Measuring radiation dose to patients undergoing fluoroscopically-guided interventions

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Abstract. The increasing prevalence and complexity of fluoroscopically guided interventions (FGI) raises concern regarding radiation dose to patients subjected to the procedure. Despite current evidence showing the risk to patients from the deterministic effects of radiation (e.g. skin burns), radiation induced injuries remain commonplace. This review aims to increase the awareness surrounding radiation dose measurement for patients undergoing FGI. A review of the literature was conducted alongside previous researches from the authors' department. Studies pertaining to patient dose measurement, its formalism along with current advances and present challenges were reviewed. Current patient monitoring techniques (using available radiation dosimeters), as well as the inadequacy of accepting displayed dose as patient radiation dose is discussed. Furthermore, advances in real-time patient radiation dose estimation during FGI are considered. Patient dosimetry in FGI, particularly in real time, remains an ongoing challenge. The increasing occurrence and sophistication of these procedures calls for further advances in the field of patient radiation dose monitoring. Improved measuring techniques will aid clinicians in better predicting and managing radiation induced injury following FGI, thus improving patient care.

1. Introduction
Global advances in healthcare and technology have significantly increased the usage of fluoroscopically guided interventions (FGI) for diagnosis and treatment. FGI has also increased in complexity over the years due to advancing technology and increased sophistication. Although it is well-known that there is a risk of radiation induced skin injuries in adult patients' [1–3], the highest chance of which occurs during cardiac catheterization procedures [4], injuries remain commonplace [5].

Worldwide literature has historically focused on adult cardiac interventional procedures, with some reporting radiation dose to the skin surpassing 1 Gy [6–11], and occasionally more than 9 Gy [12] with complex procedures. Despite the volume literature reporting on radiation dose to adults [13–21], a large variation in results means a general consensus is hard to reach [22]. In pediatric literature, reports show lower radiation exposure (< 1 Gy) than adults, but with the added increasing risk of stochastic effects [23, 24], which is believed to double or triple the risk of radiation-induced malignancy [25]. This increase in risk may be attributed to the need for long term follow up catheterization procedures in

congenital cases [26] or to the prolonged procedure duration in high complexity cases working on small vessel sizes, which may take an average of 3-5 hours [22].

The increase in both FGI procedures and their complexity raises a need to review the radiation dose to patients. This paper aims to briefly review on radiation dose to patients undergoing FGI in catheterization laboratories, with a focus on measurement methods, advances in radiation monitoring and estimation tools, as well as to the current limitations and challenges in the field.

2. Patient dosimetry

As dosimetry in diagnostic radiology involves several quantities, there is a set of definitions that are utilized specifically for FGI. The specific geometry and configuration used in FGI procedures is used to estimate and measure the radiation dose emitted by fluoroscopic devices. Table 1 presents the quantities and measurements of radiation dosimetry utilized in both general diagnostic radiology and specifically for patient dosimetry in FGI.

The kinetic energy released per unit mass of medium irradiated by x-ray is denoted by the abbreviation, "kerma". Hence the entrance surface air kerma (ESAK; $K_{a,e}$), air kerma at reference point ($K_{a,r}$), and air kerma-area product ($P_{k,a}$) are all derived from kerma, each of which have different definitions and use (refer to table 1). The term 'dose' is used to denote the amount of energy absorbed in a unit of mass of a medium, from which the point absorbed dose (D), entrance surface absorbed dose ($D_{skin,e}$), and peak skin dose ($D_{skin,max}$) are derived. Correction factors may be needed to arrive at specific organ/tissue dose estimate (the mean organ/tissue absorbed dose, D_T). This long list of dose measures and quantities raises a need for a common standard used for communicating regulations. An example of this selection is the air kerma at reference point ($K_{a,r}$) and FDA (Food and Drug Administration, USA) compliance air kerma.

