ORIGINAL ARTICLE

Diagnostic Reference Level (DRL) of the Cardiac Catheterisation Procedures

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ABSTRACT

Introduction: The Diagnostic Reference Level (DRL) is a valuable tool for assessing radiation dose optimisation. In interventional procedures, the Kerma-Area Product (KAP) and fluoroscopic time (FT) are commonly used to evaluate radiation optimisation. However, few published research has studied DRLs for cardiac catheterisation procedures in Malaysia. Therefore, this study aims to compare the radiation dose received during the procedures at a single healthcare centre. **Materials and methods:** Retrospective analysis was conducted on 214 patients who underwent cardiac catheterisation between April 2021 and April 2022. Of these, 197 underwent coronary angiography, while 17 underwent angioplasty. **Results:** The 50th percentile of KAP and FT for coronary angiography was 19.14 Gy.cm^2, 1.8 min, while for angioplasty, it was 101.76 Gy.cm^2, 20.65 min. The observed KAP for both procedures exceeded the established Malaysia Ministry of Health (MOH) DRL. Spearman's rho correlation for coronary angiography showed significant associations between KAP and BMI ($r = 0.471$, $p < 0.001$, $n = 197$) and between KAP and FT ($r = 0.619$, $p < 0.001$, $n = 197$). However, for angioplasty, no significant correlation was found between KAP and BMI ($r = 0.395$, $p = 0.117$, $n = 17$) and KAP and FT ($r = 0.381$, $p = 0.131$, $n = 17$). **Conclusion:** The observed DRL exceeded MOH-established DRL, highlighting the need to refine radiation dose management strategies through staff training, equipment calibration, and procedural improvements. A higher DRL raises concerns about increased radiation exposure, which can elevate the risk of deterministic and stochastic effects.
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Keywords: Cardiac catheterisation, Diagnostic reference level, DRL, Fluoroscopic time, Kerma-area product

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INTRODUCTION

Cardiovascular disease remains the leading cause of mortality in Malaysia [1] and this trend has persisted since 2019. Cardiac catheterisation has been utilised for evaluation and treatment of ischemic heart diseases, particularly in cases of acute coronary syndrome such as unstable angina or a heart attack [2-3]. Coronary angiography and coronary angioplasty are two cardiac catheterisation procedures that serve as crucial diagnostic and therapy tools for patients with cardiovascular diseases.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) report highlights that cardiac catheterisation is a significant source of radiation exposure for patients [4]. Globally, the increasing number of these procedures raises concerns about radiation exposure for both operators and patients [5]. Excessive radiation exposure, including during cardiac catheterisation, can lead to deterministic (direct injuries) or stochastic (injuries that occur in proportion to cumulative radiation dose over time) effects on human tissues [6-9]. Deterministic radiation injuries occur when exposure exceeds a threshold dose, leading to cell death and organ dysfunction, such as radiation-induced skin damage and lens opacities. Stochastic radiation injuries develop over time and primarily manifest as malignancies affecting the skin, gastrointestinal tract, nervous system, and thyroid gland [7-8].

The Diagnostic Reference Level (DRL) is a crucial tool for optimising and managing radiation doses by identifying unreasonably high or low patient doses and providing guidelines for the average dose for the specific kind of imaging procedure. DRLs are not used as dose limits. Instead, it represents the direction of the higher reference values [10]. The establishment of DRLs was carried out by regulatory bodies, professional societies, or experts

in clinical and medical physics. National patient dose or dose index registers have been developed in several nations, while others, such as Indonesia, Ukraine, and Malaysia, have enacted legislation governing the establishment and utilisation of DRLs [11]. In Malaysia, the DRL for cardiac catheterisation procedures was established by the MOH and published in the Medical Radiation Exposure Report in May 2013, with an acceptable DRL limit of 5.4×10^{-7} Gy·cm . Since then, no updated local DRL has been published. As DRLs are recommended to be reviewed and updated every 3–5 years [7], the existing reference level appears to be outdated.

