside the limits of agreement. Outlier 1 represents the difference between fetal dose estimations for Participant 13 by both software tools, this relatively high difference might be a result of the high mAs ( $274$  mAs) used in the CT protocol for this participant, since mAs is not one of the required inputs in FetalDose.org software, VirtualDose CT recorded higher dose as it accounts for the mAs value used. Outlier 2 represents the difference between fetal dose estimations for Participant 6 by both tools, this high difference is also explained by the high mAs ( $309$  mAs) used in the protocol for this participant. Overall, the results confirm the strong agreement between VirtualDose CT and FetalDose.org in estimating fetal doses, with caution advised in the cases where high mAs values are used.

The agreement between pairs of tools, where one tool estimates fetal dose and the other estimates uterine dose was assessed, choosing Waza-ari and FetalDose.org software tools in estimating fetal doses, using Bland-Altman plot (Figure 4.4).

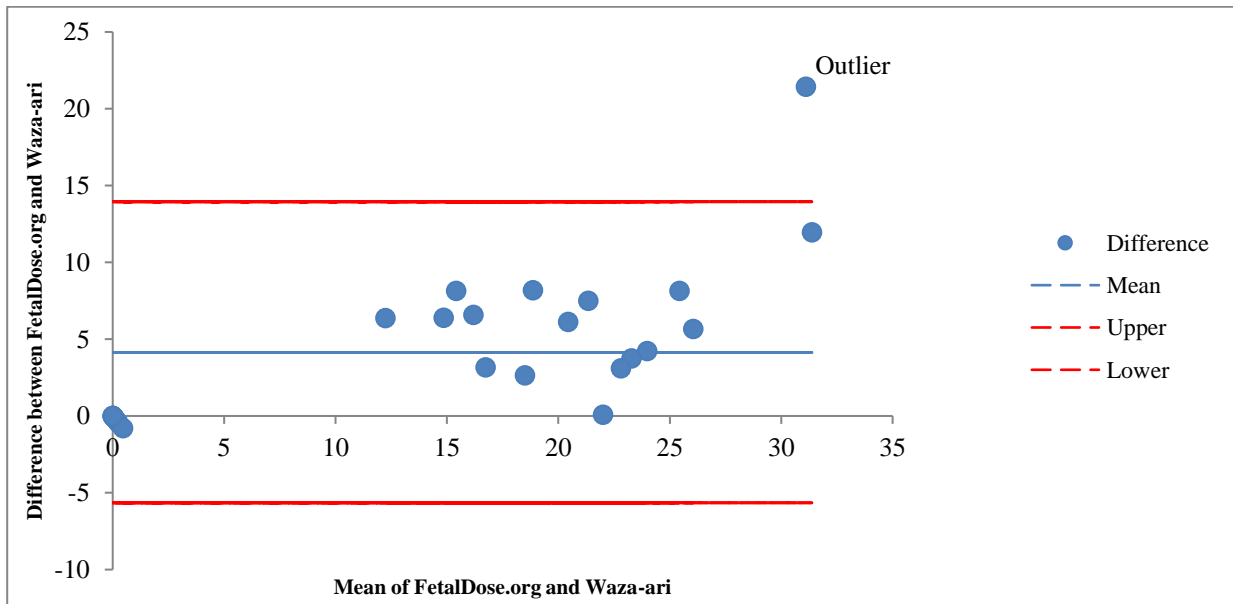


Figure 4.4: Bland-Altman plot of difference in fetal dose estimations between Waza-ari and FetalDose.org software tools.

Mean difference is  $4.14$ , the lower agreement limit is  $-5.66$ , the upper agreement limit is  $13.94$ . Waza-ari and FetalDose.org software tools showed relatively high mean difference indicating that there is a considerable variability between both tools. The wide range of agreement limits also indicates that while most differences fall within this range, there is a high

variability across fetal doses estimated by these software tools. The presence of one outlier with a difference value of 21.45 highlights a significant difference in dose values estimated by these software tools for Participant 26b. As mentioned earlier, Waza-ari software estimates the dose to uterus, whereas FetalDose.org software estimates the dose to fetus, both depend on different principles for dose measurements which might be the cause of this low agreement between dose estimations from both tools.

