GAS Journal of Clinical Medicine and Medical Research (GASJCMMR)

Volume 2, Issue 4, 2025 Journal Homepage: https://gaspublishers.com/gasjcmmr/ ISSN: 3049-1568
Email: gaspublishers@gmail.com

Establishing Diagnostic Reference Level for Coronary Angiography and Percutaneous Transluminal Coronary Angioplasty – A Retrospective Study

Nandana krishna R[1], Dr. Aswathi Raj [1], Dr. Hridhya V T[1], Mrs. Athuliya K [1], Mr. Mohan Kumar Thota[1], Mrs. Bhavya Shree P[2]

[1] *ASTER Malabar institute of medical science, Calicut, Kerala, India*
[2] *Assistant Professor Division of Medical physics, School of life sciences- JSSAHER Karnataka, Mysuru*

Received: *08.05.2025* | ***Accepted:*** *12.05.2025* | ***Published:*** *14.05.2025*

***Corresponding Author:** *Nandana Krishna R*

DOI: *10.5281/zenodo.15403447*

Abstract **Original Research Article**

This research aimed to establish radiation Diagnostic Reference Levels (DRLs) for two commonly performed cardiac catheterization procedures, coronary angiography (CAG) (diagnostic) and percutaneous transluminal coronary angioplasty (PTCA) (therapeutic) at a tertiary care hospital.

The study focused on patients who underwent PTCA (200) and CAG (400) at our hospital between October 2024 and January 2025, on the advanced interventional radiological machines and the population is classified into two groups based on patient weight. Data collected are patient age, weight, dose surface product (P_{KA}), skin surface entry dose (K_{AR}) and fluoroscopic time. According to ICRP recommendations, the DRL was set for the entire population and was determined from the 75th percentile of the P_{KA} value for the corresponding weight category in each procedure.

In this study, the DRL established for the CAG and PTCA procedures is within the safety guidelines provided by the hospital and the regulatory board. The DRL for the CAG group is 2834 µGym² and for PTCA is 8963 µGym² which is within the limit.

It was observed that DRL linearly responds to the patient's weight, concluding that patient weight is a factor affecting DRL. The DRL can serve as an audit tool for quality analysis and improvement.

Keywords: Diagnostic Reference Levels, Coronary Angiography, Percutaneous Transluminal Coronary Angioplasty, Patient Radiation Dose, Interventional Radiology, Fluoroscopic Time, Patient Weight.

Citation: Nandana krishna., Aswathy Raj., Hridhya, V. T., Athuliya, K., Thota, M. K., & Bhavya Shree, P. (2025). Establishing Diagnostic Reference Level for Coronary Angiography and Percutaneous Transluminal Coronary Angioplasty – A Retrospective Study. *GAS Journal of Clinical Medicine and Medical Research (GASJCMMR)*, 2(4), 120-125, ISSN: 3049-1568.

INTRODUCTION

Cardiovascular disease is the leading cause of death globally and has been the second most common cause of death in the United States since 1975, accounting for 633,842 deaths [1]. For over three decades, invasive coronary angiography has been employed to diagnose and treat coronary artery disease (CAD) and the frequency of these procedures is on the rise [2]. CAG and PTCA procedures have become increasingly prevalent in recent years. Although high-dose diagnostic procedures represent only 10% of all ionizing radiation, they are estimated to contribute nearly 80% of the average cumulative exposure. In India, diagnostic x-rays account for 80% of the total population dose, and the UNSCEAR report indicates a roughly 50% increase in diagnostic cases over a decade. However, during lengthy and complex procedures the skin doses delivered are often very high [3].

The ICRP 135 provides guidelines for radiation protection in diagnostic radiography to prevent skin reactions like erythema, blisters, and in severe cases ulcers, and improve patient monitoring [4]. The core principle of patient protection in medical exposure is to maximize the therapeutic benefits of radiation while minimizing the dose to the lowest feasible level.

