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Radiation doses during cardiac catheterisation procedures in India: a multicentre study

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KEYWORDS

- other imaging modalities
- radiation protection
- training and education

Abstract

Aims: Established, evidence-based measures of radiation are required to minimise its hazards, while maintaining adequate image quality. The aim of this study is to evaluate radiation data and generate reference radiation levels for commonly performed coronary catheterisation procedures in India.

Methods and results: In this prospective, observational study, all procedures were performed in accordance with the established standards using Innova IGS 520/2100-IQ catheterisation laboratories. Demographic, procedural and radiation data were collected. Dose reference limits (DRL) were established as the 75th percentile of the total distribution. There were 2,906 coronary angiograms (CAG), 750 percutaneous coronary interventions (PCI) and 715 CAG+PCI. DRLs for dose area product were: 19.6 Gy·cm^2 for CAG, 49.8 Gy·cm^2 for PCI and 72.0 Gy·cm^2 for CAG+PCI, respectively. Median cumulative air kerma levels were: 185 mGy for CAG, 533mGy for PCI, and 891 mGy for CAG+PCI. Male gender, higher BMI, combining CAG+PCI, fluoroscopy time, number of cine frames, and image acquisition settings were significant contributors to increased radiation dose.

Conclusions: This study established reference radiation dose levels for diagnostic and interventional coronary procedures in India, which were comparable to and in the lower range of international standards.

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Abbreviations

BMI body mass index
CAG coronary angiography
CAK cumulative air kerma
DAP dose area product
FT fluoroscopy time
PCI percutaneous coronary intervention

Introduction

Radiation-based imaging has revolutionised the practice of modern medicine. Though it is used extensively in various fields of medicine, it remains the predominant modality for imaging in the cardiac catheterisation laboratory. However, these procedures place both the patient and the laboratory personnel at risk from ionising radiation. Excessive exposure to ionising radiation may have a deterministic effect from direct injury to skin or a stochastic effect in the form of neoplasms[1]. Professional societies have emphasised the need to develop radiation safety programmes for catheterisation laboratories, which include parties responsible for protection and safety, training/education of staff, radiation monitoring and protective shielding[2,3]. Guidelines have proposed a dose threshold of 5 Gy or 500 Gy·cm², beyond which patients must be monitored for skin injuries[2].

In India, approximately 1,000 hospitals offer cardiovascular catheterisation facilities. The number of coronary interventional procedures increased from 177,240 in 2012 to 373,579 in 2016 [4]. An estimated 30% of these are multivessel or complex interventional procedures. In addition, approximately 30,000 non-coronary interventions are performed yearly and the number of diagnostic procedures is close to thrice the number of all other procedures performed[4]. Though there has been a steady growth in the number of catheterisation laboratories and procedures over the years, systematic reporting of patient radiation doses is not practiced in India. The aim of this study is to establish a baseline radiation reference dose for commonly performed coronary catheterisation procedures in India and to compare them with established international standards.

Methods

STUDY DESIGN AND POPULATION

This prospective observational study was conducted at four prominent tertiary cardiac centres across India. From June 2015 to January 2017, 4,603 consecutive patients undergoing diagnostic and interventional coronary procedures were prospectively included in the study. All the procedures were performed in accordance with the participating centres' established internal standards. Procedures were categorised into the following three groups: Group I, coronary angiography (CAG); Group II, percutaneous coronary intervention (PCI); Group III, coronary angiography followed by *ad hoc* percutaneous coronary intervention (CAG+PCI). Other procedures such as peripheral, endovascular, structural, electrophysiological, or paediatric catheterisation were excluded. This study was approved by an ethical review board, and all patients signed an informed consent prior to the procedure. The study was registered with Clinical Trial Registry-India (CTRI), reference number: CTRI/2015/11/006359.

IMAGING EQUIPMENT

All procedures were performed using 3 Innova IGS 520 and 2 Innova 2100-IQ catheterisation laboratories (GE Healthcare, Chicago, IL, USA), installed between 2011 and 2015. All systems offered similar capability to customise dose and image quality among 5 "dose personalisation" settings according to the preference of individual institution. The choice of configurable settings, as well as the selection of acquisition frame rates and normal versus low dose level preference was left to the physician's discretion. Together, configurable settings and selectable operational settings provided a typical 6:1 range in fluoroscopy and cine dose rate adjustment capability. The configurations of the system and selectable settings of acquisition protocols with radiation dose limit (RDL) used at the different hospitals are summarised in **Supplementary Table 1**. All systems provided built-in dosimetry capability, to monitor patient radiation data throughout the procedure.

DATA COLLECTION

The following data were prospectively collected for each procedure: baseline demographics, clinical characteristics of the patient, radiation dose indicators from the system at the end of the procedure (dose area product [DAP, Gy·cm²]) and cumulative air kerma [CAK, mGy], fluoroscopy time [FT, minutes]), as well as other procedural data such as procedure type, access route, number of vessels treated, number of stents implanted, duration of the procedure, procedural complications, quantity of contrast, use of adjunctive technology such as intravascular imaging, fractional flow reserve assessment and rotational atherectomy. In addition to the patient radiation data, other parameters such as acquisition mode, frame rate, radiation exposure data split between fluoroscopy and cine x-ray acquisition duration, and number of cine exposures were automatically recorded for each x-ray acquisition and were analysed. For comparison between institutions, DAP rates were used to normalise differences in procedural time, which might be attributed to differences in operator experience or complexity of the procedure[5]. For each type of procedure, radiation data reference levels (RLs) were established as the third quartile of the total distribution[6]. For this study, the 75th percentile of the distribution of DAP values was defined as dose reference level (DRL).

