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Patient radiation dose during diagnostic and interventional cardiology procedures: A study in a tertiary hospital

Abstract

Background: Fluoroscopy-guided diagnostic and interventional cardiology (IC) procedures help to identify and treat several problems associated with the heart. However, these procedures expose patients, cardiologists, radiographers, and nurses to radiation doses. Due to the risk that ionizing radiation poses, concerns have been raised and studies are continually being done to ensure that optimization is achieved during such procedures. This study assessed patient radiation dose during diagnostic and interventional cardiology procedures as well as right heart studies at a tertiary hospital in Ghana to formulate the facility's diagnostic reference levels (DRLs) for optimization purposes. As this study was the first of its kind in Ghana, it was a vital step towards dose optimization within the local department, as well as contributing to future DRLs in Ghana.

Methods: The study collected dose (air kerma, and kerma area product (KAP) and procedural data, and assessed any correlation between parameters such as fluoroscopy time and KAP, and between body mass index (BMI) and KAP. The DRL values were determined as the 75th percentile level for the dose distribution for the various IC procedures including percutaneous coronary interventions (PCI), coronary angiography (CA), and right heart catheterization (RHC). Data were analyzed using SPSS version 23.

Results: CA was the most frequently performed IC procedure (77.3%), while RHC was the least recorded (3.3%). The highest mean KAP was observed during the PCI procedure. The proposed diagnostic reference levels (DRLs) were 162.0 Gy.cm² (PCI), 69.4 Gy.cm² (CA), 39.8 Gy.cm² (RHC) and 159.9 Gy.cm² (CA+PCI). Patients who presented for the CA+PCI and RHC procedures received the highest and lowest mean KAP of 159.9 Gy.cm² and 39.8 Gy.cm² of radiation respectively.

Conclusion: This study, therefore, concludes that there is a need for dose optimization of radiation exposures for IC procedures at the cardiothoracic center in Ghana.

Keywords: Interventional cardiology, fluoroscopy, radiation, dose, kerma area product

Introduction

The use of interventional radiology and fluoroscopy as an imaging modality that uses continuously emitted x-rays allows real-time visualization of body structures and real-time capture of dynamic images [1]. Interventional cardiology (IC) examinations include coronary angiography (CA), percutaneous coronary intervention (PCI), right heart catheterization (RHC), and radiofrequency catheter ablation (RFA). These procedures in particular, restore good blood flow to the heart using fluoroscopy techniques. The use of interventional radiography and the number of fluoroscopically guided IC procedures have tremendously increased in recent times [2,3]. Due to advancing technologies, the number and complexity of IC procedures have also increased [4]. Notwithstanding its benefits, IC procedures are associated with high levels of radiation and hence, pose health risk to patients presenting for them. The complexity of IC procedures requires longer fluoroscopic duration resulting in increased exposure to patients and medical staff [4].

Radiation quantities that may be used to assess patient dosimetry are fluoroscopy time, dose area product (DAP) or kerma area product (KAP), the number of cine frames, cine time, effective dose, skin dose and coronary dose [5]. As indicated in the literature, KAP is a measure of dose intensity or total amount of radiation delivered to a patient and numerically equal to the product of air kerma and the X-ray radiation field area (area of irradiated tissue) [6, 7]. It is also a cumulative sum of the instant x-ray energy delivered to air and x-ray field area (exposure area), and includes field non-uniformity effects, such as anode heel effect, and the use of semitransparent beam-equalizing shutters (lung shutter) [8,9]. Mathematically, for diagnostic x-rays, the KAP (or dose-area product [DAP]) is the integral of air kerma (the dose delivered to a defined volume of air) across the entire x-ray beam emitted from the x-ray tube or over a plane perpendicular to the central of the x-ray beam multiplied by the beam area in the same plane [10] (eqn. 1):

$$P_{KA} = \int_A K_a(x,y) dx dy \quad (1)$$

where Ka is the air kerma and $dx dy$ is the beam area. The DAP is quantified as

$$DAP = D_{ab} A \quad (2)$$

where D_{ab} is the absorbed dose and A is the irradiated area. For purposes of practical radiation protection, the KAP is related to the DAP via the expression