For the assessment of agreement between CODE and other software tools, which showed the lowest reliability, CODE and CT-Expo were the software tools chosen to assess their agreement in estimating fetal doses using Bland-Altman plot as shown in (Figure 4.5).

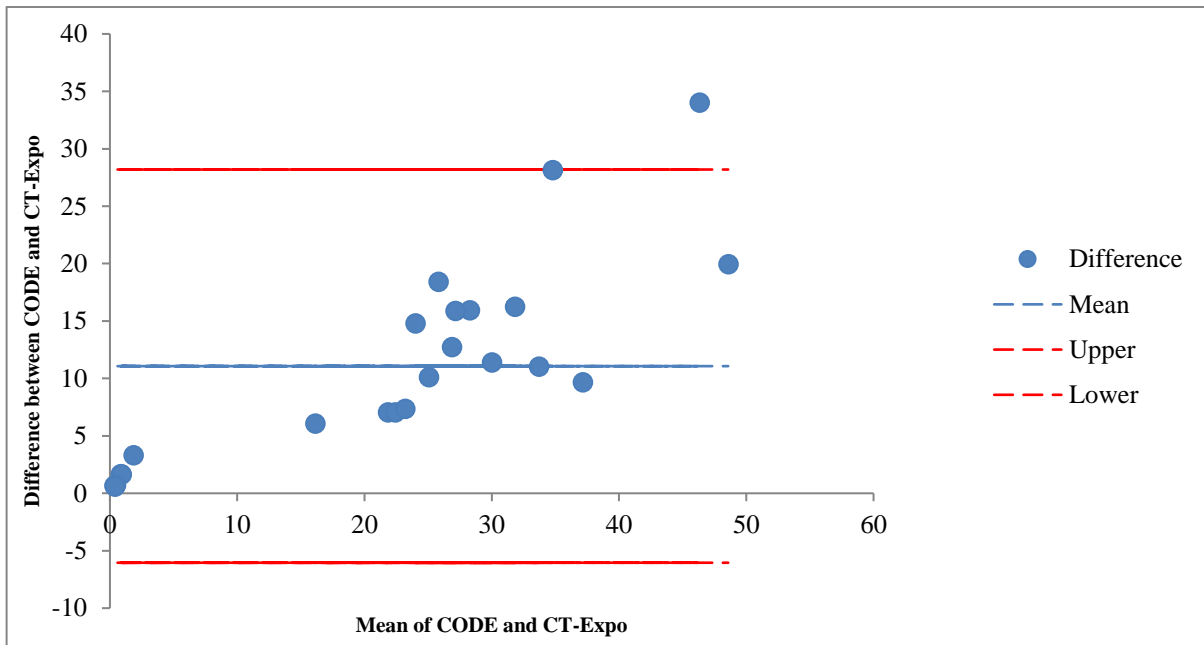


Figure 4.5: Bland-Altman plot of difference in fetal dose estimations between CODE and CT-Expo software tools.

Mean difference is 11.07, the lower agreement limit is  $-6.05$ , the upper agreement limit is 28.19. CODE and CT-Expo software tools showed such a high mean difference indicating that there is a significant variability between both tools. The wide range of agreement limits also indicates that while most differences fall within this range, there is a very high variability across fetal doses estimated by these software tools. The presence of one outlier with a difference value of 34.04 highlights a significant difference between dose values estimated by these software tools for Participant 15. Overall, the high mean difference, the wide range of agreement limits, and the significant outlier suggest that dose estimations by these tools can vary significantly, and eventually demonstrate a low agreement between CODE and CT-Expo software tools, confirming the low reliability showed by the low ICC (single measures) value of these tools.

