Original Article

National Diagnostic Reference Levels of Procedures in Cardiac Catheterization Laboratory in Thailand: A Multi Centers Survey

Suphot Srimahachota MD[1], Panruethai Trinavarat MD[2], Kanjana Sukwijit BSc[3], Waraporn Sudchai MSc[4], Khanittha Kaewta BSc[5], Marayat Chamnan BSc[6], Thanwa Pitaksuteepong MD[7], Raksakhet Na Nan BSc[8], Ananya Sae-oui BSc[9], Artit Torpongpun MD[10], Nikom Namkoch BSc[11], Manatsanan Kupharangchotsin BSc[12], Suthep Thungsuk BSc[13], Anchali Krisanachinda PhD[2]

[1] Cardiac Center and Department of Medicine, Faculty of Medicine, King Chulalongkorn Memorial Hospital and Chulalongkorn University, Bangkok, Thailand; [2] Department of Radiology, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand; [3] Department of Radiology, King Chulalongkorn Memorial Hospital, Bangkok, Thailand; [4] Thailand Institute of Nuclear Technology (Public Office), Nakhon Nayok, Thailand; [5] Cardiac Catheterization Laboratory, Rajavithi Hospital, Bangkok, Thailand; [6] Cardiac Catheterization Laboratory, Suratthani Hospital, Surat Thani, Thailand; [7] Cardiac Center of Excellence, King Prajadhipok Memorial Hospital, Chanthaburi, Thailand; [8] Cardiac Catheterization Laboratory, Maharaj Nakorn Chiang Mai Hospital, Chiang Mai, Thailand; [9] Cardiovascular Center, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand; [10] Department of Medicine, Chonburi Hospital, Chonburi, Thailand; [11] Cardiac Catheterization Laboratory Division, Queen Sirikit Heart Center of the Northeast, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand; [12] Cardiac Catheterization Laboratory, Naresuan University Hospital, Phitsanulok, Thailand; [13] Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand

Background: Diagnostic reference level (DRL) was initially introduced by the International Commission on Radiological Protection, ICRP Publication 73 in 1996. The DRL has been proven to be an effective tool that aids in optimization of protection in the medical exposure of patients for diagnostic and interventional procedures. As the data on the cardiac procedures are limited, particularly in Southeast Asian region, the DRL in cardiac procedures has never been established in this region.

Materials and Methods: The survey in cardiac procedures covered 1,102 examinations from three procedures including coronary angiography (CAG), percutaneous coronary intervention (PCI), and permanent pacemaker (PPM) at 10 cardiac centers all over Thailand during 2019.

Results: For the CAG procedures, the DRLs of kerma area product (KAP) and air kerma (AK) were 29.3 $Gycm^2$ and 395 mGy, respectively. In PCI, DRLs for KAP and AK were 83.7 $Gycm^2$ and 1397 mGy respectively. For PPM, the DRLs of KAP and AK were 5.8 $Gycm^2$ and 59.0 mGy, respectively.

Conclusion: The present report is the first national DRLs on common cardiovascular procedures in Thailand. The results will help the optimization of patient dosages in the cardiac procedures in Thailand and in the neighboring countries, which can be used as the reference.

Keywords: Diagnostic reference level; Coronary angiography; Percutaneous coronary intervention

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Cardiac interventional procedures are a leading field in using high fluoroscopy exposure doses. During the procedure, the patients are exposed to radiation doses according to the period of fluoroscopy, the longer the period, the higher the level of radiation. The period variation is based on the thickness of the body part, the complexity of the procedures, and experience of the operator. This may result in the development of radiation skin injury to the patients(1,2), development of lens opacity(3,4), or an increase of stochastic effect both in medical staffs and patients(5). The optimization in radiation exposure is quite important to both the patients and medical staffs. The International Commission on Radiological Protection (ICRP)(6,7) recommended the establishment of the diagnostic reference levels (DRLs) as the method for optimization of the radiation exposure. DRL was introduced by the ICRP Publication 73 in 1996 and updated on Publication 135 in 2017. Most of the data of DRLs came from the European countries or East Asia like a Japan and South Korea. Due to

Correspondence to:

Srimahachota S.

Cardiac center and Department of Medicine, Faculty of Medicine, King Chulalongkorn Memorial Hospital and Chulalongkorn University, Bangkok 10330, Thailand.