Even when the same treatment is used, the measured or irradiation dose in a radiology examination facility varies based on the professionals, patient, and hospital. Consequently, establishing a reference dose for a procedure has become crucial. According to guidelines the IAEA also advocates for the establishment of DRLs, based on the medical conditions in each country [4].To enhance patient dose management, the US and Europe are conducting DRL research on various diagnostic procedures and radiation exposure status surveys [5]. The latest study on the establishing DRL for cardiac procedure in India, New Delhi in 2021 shows the values are within the limit for the diagnostic procedure, more comprehensive study can lead to the formation of regional level and thereby the National level of DRL [6].

In accordance with ICRP 135 recommendations, the DRL was set for the entire population for each procedure and is determined by the 75th percentile of the P_{KA} [3]. If an audit reveals that a DRL for any procedure is consistently exceeded, then an investigation should be initiated without undue delay and appropriate corrective action should be taken. Corrective action should include a review of equipment performance, the settings used and the examination protocols [3]. Generally, it is easiest to check the x-ray system settings first as this is less time-consuming then review the examination protocols and finally, how the operators use the examination protocols.

The aim of this study was to establish DRLs for two common cardiac catheterization procedures at a tertiary care hospital. This was intended to serve as a benchmark for ongoing quality assurance, audits and to assess the impact of patient weight on the skin surface entrance dose in the established DRL. This would also help create a framework for similar studies in other institutions, facilitating the development of a national reference level. Ensuring radiation safety in the catheterization lab is crucial due to the potential risks of ionizing radiation exposure to both patients and medical staff.

There are few articles in the scientific literature that provide clinical CT DRLs and some are usually specific to a particular indication focusing solely on fluoroscopically guided procedures [7]. Interventional cardiologists are usually exposed to the highest dose of ionizing radiation among the medical staff [8]. It is estimated that the exposure per head per year of this group is 2to3 times higher than that of radiologists so the radiation safety aspect is crucial in cath1labs [9]. Generally, setting DRLs in the catheterization lab is rare and most do not provide much information on how DRLs respond based on the weight of adult patients.

METHODOLOGY

In this retrospective study, adult patients who underwent CAG and PTCA procedures at our hospital between October 2024 and January 2025 are included. The patient weight in the range of 75±25kg is collected for this study thus a 400- CAG and 200- PTCA cases are selected.

The DRL is calculated separately for each procedure as recommended by the guidelines. Then the CAG cases are equally divided into two groups, in group 1, the weight range is 50-70kg and for group 2 is 70-90kg. The DRL is calculated for all groups. The same method is followed for PTCA cases, but the classified weight range is 60-80kg and 80-100kg.

Each patient was assigned a unique ID, along with their age, weight, P_{KA}, K_{AR} and fluoroscopic time. The data collected were entered into an Excel spreadsheet, with separate files for PTCA and CAG cases. The procedures were conducted using SIEMENS ARTIS ZEE / Wipro GE Innova 2100 IQ. The X-ray energy range is from 80kV to 120kV, kV and mA values are selected automatically to acquire proper image quality. The frame per second is fixed for all patients at 15 frames per second.

DATA COLLECTION

Radiation Data collected include:

1. Fluoroscopic time -Ft(min)

The duration during which X-rays are used to create a real-time continuous image of the heart and blood vessels.

2. Dose area product -P_{KA}(μGym²)

It is the measure of the total radiation dose absorbed by a specific area of tissue. Generally, it provides a good index for estimating stochastic risk [11,12,13]. The official notation recommended in ICRU Report 74 is P_{KA}.

$$P_{KA}(\mu Gym^2) = \text{Dose} \times \text{beam area}$$

3. Total dose-area product-P_{KA}(μGym²): Total exposure includes all radiation exposure throughout the procedure, including fluoroscopy and cine angiography [11,12,13].