### 4.3 Comparative Analysis of Software Tools' Performance

Total performance scores for all software tools were estimated, by assessing each software tool on the predefined performance criteria. Table (4.5) presents the total performance scores of the six MC-based software tools used in this study, providing an overall performance assessment of these tools in estimating fetal dose from various CT examinations.

Table 4.5: Resulting total performance scores of MC-based software tools for estimating fetal dose from CT examinations.

<b>Software Tool</b>	<b>Total Performance Score</b>
<b>VirtualDose CT</b>	485.25
<b>Waza-ari</b>	309.9
<b>CT-Expo</b>	277.8
<b>CODE</b>	268.65
<b>FetalDose.org</b>	266
<b>ImPACT</b>	243.2

VirtualDose CT emerged as the best performer with a total score of 485.25, indicating that it outperformed the other software tools across most evaluation criteria. This high score confirmed that this software tool provides specialized features for fetal dose estimations that are not commonly found in the other software tools, primarily the offered comprehensive details on both total fetal dose and radiation doses to some fetal organs, and the use of phantom models for pregnant women in three gestational ages as well. Availability of different CT scanner models and procedures, its compatibility with mobile systems, and its user-friendly interface also contributed to increase the total score. However, the cost required to use this software tool (the need for subscription), and its fewer input parameters compared to other tools contributed to the minimal reduction in the total performance score of this software tool.

Waza-ari scored 309.9, reflecting a good performance across the evaluated criteria. However, it mainly fell short in availability of pregnant phantoms and providing fetal dose details, though it scored highly in offering detailed CT procedures, and scanner models, and in being free of charge as well. Considering the target of directly measuring fetal dose rather than uterine dose would significantly improve this tool's performance in fetal dose estimations.

CT-Expo achieved a total score of 277.8, indicating some limitations, particularly in the unavailability of pregnant phantoms and direct fetal dose estimations, and the limitation of the free version of this software tool, such as the lack of options for selecting scanner models. Making some adjustments to this tool would enhance its performance in estimating fetal doses, mainly including, direct dose estimates to the fetus, and upgrading to a more modern and intuitive software, instead of MS spreadsheet.

CODE and FetalDose.org presented almost similar total scores, 268.65 and 266, respectively. They both offer phantom models for pregnant women, share the feature at no cost. However, the lack of CT scanner models available within these software tools is one of the disadvantages. For FetalDose.org, it is recommended to include additional input parameters, as the tool currently requires only the kVp and L. While CODE would perform better if the phantoms were available with all body parts rather than only the trunk.

ImPACT ranked the lowest among the compared software tools, with a total score of 243.2. This low score was attributed to various factors such as unavailability of direct dose measurements to the fetus, unavailability of lower limbs within the phantom used in this tool, and cumbersome user interface compared to other tools. These limitations may potentially lead to suboptimal clinical decisions making it the least favorable option for fetal dose estimation purposes.

Eventually, integrating the reliability and comparative findings revealed that VirtualDose CT, with its superior performance and high reliability, is a standout tool. As the high performance in estimating the dose to fetus and consistent measurements are both critical in selecting a tool, VirtualDose CT is recommended for fetal dose estimations from CT examinations, particularly when high performance and reliability are required.

Previous research assessed the validity of VirtualDose CT in estimating fetal radiation dose, such as Begano et al. study, where the estimated fetal dose values by VirtualDose CT corresponded well to their measured dose by TLD (Begano, Söderberg, and Bolejko 2021). Another study showed an agreement of within  $\pm 10.8\%$  between the TLD measurements and the estimated fetal doses by VirtualDose CT for pregnant women who underwent both, CT and conventional chest X-Ray examinations (Saeed 2021). These findings support the choice of VirtualDose CT software tool as a standout tool for fetal dose estimation, not only for its high performance and reliability, but also for its validity as proven by previous studies.