Phone & **Fax**: +66-2-2564291

Email: s_srimahachota@yahoo.co.th

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Table 1. The X-ray machine characteristic according to hospitals

	Hospital	No. of cath lab	X-ray machine no.1			X-ray machine no.2			X-ray machine no.3			X-ray machine no.4		
			Frame rate fluro (fps)	Frame rate cine (fps)	Manufacturer/ model/ year	Frame rate fluro (fps)	Frame rate cine (fps)	Manufacturer/ model/ year	Frame rate fluro (fps)	Frame rate cine (fps)	Manufacturer/ model/ year	Frame rate fluro (fps)	Frame rate cine (fps)	Manufacturer/ model/ year
1	King Chulalongkorn Memorial Hospital	4	7.5 (adult) 30 (child) 3.75 (EP)	7.5 (adult) 30 (child) 3.75 (EP)	Siemens/ Axiom Artis Zee/ 2018	7.5 (adult) 30 (child) 3.75 (EP)	7.5 (adult) 30 (child) 3.75 (EP)	Siemens/ Artis dBC, Artis Zee/ 2018	7.5 (adult) 30 (child) 3.75 (EP)	7.5 (adult) 30 (child) 3.75 (EP)	Philips/ Allura Xper FD20/10/ 2018	7.5 (adult) 30 (child) 3.75 (EP)	7.5 (adult) 30 (child) 3.75 (EP)	Philips/ Allura FD10/ 2018
2	Queen Sirikit Heart Center of the Northeast	2	15	15	Philips/ Azurion/ 2020	15	15	Philips/ Azurion/ 2020						
3	King Prajadhipok Memorial Hospital	2	10	10	Siemens/ Axiom Artis/ 2008	10	10	Siemens/ Artis Zee Ceiling/ 2017						
4	Chonburi Hospital	2	15	15	GE/ Innova 2000/ 2003	15	15	GE/ Optima IGS320/ 2015						
5	Naresuan University Hospital	2	15	15	Philips/ Allura Xper FD20/ 2014	15	15	Siemens/ Artis Zee Biplane/ 2011						
6	Maharaj Nakorn Chiang Mai Hospital	3	3, 5, 7.5, 10, 15, 20, 30, 50	15	Toshiba/ Infinit/ 2011	7.5, 15, 30	7.5, 15, 31	GE/ Innova 2000/ 2004	3.75, 7.515, 30	15, 30	GE/ Optima 320 TCH/ 2016			
7	Maharat Nakhon Ratchasima Hospital	4	12.5	15	Philips/ Azurion/ 2018	15	15	Philips/ Allura FD10 Clarity/ 2019	15	15	Philips/ Allura FD10 Clarity/ 2015	15	15	Toshiba/ Infinit/ 2013
8	Rajavithi Hospital	2	7.5	15	Siemens/ Artis Biplane/ 2011	7.5	15	Philips/ Azurion Biplane/ 2019						
9	Ramathibodhi Hospital	3	5	7.5	Toshiba/ Infinit/ 2015	5	7.5	Toshiba/ Infinit/ 2015	5	7.5	Toshiba/ Iinfinit/ 2015			
10	Suratthani Hospital	2	3.75, 7.5, 15	15	Philips/ Allura Xper FD10/ 2008	3.75, 7.5, 15	3.75, 7.5, 15	Philips/ Allura Centron/ 2018						

differences in radiation practice for fluoroscopic guided intervention and body mass index, the DRLs in Thailand need to be established. So far, there is no data of DRLs for common cardiac procedures in Thailand and Southeast Asian region.

Materials and Methods

The present report was the survey of radiation dose in common cardiac procedure using fluoroscopic guidance for intervention. The patient dose data of kerma area product (KAP) (Gycm²), cumulative air kerma (CAK) (mGy), and fluoroscopy time had been collected at ten hospitals including university and non-university hospitals all over Thailand. Three procedures including coronary angiography (CAG), percutaneous coronary intervention (PCI), and permanent pacemaker implantation (PPM) had been selected. Those procedures covered more than 90% of all cardiac procedures in the catheterization laboratory. The pediatric cases had been excluded due to the large variation in cases. Baseline characteristics parameters affecting radiation doses have also been collected. Category data are shown in number and in percent, while continuous data are demonstrated in mean ± standard deviation (SD). National DRLs (NDRLs) of each procedure using the seventy-fifth percentile was derived from the median level of all participant hospitals as recommended by ICRP. A minimum of 20 cases per procedure were recommended to evaluate for local DRL according to ICRP. Then the authors used 30 cases for each procedure for each participant hospital to determine DRL. The authors tried to distribute the centers all over Thailand to represent the NDRL. Data were collected and analyzed using Stata version 10. Comparison of category data using chi-square test and continuous data using Student-t test and ANOVA in which p-value of less than 0.05 was considered as statistically significant. The present study was approved by the Central Research Ethics Committee (CREC) of Thailand with reference number CREC012/59BRm.

The present study did not have any patient and public involvement during the data correction; however, the results will influence quality improvement for interventionists and electrophysiologists about the using of fluoroscopy guidance cardiac procedures. The potential reduction in radiation will protect the patients and medical staffs, making these procedures safer from the side effect of radiation.