Radiation doses during interventional procedures can be measured through Kerma-Area Product (KAP) and fluoroscopy time (FT), which are both commonly used to evaluate radiation optimisation [12-13], analyse fluoroscopic equipment performance, operator competency, and compare radiation doses received for each examination to those recorded at other hospitals or standards [12]. KAP is derived for DRL because it is a product of the dose output and the area exposed, whilst FT demonstrates 'beam on' time [7]. KAP, as defined by Huda [14], represents the cumulative radiation exposure experienced by a patient. It serves as a measure of the total amount of radiation utilised during ionising procedures and provides an estimation of radiation absorbed by organs or tissues. Additionally, KAP can be employed to assess the probability of both stochastic and deterministic radiation risks [15].

FT and patient exposure dose are found to be strongly associated. A decrease in FT is expected to have an impact on the reduction of the patient's exposure dose. Several researchers have documented that the KAP value has a positive correlation with the increase in FT [16]. Prolonged utilisation of these procedures raises issues concerning radiation safety due to the requirement for longer fluoroscopy times and a higher quantity of images, resulting in substantial radiation exposure for both the patient and medical personnel [17]. Thus, both KAP and FT can be used to compare the effectiveness of equipment and operator abilities, to assess the optimal radiation levels utilised in radiological practise, and to assess current procedures across various centres [18]. Hence, this study aimed to investigate the Diagnostic Reference Levels (DRL) of cardiac catheterisation procedures at a specific healthcare institution in northern Peninsular Malaysia.

MATERIALS AND METHODS

Study design and population

This retrospective study involved secondary data from 214 patients who underwent cardiac catheterisation at a single private medical institution in northern Peninsular Malaysia. The cardiac catheterisation procedures were performed using a floor-mounted, single-plane C-arm Toshiba Cardiology System (Canon Medical Systems). The data was retrieved from the Clinical Information System (CIS) for the period from April 2021 to April 2022. This study retrieved information from patients aged 30 to 80 years old who underwent solely coronary angiography and solely single-vessel coronary angioplasty. The exclusion criteria for this study were patients who have undergone graft studies, complex multi-vessel coronary angioplasty, and fractional flow reserve (FFR) assessments.

Data collection

Demographic data were collected from 214 patients, including gender, age, height, weight, total KAP in Gy·cm , and FT in minutes (min) for coronary angiography and angioplasty procedures. The body mass index (BMI) was calculated using the recorded height and weight. To ensure patient confidentiality, only the specified demographic and procedural data were gathered, with no personally identifiable information recorded. Ethical guidelines on data protection were strictly adhered to, ensuring the privacy and anonymity of all patients.

Statistical analysis

The data were analysed using the Statistical Package for Social Sciences (SPSS) software, version 20. Patient demographic data were analysed descriptively. The mean, 25th percentile, 50th percentile, and 75th percentile were reported for KAP, FT, and BMI in coronary angiography and angioplasty procedures. Extremely high or low KAP values, potentially resulting from measurement errors, procedural anomalies, or patient-specific conditions, were identified and excluded from the dataset before determining the DRLs. Spearman's rho correlation analysis was performed to determine the correlation between KAP and BMI, as well as between KAP and FT, with statistical significance set at $p < 0.001$. The 50th percentile values for both procedures were then compared with the DRLs established by the MOH and those reported in the published literature. In this study, the 50th percentile or median was used as it is recognised to be more robust and better represents the patient population, particularly in a study conducted within a single healthcare facility [10].

Ethical Clearance

The study was approved by the Universiti Teknologi MARA (UiTM) Research Ethics Committee (FERC/FSK/EM/2022/0006) and conducted in accordance with the Declaration of Helsinki 1964. Consent was obtained from the participating radiology department.

RESULTS

Demographic characteristic

Among the 214 patients whose data was obtained between April 2021 and April 2022, 197 of them underwent coronary angiography, while 17 underwent

angioplasty procedures. Referring to Table I, the majority of patients undergoing coronary angiography were male, with 59.4% (n = 117) and 45.2% (n = 89) having an overweight BMI. Meanwhile, the majority of the patients who underwent the coronary angioplasty procedure were male, which comprises 94.1% (n = 16), and the majority of patients had a normal BMI (58.8%, n = 10).

