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Original Article

Establishing a diagnostic reference level of radiation dose in coronary angiography and intervention: A prospective evaluation

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ABSTRACT

Introduction: Invasive Coronary Angiography (CAG) leads to significant radiation exposure to the patients. Guidelines suggest that a local landmark or Diagnostic Reference Level (DRL) for these procedures should be established for every region and country. This study attempts to create a DRL for a tertiary care hospital, acting as an interim DRL for the country/region.

Methods: Radiation exposure data for all coronary procedures done at a tertiary care hospital between October 2016 to September 2018 were collected. Data was segregated into diagnostic Coronary Angiography (CAG) and single-vessel Percutaneous Intervention (PCI). The parameters collected include dose surface product (P_{KA}), skin surface entry dose (K_{AR}), and fluoroscopy time (FT). The 75th percentile of the P_{KA} was used to define the DRL.

Results: 500 Patients were included in the CAG group, in which the Median K_{AR} was 412.05 mGy, Median P_{KA} was 2635.7 μGysqm, and median FT was 2.25 min. The DRL for coronary angiography was calculated as 3695.1 μGysqm. Two hundred fifty patients were in the PCI group, the Median K_{AR} was 1649 mGy, Median P_{KA} was 8822.1 μGysqm, the median FT being 8.2 min. The DRL for single-vessel coronary intervention was calculated as 11038 μGysqm.

Conclusion: This study establishes a benchmark for radiation dose for diagnostic coronary angiography and single-vessel coronary intervention at a tertiary care hospital in NCR. It establishes an interim DRL that can be used for future studies in other institutions in the region and country and to compare with other countries.

Coronary Artery Disease, the most common cardiovascular disease (CVD), is the leading cause of death in India and worldwide.

Invasive Coronary Angiography (CAG) and Percutaneous Coronary Interventions (PCI) remain the cornerstone for diagnosis and treatment of obstructive coronary artery disease. Although the gold standard, invasive coronary interventions carry the risk of radiation exposure both to the patient and the operator from the fluoroscopy used during the procedure.[1]

The risk associated with radiation exposure increases with the dosage, and hence the doctrine of 'as low as reasonable' (ALAR) has been advocated. The risks include erythema, dermal atrophy, and ulcerations. There is also an increased risk of developing cancer, which seems to be related to the cumulative dose received.[2] Despite advances in imaging technology and increasing awareness of radiation hazards, radiation doses delivered during CAG and PCI remain one of the highest of any X-ray examination in acute care settings.[3] The dose received by the operator from scattered radiation is also an important consideration as more and more complicated procedures are done. The long-term effects of low energy ionizing radiations in form of increasing cancers in operators are increasingly reported.[4,5] Most modern cardiac cath labs can report radiation exposures in real-time, and a cumulative radiation report is generated at the end of the procedure.

The radiation protection and advisory bodies suggest monitoring of the radiation doses at the local, regional and national levels.[6] To keep the radiation dose minimum without compromising image quality, evidence-based data to benchmark against is required. To date, no such benchmarking data is available for NCR or India. A diagnostic reference level (DRL) or benchmark has been published by numerous radiation regulatory bodies around the world but none in India. The DRL provides physicians with a guide below which the median radiation exposure of a particular

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Table 1
Coronary angiography group.

	fluoro time (min)	fluoro exp (μGysqm)	fluoro exp (mGy)	Cine exp (μGysqm)	Cine exp (mGy)	Total exp (μGysqm)	Total exp (mGy)
		P_{KA}	K_{AR}	P_{KA}	K_{AR}	P_{KA}	K_{AR}
Average	3.66	1647.58	246.58	893.59	162.05	3404.97	565.28
Median	2.25	917.10	133.3	476.71	82.15	2635.7	412.05
75th Percentile	4.1	1657.35	219.23	1553.82	283	3695.1	606.68

P_{KA} (Dose-area product), K_{AR} (skin surface entrance dose).

Table 2
Coronary angioplasty group (single vessel).

	fluoro time (min)	fluoro exp (μGysqm) P_{KA}	fluoro exp (mGy) K_{AR}	Cine exp (μGysqm) P_{KA}	Cine exp (mGy) K_{AR}	Total exp (μGysqm) P_{KA}	Total exp (mGy) K_{AR}
Average	10.73	5479.07	959.35	4873.04	941.48	10352.1	1900.82
Median	8.2	4073.2	711.2	4461	837.7	8822.1	1649
75th Percentile	11.45	5205.25	928.35	6070	1230.95	11,038	2126

P_{KA} (Dose-area product), K_{AR} (skin surface entrance dose).

procedure type should fall. It is not a dose limit or threshold to define operator competence; it is just a guide to good practice.[7] This study was designed to establish radiation DRLs for cardiac catheter procedures at a tertiary care hospital to provide benchmarks for ongoing quality assurance and audits and a framework for such studies in other institutions also to enable formulation of a national reference level.