$$DAP = KAP (1-g) \quad (3)$$

where g is the fraction of energy of liberated charged particles lost in radiative processes in the material and the dose is expressed in absorbed dose to air [11]. Since g for diagnostic X-rays is only a fraction of a percent,

$$DAP \approx KAP \quad (4)$$

The value of KAP is approximately invariant or independent of source distance (distance to the tube focus). This is because, in accordance with the inverse square law and for a given solid angle, Ka is proportional to the inverse square of the distance, and the beam area varies with the square of the distance, assuming zero air attenuation. Thus, KAP can be measured at any plane between the collimator and the patient which is the appropriate way to measure the total amount of radiation incident on the patient [12]. Since KAP indicates the total amount absorbed in a volume of tissue, it estimates the potential for stochastic effects. In contrast, air kerma is generally utilized to estimate the potential for deterministic (i.e. skin effects). These are important measurements and are useful in assessing radiation risks from diagnostic X-ray and interventional procedures [13,14]. It is however not directly useful for estimating tissue reactions.

Presently, there is no documentation of radiation dose levels in IC procedures performed in Ghana. Formulation of facility reference levels is a vital step towards dose optimization within the local department, as well as contributing to future DRLs in Ghana. The study was therefore

aimed at collecting dose and procedural data for diagnostic and interventional coronary angiography, as well as right heart studies, identifying any correlation between parameters such as fluoroscopy time and KAP, and between body mass index (BMI) and KAP, and utilizing this data to formulate facility DRLs and compare values with other published dose reference levels. As this study was the first of its kind in Ghana, it is seen as a vital step towards dose optimization within the local department, which will hopefully inspire other centers to do the same, leading to the formulation of future national DRLs in Ghana.

Materials and Methods

The study site was conducted at the cardiothoracic center of a tertiary hospital which provides for cardiothoracic surgeries and IC procedures. A non-probability purposive sampling method was used to deliberately select a population of 300 adult patients (≥ 18 years) presenting for IC procedures at the study site which operates a Phillips 120-131 EM HS 01 A05308 fluoroscopy X-ray machine. A retrospective quantitative cross-sectional study design was used as readily available patient KAP clinical data retrospectively documented between February 2019 and December 2020 at the Centre was required. Archived data of IC procedures performed over the study period were retrospectively retrieved from the facility workstation. The radiation dose data included fluoroscopy time, patient dose, mean tube potential, mean tube current, and mean tube filtration. Diagnostic reference levels (DRLs) are typically determined at the local, national, and international levels and may be used to examine and assist dose optimization processes and image quality [15].

Most national DRLs exist for a specific procedure and are as a means to promote optimization in patient radiation protection and to also serve as a basis for comparison when new levels are being set [15]. In this study, the DRL values were determined as the 75th percentile level

for doses, KAP and fluoroscopy time distribution quantities for the various IC procedures. The patients' demographic characteristics included identification number (ID), gender, age, weight, and height. Scatter plots and Pearson's correlation analyses were used to determine correlations between patients' anthropometry and measured doses. Descriptive statistics were generated with a Microsoft Excel 2016 spreadsheet and represented in the form of frequencies, percentages, 75th percentiles, means, and standard deviations. SPSS version 23.0 was used for data analysis and inferential statistics.

Ethical approval was provided by the Ethical and Protocol Review Committee (EPRC) of the University of Ghana School of Biomedical and Allied Health Sciences (SBAHS). Confidentiality and anonymity of patients were ensured by using a patient identification number in accordance with ethical considerations.

Results

Patient Characteristics

From Table 1, both male ($n=215$, 71.7%) and female ($n=85$, 28.3%) patients presented for all the IC procedures. Specifically, there were more male presentations for the various IC procedures except for RHC where more females ($n=9$, 3.0%) presented. Coronary angiography was the most frequently (77.3%) performed IC procedure (males: $n=168$, 6.0%; females: $n=64$, 21.3%). The mean age of the population was 57.9 ± 3.2 years (range: 21 to 84 years; median: 61). The youngest patients (20 - 29 years) had the least turnout of 5 patients (1.3%). Out of 232 patients who presented for the CA procedure, 227 of them (97.8%) were aged 40 – over 80 years, of which the majority were aged 60– 69 years ($n=83$, 27.7%).