Table I: Demographic data on gender and body mass index (BMI) categories for cardiac angiography and angioplasty procedures.

	Coronary angiography		Coronary angioplasty	
	Frequency	Percentage	Frequency	Percentage
Demographics	n = 197		n= 17	
Gender				
Male	117	59.4	16	94.1
Female	80	40.6	1	5.9
BMI groups				
Underweight	2	1	-	-
Normal	61	31	10	58.8
Overweight	89	45.2	2	11.8
Obese	33	16.8	4	23.5
Severely obese	12	6.1	1	5.9

Mean and percentiles of Kerma-Area Product (KAP), fluoroscopy time (FT) and body mass index (BMI) for cardiac catheterisation

Table II show the cardiac catheterisation procedure's mean and percentile values. The mean values of KAP, FT, and BMI for both coronary angiography and angioplasty procedures were 26.72 Gy.cm^2, 4.0 min, and 27.38 kg/m^2, and 93.39 Gy.cm^2, 14.55 min, and 26.32 kg/m^2, respectively. The 50th percentile values of KAP, FT, and BMI for the coronary angiography procedure were 19.14 Gy.cm^2 (with a range of 6.35 - 471.1 Gy.cm^2), 1.8 min (with a range of 0.6 - 88.7 min), and 26.36 kg/m^2 (with a range of 14.86 - 49.33 kg/m^2), respectively. The 50th percentile values of KAP, FT, and BMI for the coronary angioplasty procedure were 101.76 Gy/cm^2 (with a range of 26.97–212.42 Gy/cm^2), 13.0 min (with a range of 5.9–35.2 min), and 24.91 kg/m^2 (with a range of 19.2–37.7 kg/m^2), respectively.

Table II: Mean and percentiles of for Kerma-Area Product (KAP), fluoroscopy time (FT), and BMI for coronary angiography and angioplasty procedures.

	KAP (Gy.cm2)	FT (min)	BMI (kg/m2)
Coronary angiography procedure.			
Mean	26.72	4.00	27.38
10th percentile	10.09	0.90	21.23
25th percentile	13.81	1.20	24.37
50th percentile	19.14	1.80	26.36
75th percentile	26.59	2.80	29.83
Coronary angioplasty procedure.			
Mean	93.39	15.72	26.32
10th percentile	27.91	7.58	19.31
25th percentile	56.11	11.30	23.24
50th percentile	101.76	20.65	24.91
75th percentile	110.95	28.40	30.86

Correlation between Kerma-Area Product (KAP) and body mass index (BMI)

The Shapiro-Wilk Normality test was performed on KAP, FT, and BMI values for both coronary angiography and coronary angioplasty, indicating that the data was not normally distributed. Therefore, Spearman's rho was employed to find the correlation between KAP and BMI, and between KAP and FT. For the coronary angiograph, a statistically significant and positive correlation was seen between KAP and BMI, n (197) = 0.471, p = 0.000 (p < 0.001). However, for coronary angioplasty, no statistically significant correlation was found between KAP and BMI, n (17) = 0.395, p = 0.117 (Table III).

Table III: Correlation between KAP and BMI in coronary angiography and coronary angioplasty procedures.

			Coronary angiography		Coronary angioplasty	
			KAP (Gy.cm^2)	BMI (kg/m^2)	KAP (Gy.cm^2)	BMI (kg/m^2)
Spearman's rho	KAP (Gy.cm2)	Correlation Coefficient	1.000	0.471**	1	0.395
		Sig. (2-tailed)		0.000		0.117
		N	197	197	17	17
	BMI (kg/m2)	Correlation Coefficient	0.471**	1	0.395	1
		Sig. (2-tailed)	0.000		0.117	
		N	197	197	17	17

**. Correlation is significant at the level 0.01 level (2-tailed).

Correlation between Kerma-Area Product (KAP) and fluoroscopy time (FT)

The correlation between KAP and FT for both coronary angiography and coronary angioplasty was determined using Spearman's rho. Both coronary angiography and coronary angioplasty showed statistically significant and positive correlation between KAP and FT, n (197) = 0.619, p = 0.000 (p < 0.001), and n (17) = 0.673, p = 0.003, respectively (Table IV).