1. Methods

Patients who had undergone coronary interventions in a tertiary care hospital between October 2016 and September 2018 were analyzed in the study.

The study included 500 coronary angiography procedures and 250 Coronary Angioplasty procedures.

This enabled analysis in two groups.

- Diagnostic Coronary Angiography (CAG) only group
- Diagnostic Coronary Angiography group along with single vessel percutaneous coronary intervention group (PCI)

All adult patients matching the above criteria were included in the study. Procedures involving graft angiography, multi-vessel PCI, or chronic total occlusion angioplasty were excluded from the study.

2. Data collection

Radiation exposure data is automatically stored in all patients by the X-Ray machine (Seimens, Artis Zee). The data was extracted from the cardiac catheter laboratory imaging system and exported to a statistical analysis program.

Radiation Data collected include:

- Examination type
- Fluoroscopy time
- Dose-area product (DAP or P_{KA}) and System-calculated skin surface entrance dose (K_{AR}) during fluoroscopy
- Dose-area product (DAP or P_{KA}) and System-calculated skin surface entrance dose (K_{AR}) during cine angiography
- Total Dose-area product (DAP or P_{KA}) and System-calculated skin surface entrance dose (K_{AR})
- Frames per second for fluoroscopy
- Frames per second for cine angiography
- Number of cine exposures

3. Data analysis

The 75th percentile of the P_{KA} was taken as the DRL for the entire population for each procedure as per ICRP recommendations.[6]

Fluoroscopy time was collected as it demonstrates 'beam on' time and any future behavioural modification interventions can target this. K_{AR} is an essential indicator as in many countries, exceeding the entrance surface dose of 5Gy is a reportable event and warrants subsequent patient follow-up.

The dose area product meter (DAP meter) was housed within the X-ray tube and was calibrated before the data collection. The equipment vendor services the cath lab in our hospital regularly, and the X-ray output of the systems is measured annually to ensure compliance and quality assurance.

4. Results

All patients who underwent coronary intervention between October 2016 and September 2018 were studied, and the radiation exposure data were analyzed. All 387 PCI patients and 1024 CAG patients were analyzed.

Of the CAG group, 513 patients were excluded as they underwent further procedures and radiation data of 11 patients were not available; thus 500 patients with coronary angiography only were included in the analysis.

Of the PCI group, 130 patients had multivessel PCI or CTO interventions; hence they were excluded from the analysis, and radiation data of 7 patients were not available; thus 250 patients of coronary angiography with single-vessel PCI were included in the analysis.

The dose results data for the CAG and PCI groups are summarised in Tables 1 and 2.

In patients undergoing only diagnostic coronary angiography, the median Fluoroscopy time was 2.25 min, using a frame rate of 15fps for fluoroscopy and cine-angiography, the median number of cine exposures was 6.5.

In patients undergoing only single vessel angioplasty, the median Fluoroscopy time was 8.2 min; using a frame rate of 15fps for fluoroscopy and cine-angiography, the median number of cine exposures was 22.

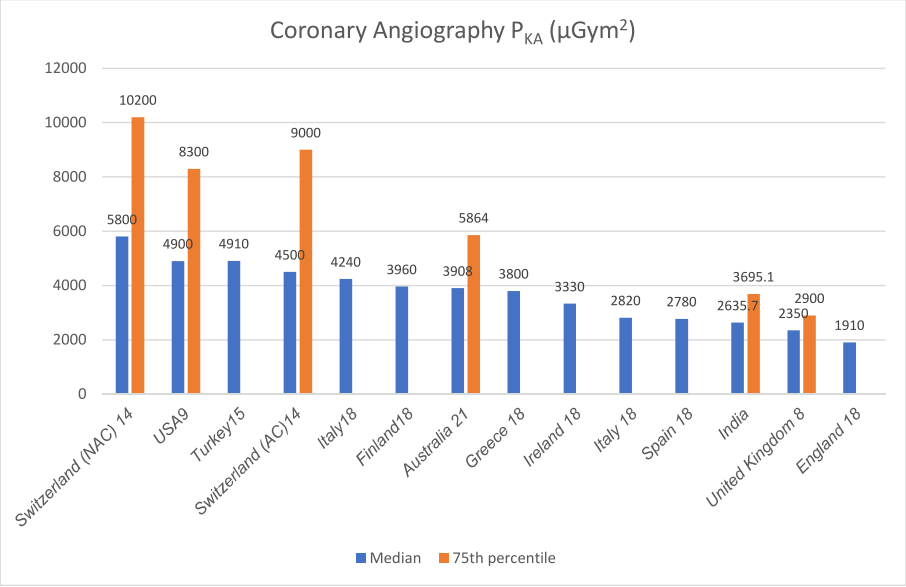

Fig. 1. Coronary Angiography P_{KA} reported from other countries as compared to our data. The reference number in written in front of the country name. NAC (Non- Academic Centers), AC (Academic Centers), P_{KA} (Dose-area product).