The peak skin dose (Dskin,max) is a measure of the highest absorbed dose in any part of a patient's skin accumulated during a procedure [22]. In addition to the dose from the primary x-ray beam, the quantity also includes the contributions of any existing tube leakage and back-scattered radiation. As skin injury may take place at a certain threshold, the peak skin dose information becomes useful for prediction or estimating any potential onset of radiation injury to the patient's skin. The concept of Ka,r was first described in the technical standard for interventional x-ray equipment published by the International Electrotechnical Commission (IEC) in 2000, being described as the air kerma measured on the beam's central axis at 15 cm away from the isocentre towards the x-ray tube [27]. This is meant to represent the entrance air kerma point on the patient's body. Subsequently the standard was adopted by the FDA in regulating the performance standards for any medical fluoroscopy system operating in the U.S., with the reference point described as 30 cm away from the image receptor with minimum distance between the x-ray focal spot and image receptor surface [28]. All medical fluoroscopy devices conforming with IEC standards or produced after 2006 in the U.S. have the feature of calculating and displaying $K_{a,r}$ on the interface [22].

Table 1. Radiation quantities involved in FGI radiation dosimetry[1].

| Quantity	Description	Symbol	SI Unit	Reference
Incident air kerma	Air kerma from the incident x-ray beam at beam axis at a certain source-to-surface distance (SSD).	$K_{a,i}$	Gray (Gy)	[29]
Entrance-surface air kerma	Air kerma from the incident x-ray beam at beam axis at patient's entrance point, including contribution from back-scattered radiation.	$K_{a,e}$	Gray (Gy)	[29]

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[1] Table reformulated from NCRP Report No. 168 (2010) [22]

Point absorbed dose	Energy absorbed per unit mass at a certain point in a medium including contribution from back-scattered radiation.	D	Gray (Gy)	[29]
Entrance-surface absorbed dose	Energy absorbed on the central x-ray beam axis at patient's entrance point including contribution from back-scattered radiation.	$D_{skin,e}$	Gray (Gy)	[29]
Mean organ/tissue absorbed dose	Integral or average absorbed energy over a whole tissue/organ mass.	D_T	Gray (Gy)	[30]
Peak skin dose	Energy absorbed per unit mass at the most irradiated local area of patient's skin including contribution from back-scattered radiation.	$D_{skin,max}$	Gray (Gy)	[29]
Air kerma at the reference point	The air kerma (K_a) without any contribution of back-scattered radiation on certain, regulated/standardized positions. In IEC standard, the position is defined at the beam central axis 15 cm away from the isocenter towards the x-ray tube.	$K_{a,r}$	Gray (Gy)	[27,28,31, 32]
Air kerma-area product or dose-area product	The integral of air kerma without any contribution of back-scattered radiation over the area of the x-ray beam in a plane perpendicular to the beam axis.	P_{KA}	Gy cm^2	[29]
FDA compliance air kerma rate	Air kerma per unit of time measured under FDA compliance conditions.	$\dot{K}_{FDA}$	mGy / min	[28,33]

The clinical setting introduces further variables that increase the complexity of measuring or estimating a patient's radiation dose. Factors such as patient size and positioning beam energy spectrum, gantry tilting and angulation, attenuation-governed radiological parameters, and variable distances are key in determining dose to patients. The factors may relate to patient, the size of the patients, or both.

A typical catheterization laboratory uses ceiling- or floor-mounted fluoroscopy device, where a high degree of freedom in setting patient position exists. This is due to the freely movable ("floating"), tiltable, and rotatable gantry, as well as the ability to adjust the patient table in x-, y-, and z-axis directions. Additionally the SID (Source to Image Distance), which indicates the distance between the x-ray tube's focal spot to the image receptor, is also variable with the image receptor being able to move toward or away from the x-ray tube. Furthermore, the use of Automated Exposure Rate Control (AERC) enables the device to set the radiological parameters (the tube voltage, kVp, and tube current, mA) according to the amount of radiation received by the AERC sensor, which is mounted adjacent to the image receptor. Thus a larger patient will attenuate more radiation, which in turn reduces the signal (radiation) to the AERC sensor, and reduces the image contrast. In such circumstances, the AERC system will automatically increase radiological parameters to improve image contrast, which increases the patient dose. Figure 1 demonstrates how the patient size has implications to patient positioning and, therefore, patient dose.