STATISTICAL ANALYSIS

Statistical analysis was performed using Microsoft® Excel® 2010 (Version 14.0.7165.5000) and Minitab® 17 statistical software (2010) (Version 17.3.1; Minitab, State College, PA, USA). Categorical variables are presented as numbers and percentages. Continuous variables are described with mean ± standard deviation or median (with interquartile range) depending on their distribution. Kruskal-Wallis test was used for one-way

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analysis of variance for comparison of radiation data between sites. Comparison of radiation data was performed using the one-sided non-parametric one sample sign test, when referenced data were provided as median, to test the null hypothesis that no difference would be found between study and reference median and with the alternative hypothesis that the study median would be lower than the reference median. Similarly, when referenced data was provided as mean, a one sample t-test was used. Multivariate analysis was performed for the patient subset of coronary interventions (PCI and CAG+PCI) to identify individual risk factors with logarithm-transformed DAP as the dependent variable using back-ward stepwise analysis. All the patient-related and image acquisition-related characteristics listed above were used as covariates. Beta-coefficients are given after re-transformation (exp [beta coefficient]) to describe the relative influence of each variable on DAP. A 95% confidence level was used for all statistical calculations and a p-value of 0.05 or less was considered significant.

Results

Overall 4,603 patients were included in the study. Of these 4,371 had analysable data (195 incomplete radiation datasets, and 37 excluded from analysis as other types of procedures). Procedure distribution, demographic profile, cardiovascular risk factors and indications for the procedure are summarised in **Table 1**. The majority of patients were male (71%). Diabetes and hypertension were prevalent at 39% and 42%, respectively. Most of the procedures were performed electively (69%). The impact of BMI on radiation is depicted in **Figure 1**, and there is a stepwise increase in DAPs in both PCI and CAG+PCI groups across increasing BMIs. This trend, however, is not seen in the CAG group. Procedural data are shown in **Table 2**. The transradial technique was used in 76% of the patients. There were 2,906 CAGs, 750 PCIs and 715 CAG+PCIs. Adjunctive technologies were used in 99 (2.9%) patients. On an average, there were 1.2±0.4 vessels treated and 1.3±0.6 stents implanted per each therapeutic procedure.

Procedure specific radiation data are summarised in **Table 3**. Reference levels for DAP, CAK and FT from the study for the above procedures were: 19.6 Gy·cm², 325 mGy, 4.5 min for CAG; 49.8 Gy·cm², 1016 mGy, 18.2 min for PCI; and 72.0 Gy·cm², 1461 mGy, 15.1 min for CAG+PCI, respectively. As expected, both DAP level, CAK level, and number of cine frame rates were higher when *ad hoc* PCI was performed. Male gender, higher BMI, combining CAG+PCI, fluoroscopy time, number of cine frames, and image acquisition settings were significant contributors to increased radiation dose **(Table 4)**. Among the fluoroscopy settings, using '7.5 fps RDL+Low' significantly decreased DAPs while '15 fps Smart IQ Low' did not show any statistical significance. On the other hand, 15 fps with either 'Normal or Smart IQ Normal' adversely impacted the DAPs. Similarly, cine settings at 15fps when used with 'RDL+Low' notably reduced the radiation levels while other cine settings did not. There was significant dispersion of 75th percentile of DAP between the 4 centres for all procedures ('p'<0.05) **(Figure 2)**. The maximal range of median DAP between centres was 7-21 Gy·cm²,13-52 Gy·cm², and 20-57 Gy·cm² for CAG, PCI and CAG+PCI respectively. Institution 4 had the lowest DAP median

Table 1. Procedure distribution, demographic profile, cardiovascular risk factors and indications for procedure.

	All procedures	CAG	PCI	CAG+PCI
Number	4371	2906	750	715
Institution 1 (%)	835 (19)	546 (19)	76 (10)	213 (30)
Institution 2 (%)	982 (22)	513 (18)	95 (13)	374 (52)
Institution 3 (%)	1147 (26)	778 (27)	274 (37)	95 (13)
Institution 4 (%)	1407 (32)	1070 (37)	304 (41)	33 (5)
Age (mean, SD) years	57.7±10.7	57.4±10.7	58.0±10.6	58.5±11.0
Male (%)	3247 (71)	2073 (71)	572 (76)	602 (84)
Diabetes (%)	1795 (39)	1186 (41)	298 (40)	311 (43)
Hypertension (%)	1951 (42)	1318 (45)	310 (41)	323(45)
BMI* (mean, SD) kg/m²	26.0±4.2	26.3±4.3	26.1±4.1	25.1±3.5
BMI* <25 (%)	1923 (44)	1207 (42)	316 (43)	400 (57)
BMI* ≥25 to <30 (%)	1699 (39)	1148 (40)	311 (42)	240 (34)
BMI* ≥30 (%)	705 (16)	536 (19)	108 (15)	63 (9)
Prior PCI (%)	238 (5)	129 (4)	51 (7)	58 (8)
Prior CABG (%)	89 (2)	60 (2)	15 (2)	14 (2)
STEMI (%)	353 (8)	140 (5)	18 (2)	195 (27)
NSTEMI/unstable angina (%)	840 (18)	513 (18)	71 (9)	256 (36)
Elective (%)	3177 (69)	2256 (78)	658 (88)	263 (37)

*BMI data is available for 4327 patients. BMI: body mass index; CABG: coronary artery bypass graft surgery; CAG: coronary angiography; NSTEMI: non-ST-segment elevation myocardial infarction; PCI: percutaneous coronary intervention; STEMI: ST-segment elevation myocardial infarction

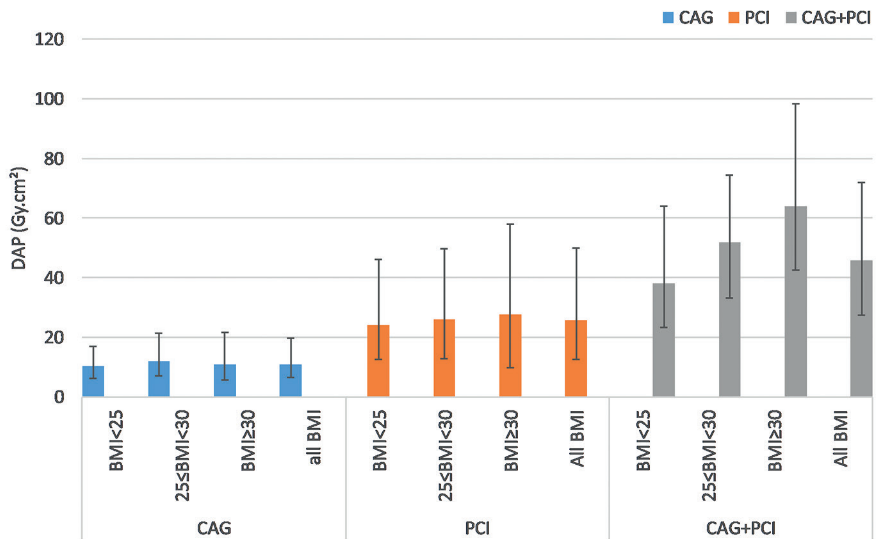

Figure 1. *Impact of BMI on patient radiation dose. BMI: body mass index, DAP: dose area product*

Table 2. Procedural data.