Table 1: Patient characteristics

Demographic		IC procedures <i>n</i> (%)				
		PCI	CA	RHC	CA + PCI	Total
Gender	Male	20 (6.7)	168 (56.0)	1 (0.3)	26 (8.7)	215 (71.7)
	Female	8 (2.7)	64 (21.3)	9 (3.0)	4 (1.3)	85 (28.3)
	Total	28 (9.4)	272 (77.3)	10 (3.3)	30 (10.0)	300 (100)
Age (yrs)	20 – 29	0	1	4	0	5 (1.7)
	30 – 39	0	4	3	2	9 (3.0)
	40 – 49	2	33	2	6	43 (14.3)
	50 – 59	11	59	1	9	80 (28.7)
	60 – 69	7	83	0	11	91 (33.7)
	70 – 79	7	41	0	2	50 (16.7)
	80 – 89	1	11	0	0	12 (4.0)
	Mean	62.7	61.3	34.6	56.5	57.9±3.2
	Median	61.0	62.0	34.0	57.5	61.0
Weight (kg)	Min	47	45	51	51	45
	Max	119	159	163	125	159.2
	Mean	85.3±15.0	82.4±15.0	68.7±8.1	83.3±15.2	82.3±15.2
	Median	84.0	80.0	66.3	83.0	80.25
Height (cm)	Min	151	130	154	152	130
	Max	190	191	179	185	191
	Mean	169.2±9.7	169.2±8.8	167.5±8.1	170.8±8.3	169.2±8.8
	Median	171.0	170.0	167.5	170.0	170.0
Mean BMI (kg/m ²)		29.8	28.9	24.5	28.6	28.8
Median BMI (kg/m ²)		24.5	27.7	19.8	24.4	23.6

Key: *n*=number, %=percentage, BMI=body mass index, Max=maximum, Min=minimum, PCI=percutaneous coronary interventions, CA=coronary angiography, RHC=right heart catheterization, CA+PCI= combination of coronary angiography and percutaneous coronary interventions

Patients in all age categories underwent the CA procedure. Most patients referred for the CA + PCI combination and PCI procedures were aged 60–69 years (*n*=11, 3.7%) and 50 –59 years

($n=11$, 3.7%) respectively. No CA + PCI, and PCI procedures were performed among patients under 29 years and over 80 years. PCIs were not performed on patients under 39 years. The RHC procedure was the least performed procedure (3.3%) and was mostly (40.0%) done on the youngest patients. Older patients had higher BMI (28.6 kg/m^2 - 29.8 kg/m^2), and RHC patients were younger and lighter (24.5 kg/m^2).

Dose Parameters and dose levels for Interventional Cardiology Procedures

Table 2 shows the exposure parameters used for the various IC procedures and the measured dose and KAPs. The mean tube voltage and current-time product for all the IC procedures were 79.5 kVp and 499.5 mAs respectively. The mean filtrations for CA, PCI, and CA+PCI procedures were the same (0.1mmCu), and the lowest was during PCI (0.086 mmCu).

Table 2: Exposure parameters and dose readings for IC procedures

IC procedures	Mean [median] exposure factors, and measured dose and KAP					
	Tube potential (kVp)	Tube current- time-product (mAs)	Filtration (mmCu)	Time (min)	Dose (mGy)	KAP (μGym^2)
PCI	79.7 [77.3]	536.3 [524.8]	0.086 [0.1]	30.5 [30.5]	3526.7 [3002.5]	16203.4 [15801.7]
CA	79.4 [77.3]	492.3 [483.1]	0.1 [0.1]	9.7 [8.7]	1126.5 [700.0]	6942.4 [4416.5]
RHC	78.4 [77.3]	492.2 [456.4]	0.1 [0.1]	9.1 [8.2]	395.0 [221.5]	3978.9 [2454.2]
PCI+CA	80.4 [77.3]	523.0 [505.5]	0.1 [0.1]	20.1 [19.5]	2611.3 [2618.0]	15980.9 [15980.9]
Total	79.5 [77.3]	499.5 [488.7]	0.93 [0.1]	12.7 [6.3]	1474.6 [777.5]	8611.9 [5569.7]