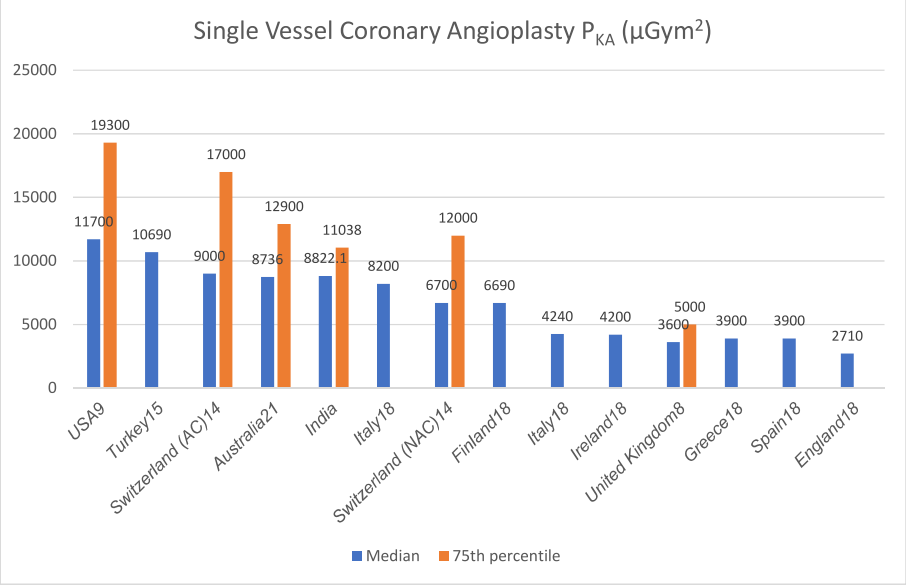

Fig. 2. Single Vessel Coronary Angioplasty P_{KA} reported from other countries as compared to our data. The reference number in written in front of the country name. NAC (Non-Academic Centers), AC (Academic Centers), P_{KA} (Dose-area product).

The Diagnostic Reference Level (DRL), as calculated from the 75th percentile of the P_{KA} value for the study population, was 3695.1 μGysqm for the CAG group and 11,038 μGysqm for the single-vessel PCI group.

5. Discussion

DRL values for coronary angiography are published every 5 years in the UK since 1992.[8] Similar studies are available from Europe and the United States.[9,10] Studies in the UK have found a progressive drop in the radiation doses since they started investigating and reporting radiation data.[8]

There as many factors that influence radiation dose in coronary interventions. The setup of the X-ray system, the operator preference, and clinical practice are all critical determinants, which makes it useful to locally investigate these factors and formulate strategies to reduce radiation doses without compromising the image quality and procedure outcomes.[11,12,13]

Patient weight also has a bearing on the radiation dose but normalizing the DRL by weight may not be logical as the DRL needs to be relevant for patients falling in all weight range; hence multicentre studies have not done this.[9,16–18,21]

The results found in our study are comparable to similar studies in literature from other countries.[8,9,14,15,18,21] Figs. 1 and 2 show comparisons to similar studies done all over the world. Operator experience has been cited as one of the reasons for higher doses at teaching hospitals as younger operators during their initial training use higher levels of radiation due to extended fluoroscopy.[18,19] Our

hospital has operators with experience ranging from 2yrs to 25yrs post-interventional cardiology training and the radiation exposure is within the lower range of reported radiation exposures in literature.

Although we have a large sample size, it has been proposed that 50 sample examinations from each facility are sufficient to produce statistically robust data in these types of studies.[9,20] This gives us the confidence that the sample size of 500 CAG examinations and 250 PCI examinations allows us to calculate the DRLs with a sufficiently strong statistical base.

Although this study indicates that our hospital has been delivering cardiac care with low radiation exposure, there are still measures that can be taken to improve it further. A new imaging protocol has been implemented following this study, and its results shall be analyzed once a sufficient sample size is obtained.