#### **4.4 Comparison of Fetal Dose Estimates with Previous Studies**

The results of fetal doses estimated by MC-based software tools from five previous studies were summarized for comparison with our results. Two studies estimated fetal doses from chest CT examinations, two studies estimated fetal doses from abdomen-pelvis CT examinations, and one study estimated fetal doses from both chest, and abdomen-pelvis CT examinations. The estimation method of fetal dose and the fetal dose estimates from each study were reported. Table (4.6) compares the estimated fetal doses from chest CT examinations.

Table 4.6: Results of mean estimated fetal doses (mGy) from chest CT examinations reported in previous studies and our study as well.

Source	VirtualDose CT	CODE	CT-Expo	ImPACT
Dimitroukas et al. (2023)	0.16	0.2	x	x
Dabli et al. (2022)	x	x	0.1	x
Litmanovich et al. (2009)	x	x	x	0.02
<b>Our results</b>	0.34	1.31	0.07	0.03

Our results showed that the average of estimated fetal doses for chest CT examinations by VirtualDose CT in our study was 0.34 mGy, by CODE software was 1.31 mGy, by CT-Expo software was 0.07, and by ImPACT software was 0.03 mGy. Dimitroukas et al. study reported mean estimated fetal doses of 0.16 mGy (by VirtualDose CT), and 0.2 mGy (by CODE software), which are much lower than our findings that were obtained using the same estimation methods. This might be primarily due to the use of different scan parameters for the chest protocol, or the use of different CT scanner models for imaging. However, our study showed more similar findings to the studies of Dabli et al. and Litmanovich et al. who reported average fetal doses of 0.1 mGy estimated by CT-Expo software, and 0.02 mGy estimated by ImPACT software, respectively. CODE software reported higher mean fetal doses than VirtualDose CT in our study, which is aligned with Dimitroukas’s study, where CODE software also reported a slightly higher mean fetal dose (0.2 mGy) than VirtualDose CT (0.16 mGy). Regarding abdomen-pelvis CT examinations, Table (4.7) presents a comparison of our results with the mean fetal dose estimates reported by previous studies.

Table 4.7: Results of mean estimated fetal doses (mGy) from abdomen-pelvis CT examinations reported in previous studies and our study as well.

Source	VirtualDose CT	CODE	CT-Expo	ImPACT
Carlstein (2020)	14.3	14.5	15.95	x
Dabli et al. (2022)	x	x	10.93	x
S. Goldberg-Stein et al. (2011)	x	x	x	24.8
<b>Our results</b>	18.18	32.74	19.73	23.3

Our results showed that the average of estimated fetal doses for abdomen-pelvis CT examinations by VirtualDose CT was 18.18 mGy, by CODE software was 32.74 mGy, by CT-Expo software was 19.73, and by ImPACT software was 23.3 mGy. Carlstein’s study showed average fetal doses of 14.3 mGy (estimated by VirtualDose CT), 14.5 mGy (estimated by CODE software), and 15.95 mGy (estimated by CT-Expo software) for abdomen-pelvis CT scans, which are lower than our resulting mean fetal dose estimates, that were obtained by the same estimation methods. These differences may be attributed to variations in scanning parameters, the use of different CT scanner models, or differences in the study population such as gestational age. Dabli et al. also reported a lower mean fetal dose of 10.93 mGy estimated by CT-Expo software in their study compared to our results estimated by the same software tool. This is likely due to differences in sample size, as well as variations in the study population, such as gestational age.

However, Goldberg-Stein et al. reported a mean fetal dose for abdomen-pelvis CT examinations of 24.8 mGy, which is more similar to our findings using ImPACT software. Furthermore, while our findings aligned with Carlstein's study regarding VirtualDose CT, which recorded lower estimations compared to the other two software tools in all cases, our results showed that CODE recorded higher estimations than CT-Expo in all cases, which contrasts with Carlstein's findings.