PCI=percutaneous coronary interventions, CA= coronary angiography, RHC= right heart catheterization, CA+PCI= combination of coronary angiography and percutaneous coronary interventions, KAP= Kerma area product, mmCu= mm of copper

The highest kerma doses were associated with PCI (mean: 3526.7mGy; median: 3002.5 mGy) and CA+ PCI (mean: 2611.3mGy; median: 2618.0mGy) procedures, and the lowest was during RHC (mean; 395.5mGy; median: 221.5mGy). As KAPs are the kerma area products, accordingly, the highest mean KAP values of 16203.4 μGym^2 (median 15801.7 μGym^2) and 15980.5 μGym^2 (median: 15980.9 μGym^2) were recorded in the PCI and CA+PCI procedures, respectively, while the lowest (mean: 3978.9 μGym^2 ; median:2454.2 μGym^2) was during RHC.

Correlation between examination parameters and anthropometry characteristics, and KAP

The Pearson rank correlation showed the existence of a strong positive correlation and statistically significant association ($R^2= 0.716$; $p = 0.001$) between fluoroscopy time and KAP (Figure 1).

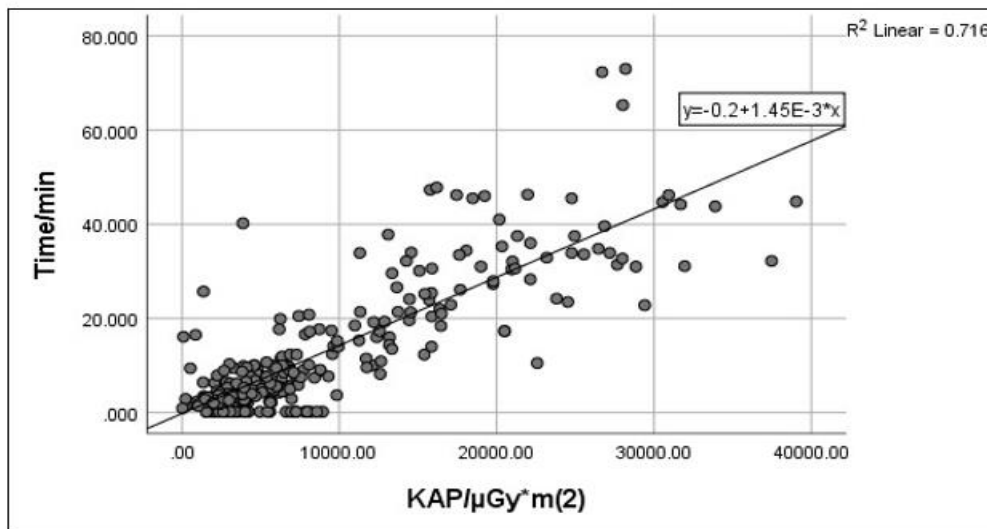


Figure 1: Relationship between KAP and fluoroscopy time

The linear relation between KAP and fluoroscopy time can be expressed as

$$T_f = 0.2 + 1.45KAP \times 10^{-3} \quad (5)$$

where T_f is the fluoroscopy time. Similarly, linear variations of the KAP with the tube voltage V_p and tube current I were found for the entire IC procedure (Figs 2 and 3) via the equations

$$V_p = 78.54 + 1.08KAP \times 10^{-4} \quad (6)$$

$$I = 0.0491 + 9.81KAP \times 10^{-4} \quad (7)$$

The Pearson rank correlations between KAP and patients' anthropometry were weakly positive (weight: $R^2 = 0.028$, $p = 0.01$; height: $R^2 = 0.001$, $p = 0.01$; BMI: $R^2 = 0.022$, $p = 0.01$). However, there was no significant relationship between KAP and age ($R^2 = 0.002$, $p = 0.684$). The Pearson correlations between the exposure factors and KAP were weakly positive with respect to tube voltage ($R^2 = 0.022$, $p = 0.01$) and insignificant for tube current ($R^2 = 0.002$, $p = 0.908$).