4. Total skin surface entrance dose - K_{AR} (mGy): The Skin surface entrance dose is the measure of the radiation dose that is absorbed by the skin as it reaches the patient. The International Electrotechnical Commission defines a patient entrance reference point as 15cm from the isocenter of a C-arm x-ray unit. Obese patients may have a dosage increase of up to 80 times the usual dose.

$$K_{AR} = BSF \times \text{Tube output} \times (100/FSD)^2 \times mAs$$

Where BSF is the backscatter factor, Tube output is the beam output in μGy/mAs of the X-ray tube at different kVp settings at a distance of 1 m, mAs is the product of the tube current (mA) and the exposure time in seconds and FSD is the focus-to-skin distance used [13,14].

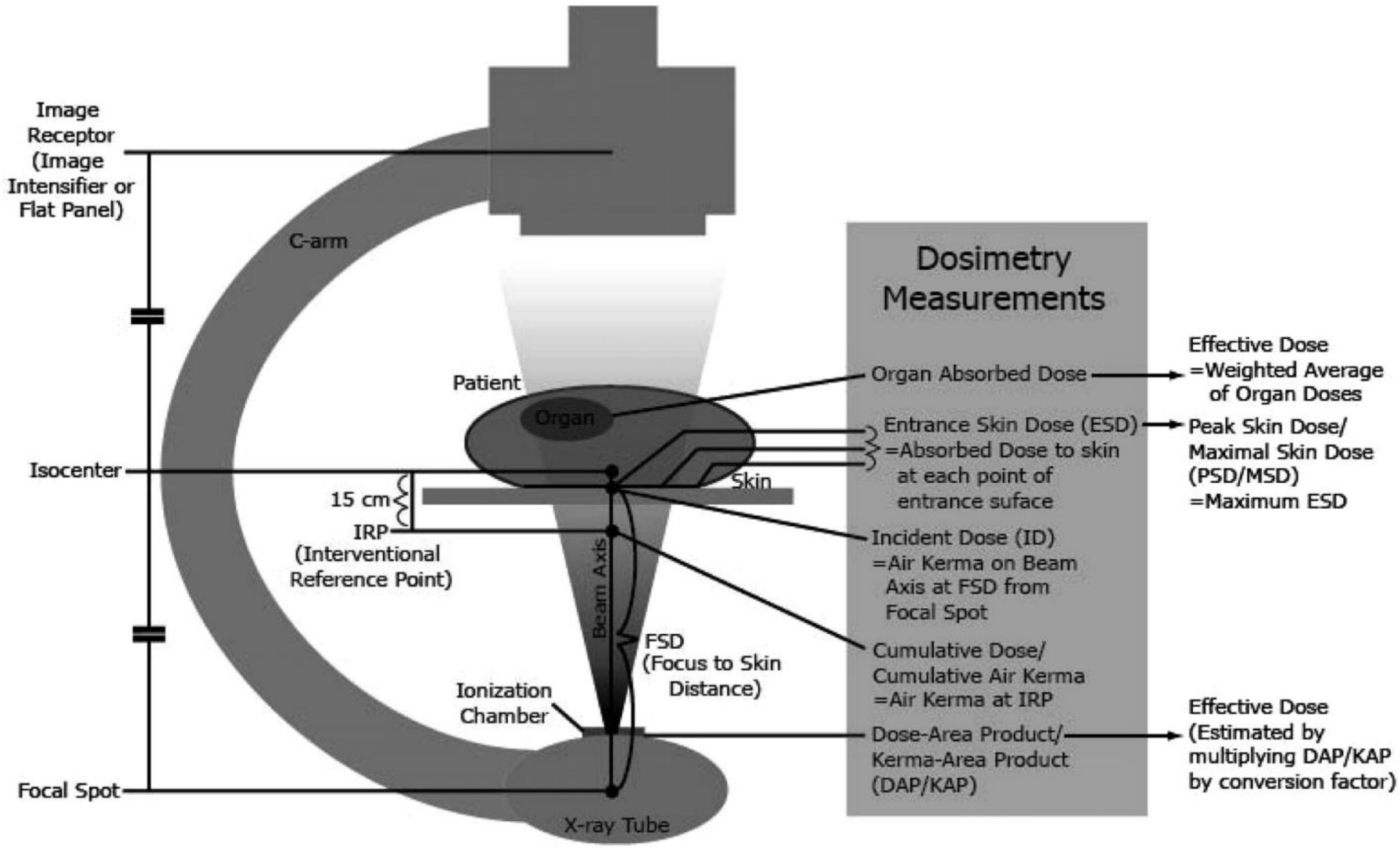

Figure 1: Fluoroscopy dosimetry terminology.

To calculate the DRL using P_{KA} and K_{AR},

(A) Calculate the average and median of the following parameters (a) P_{KA} (µGym²) (b)total P_{KA} (µGym²) (c)FT and (d)total K_{AR} (mGy) for all groups of CAG and PTCA [11].

(B) The 75th percentile of the total P_{KA} was taken as the DRL for the entire population for each procedure as per ICRP 135 recommendations [3].

RESULT AND DISCUSSION

In this study a total of 600 cases,400 diagnostic and 200 therapeutic were noted for adult patients with a standard weight range of 75 ±25kg. The average, median and 75th percentile of P_{KA} and K_{AR} values for all the groups of CAG and PTCA cases are determined. The majority of the patients were males between the ages of 40 and 60.

The CAG group comprised of 400 patients, and the calculated DRL is 2834 µGym² with the median fluoroscopy time of 7 minutes 03 seconds. The PTCA group consists of 200 patients with a median fluoroscopy time of 33 minutes and 50 seconds, and DRL is 8962 µGym². The determined DRL is within the limit as recommended by ICRP 135. While comparing the DRL values for both procedures, PTCA has higher DRL than CAG because the DRL for therapeutic procedure will be always higher than the DRL of a diagnostic procedure due to the large fluoroscopic time needed for therapeutic procedure.