All estimated fetal and uterine doses from the six MC-based software tools in this study were below the threshold value of deterministic effects recommended by the ICRP i.e. 100 mGy, confirming the safety of the CT protocols employed for pregnant participants in the sample set, where the deterministic radiation risks to fetuses minimized while achieving the required diagnostic outcomes. This finding is in agreement with the previous studies' (mentioned in this section) findings related to fetal doses estimated by various software tools for different CT examinations, all of which were below 100 mGy.

## Chapter 5: Conclusion and Recommendations

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### 5.1 Conclusion

In conclusion, fetal doses from various CT examinations were estimated by six different MC-based software tools. The resulting fetal dose estimates were compared with previous studies and with the threshold value of deterministic effects recommended by the ICRP as well. Our resulting fetal dose estimates were consistent with those from some previous studies using the same methods, but differed from others. In accordance to deterministic threshold value set by the ICRP, the reported fetal dose estimates in this study were within acceptable limits, as all dose values were below 100 mGy for all CT examinations. Furthermore, the reliability of the six software tools was assessed by Intraclass correlation coefficient (single measures and average measures). Average measures ICC at 95% CI indicated an excellent reliability for all tools, where single measures ICC at 95% indicated a level of reliability regrading from moderate to excellent. Single measures ICC values were also analyzed for pairs of software tools, where VirtualDose CT and FetalDose.org showed the highest value of ICC indicating the highest reliability. However, the lowest single measures ICC values were recorded for CODE software with all other tools, which indicated a low reliability of this software tool. A comparative analysis of the performance of the six software tools was also conducted, with VirtualDose CT achieving the highest total performance score, while ImpACT received the lowest score based on the predefined criteria established in this study. Ultimately, the reliability and performance comparative analyses revealed that VirtualDose CT emerged as the optimal choice with a superior performance and high reliability for fetal dose estimates from various CT examinations, therefore it is recommended to be adopted by the Palestinian healthcare institutions.

## **5.2 Recommendations**

While this study offered valuable insights, further research should aim to include a larger patient sample to provide more comprehensive results across various demographics and CT procedures. Furthermore, to enhance the validity of dose calculations, phantom measurements should be integrated with patient data in subsequent research. Additionally, it is crucial to expand the criteria used in the comparative analysis of software tools, to include the involvement of user and expert reviews, and the integration with clinical workflows, so that a holistic evaluation of each tool will be provided. Addressing these recommendations will advance the fetal radiation safety by enhancing the accuracy and reliability of fetal dose assessments, eventually leading to safer and more effective CT imaging procedures during pregnancy.

In clinical settings, it is recommended to prioritize non-ionizing radiation modalities whenever possible for imaging and diagnostic purposes in pregnant patients, to minimize potential radiation-induced bioeffects on both the fetus and the pregnant mother.

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# Appendices

## Appendix A: Ethical Approval Letter from RESC Al-Quds University

Al Quds University  
Faculty of Health Professions  
Jerusalem –Abu Dis



جامعة القدس  
كلية المهن الصحية  
القدس – أبو ديس

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Research Ethics Subcommittee of Faculty of Health Professions  
Letter of approval

Aug. 25, 2024  
Ref. No.: RESC/2024-52

Dear Applicants, (Prof Adnan Lahham, Ms. Huda Nasser)

Program: MSc Medical Imaging Department

The Research Ethics subcommittee of the Faculty of Health Professions has recently reviewed your proposal entitled (**Evaluation of Fetal Radiation Dose from CT Examinations using Six Different Software Tools: A Comparative Study**) submitted by (**Prof Adnan Lahham**). Your proposal is deemed to meet the requirements of research ethics at Al-Quds University, but further assessment is required by the Central Research Ethics Committee of Al-Quds University. We wish you all best for the conduct of the project.