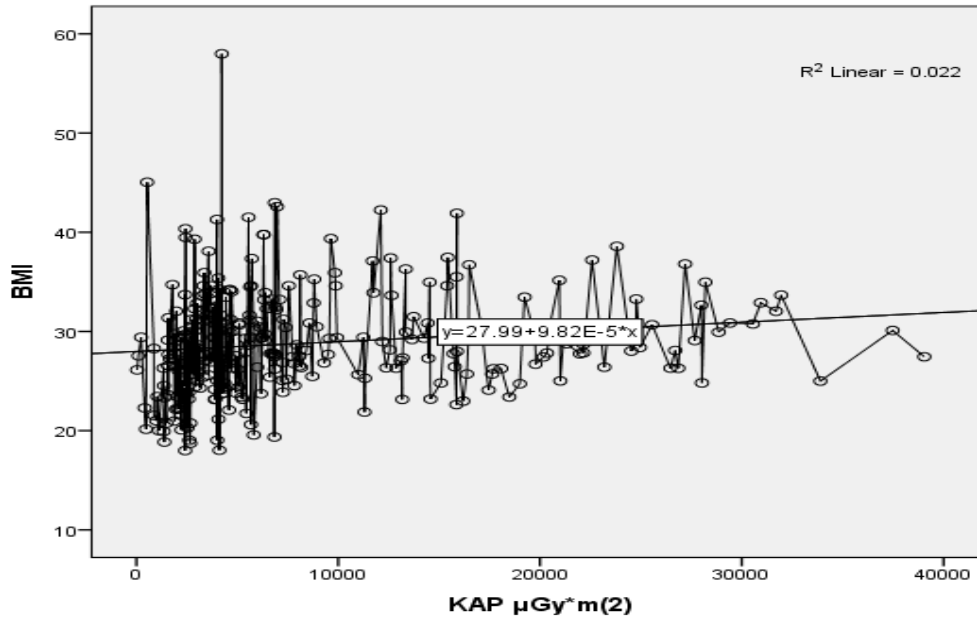


Figure 2: Relationship between KAP and BMI

75th Percentile Values for Dose, KAP, and Fluoroscopy Time

A diagnostic reference level (DRL) value is defined as an arbitrary national value quantity determined or set as a 75th percentile level of the distribution quantity under review. Accordingly, the 75th percentile values for fluoroscopy time patient air kerma, and KAP and distribution quantities for the IC procedures are shown in Table 3.

Table 3: 75th percentile of time, patient air kerma and KAP for each procedure

IC procedure	DRLs (75 th percentiles)		
	Fluoroscopy time (min)	Patient air kerma (mGy)	KAP (μGym^2)
PCI	40.2	5036.0	22102.1
CA	10.0	1140.8	7787.5
RHC	12.1	530.8	5911.0
CA+ PCI	27.4	3629.0	22888.8
Total	17.4	2137.5	12513.4

PCI=percutaneous coronary interventions, CA= coronary angiography, RHC= right heart catheterization, CA+PCI= combination of coronary angiography and percutaneous coronary interventions, KAP= Kerma area product, DRL= diagnostic reference level

The longest time (40.2 mins) and highest patient kerma (5036.0 mGy) were recorded in the PCI procedure, while the shortest time and least patient kerma were measured during the CA (10 mins) and RHC (530.8 mGy) respectively. The highest suggested DRLs (75th percentile) were associated with CA+PCI (22888.8 μGym^2), and PCI (22102.1 μGym^2) procedures respectively, while the lowest was during RHC (5911.0 μGym^2).

Diagnostic Reference Levels

The results of the DRLs are presented in Table 4.

Table 4: 75th percentile (DRLs) values for each examination and comparison with other studies conducted within the last 10 years.