For a larger patient, operators commonly increase the SID as well as lower the patient table to facilitate the size of the patient. Such changes, in addition to high patient attenuation, contributes to an increase of patient dose. This occurs for several reasons. Firstly, the skin of the patient lying supine on the table will obviously get closer to the radiation source, increasing the radiation dose due to the inverse-square law (ISL). Secondly, by moving the image receptor away from the x-ray tube causes less radiation to be received by the receptor also due to the ISL. Both the high attenuation and SID will contribute to inducing the AEC to adjust the the tube voltage and/or current, which will have an effect on patient dose. The influence of patient size to patient radiation dose has been discussed by Kotre *et al*. (2005), involving an attempt to formulate a correction factor between Dose Area Product (DAP, or P_{KA}) and varying patient size, to incorporate them to standard ICRP reference patient [34].
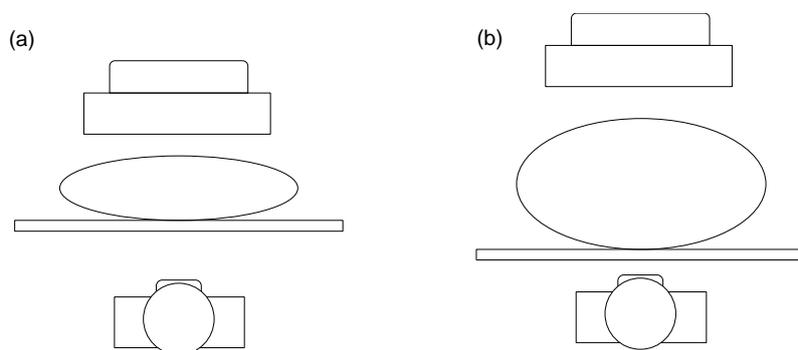
**Figure 1.** Distance setting of a (a) thin patient and (b) thick patient.

3. Current equipment advances

Real time patient dose monitoring has enabled operators to optimize dose during procedures, as well as provide accurate documentation in patient records for surveillance of deterministic effects. A number of tools are available to estimate patient skin dose in real time, including the Toshiba Dose Tracking System (DTS), Siemens CareGraph system, GE DoseMap and PEMNET. Of these, the PEMNET was the first to be developed. The PEMNET was an accurate and convenient method of monitoring patient dose, and was useful as a teaching tool in predicating deterministic effects, as well as practically evaluating the trade-off between image quality and patient dose [35]. However, the downsides include not taking into account overlapping fields from several sources [36] and the complexity involved in its installation.

The Siemens CareGraph used mathematical models to monitor real time skin dose, with reports of estimation of peak skin dose within 15% accuracy in the anterior posterior plane [37]. However, an underestimation of 67% in the lateral planes proved a downfall and a lack of demand eventually lead to discontinuation of the system. A similar system developed by Toshiba has been tested in studies of its efficacy in interventional procedures; with dose distribution was found to correlate well with directly measured values. The software was found to estimate dose rate at patient skin within 10% [38,39]. The GE DoseMap system was introduced in 2013 to monitor real time dose in fluoroscopic units, however at time of writing no studies validating this system currently exist.