In table 2 and 3 the average, median and 75th percentile for P_{KA} and K_{AR} values are calculated and the DRL shows a linear response with the weight ,the DRL for lower weight group(50-70kg) is 2323 µGym² and for higher weight group (70-90kg) is 3498 µGym². While comparing table 5 and 6 it shows the same output like table 2 and 3 ie, the DRL determined for the higher category (80-100kg)is more than the lower weighted(60-80kg)category and the values are 11584 µGym² and 8433 µGym² respectively. Obese patients may have a dosage increase of up to 80 times the usual dose.

In this case, the DRL values are within the limit. Our analysis showed that the patient weight directly affects the P_{KA} and the DRL values. Patients with higher body mass index (BMI), generally require more fluoroscopy time and a higher overall radiation dose to achieve comparable image quality. This is because the x-ray beam needs to penetrate more tissue potentially leading to increased dose to the patient. The DRL increases linearly with the body weight of the population underwent the procedure.

Table 1: The average, median and 75th percentile of P_{KA}, total P_{KA} and K_{AR} values of the total number of CAG cases.

Parameters	Dose area product(P_{KA}) µGym²	Total dose area product (P_{KA}) µGym²	Total skin surface entrance dose (K_{AR}) mGy
Average	1505	4317	640
Median	970	3778	550
75th percentile	728	2834	413

Table 2: The average, median and 75th percentile of P_{KA}, total P_{KA} and K_{AR} values DRL of the 200 CAG patients with weight in the range of 50-70kg

Parameters	Dose area product(P_{KA}) µGym²	Total dose area product (P_{KA}) µGym²	Total skin surface entrance dose (K_{AR}) mGy
Average	1303	3603	527
Median	830	3098	411
75TH PERCENTILE	622	2323	309