ACCESS ROUTES*	N (%)
Radial (%)	3312 (76.0)
Femoral (%)	991 (22.8)
Bi femoral (%)	15 (0.3)
Radial+Femoral (%)	38 (0.4)
PROCEDURE TYPE	
CAG (%)	2906 (63.2)
PCI (%)	750 (16.3)
CAG+PCI (%)	715 (15.5)
No of vessels treated (mean, SD)	1.2±0.4
No of stents implanted (mean, SD)	1.3±0.6
AMOUNT OF CONTRAST MEDIA USED	
CAG (mean, SD) ml	51±9
PCI (mean, SD) ml	150±18
CAG+PCI (mean, SD) ml	146±35
ADJUNCTIVE TECHNOLOGIES USED	
Rotablator (%)	17 (0.5)
OCT (%)	17 (0.5)
FFR (%)	25 (0.7)
IVUS (%)	34 (1.0)
IABP (%)	6 (0.2)
PROCEDURE COMPLICATION	
Dissection (%)	11 (0.3)
Unsuccessful procedure (%)	4 (0.1)
Thrombosis (%)	5 (0.2)
Occlusion (%)	15 (0.4)

*Information missing regarding access route for 15 procedures.
CAG: coronary angiography; FFR: fractional flow reserve;
IABP: intra-aortic balloon pump; IVUS: intravascular ultrasound;
OCT: optical coherence tomography; PCI: percutaneous coronary intervention

for each of the 3 groups and this was the only institution which used "7.5 frame/s RDL+Low" settings for fluoroscopy.

Distribution of CAK is depicted in **Figure 3**. Overall, 87.4% of the procedures were below 1 Gy, including 98% of CAG, 74% of PCI and 57% of CAG+PCI. 98.8% of the procedures were below the first notification threshold of 3 Gy. 1% of the examinations attained a radiation dose between 3 and 5 Gy. Only 0.3% of all PCIs (6 elective and 6 *ad hoc*) exceeded the substantial radiation dose level of 5 Gy, above which patient follow-up is recommended[2]. This category was inclusive of 3 patients with complex primary PCI, 4 PCIs for calcified lesions, 1 complex bifurcation PCI, 3 PCIs for chronic total occlusion, and 1 patient who had PCI-related complications. However, lesion complexity data was not included in the study analysis as it was not available for all patients. Comparison of radiation data from the current study with international references and recent literature are shown in **Figure 4** as well as in **Supplementary Table 2** and **Supplementary Table 3** [6-16]. For each procedure category, the study median DAP and 75th percentile DAP were compared with data from previously published studies: 4 study datasets out of 31 had comparable or lower DAP for CAG and 9 out of 40 had similar outcomes for PCI. This trend also continued with comparisons of CAK and FT.

Discussion

The major observations of our study are firstly that DAP and CAK during diagnostic and interventional coronary procedures from a selection of Indian centres are comparable, and in the low range in reference to international standards. Secondly, only 1% of all the procedures received a dose between 3 Gy and 5 Gy and 0.3% of the examinations attained a dose above the cut-off value 5 Gy. Thirdly, there is considerable variation across the sites with regard to the radiation parameters. Fourthly, male gender, higher

Table 3. Procedure specific radiation data.

	N	Mean±SD	Median	25th Percentile	75th Percentile
Goup I: CAG Group I	**2906**				
DAP (Gy·cm²)		15.8±16.4	11.0	6.4	19.6
Fluoroscopy DAP (Gy·cm²)		4.4±8.9	1.9	0.9	4.5
Cine DAP (Gy·cm²)		11.5±9.7	8.4	5.1	14.5
CAK (mGy)		261±255	185	112	325
Fluoroscopy CAK (mGy)		63±129	28	12	64
Cine CAK (mGy)		198±162	150	91	251
Acquisition duration (min)		4.3±4.5	2.8	1.7	5.1
Fluoroscopy time (min)		3.8±4.4	2.4	1.3	4.5
Cine time (min)		0.5±0.2	0.5	0.4	0.6
Number of cine frames		460±204	427	320	552
Group II: PCI	**750**				
DAP (Gy·cm²)		40.4±47.1	25.7	12.5	49.8
Fluoroscopy DAP (Gy·cm²)		20.8±29.9	11.4	5.3	23.3
Cine DAP (Gy·cm²)		19.5±21.0	13.1	6.5	25.6
CAK (mGy)		825±941	533	243	1016
Fluoroscopy CAK (mGy)		418±591	229	98	488
Cine CAK (mGy)		406±423	280	138	533
Acquisition duration (min)		15.1±11	12.4	7.9	19.3
Fluoroscopy time (min)		14.1±10.6	11.4	7.1	18.2
Cine time (min)		1.0±0.6	0.8	0.6	1.3
Number of cine frames		885±551	738	520	1128
Group III: CAG+PCI	**715**				
DAP (Gy·cm²)		56.2±42.7	45.8	27.3	72.0
Fluoroscopy DAP (Gy·cm²)		25.0±26.7	17.3	9.6	31.7
Cine DAP (Gy·cm²)		31.2±21.7	26.9	15.7	41.5
CAK (mGy)		1135±939	891	526	1461
Fluoroscopy CAK (mGy)		494±595	325	174	609
Cine CAK (mGy)		641±454	539	324	861
Acquisition duration (min)		13.6±9.3	11.7	7.7	16.3
Fluoroscopy time (min)		12.4±9	10.6	6.7	15.1
Cine time (min)		1.2±0.5	1.1	0.8	1.4
Number of cine frames		1039±474	962	729	1245

CAG: coronary angiography; CAK: cumulative air kerma; DAP: dose area product

Table 4. Contributors to increased radiation dose.