**Hussein ALMasri, PhD**  
Associate Professor of Medical Imaging  
Research Ethics Subcommittee Chair  
Faculty of Health Professions

*Hussein ALMasri*

CC: File  
CC: Committee members

## Appendix B: Ethical Approval from the Ministry of Health

State of Palestine  
Ministry of Health  
Assistant Deputy for Allied Medical  
Professions and Blood Banks

دولة فلسطين  
وزارة الصحة  
الوكيل المساعد  
للمهن الطبية المساندة وبنوك الدم

الايخ الدكتور معتصم محيسن المحتشم  
الوكيل المساعد لشؤون المستشفيات والطوارئ

الموضوع: تسهيل مهمة

تحية طيبة وبعد...

بعد التحية وبالإشارة للموضوع أعلاه، يرجى تسهيل مهمة الطالبة هدى حسني ناصر  
من جامعة القدس.

بعنوان: Evaluation of Fetal Radiation Dose from CT Examinations using Six  
Different Software Tools:A Comparative Study

وذلك السماح لها في جمع المعلومات اللازمة من نظامي (PACS,HIS) لدراسة وتقييم جرعة الاشعاع  
للجنين من فحوصات التصوير الطبي باستخدام ستة ادوات برمجية مختلفة: دراسة مقارنة.  
على ان يتم التعامل مع كافة المعلومات بسرية تامة وتستخدم لأغراض البحث العلمي فقط.

وتفضلوا بقبول فائق الاحترام...

أخوكم  
أسامة النجار  
الوكيل المساعد  
للمهن الطبية المساندة وبنوك الدم

دولة فلسطين  
وزارة الصحة  
2024-968  
2/9/2024

R  
Lana



Date: 27/Aug/2024



حضرة د. أسامة النجار المحترم / الوكيل المساعد للمهن الطبية – وزارة الصحة الفلسطينية

تحية طيبة وبعد،

مكتب الوكيل المساعد للمهن الطبية الساندة وبنوك الدم  
الموضوع: تسهيل مهمة باحثة من جامعة القدس – أبو ديس م.  
التاريخ: 20/8/2024

إيماناً منا بدوركم في خدمة وتطوير المجتمع الفلسطيني واستناداً لمعرفتنا بالدور الهام الذي تقومون به في دعم التعليم والبحث العلمي،

نتوجه لحضرتكم بالتكريم بالايجاز للمعنيين المساعدة بتسهيل مهمة الباحثة هدى حسني ناصر من برنامج ماجستير تكنولوجيا التصوير الطبي – كلية المهن الصحية / جامعة القدس في جمع المعلومات اللازمة من نظامي (PACS , HIS) لدراسة وتقييم جرعة الإشعاع للجنين من فحوصات التصوير الطبي باستخدام ستة أدوات برمجية مختلفة: دراسة مقارنة.

ستقوم الطالبة بعمل بحث بعنوان:

**Evaluation of Fetal Radiation Dose from CT Examinations using Six Different Software**

**Tools: A Comparative Study**

وسيتم اطلاعكم على نتائج البحث.