Table 3: The average, median and 75th percentile of P_{KA}, total P_{KA} and K_{AR} values of the 200 CAG patients with weight in the range of 70-90kg

Parameters	Dose area product(P_{KA}) µGym²	Total dose area product (P_{KA}) µGym²	Total skin surface entrance dose (K_{AR}) mGy
Average	1707	5032	753
Median	1080	4664	652
75th percentile	80	3498	489

Table 4: The average, median and 75th percentile of P_{KA}, total P_{KA} and K_{AR} values of total PTCA patients

Parameters	Dose area product(P_{KA}) µGym²	Total dose area product (P_{KA}) µGym²	Total skin surface entrance dose (K_{AR}) mGy
Average	7558	14848	2530
Median	5209	11950	1855
75th percentile	3901	8963	13908

Table 5: The average, median and 75th percentile of P_{KA}, total P_{KA} and K_{AR} values of 100 PTCA patients weight ranges in 60-80kg.

Parameters	Dose area product(P_{KA}) µGym²	Total dose area product (P_{KA}) µGym²	Total skin surface entrance dose (K_{AR}) mGy
Average	4742	10696	1845
Median	4153	11244	1554
75th percentile	3115	8433	1165

Table 6: The average, median and 75th percentile of P_{KA}, total P_{KA} and K_{AR} values of 100 PTCA patients weight ranges in 80-100kg

Parameters	Dose area product(P_{KA}) µGym²	Total dose area product (P_{KA}) µGym²	TOTAL EXP(KAR) mGy
Average	9982	17922	3172
Median	7275	15445	2314
75th percentile	5456	11584	1735

CONCLUSION

This study made it possible to establish DRL in our hospital for coronary angiography and percutaneous transluminal coronary angioplasty procedures. The DRL was calculated for all groups to understand the role of patient weight in the determination of DRL and a linear relationship between the DRL and patient weight was observed. It was concluded that one of the factors influencing the DRL is patient weight and the DRL values obtained are within the acceptable range. DRLs act as benchmarks allowing to compare the radiation dose practices with established standards ultimately leading to a reduction in unnecessary radiation exposure.

FINANCIAL DISCLOSURE

None for all authors.

INSTITUTIONAL REVIEW BOARD STATEMENT

The study was approved by the institutional review board and the ethics committee, IEC Ref No. :109/24 date of approval 28.09.2024.

DECLARATION OF THE COMPETING INTEREST

"The author declares no conflict of interest."

REFERENCES

1. Mc Namara, K., Alzubaidi, H., & Jackson, J. K. (2019). Cardiovascular disease as a leading cause of death: how are pharmacists getting involved?. *Integrated pharmacy research and practice*, 1-11.
2. Coronado, F., Melvin, S. C., Bell, R. A., & Zhao, G. (2022). Global responses to prevent, manage, and control cardiovascular diseases. *Preventing chronic disease*, *19*, E84.
3. Chen, J. (2024). A summary of UNSCEAR evaluation on medical exposure to ionizing radiation and call for more representative data. *Radiation Medicine and Protection*, *5*(01), 7-10.
4. Vañó, E., Miller, D. L., Martin, C. J., Rehani, M. M., Kang, K., Rosenstein, M., ... & Rogers, A. (2017). ICRP publication 135: diagnostic reference levels in medical imaging. *Annals of the ICRP*, *46*(1), 1-144.
5. Faj, D., Edyvean, S., Lajunen, A., Katukhov, A., & Vassileva, J. (2023). Establishment and utilization of diagnostic reference levels in medical imaging: Results from a survey and consultation under the IAEA technical cooperation programme in Europe and Central Asia. *Physica medica*, *108*, 102565.
6. Kataria, V., Yaduvanshi, I., Singal, G., & Nair, M. (2021). Establishing a diagnostic reference level of radiation dose in coronary angiography and

intervention: A prospective evaluation. *Indian Heart Journal*, *73*(6), 725-728.