Variables	'β'	SE	95% CI	'*p*'-value
Gender: male vs female	1.3311	1.04	(1.22-1.43)	<0.001
BMI (kg/m²)	1.0300	1.00	(1.02-1.04)	<0.001
Procedure type: PCI vs CAG+PCI	0.9205	1.04	(0.95-0.99)	<0.001
Fluoroscopy time (min)	1.0276	1.00	(1.02-1.03)	<0.001
Number of cine frames	1.0006	1.00	(1.00-1.00)	<0.001
Fluoroscopy setting				0.023
7.5fps RDL+Low	0.6107	1.05	(0.56-0.67)	<0.001
15fps RDL+Normal	1.6620	1.11	(1.37-2.04)	<0.001
15fps Smart IQ Low	0.9418	1.15	(0.71-1.24)	0.667
15fps Smart IQ Normal	1.3825	1.08	(1.18-1.61)	<0.001
Cine setting				<0.001
15fps IQ Standard Low	0.6157	1.34	(0.35-1.34)	0.096
15fps RDL+Low	0.6480	1.08	(0.56-1.08)	<0.001
15fps RDL+Normal	1.0367	1.13	(0.91-1.13)	0.769

BMI: body mass index; CAG: coronary angiography; PCI: percutaneous coronary intervention. Beta coefficients (β) are given after re-transformation [exp(beta coefficient)] to describe the relative influence of each variable.

BMI, combining CAG+PCI, fluoroscopy time, number of cine frames, and image acquisition settings were significant predictors of higher DAP.

Historically, radiation dose during catheterisation procedures varies widely based on age, BMI, radial route, previous bypass grafting, lesion complexity, equipment generation, technical settings and operator experience[17,18]. Gender-based patterns for radiation exposure across catheterisation laboratories are unknown. In this study, male gender is an important predictor but women were under-represented (29%) and the significance of this finding after adjustment for lesion complexity is not analysed. However, in a study exploring mean effective radiation dose for nuclear cardiology procedures, it was shown that women required a slightly lower radiation dose (9.6±4.5 mSv) than men (10.3±4.5mSv, $p<0.001$)[19]. On the other hand, the adverse relationship between BMI and radiation dose is well established[18]. *Ad hoc* PCI increased DRL significantly, with mean DAP 56.2±42.7 Gy·cm² where as the PCI group had a mean of 40.4±47.1 Gy·cm². In a study published by Truffa et al[20], the *ad hoc* group had lower total DAP 119.7±70.7 Gy·cm², compared to the staged group, 139.2±5.3 Gy·cm² ($p<0.001$), but the staged group's total DAP included the radiation during both CAG and PCI, and thus cannot be compared to the present study. Fluoroscopy time, number of cine frames, and image acquisition settings are conventional risk factors of radiation[18].

All the hospitals participating in the study have used the same equipment for X-ray imaging but the choice of configurable settings was left to the physician's preference. At the institution which recorded the lowest mean DAP for all procedures, the physicians opted for low frame rates as well as low radiation protocols for all the procedures. Preference of image technical settings between sites to accomplish a clinical task, operator's practice and awareness of radiation reduction techniques (such as usage of collimation while limiting magnification, limitation of steep angulations, optimal placement of image receptor as close as possible to the patient, selection of lower frame rates and lower dose level preference, use of fluoro-store function instead of cine) all have an impact on the levels of radiation. Georges et al[17], in their analysis of 34,436 CAGs and 28,932 PCIs across 44 centres in France, observed significant differences in the radiation doses between participating centres. The maximal range of median KAP between centres was 9-54 Gy·cm² and 16-126 Gy·cm² for CAG and PCI

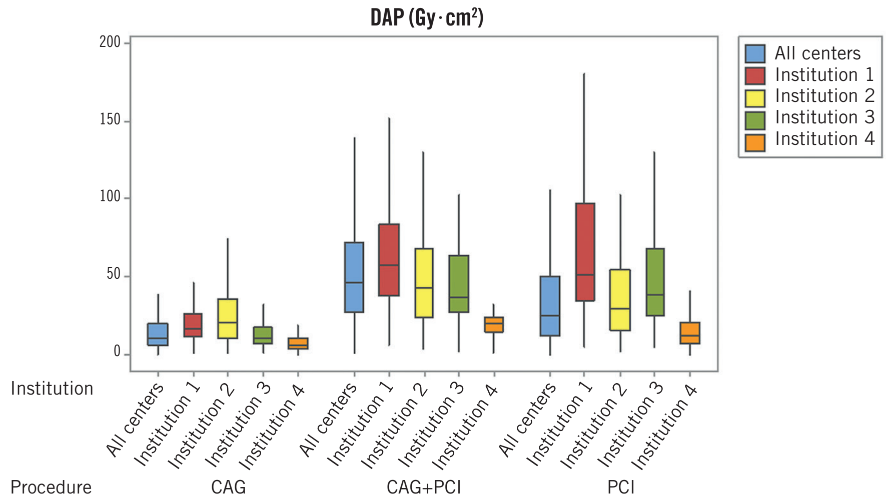

Figure 2. *75th percentile DAP data by institutions. CAG: coronary angiography; CAG+PCI: coronary angiography followed by percutaneous coronary intervention; DAP: dose area product; PCI: percutaneous coronary intervention*

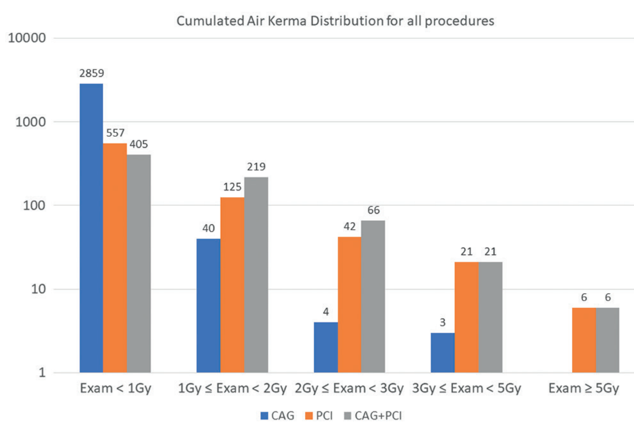

Figure 3. *Cumulative air kerma distribution for all procedures, (CAG, PCI, CAG+PCI) – Log scale. CAG: coronary angiography; CAG+PCI: coronary angiography followed by percutaneous coronary intervention; PCI: percutaneous coronary intervention;*