Studies	DRLs (75 th percentiles) [Gy.cm2]			
	PCI/PT CA	CA	RHC	CA+PCI
Current study	221.0	77.9	59.1	228.9
Siiskonen <i>et al.</i> [19]	85.0	35.0	–	–
Georges <i>et al.</i> [20]	95.0	45.0	–	–
Järvinen <i>et al.</i> [21]	75	30	-	-
Ngaile <i>et al.</i> [22]	86.5	37.8	-	-
Rizk <i>et al.</i> [23]	124	45		147
Ou-Saada <i>et al.</i> , [24]	87.1	37.3	-	-
Hayashi <i>et al.</i> [25]	148 ⁺ / 312*	64	-	-
Subban <i>et al.</i> [26]	49.8	19.6	-	72

Key: PTCA= Percutaneous transluminary coronary angioplasty, PCI=percutaneous coronary interventions, CA= coronary angiography, RHC= right heart catheterization, CA+PCI= combination of coronary angiography and percutaneous coronary, interventions, KAP= Kerma area product. ⁺= percutaneous coronary intervention (PCI) excluding chronic total occlusion; * = PCI for chronic total occlusion.

Discussion

Patient and Procedure Characteristics

In this study, higher numbers of males proceeded to all the IC procedures with the exception of the RHC examination. Similar results were observed in a Polish study where more male patients presented for PCI diagnostic catheterization and CA examinations [16]. In another study, more females (55.8%) reportedly for CA procedures than males (44.2%), while a higher number of males proceeded to PCI than females [17]. From the authors' experience, several factors including the type of disease, availability of diagnostic and therapeutic facilities, as well as associated costs account for the gender-based presentation of patients for imaging examinations including IC procedures.

According to Brilakis *et al.* [18], old age is associated with health conditions such as advanced coronary atherosclerosis and greater coronary artery calcification which predisposes them to undergo interventional procedures. In line with this, the majority of patients who turned out for referrals. This is suggestive that older patients presented with underlying conditions and illnesses that predisposed them to undergo IC techniques.

The main fluoroscopy-based cardiology procedures performed at the facilities were CA, PCI, RHC and CA+PCI. CA was the most frequently performed IC procedure in this study. The same findings have been observed in the literature [19-26]. Compared to the other IC procedures CA is less complicated. The high rates of CA examinations could be attributed to the fact that it is one of the first lines of imaging procedures for assessing the extent of coronary artery disease before interventions are provided. In most cases, no intervention is needed after the CA procedures.

Doses levels in Interventional Cardiology Procedures

The observed radiation dose levels (both kerma and KAP as shown in Tables 2) associated with PCI procedures were the highest among all the procedures. This is not surprising because the highest mean and median values of tube current and fluoroscopy time were associated with the PCI procedure. Thus, patients who presented for elective PCIs received high doses of radiation resulting from the long use of fluoroscopy time which accounts for 80% of the patient air kerma during PCI procedures [27]. Other factors such as the operators' experience and their level of radiation protection training and awareness could have contributed observed trend in doses as supported by other studies [12, 28]. KAPs represent the total energy incident on the patients undergoing IC examinations, therefore there a need to optimize dose levels by collimating, reducing frames rates and using 'fluro save' mode instead of 'cine mode' when performing these procedures [15, 27,28].

CA+PCI was the next procedure that subjected patients to high radiation levels. This study found that high mean and median tube potentials were associated with CA+PCI examinations relative to other IC procedures. Moreover, the corresponding values for ~~mean~~ tube current, fluoroscopy time, dose, and KAP were also high. Similar findings of high dose parameters associated with the CA+PCI procedure have been reported [19]. High patient doses during such procedures may be attributed to the complexity of the procedure, as confirmed by Biso & Vidovich [28]. In particular, many combined IC procedures require an elective CA procedure of the coronary vessels, followed by PCI depending on the degree of stenosis within the vessel. However, elective procedures begin with known or identified stenotic or treated part and hence, use less radiation [19] compared PCI. The findings are consistent with results of other studies [8, 16-29] which found that patients who underwent PCI and CA+ PCI procedures received the highest KAP doses.

The RHC which is normally performed to check the pressure and blood flow in the right side of the heart recorded the lowest dose levels (median kerma and KAP: 221.5 mGy and 2454.2 μGym^2). The less complexity of procedure compared to the others and as well as the lesser exposure/fluoroscopy time associated with this procedure could have accounted for observed dose values.