تفضلوا بقبول فائق الاحترام والتقدير

د. عدنان اللحام  
المشرف الاكاديمي

A. Lahham

د. عدنان اللحام  
11/9/2024

# دراسة مقارنة لست أدوات برمجية تستخدم لقياس جرعة الإشعاع التي يتعرض لها الجنين من فحوصات التصوير المقطعي

إعداد: هدى حسني محمود ناصر

إشراف: أ.د. عدنان اللحام

## ملخص

يُعدّ تقييم جرعة الإشعاع للجنين خلال فحوصات التصوير المقطعي أمر بالغ الأهمية لضمان سلامة المريضات الحوامل وأجنتهن. هدفت هذه الدراسة بشكل أساسي إلى إجراء تحليلات مقارنة لست أدوات برمجية قائمة على طريقة مونت كارلو VirtualDose CT و FetalDose.org و CODE و Waza-ari و CT-Expo و IMPACT لتقييم موثوقيتها وأدائها، كما تضمنت حساب جرعات الإشعاع التي تعرض لها الأجنة في مجموعة العينة لدينا. تم استخدام الأدوات البرمجية الستة لحساب جرعة الإشعاع لست وعشرين مريضة مع سبعة وعشرين فحصاً مختلفاً للتصوير المقطعي، بما في ذلك الرأس، والعمود الفقري العنقي، والصدر، والبطن والحوض، والعمود الفقري القطني، والكاحل. تم حساب قيم معامل التوافق الداخلي للقياسات الفردية والمتوسطة عند مستوى ثقة 95% لتقييم موثوقية أدوات البرامج الستة معاً، وكذلك تقييم موثوقية كل زوج من الأدوات البرمجية بشكل منفصل. كما تم استخدام مخططات بلاند-ألتمن لتقييم التوافق بين بعض الأزواج من الأدوات البرمجية. تم إجراء تحليل مقارنة لأداء أدوات البرمجيات الستة في حساب جرعة الجنين من فحوصات التصوير المقطعي، حيث تم تحديد درجة الأداء الإجمالي لكل أداة بعد تقييمها وفقاً للمعايير الموضوعية، والتي تعتبر حاسمة في إجراء حسابات الجرعة للجنين، بما في ذلك توفر الفانتوم لست حوامل، و عدد المدخلات المطلوبة، وتوافر إجراءات التصوير المقطعي، وعدد نماذج أجهزة التصوير المقطعي المتوفرة، وتفاصيل الجرعات الناتجة للجنين والأم، وعدد الفانتوم المستخدمة، والتكلفة، وسهولة الاستخدام، والتوافق مع الأنظمة المحمولة. كانت حسابات جرعة الجنين الناتجة جميعها ضمن الحدود المقبولة للجرعة الموصى بها من قبل اللجنة الدولية للحماية من الإشعاع، أي أقل من 100 ملي غراي. كما أن الجرعات الجنينية الناتجة تتفق مع قيم الجرعات للأجنة من فحوصات التصوير المقطعي المسجلة في دراسات سابقة باستخدام نفس طرق الحساب. وُجدت قيمة متوسط القياسات لمعامل التوافق الداخلي لأدوات البرمجيات الست بمعدل 0.96 عند مستوى ثقة 95% يتراوح من 0.91 إلى 0.98، مما يدل على موثوقية ممتازة، بينما وُجدت قيمة القياسات الفردية لمعامل التوافق الداخلي لأدوات البرمجيات الست بمعدل 0.80 عند مستوى ثقة 95% يتراوح من 0.63 إلى 0.90، مما يدل على موثوقية متوسطة إلى ممتازة لكل أداة برمجية فردية مقارنة بالأدوات الأخرى. أظهرت أدوات VirtualDose CT و FetalDose.org أعلى قيمة قياسات فردية لمعامل التوافق الداخلي عبر جميع الأزواج من أدوات البرمجيات بمعدل 0.98 عند مستوى ثقة 95% يتراوح من 0.96 إلى 0.99، مما يدل على موثوقية ممتازة لكلا الأدوات. بينما أظهرت أداة CODE أقل قيم قياسات فردية لمعامل التوافق الداخلي مع جميع أدوات البرمجيات الأخرى، مما يدل على انخفاض موثوقية هذه الأداة. أظهر مخطط بلاند-ألتمن فرق متوسط قدره 0.79 لأدوات VirtualDose CT و FetalDose.org، مع حدود توافق تتراوح من -2.45

إلى 4.03، مما يدل على توافق جيد بين الأدوات، ويؤكد موثوقيتهما أيضًا. أما بالنسبة للتحليل المقارن لأداء أدوات البرمجيات في حساب جرعة الجنين من فحوصات التصوير المقطعي، تم تحديد VirtualDose CT كأفضل أداء وفقًا للمعايير المحددة التي تم تقييمها في هذه الدراسة مع مجموع أداء إجمالي قدره 485.25. في النهاية، تم التوصية بأداة VirtualDose CT، نظرًا لأدائها الممتاز وموثوقيتها العالية، كأداة متميزة لحساب جرعات الجنين من فحوصات التصوير المقطعي.