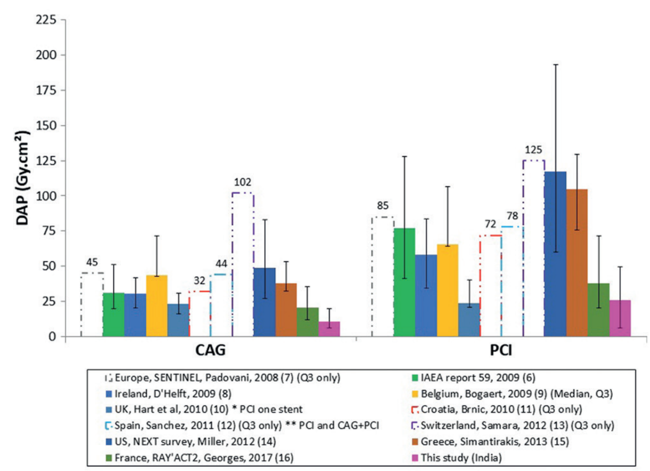

Figure 4. *Cumulative DAP (Gy.cm²) in comparison with international references for CAG and PCI categories. Median and interquartile range are given, unless otherwise indicated. CAG: coronary angiography; DAP: dose area product; PCI: percutaneous coronary intervention*

respectively. When comparison was made between centres delivering lower and higher radiation doses, use of old equipment, routine left ventriculography, and use of frame rates >7.5 fps were more frequent in centres delivering higher doses.

The incidence of high dose exposure varies between 0.1% and 1.0% among different studies[17]. Historically, high radiation doses commonly occur in patients with high BMI and in those undergoing complex interventional procedures such as chronic total occlusions or treatment of calcified lesions or anomalous coronary arteries, or when procedure complications occur[21]. Similar findings were observed in this study and are consistent with other published studies[17]. None of the patients with radiation doses above 5 Gy reported skin injuries. However, the current study did not mandate follow-up of patients who received high radiation doses.

The main objective of any radiation dose assessment is to minimise the detrimental effects of radiation by reducing exposure to it in the catheterisation laboratory. DRLs serve as a benchmark that gives an opportunity for the individual laboratories to compare their performance and to adapt policies to curtail unnecessary exposure to radiation. The DRLs from the current study were 19.6 Gy·cm² for CAG; 49.8 Gy·cm² for PCI; and 72 Gy·cm² for CAG+PCI, considerably lower than the reference limits of other international studies **(Supplementary Table 2 and Supplementary Table 3)**. Various factors could have contributed to this. Indians with cardiovascular disease are known to have a lower BMI than other ethnicities[22]. Most of the reference studies were much older; hence, this study might have had the benefit of improved radiation awareness, better experience of the operators, and recent advances in technical equipment.

Limitations

The current study has some important limitations. Radiation dose measurements were restricted to the three selected procedures (CAG, PCI, CAG+PCI) and hence no reference values can be deduced from this study for other catheterisation procedures. Detailed technical factors such as field of view, collimation, source-to-image distance and angulations have not been monitored. Lesion complexity and operator experience were not considered. There is no follow-up of patients who have received high radiation doses and the adverse effects of these high doses have not been reported.

Conclusions

DRLs for diagnostic and interventional coronary angiography procedures in India were calculated in this study. Despite variations across centres, radiation doses from a selection of tertiary cardiac care centres using similar equipment are comparable and are in the low range with reference to international standards. The establishment of these DRLs can be used as a benchmark for new or similar catheterisation laboratories.

Impact on daily practice

The current study provides preliminary radiation exposure reference levels for commonly performed coronary procedures in India. This may serve as a reference for evaluation of radiation dose in individual catheterisation laboratories, to adapt policies and practices to improve their radiation doses.

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Conflict of interest statement

V. Subban has received an institutional research grant from GE Healthcare. S. Amelot is a GE Healthcare employee. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Table 1. Site equipment and preferred acquisition protocol configurations.

Supplementary Table 2. Comparison with international references.

Supplementary Table 3. Comparison with recent literature data.

The supplementary data are published online at: www.asiaintervention.org

Supplementary data

Supplementary Table 1. Site equipment and preferred acquisition protocol configurations.

Institutions	Equipment	Installed	Acquisition protocol configurations	
			Fluoroscopy	**Cine angiography**
1	Innova 2100-IQ	2011	15 frames/s RDL+ Normal	15 frames/s RDL+ Normal
	Innova 2100-IQ	2012	15 frames/s RDL+ Normal	15 frames/s RDL+ Normal
2	Innova IGS 520	2015	• Low dose protocol: 15 frames/s RDL+ Low • Improved image quality protocol: 15 frames/s Smart IQ Normal	• Low dose protocol: 15 frames/s RDL+ Low • Improved image quality protocol: 15 frames/s IQ standard Normal
3	Innova IGS 520	2012	15 frames/s RDL+ Low	15 frames/s RDL+ Low
4	Innova IGS 520	2013	7.5 frames/s RDL+ Low	15 frames/s RDL+ Low

RDL: radiation dose limit

Supplementary Table 2. Comparison with international references.