Table IV: Correlation between KAP and FT in coronary angiography and coronary angioplasty procedures.

			Coronary angiography		Coronary angioplasty	
			KAP (Gy.cm^2)	FT (min)	KAP (Gy.cm^2)	FT (min)
Spearman's rho	KAP (Gy.cm2)	Correlation Coefficient	1.000	0.619**	1.000	0.381**
		Sig. (2-tailed)		0.000		0.131
		N	197	197	17	17
	FT (min)	Correlation Coefficient	0.619**	1.000	0.381**	1.000
		Sig. (2-tailed)	0.000		0.131	
		N	197	197	17	17

**. Correlation is significant at the level 0.01 level (2-tailed).

Comparison of Diagnostic Reference Levels (DRL)

The Diagnostic Reference Levels (DRLs) for both procedures were observed and compared with the established DRLs by the MOH and published literatures. Table V shows the measured KAP values for coronary

angiography and coronary angioplasty, which were 19.14 Gy.cm^2 and 101.76 Gy.cm^2, respectively. These values were found to be higher than the established DRL by the MOH, which is 5.4 x10^{-7} Gy.cm^2.

Table V: DRL of this study.

Procedure	Coronary angiography	Coronary angioplasty	Established DRL by MOH
KAP (Gy.cm^2)	19.14	101.76	5.4 x 10^{-7}
Fluoroscopy time (min)	1.80	20.65	

Table VI shows the observed coronary angiography and angioplasty DRLs value in comparison to DRL values reported in published literatures. The observed KAP was the second lowest in comparison to published literatures, with the study conducted by Ahmed et al. (19) reported the lowest. Nevertheless, the observed FT was the shortest (1.80 min) when compared to all the published literatures. In contrast, Simantirakis et al. (17) reported an FT of 5.4 min, while Al-Jabari et al. (18) reported an FT of 5.3 min.

Table VI: Comparison of observed coronary angiography and angioplasty DRLs with literatures.

Study	KAP (Gy.cm^2)	Fluoroscopic time (min)
Coronary angiography.		
This study	**19.14**	**1.80**
Al-Jabri et al. (2018)	60.9	5.3
Kulkarni et al. (2019)	21.0	3.5
Kim et al. (2016)	32.6	2.3
Zanca et al. (2020)	63.1	3.0
Zucca et al. (2020)	21.0	2.8
Rizk et al (2019)	26.0	3.0
Kim et al (2019)	33.1	2.8
Simantirakis et al (2013)	37.9	5.4
Georges et al (2017)	20.8	3.3
Crowhusrt et al (2014)	39.1	3.5
Miller et al (2012)	49.0	2.9
Ou-Saada et al (2020)	23.8	2.54
Ahmed et al. (2013)	17.9	3.4
Coronary angioplasty.		
This study	**101.76**	**20.65**
Al-Jabri et al. (2018)	174.0	20.2
Kulkarni et al. (2019)	111.5	14.9
Kim et al. (2016)	165.9	15.4
Zanca et al. (2020)	125.0	14.0
Zucca et al. (2020)	59.0	11.1
Rizk et al (2019)	75.0	11.0
Kim et al (2019)	102.6	13.04
Simantirakis et al (2013)	104.7	13.8
Georges et al (2017)	39.0	9.8
Crowhusrt et al (2014)	87.4	11.2
Osei et al (2019)	80.2	12.7
Miller et al (2012)	117.0	11.0
Ou-Saada et al (2020)	57.5	9.3
Ahmed et al. (2013)	50.3	14.8

The coronary angioplasty DRL observed in this study was within the range of DRLs reported in published literature. The observed KAP was higher than studies conducted by Zucca et al. [20], Rizk et al. [21], Georges et al. [12], Crowhurst et al. [7], Osei et al. [22], Ahmed et al. [19], and Ou-Saada et al. [23]; and lower than studies conducted by Sharma et al. [24], Zanca et al. [25], Kim et al. [26], Simantirakis et al. [17], and Miller et al. [27]. Meanwhile, the observed FT was lower than the studies conducted by Kim et al. [26], Simantirakis et al. [17], Zanca et al. [25], Ahmed et al. [19], Sharma et al. [24], Kim et al. [28], and Al-Jabari et al. [18]. Ou-Saada et al. [23] reported the shortest FT of 9.3 minutes.