7. Wang, X., Ding, W., Xu, M., Zhang, W., & Zhang, M. (2020). Establishment of the DRL and warning dose value for CT examinations in our hospital and its application in chest CT dose optimization. *Chinese Journal of Radiological Medicine and Protection*, 543-548.
8. Leyton, F., Canevaro, L., Dourado, A., Castello, H., Bacelar, A., Navarro, M. T., ... & Rodrigues, B. (2014). Radiation risks and the importance of radiological protection in interventional cardiology: a systematic review. *Revista Brasileira de Cardiologia Invasiva (English Edition)*, *22*(1), 87-98.
9. Mohammadi, M., Danaee, L., & Alizadeh, E. (2017). Reduction of radiation risk to interventional cardiologists and patients during angiography and coronary angioplasty. *The Journal of Tehran University Heart Center*, *12*(3), 101.
10. Wang, X., Ding, W., Xu, M., Zhang, W., & Zhang, M. (2020). Establishment of the DRL and warning dose value for CT examinations in our hospital and its application in chest CT dose optimization. *Chinese Journal of Radiological Medicine and Protection*, 543-548.
11. Crowhurst, J. A., Whitby, M., Thiele, D., Halligan, T., Westerink, A., Crown, S., & Milne, J. (2014). Radiation dose in coronary angiography and intervention: initial results from the establishment of a multi-centre diagnostic reference level in Queensland public hospitals. *Journal of medical radiation sciences*, *61*(3), 135-141.
12. Harbron, R. W., Dreuil, S., Bernier, M. O., Pearce, M. S., Thierry-Chef, I., Chapple, C. L., & Baysson, H. (2016). Patient radiation doses in paediatric interventional cardiology procedures: a review. *Journal of Radiological Protection*, *36*(4), R131.
13. IAEA (Corporate Author), & IAEA (Corporate Editor). (2010). *Patient dose optimization in fluoroscopically guided interventional procedures*. International Atomic Energy Agency.
14. Alomairy, N., Hadi, D., Al-Zaid, A., Fasikh, R., Arif, R., Al-Hazmi, R., ... & Shubayr, N. (2023). Evaluation of the Entrance Surface Doses (ESD) for common diagnostic X-ray examinations. *Journal of Radiation Research and Applied Sciences*, *16*(4), 100754.
15. Sánchez, R., Vañó, E., Soto, J. M. F., Ten, J. I., Escaned, J., Delgado, C., ... & Tobarra, B. (2020). Updating national diagnostic reference levels for interventional cardiology and methodological aspects. *Physica Medica*, *70*, 169-175.
16. İnal, T., & Ataç, G. (2013). Dose audit for patients undergoing two common radiography examinations with digital radiology systems. *Diagnostic and Interventional Radiology*, *20*(1), 100.
17. Greffier, J., Ty, C. V. N., Bonniaud, G., Moliner, G., Ledermann, B., Schmutz, L., ... & Pereira, F. (2017). Assessment of peak skin dose in interventional cardiology: a comparison between Gafchromic film and dosimetric software em. dose. *Physica Medica*, *38*, 16-22.
18. Siiskonen, T., Ciraj-Bjelac, O., Dabin, J., Diklic, A., Domienik-Andrzejewska, J., Farah, J., ... & Vano, E. (2018). Establishing the European diagnostic reference levels for interventional cardiology. *Physica Medica*, *54*, 42-48.
19. Lee, M. Y., Kwon, J., Ryu, G. W., Kim, K. H., Nam, H. W., & Kim, K. P. (2019). Review of national diagnostic reference levels for interventional procedures. *Progress in Medical Physics*, *30*(4), 75-88.
20. Salama, D. H., Vassileva, J., Mahdaly, G., Shawki, M., Salama, A., Gilley, D., & Rehani, M. M. (2017). Establishing national diagnostic reference levels (DRLs) for computed tomography in Egypt. *Physica medica*, *39*, 16-24.