Reference	Year	N	BMI (kg/m²)	Total DAP (Gy.cm²)	P-Value	CAK (mGy)	P-Value	FT (min)	P-Value	Number of exp. frames	P-Value	Site/country
CAG												
This Study – CAG	**2017**	**2906**	**26.3 ± 4.3**	**10.9 (6.4-19.6)**	**-**	**185 (112-325)**	**-**	**2.4 (1.3-4.5)**	**-**	**427 (320-552)**	**-**	**4 hospitals, India**
Europe (SENTINEL) (7)	2008	672	na	45[d]	-	na	-	6.5[d]	-	700[d]	-	9 centres, Europe
IAEA (6)	2009	2265	Height (m): 1.68[a]; Weight (kg): 78.5[a]	31.8 (20.8-49.4)	<0.001	700 (500-1000)	<0.001	5 (3-9)	<0.001	810 (655-1003)	<0.001	7 centres
Ireland (8)	2009	967	na	30.6 (20.2-41.7)	<0.001	na	-	na	-	na	-	14 hospitals, Ireland
Belgium (9)	2009	200	27[a] (19–49)[c]	43.8 (na-71.3)	<0.001	na	-	na	-	na	-	8 hospitals, Belgium
UK (10)	2009	na	Weight (kg): 75-85[c]	29[e]	-	na	-	4.5[e]	-	na	-	110 centres, UK
Croatia (11)	2010	138	28.2 (18.6-37.2)	25.3[a] (na-32)	<0.001	na	-	5.5[a] (na-6.6)	<0.001	554[a] (na-610)	<0.001	4 centres, Croatia
Spain (12)	2011	na	na	44[d]	-	na	-	8.0[d]	-	869[d]	-	6 hospitals, Spain
Switzerland (13)*	2012	311	na	87[a] (na-102)	<0.001	na	-	3.2[a] (na-10)	1.000	1039[a] (na-1549)	<0.001	23 centres, Switzerland
United States (NEXT Survey) (14)	2012	1326	na	46.2 (27.0-83.0)	<0.001	680 (440-1180)	<0.001	2.7 (1.8-5.4)	<0.001	na	-	United States
Greece (15)	2013	2572	na	37.9 (32.5-53.3)	<0.001	na	na	5.4 (4.1-5.7)	<0.001	na	-	26 centres, Greece
France, RAY'ACT-2 (16)	2016	51229	26.8 (24.2–30.1)	20.8 (11.8–35.7)	<0.001	294 (164–498)	<0.001	3.3 (2.1–5.7)	<0.001	404 (284–566)	1.000	61 centres, France
PCI												
This Study – PCI	**2017**	**750**	**26.0 ± 4.1**	**25.7 (12.5-49.8)**	**-**	**533 (243-1020)**	**-**	**11.4 (7.1-18.2)**	**-**	**738 (520-1128)**	**-**	**4 hospitals, India**
Europe (SENTINEL) (7)	2008	662	na	85[d]	-	na	-	15.5[d]	-	1000[d]	-	9 centres, Europe

IAEA (6)	2009	1027	Height (m): 1.68[a]; Weight (kg): 77.4[a]	53.3 (29.9-98.4)	<0.001	1900 (1100-3000)	<0.001	12 (7-20)	0.0772	881 (527-1465)	<0.001	
Ireland (8)	2009	463	na	58.1 (34.3-83.6)	<0.001	na	-	na	-	na	-	14 hospitals, Ireland
Belgium (9)	2009	118	28[a] (20–47)[c]	65.4 (na-106.6)	<0.001	na	-	na	-	na	-	8 hospitals, Belgium
UK (10)**	2009	na	Weight: 75-85[c] kg	50[e]	-	na	-	13.0[e]	-	na	-	28 centres, UK
Croatia (11)	2010	151	28.4 (18.6-38.9)	55.2[a] (na-72)	<0.001	na	-	15.5[a] (na-19)	<0.001	1067 (na-1270)	<0.001	4 centres, Croatia
Spain (12)***	2011	na	na	78[d]	-	na	-	22.0[d]	-	1762[d]	-	6 hospitals, Spain
Switzerland (13)	2012	119	na	91[a] (na-125)	<0.001	na	-	14[a] (na-19)	0.584	1277[a] (na-1837)	<0.001	23 centres, Switzerland
United States (NEXT Survey) (14)	2012	144	na	99.3 (60.0-193.0)	<0.001	1610 (1000-3120)	<0.001	10.1 (6.8-18.5)	1.000	na	-	United States
Greece (15)	2013	1899	na	104.7 (75.8-129.3)	<0.001	na	-	13.8 (11.0-17.8)	<0.001	na	-	25 centres, Greece
France, RAY'ACT-2 (16)	2016	6743	26.8 (24.2–30.1)	38.0 (20.3–71.4)	<0.001	668 (351–1285)	<0.001	9.8 (5.7–16.8)	1.000	537 (339–788)	1.000	61 centres, France
CAG +PCI												
This Study – CAG+PCI	**2017**	**715**	**25.1 ± 3.5**	**45.8 (27.3-72.0)**	**-**	**891 (526-1461)**	**-**	**10.6 (6.7-15.1)**	**-**	**962 (729-1245)**	**-**	**4 hospitals, India**
IAEA (6)	2009	817	Height (m): 1.69[a]; Weight (kg): 82.3[a]	92.9 (59.1-138.3)	<0.001	1900 (1300-2700)	<0.001	15 (10-24)	<0.001	1468 (1174-1976)	<0.001	7 centres
Ireland (8)	2009	134	na	77.1 (50.2-106.7)	<0.001	na	-	na	-	na	-	14 hospitals, Ireland
United States (NEXT Survey) (14)	2012	528	na	111.8 (73.0-199.0)	<0.001	1780 (1200-3000)	<0.001	10.8 (7.3-18.1)	0.1309	na	-	United States
France, RAY'ACT-2 (16)	2016	35479	26.8 (24.2–30.1)	46.4 (26.9–78.7)	0.3268	757 (433–1285)	1.000	9.8 (6.4–15.2)	0.9989	710 (501–991)	1.000	61 centres, France

Note. Radiation data values are given as median (IQR) and BMI as mean ± standard deviation; unless otherwise indicated.
CAK: cumulative air kerma.s; DAP: dose area product; FT fluoroscopy time
[a] Mean; [c] Range; [d] Dose Reference Level (based on 75th Percentile); [e] 75th percentile of means of the rooms; na: not available; * Data normalized to average size patient (height 1.70m and weight 70kg); **Single stent PCI; *** PCI and CAG+PCI combined
p-value from non-parametric 1 sample sign test when referenced data provided as median and 1 sample t test when referenced data provided as mean.