4. Present limitation and challenges

Currently two machine dose metrics are used as a surrogate for patient dose: Reference Air Kerma and DAP (or Kerma-Area Product). However, these values, whilst a good indication for the radiation output of the system, are not accurate predictors for peak skin dose. Balter (2006) illustrates that based on patient size and reference point locations, the dose measurement point on units may not coincide with the patient's skin [40]. Chida *et al.* (2011) concluded that understanding the different regulations regarding interventional reference points may lead to better indirect dose estimations [41]. It was found that different manufacturers might use different reference points of measurements. This would lead an error in dose calculations if the reference point was assumed as the IEC standard.
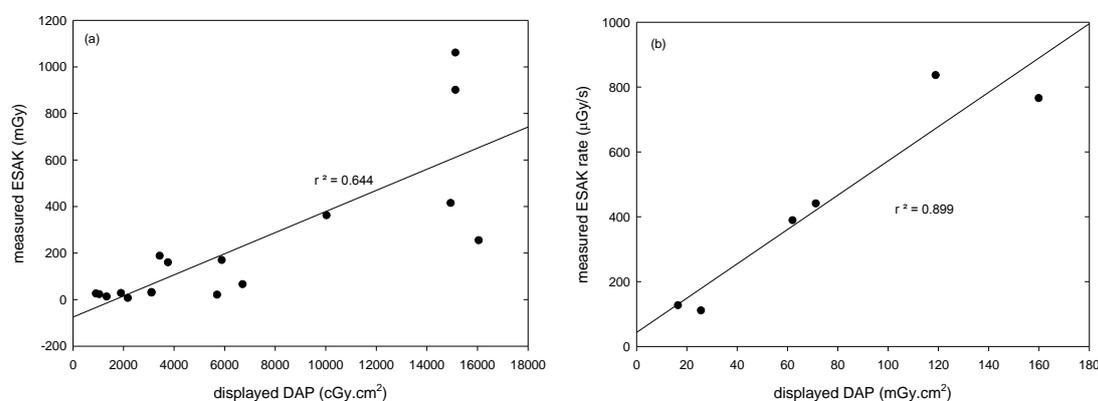
Figure 2. Correlation between displayed DAP and (a) accumulated ESAK in patient and (b) ESAK rate in phantom; both showing weak correlation ($r^2 < 0.95$). Graphs was reproduced from Yohannes *et al*. (2003) (a) and a recent work of the author (b).

DAP is currently the most commonly recorded and used to assess radiation safety in FGI. This value is used to compare the difference of radiation exposure between cases and to set threshold dose limits for deterministic effects. However, it is limited in predicting deterministic effects since the same DAP value could be used to describe a high intensity beam in a small area or a low intensity beam in a large area. Chu *et al*. (2006) used Gafchromic Film® to correlate peak skin entrance dose to the more readily available parameters: DAP and fluoroscopy time. Yohannes *et al*. (2003) had carried out a slightly similar work with TLD measurement, finding entrance surface dose correlation with DAP [42]. The results of both studies show weak correlations and that current estimation methods do not provide values which correspond closely to the direct measured dose at the patient's skin [43]. We also compared the work of Yohannes *et al*. (2003) with our recent measurement in phantom, as seen on figure 2 (b), imposing similar idea to that of Yohannes *et al*. Results from van de Putte *et al*. (2000) agree with this finding however they suggest that using DAP averaged over a large group was a reasonable indicator of skin dose rather than being a reliable method for per patient specific skin dose calculation [44].

5. Conclusion

With the increased prevalence on fluoroscopically-guided interventions, there lies a notable increase of concern on the delivered radiation dose to patients. Aside from the available direct, independent measurement tools all of which have their limitations, some modern x-ray units are equipped with sophisticated tools with ability to present real-time patient dosimetry. These tools, however, have demonstrated a range of shortcomings (i.e being manufacturer bound, poor accuracy) that warrant further investigation. As a result, radiation dose measurement to patients undergoing FGI remains a challenge. Improvements in this field will lead to optimising patient dose monitoring through improved measurement and estimation methods. Reliable accuracy will enable clinicians to ensure better patient care through ongoing radiation dose optimisation.

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