DISCUSSION

Correlation between Kerma-Area Product (KAP) and body mass index (BMI)

ICRP publication 135 emphasized the importance of standardising the data by considering patient body habitus and weight differences [10]. Published research has consistently demonstrated a positive correlation between BMI and KAP. Kim et al. [26] reported that obese patients require greater radiation exposure during coronary angiography and coronary angioplasty. Additionally, Crowhurst et al. [29] found that individuals with a higher BMI (>30 kg/m^2) were 19.1 times more likely to receive a greater radiation dose. This demonstrates that increasing BMI in patients correlates to increased body thickness, necessitating a greater amount of x-ray energy to penetrate the thicker body tissue.

Another study was conducted to examine the impact of BMI on cardiac catheterisation procedures. The results showed that KAP increased with BMI for both coronary angiography and coronary angioplasty. However, this relationship was found to be statistically significant only for coronary angiography procedures. Additionally, it was observed that there was a rising trend in KAP as BMI increased [24]. The result coincides with the findings of this study, which revealed that significant results were exclusively observed in coronary angiography procedures. Both of these approaches demonstrate that BMI may not be a reliable predictor of elevated KAP.

Correlation between Kerma-Area Product (KAP) and fluoroscopy time (FT)

This study also evaluated the correlation between KAP and FT in coronary angiography and coronary angioplasty. The findings of this study show a statistically significant correlation between KAP and FT in both procedures, which were in agreement with the findings of previous studies conducted by Al-Jabri et al. [18] and Kim et al. [28].

Cardiac catheterisation usually involves a prolonged period of fluoroscopy and the acquisition of a large number of images. Consequently, the patient may experience prolonged exposure to radiation. KAP and FT can be employed to assess the optimal doses of radiation utilised in radiological practice. Nevertheless, FT is widely accepted as a standard for minimising the amount of radiation received by the patient [18].

Decreasing the FT will likely lead to a reduction in patient exposure. Total FT may be incorporated when calculating DRLs based on the patient's body habitus, but only in the coronary angiography procedure [25]. Ahmed et al. [19] argued that FT did not significantly correlate with increased KAP, and FT should not be the only factor considered when assessing the patient's dose [30]. Therefore, relying solely on FT for radiation optimisation can result in inaccurate outcomes and is not a recommended approach.

Comparison of diagnostic reference levels (DRL)

The findings from this study revealed that the DRLs for coronary angiography and coronary angioplasty were 19.14 Gy.cm^2 and 101.76 Gy.cm^2, respectively; and the corresponding FT were 1.80 min, and 20.65 min. The DRLs for cardiac catheterisation in this investigation were found to be significantly higher than the standard DRL set by the MOH, which is 5.4 x 10-7 Gy.cm^2.

The DRLs for cardiac catheterisation in this study were significantly higher than the standard DRLs set by the MOH, likely due to variations in BMI, body surface area (BSA), and gender among the study population and are consistent with publish studies [31-34]. The majority of participants in this study were overweight, obese, or severely obese and predominantly male. As BMI and BSA are closely related, an increase in BMI is typically associated with a larger BSA, both of which contribute to higher radiation doses during cardiac catheterisation. However, as this was a retrospective study, individual BSA values were not recorded.

Patients with higher BMI and BSA require greater radiation doses due to increased X-ray output needed to penetrate thicker body tissue, resulting in greater scatter radiation exposure for both patients and operators. Madder et al. [34] reported that patients with BMI ≥40 experienced a 2.1 times increase in radiation dose compared to those with normal BMI (BMI <25). Additionally, operating on obese patients led to a sevenfold increase in radiation exposure for the operator or cardiologist.