Supplementary Table 3. Comparison with recent literature data.

Author	Year	N	BMI (kg/m²)	Total DAP (Gy.cm²)	P-Value	CAK (mGy)	P-Value	FT (min)	P-Value	Number of exp. frames	P-Value	Site/country	Details
CAG													
This Study – CAG	**2017**	**2906**	**26.3 ± 4.3**	**10.9 (6.4-19.6)**	**-**	**185 (112-325)**	**-**	**2.4 (1.3-4.5)**	**-**	**427 (320-552)**	**-**	**India (4 sites)**	
Abdelaal (23)	2014	89	28.6 ± 5.6	23 (15–31)	<0.001	na	-	2.6 (1.8–4.5)	<0.001	na	-	Canada	1.Transradial access 2.Reduced Fluoro framerate group (7.5fps)
Eloot (24)	2015	35	26.1 (23.8–31.0)	8.8 (6.33-17.6)	1.000	na	-	2.9 (1.9-5.0)	<0.001	na	-	Belgium	Novel Imaging system
Bracken (25)	2015	88	26.8 (22.8-32.3)	20.1 (12.3-36.5)	<0.001	197 (124-360)	<0.001	5.5 (3.7-9.2)	<0.001	517 (337 - 657)	<0.001	USA	Dose reduction technology
Livingstone (26)	2015	222	na	24.4 ± 14.5	<0.001	na	-	3.9[a] (0.5-10.4)[c]	0.143	na	-	India	Flat panel detector
Nakamura (27)	2015	307	23.2 ± 3.7	52.0 (na-80.4)	<0.001	na	-	9.9 (na - 18.7)	<0.001	2510 (na-3378.5)	<0.001	Japan	Upgraded Imaging system
Varghese (28)	2016	140	25[a]	14.0[a] (4.0-37.6)[c]	1.000	231[a] (74-622)[c]	1.000	3.2[a] (0.5-10.5)[c]	1.000	525[a] (246-1063)[c]	<0.001	India	Novel imaging system
Ryckx (29)	2016	877	na	na (na-69)	na	na (na-41)	-	na (na-8.9)	-	na	-	Switzerland	
Didier (30)	2016	598	26.8 ± 5.0	27.1 (16.7-41.6)	<0.001	336 (207-507)	<0.001	na	-	na	-	France	Cardiovascular automated reduction x-ray system
Hansen (31)	2016	130	Height (m): 1.69[a] Weight (kg): 64.7[a]	44.0 (28.6-69.6)	<0.001	621 (405-909)	<0.001	8.5[a]	<0.001	na	-	USA	Reduced Fluoro framerate group (7.5fps)
Jurado-Roman (32)	2016	558	28.6 ± 5.7	43.3 ± 40.1	<0.001	na	-	8.0 ± 7.0	<0.001	na	-	Spain	Radiation Reduction Protocol
Wilson (33)	2016	617	27.6 ± 6.0	50.4 ± 37.0	<0.001	440 ± 376	<0.001	3.3 ± 3.0	1.000	na	-	Australia	
Kastrati (34)	2016	397	28.8 ± 5.0	9.8 ± 9.8	1.000	na	-	4.7 ± 4.4	<0.001	na	-	Germany	Cohort Noise Reduction technology
Tarighatnia (35)	2016	37	na	17.3[a] (6.3-36.6)[c]	<0.001	234[a] (75-526)[c]	1.000	3.3[a] (0.8-9.5)[c]	1.000	na	-	Iran	Transradial access
Tarighatnia (35)	2016	37	na	19.5[a] (6.8-107.8)[c]	<0.001	211[a] (87-433)[c]	1.000	1.8[a] (0.5-8.4)[c]	1.000	na	-	Iran	Transfemoral access
Sinha (36)	2016	921	23.8 ± 3.6	22.3 ± 3.46	<0.001	na	-	2.8 ± 1.3	1.000	na	-	India	Transfemoral access

Author	Year	N	BMI (kg/m²)	Total DAP (Gy.cm²)	P-Value	CAK (mGy)	P-Value	FT (min)	P-Value	Number of exp. frames	P-Value	Site/country	Details
Sinha (36)	2016	1076	24.9 ± 2.8	24.2 ± 4.21	<0.001	na	-	2.5 ± 1.2	1.000	na	-	India	Transradial access
Uniyal (37)	2017	40	Weight: 74 ± 9.5 kg	21.1 ± 19.8	<0.001	420 ± 373	<0.001	2.4 ± 2.9	1.000	360 ± 129	1.000	India	
Balter (38)	2017	307	na	34.0 (23.0-54.0)	<0.001	350 (230-540)	<0.001	6.4 (3.8-10.5)	<0.001	na	-	USA	Third Imaging configuration
Ordiales (39)	2017	195	29.9 ± 5.1	18.5 (na-na)	<0.001	220 (na-na)	<0.001	2.70 (na-na)	<0.001	449 (na-na)	<0.001	Spain	Period 5 Optimized Imaging protocol
Gunja (40)	2017	na	na	30.2 ± 23.5	<0.001	na	-	7.7 ± 5.9	<0.001	na	-	USA	Novel imaging system
Faroux(41)	2017	508	28.0 ± 5.4	12.4 ±13.0	1.000	176 ± 130	1.000	na	-	na	-	France	Novel imaging system
Sciahbasi (42)	2017	7631	28 ± 5	26 (16-46)	<0.001	na	-	3.0 (1.9-5.4)	<0.001	na	-	Italy, Germany, USA	Italy (4 sites), Germany (1), USA (1)
PCI													
This Study – PCI	**2017**	**750**	**26.0 ± 4.1**	**25.7 (12.5-49.8)**	**-**	**533 (243-1020)**	**-**	**11.4 (7.1-18.2)**	**-**	**738 (520-1128)**	**-**	**4 hospitals, India**	
Abdelaal (23)	2014	93	28.6 ± 5.6	55 (35–83)	<0.001	na	-	9.2 (5.7–15.0)	1.000	na	-	Canada	1. Transradial Access 2.Reduced Fluoro framerate group (7.5fps)
Nakamura (27)	2015	127	23.2 ± 3.7	85.8 (na-144.3)	<0.001	na	-	32 (na-52.9)	<0.001	3768 (na-6025)	<0.001	Japan	Upgraded Imaging system
Bracken (25)	2015	47	27.7 (25.1-32.8)	83.8 (47.5-118.5)	<0.001	980 (627.5-1370.5)	<0.001	17.7 (13.1-27.7)	<0.001	1045 (877-1387)	<0.001	USA	Dose reduction technology
Livingstone (26)	2015	75	na	63.6 ± 39.4	<0.001	na	-	12.49^{a} (3.51-25.5)^{c}	1.000	na	-	India	Flat panel detector
Sciahbasi (42)	2016	5465	27 ± 4	66 (40-109)	<0.001	na	-	10.4 (7.0-16.5)	0.9988	na	-	Italy, Germany, USA	Italy (4 sites), Germany (1), USA (1)
Kastrati (34)	2016	208	29.4 ± 6.7	24.8 ± 19.8	1.000	na	-	11.1 ± 7.1	1.000	na	-	Germany	Cohort Noise Reduction technology
Tarighatnia (35)	2016	74	na	43.4^{a} (5.2-118.4)^{c}	0.041	734^{a} (86-2336)^{c}	0.996	8.4^{a} (1.0-21.1)^{c}	1.000	na	-	Iran	Transradial access
Tarighatnia (35)	2016	74	na	52.8^{a} (4.8-194.5)^{c}	<0.001	855^{a} (93-3464)^{c}	0.188	8.8^{a} (0.9-37.1)^{c}	1.000	na	-	Iran	Transfemoral access
Jurado-Roman (32)	2016	160	28.6 ± 5.7	123.7 ± 91.6	<0.001	na	-	21.3 ± 14.6	<0.001	na	-	Spain	Radiation Reduction Protocol