Correlation between examination parameters and anthropometry characteristics, and KAP

The test of associations shows that there were weak positive correlations between KAP, and weight and height, although the relationships were statistically significant. These findings are also consistent with the literature where patients' weight ($R^2=0.028$, $p=0.01$), and height ($R^2=0.001$, $p=0.01$) weakly but positively correlated with KAPs [29-32]. Ahmed *et al.* [27] also reported no correlation between KAPs and BMI of patients presenting for CA and PCI procedures. These assertions could be attributed to the use of generally high patient doses regardless of their different body habitus.

The absence of significant associations between KAP, and tube potential, tube current, and age as found in this study is an indicative that other factors apart from exposure factors and age were heavily influencing KAP output. It is well known that IC procedures subject patients, radiographers, nurses and physicians to significantly high radiation doses due to prolonged fluoroscopy time and radiation exposure [33,34]. Consistent with this, a strong positive correlation and significant relationship between KAP and fluoroscopy time ($R^2= 0.716$; $p = 0.001$) was established in this study. This implies a long fluoroscopy time resulted in high radiation exposures and vice versa. On the contrary, Ahmed *et al.* [27] found a poor correlation between fluoroscopy

time and KAP and explained that IC procedures could be performed in shorter times but with an increased number of frames and vice versa.

Estimated DRLs and Comparison with other studies

Comparatively, the proposed DRLs were higher than as reported elsewhere in the literature. From Table 4, the 75th percentile KAP values obtained in this current study for all the procedures were higher than values reported in other studies conducted within the last ten years [19-26]. In particular, lower DRLs for PCI (49.8 Gy.cm²), CA (19.6 Gy.cm²) and CA+PCI (72 Gy.cm²) procedures have been reported [26]. Similar other relatively lower DRLs have also been proposed Gy.cm² [19-25] to indicate that there is room for personnel in the facility under study to adapt their techniques and use of the fluoroscopy machine and its related factors to optimize dose.

The high radiation doses reported in this study suggest a potential for reproductive genetic effects, taking into consideration the average age of the patients. This also ties in with the average age of the patients which will limit any potential issue with inheritable mutations.

Furthermore, the increased scatter radiation results in escalated or elevated occupational dose. The reason is that cumulative KAP correlates with the quantity of scattered radiation exposure to occupational staff, and directly with stochastic risk [5,6,9]. Therefore, there is a need for dose optimization of radiation exposures for IC procedures at the cardiothoracic centre, Radiation-sparing tactics such as decreasing fluoroscopy and cine acquisition times, and moderation of the fluoroscopy dose per frame to the minimum have been found to provide optimal image details with low dose in IC examinations [7,9,15]. Additional techniques that improve optimization in IC procedures include a reduction of field size by collimation, the use of an intermittent screening method, and a decrease in frame rate [8,9,28]. A comparison to others leads

to identification of higher than expected doses, and hence, it is needful of the Centre to identify possible strategies to lower dose and implement enhanced medical radiation protection strategies against risk of radiation effects.

Limitation

IC procedures in Ghana are generally low, and in particular, few RHC procedures are performed in the study site. As a result, the data recorded were low for some subset of patients in some instances (RHC = 10), and therefore, a generalizable conclusion must be drawn with caution. The results may also vary between centers as a result of the aforementioned limitations.

Conclusion

This study identified CA and PCI as the most numerous IC procedures in this Centre and thus, concludes that PCI and CAs are the most studied interventions. The study found that CA+ PCI and RHC procedures exposed patients to the highest and least levels of radiation, respectively. A positive correlation was found between KAP and fluoroscopy time. In accordance with the ICRP guidelines, DRLs for each IC procedure were proposed for purposes of promoting optimization although they are relatively high. The study successfully created DRLs for this Centre, which is the first cardiothoracic site in Ghana to do so. The study proposes dose optimization of radiation exposures for IC procedures at the cardiothoracic center in Ghana, after comparison to the literature as generally inferred.

Conflict of Interest

None declared.

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