Similarly, higher BSA has been linked to significantly increased radiation doses, as greater X-ray energy is required to maintain optimal image quality. Moreover, patients with high BMI and BSA contribute to greater scatter radiation, as more radiation is absorbed and dispersed, leading to an overall increase in DAP and KAP [31].

Another possible causes of these findings include the characteristics and complexity of the lesion, the severity of the disease, and the patient's age and medical history. In a study conducted by Kim et al. [28], it was shown that the DRL in their study was higher, probably as a result of the increase in lesion complexity. Crowhurst et al. [29] pointed out that the complexity of the procedure can have a significant impact on the radiation dose. Furthermore, the lack of standardisation in coronary angioplasty can significantly impact radiation exposure [12]. Additionally, Georges et al. [12] stated that establishing DRLs for fluoroscopically guided operations like cardiac catheterisation is challenging because of the significant variation in patient radiation doses, even within the same institution.

The procedures in this study were conducted by three different cardiologists, whose knowledge of radiation protection may not be as comprehensive as that of radiologists and experience levels can vary between individuals. At this facility, Cardiologist A has over 20 years of experience, Cardiologist B has 10 years of experience, while Cardiologist C has less than 5 years of experience. Consequently, patients may receive higher radiation doses depending on the cardiologist's level of experience and procedural proficiency. This rationale aligns with the findings of Järvinen et al. [30], Crowhurst et al. [7] and Ahmed et al. [19], who have all demonstrated the influence of operator experience on patient radiation exposure.

Järvinen et al. [30] in their study reported high interhospital variation in dose levels, highlighting the critical role of operator expertise and procedural techniques in determining radiation exposure. More experienced operators are better able to implement advanced imaging strategies, including varied projections, collimation, and optimised cine imaging techniques, to reduce patient radiation dose effectively. Additionally, the study conducted, revealing that variations in radiation doses during coronary angiography and coronary angioplasty across different hospitals were relatively minor. This was attributed to extensive radiation safety training received by cardiologists in Finland, facilitating effective dose optimisation. However, the study did not specifically assess the expertise and procedural proficiency of cardiologists, leaving a gap in evaluating the direct impact of operator experience on patient radiation exposure.

Similarly, Crowhurst et al. [7] investigated the impact of operator experience; least experienced (registrars), interventional fellows, and the most experienced operators (consultants), on patient radiation exposure. Their findings revealed that registrars had significantly higher KAP values compared to fellows and consultants, indicating greater radiation exposure for patients. In contrast, consultants, with the highest level of experience, delivered the lowest radiation doses. This discrepancy was attributed to longer fluoroscopy times, more frequent repeat acquisitions (DA) due to catheter manipulation difficulties, and less efficient procedural techniques among the least experienced operators. These findings underscore the necessity of structured training programmes to enhance procedural efficiency and reduce radiation exposure, particularly among less experienced cardiologists.

Table VI show the published DRLs for cardiac catheterisation procedures. The DRL of this study shows a significant decrease in radiation exposure during the coronary angiography procedure when compared to recent studies by Zanca et al. [25], Zucca et al. [20], and Ou-Saada et al. [23]. This could be due to the implementation of the lowest FT in all the studies, as FT has the potential to impact KAP. Furthermore, the DRL of the coronary angioplasty in this investigation was within the reported range of 38.0 to 174.0 Gy.cm^2, as compared to previous studies conducted by Zanca et al. [25], Zucca et al. [20], and Ou-Saada et al. [23]. Therefore, this is consistent with prior research suggesting that the complexity of the lesion, differences in experience amongst the cardiologists, and the operator's skill could affect the DRL.