Author	Year	N	BMI (kg/m²)	Total DAP (Gy.cm²)	P-Value	CAK (mGy)	P-Value	FT (min)	P-Value	Number of exp. frames	P-Value	Site/country	Details
Hansen (31)	2016	146	Height (m): 1.72[a]; Weight (kg): 64.8[a]	106.5 (67.5-143.1)	<0.001	1459 (947-6589)	<0.001	17.8[a]	<0.001	na	-	USA	Reduced Fluoro framerate group (7.5fps)
Didier (30)	2016	130	26.8 ± 4.3	26.6 (12.7-50.7)	0.4564	400 (188-840)	1.000	na		na	-	France	Cardiovascular automated reduction x-ray system
Ichimoto (43)	2017	57	29.3 ± 6.3	17.8 ± 13	1.000	205 ± 141	1.000	5.5 ± 3.0	1.000	na	-	USA	PCI with Dose Tracking System
Uniyal (37)	2017	50	Weight:77 ± 11 kg	97.0 ± 61.7	<0.001	2028 ± 1322	<0.001	15.7 ± 10.0	<0.001	888 ± 384	0.434	India	
Boland (44)	2016	30	Weight: 83 ± 16 kg	55.6 (27.0-91.5)	<0.001	551 (310-998)	0.2216	7.3 (5.4-11.0)	1.000	na	-	Australia	Novel imaging system
Chon (45)	2017	152	24.6 ± 3.3	123.4 ± 53.7	<0.001	1634 ± 718	<0.001	16.2 ± 8.8	<0.001	na	-	Korea	Radiation Reduction Protocol
Faroux (46)	2017	807	28.0 ± 5.4	19.94 ± 24.9	1.000	na	-	9.7 ± 11.2	1.000	na	-	France	Include only period 2 (2016)
Gislason-Lee (47)	2017	131	na	22.9 (na-na)	0.9844	na	-	12.5 (na-na)	<0.001	na	-	UK	Novel imaging system
Gunja (40)	2017	na	na	73.6 ± 59.3	<0.001	na	-	20.1 ± 12.6	<0.001	na	-	USA	Novel imaging system
Ordiales (39)	2017	90	29.9 ± 5.1	38.3 (na-na)	<0.001	473 (na-na)	0.9844	8.9 (na-na)	1.000	664 (na-na)	1.000	Spain	Period 5; Optimized imaging protocol
CAG+PCI													
This Study – CAG+PCI	**2017**	**715**	**25.1 ± 3.5**	**45.8 (27.3-72.0)**	**-**	**891 (526-1461)**	**-**	**10.6 (6.7-15.1)**	**-**	**962 (729-1245)**	**-**	**4 hospitals, India**	
Didier (30)	2016	228	26.7 ± 4	45.0 (26.6-75.1)	0.5888	672 (353-1082)	1.000	na	-	na	-	France	Cardiovascular automated reduction x-ray system
Ryckx (29)	2016	1527	na	na (na-150)	-	na (na-2014)	-	na (na-18.1)	-	na	-	Switzerland	
Jurado-Roman (32)	2016	442	28.6 ± 5.7	123.9 ± 48.8	<0.001	na	-	16.1 ± 9.4	<0.001	na	-	Spain	Radiation Reduction Protocol
Tarighatnia (35)	2016	52	na	56.5[a] (17.8-136.1)[c]	0.422	891[a] (251-2324)[c]	1.000	11.2[a] (3.5-25.7)[c]	1.000	na	-	Iran	Transradial access
Tarighatnia (35)	2016	52	na	67.4[a] (17.5-186.1)[c]	<0.001	1041[a] (301-2545)[c]	0.996	10.8[a] (2.4-42.3)[c]	1.000	na	-	Iran	Transfemoral access
Faroux (46)	2017	441	28.0 ± 5.4	26.7 ±20.0	1.000	471 ± 130	1.000	na	-	na	-	France	Novel imaging system

Note. Radiation data values are given as median (IQR) and BMI as mean ±standard deviation; unless otherwise indicated.

CAK: cumulative air kerma; DAP: dose area product; FT: fluoroscopy time

[a] Mean; [c] Range; [d] Dose Reference Level (based on 75th Percentile); na: not available.

p-value from non-parametric 1 sample sign test when referenced data provided as median and 1 sample t test when referenced data provided as mean