The present study can act as a benchmark for future audits and educational programs in raising awareness regarding radiation exposure. The DRL can be used to provide a measure of good practice although it may not be achievable in all patients. As there is no DRL in India, this study can be used as a temporary yardstick till more cardiac centers report their radiation data and a more extensive national study can be performed.

6. Conclusion

This study allowed for estimation of the radiation exposure in our hospital during diagnostic and interventional coronary procedures. The DRL for diagnostic angiography and single-vessel angioplasty were calculated which can be used as a benchmark for other cardiac centers in India and provide a framework for instituting a national radiation exposure study.

The DRL can be used as an audit tool for quality analysis and improvement.

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Conflict of interest

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Declaration of competing interest

The authors declare no conflict of interest.

References

1. Tsapaki V, Ahmed NA, AlSuwaidi JS, et al. Radiation exposure to patients during interventional procedures in 20 countries: initial IAEA project results. *AJR Am J Roentgenol*. 2009;193:559–569.
2. Picano E, Vano E, Rehani MM, et al. The appropriate and justified use of medical radiation in cardiovascular imaging: a position document of the ESC Associations of Cardiovascular Imaging, Percutaneous Cardiovascular Interventions and Electrophysiology. *Eur Heart J*. 2014;35:665–672.
3. Mettler FA, Huda W, Yoshizumi T, et al. Effective doses in radiology and diagnostic nuclear medicine: a catalog. *Radiology*. 2008;248:254–263.
4. Buchanan GL, Chieffo A, Mehilli J, et al. The occupational effects of interventional cardiology: results from the WIN for safety survey. *EuroIntervention*. 2012;8:658–663.
5. Roguin A, Goldstein J, Bar O. Brain malignancies and ionising radiation: more cases reported. *EuroIntervention*. 2012;8:169–170.
6. Committee 3 ICRP. *Diagnostic Reference Levels in Medical imaging:Review and Additional Advice*. 2012:1–7.
7. Cousins C, Miller DL, Bernardi G, et al. ICRP Publication 120: radiological protection in cardiology. *Ann ICRP*. 2013;42:1–125.
8. Hart D, Hillier MC, Wall BF. National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK. *Br J Radiol*. 2009;82:1–12.
9. Miller DL, Hilohi CM, Spelic DC. Patient radiation doses in interventional cardiology in the U.S.: advisory data sets and possible initial values for U.S. reference levels. *Med Phys*. 2012;39:6276–6286.
10. Aroua A, Rickli H, Stauffer JC, et al. How to set up and apply reference levels in fluoroscopy at a national level. *Eur Radiol*. 2007;17:1621–1633.
11. Larrazet F, Dibie A, Phillipe F, et al. Factors influencing fluoroscopy time and dose-area product values during ad hoc one-vessel percutaneous coronary angioplasty. *Br J Radiol*. 2003;76:473–477.
12. Azpiri-lopez J, Assad-Morell J, Gonzalez-Gonzalez J, et al. Effect of physician training on the X-ray dose delivered during coronary angiography. *J Invasive Cardiol*. 2013;25:109–113.
13. Delewi R, Hoebers LP, Ramunddal T, et al. Clinical and procedural characteristics associated with higher radiation exposure during percutaneous coronary interventions and coronary angiography. *Circ Cardiovasc Interv*. 2013;6:501–506.
14. Samara ET, Aroua A, De Palma R, et al. An audit of diagnostic reference levels in interventional cardiology and radiology: are there differences between academic and non-academic centres? *RadiatProt Dosimetry*. 2012;148:74–82.
15. Bor D, Olgar T, Toklu T, et al. Patient doses and dosimetric evaluations in interventional cardiology. *Phys Med*. 2009;25:31–42.
16. D'Helft C, McGee A, Rainford L, et al. Proposed preliminary diagnostic reference levels for three common interventional cardiology procedures in Ireland. *RadiatProt Dosimetry*. 2008;129:63–66.
17. Padovani R, Vano E, Trianni A, et al. Reference levels at European level for cardiac interventional procedures. *RadiatProt Dosimetry*. 2008;129:104–107.
18. Neofotistou V, Vano E, Padovani R, et al. Preliminary reference levels in interventional cardiology. *Eur Radiol*. 2003;13:2259–2263.
19. Watson LE, Riggs MW, Bourland PD. Radiation exposure during cardiology fellowship training. *Health Phys*. 1997;73:690–693.
20. Balter S, Miller DL, Vano E, et al. A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures. *Med Phys*. 2008;35:673–680.
21. Crowhurst JA, Whitby M, Thiele D, et al. Radiation dose in coronary angiography and intervention: initial results from the establishment of a multi-centre diagnostic reference level in Queensland public hospitals. *J Med Radiat Sci*. 2014;61:135–141.