Local studies involving multiple facilities, modalities, and radiological procedures must be carried out to verify compliance with the national DRL. An investigation must be immediately begun if the number has repeatedly exceeded the standard DRL set by the MOH, enabling immediate corrective measures. As for the DRL of cardiac catheterisation procedures, it is essential that all parties involved, including cardiologists, cardiac catheterisation technicians or technologists, and cardiac radiographers, work together to address the issue. The issue could originate from equipment performance, exposure settings, and the choice of procedure approaches. The vendors may also be invited to assist in modifying the parameters. Nonetheless, the DRL audit procedure is not completed through a single evaluation [10]. Regular evaluations of equipment performance are essential for enhancing the optimisation process. This must be incorporated into the Quality Assurance Program (QAP). The ICRP recommended that each x-ray unit be inspected every three years, particularly following significant technological or software upgrades [10]. Furthermore, the MOH may mandate healthcare facilities and institutions to submit their quarterly and annual local or institutional DRL as an essential element of the QAP and for licence renewal, which may also be utilised for the National Diagnostic Reference Level registry. Consequently, regular monitoring and intervention may be implemented to identify any adverse trends, as outlined by the ICRP [10].

Multi-facilities, multi-modalities, and multiple radiological procedures, including cardiac catheterisation procedures are essential for validating the findings of this study and for developing a National Diagnostic Reference Level (NDRL) registry. The 75th percentile of the DRL number accurately represents the population, surpassing the median (50th percentile) employed in this study when multi-facility DRL studies are conducted. Approximately 20 to 30 healthcare facilities are considered sufficient for establishing the updated DRL value [10].

This study had several limitations. Firstly, the sample size for coronary angioplasty was small, with only 17 patients, which limited the ability to derive statistically significant findings. The small dataset was primarily due to the study's exclusion criteria. Additionally, a larger dataset could have been obtained if the hospital's information and clinical management systems had been updated. Among the 367 patients who underwent cardiac catheterisation between April 2021 and April 2022, 153 patients were excluded due to missing demographic data.

Secondly, this study was limited in scope as it focused solely on coronary angiography and coronary angioplasty procedures performed at a single healthcare centre in northern Peninsular Malaysia. Consequently, it was not possible to evaluate DRLs for all cardiac catheterisation procedures across the region or the country. This limitation restricts the development of local and national DRLs for cardiac catheterisation.

Another limitation was the outdated DRL established by the MOH. The initial and most recent DRL was released in 2013, about ten years ago. Given advancements in imaging technologies and modalities, it is recommended that DRLs be updated every 3–5 years. Furthermore, this study did not take into account factors such as the experience of cardiologists, the experience of operators, and the calibration of fluoroscopic units. The aforementioned variable has been demonstrated to significantly affect the dosage and the dose reference levels (DRLs) received by the patient.

Finally, the lack of detailed data on the study setting, including the type of equipment, X-ray system setup, cardiac catheterisation protocols, and operator preferences from published literature, all of which may influence the radiation dose received by patients. This limitation affects the comparability of this study's DRLs with those reported in the literature. Therefore, future studies should consider these factors to ensure more meaningful and reliable outcomes.

CONCLUSION

In conclusion, the DRLs observed in this study exceeded the levels established by the MOH, highlighting the need for enhanced monitoring of cardiac catheterisation procedures to optimise radiation doses. However, when compared with DRLs reported in the published literature, the DRL for coronary angiography in this study was the lowest, while that for coronary angioplasty remained within the acceptable range. A significant correlation was identified between KAP and BMI, as well as between KAP and FT, with this correlation being more prominent in coronary angiography procedures.

The elevated DRLs raise concerns about increased

radiation exposure, potentially heighten the risk of both deterministic and stochastic effects. These findings underscore the urgent need to refine radiation dose management strategies, including staff training, equipment calibration, and procedural modifications, to enhance patient safety and minimise unnecessary exposure. Radiation doses should remain within the defined DRLs and be routinely assessed to ensure compliance with the As Low As Reasonably Achievable (ALARA) principle in clinical practice.

Moreover, the findings of this study reinforces the necessity for the MOH to update national DRLs to align with current clinical practices and promote standardised adherence across healthcare institutions in Malaysia. Establishing updated reference levels will help improve radiation safety standards, ensuring optimal patient care while minimising unnecessary radiation exposure.

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