Results

The patients' radiation doses were surveyed for common cardiac procedures. This study included 366 CAG consecutive cases, 397 PCI consecutive

Table 2. Baseline characteristics of the patients who underwent common cardiac procedures (coronary angiography, percutaneous coronary intervention, permanent pacemaker implantation)

Variable	All cases (n=1,102)	CAG (n=366)	PCI (n=397)	PPM (n=339)
Age (year); mean±SD	65.2±12.9	63.5±11.8	63.9±11.5	68.5±14.7
Male (%)	53.4	57.1	61.0	40.5
Body mass index (kg.m^{-2}); mean±SD	24.0±4.6	24.3±4.8	24.4±4.3	23.1±4.6

CAG=coronary angiography; PCI=percutaneous coronary intervention; PPM=permanent pacemaker implantation; SD=standard deviation

Table 3. Demonstrate of common cardiac procedures and radiation exposure in each hospital and DRLs

Procedure/hospital	Kerma area product (Gycm^2)		Air kerma (mGy)		Fluoroscopy time (minute)	
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)
CAG						
H1, n=30	12.7±10.3	8.1 (5.3, 18.1)	197±174	114 (79, 303)	4.9±4.3	3.1 (2.2, 7.2)
H2, n=30	66.5±156.8	29.3 (13.0, 50.7)	508±790	326 (162, 516)	6.0±6.9	4.3 (2.2, 6.7)
H3, n=30	22.1±11.4	18.9 (14.1, 25.0)	368±188	332 (243, 433)	2.5±2.7	1.7 (1.2, 2.8)
H4, n=30	9.9±5.6	8.9 (5.1, 15.3)	122±70	114 (64, 187)	3.6±2.7	2.5 (1.4, 4.5)
H5, n=30	37.1±26.8	29.3 (17.6, 41.7)	618±571	430 (277, 626)	6.1±5.2	4.4 (2.2, 8.2)
H6, n=90	18.2±12.0	15.7 (9.9, 23.5)	254±174	227 (121, 306)	2.5±1.4	2.1 (1.5, 3.1)
H7, n=30	10.3±6.8	9.0 (6.2, 12.7)	167±93	147 (98, 199)	3.3±3.0	2.0 (1.3, 4.0)
H8, n=52	47.1±31.4	34.3 (24.8, 64.1)	615±391	486 (366, 704)	6.9±5.2	5.5 (3.1, 8.5)
H9, n=30	26.0±12.6	24.2 (17.8, 29.9)	432±197	395 (314, 493)	5.1±3.1	4.1 (2.5, 7.7)
H10, n=14	12.2±6.9	11.3 (6.9, 16.3)	125±60	119 (71, 153)	2.0±1.0	2.1 (1.3, 2.4)
All hospitals, n=366	26.8±50.1	18.3 (10.1, 29.8	352±381	267 (140, 433)	4.2±4.2	2.7 (1.6, 5.2)
DRLs		29.3		395		4.3
PCI						
H1, n=30	34.2±31.4	26.4 (12.3, 54.2)	588±536	440 (193, 940)	13.1±8.3	12.0 (7.1, 17.1)
H2, n=30	90.9±52.6	83.7 (54.8, 103.9)	1248±646	1,041 (751, 1,561)	13.2±7.2	11.4 (7.6, 19.5)
H3, n=30	89.9±49.4	77.8 (65.6, 90.5)	1565±819	1,379 (1,104, 1,635)	12.0±5.1	10.9 (7.8, 14.3)
H4, n=30	36.6±26.3	29.2 (16.0, 50.2)	459±325	344 (190, 660)	11.6±6.1	9.5 (7.1, 16.4)
H5, n=30	161.3±76.7	157.4 (97.6, 226.7)	2088±1110	2,009 (1,192, 2,934)	36.7±17.9	33.1 (21.5, 47.4)
H6, n=90	88.3±63.6	68.6 (42.2, 117.3)	1741±1459	1,191 (777, 2,239)	21.9±12.0	17.5 (13.2, 28.4)
H7, n=27	35.2±21.6	21.3 (32.1, 39.9)	546±402	484 (313, 657)	12.8±6.6	11.1 (7.4, 18.3)
H8, n=39	146.2±102.7	120.7 (70.5, 197.1)	2172±1450	1,842 (1,134, 3,234)	23.4±20.0	16.0 (12.4, 28.0)
H9, n=30	65.9±36.0	64.4 (36.3, 83.6)	1,151±700	1,046 (565, 1,527)	16.4±10.6	13.7 (9.8, 21.1)
H10, n=61	53.0±40.6	40.3 (24.7, 58.2)	623±517	437 (328, 875)	12.6±9.6	10.3 (6.3, 16.3)
All hospitals, n=397	81.1±69.0	58.2 (34.3, 103.1)	1,277±1,158	933 (484, 1,635)	17.9±13.5	14.0 (9.3, 22.2)
DRLs		83.7		1,397		16.0
PPM						
H1, n=30	2.1±0.5	1.6 (1.1, 2.4)	17±12	13 (10, 21)	8.8±5.2	7.3 (5.5, 10.5)
H2, n=30	5.2±0.4	4.7 (2.2, 7.6)	46±29	40 (22, 67)	5.4±3.1	5.0 (3.4, 6.7)
H3, n=30	27.0±24.4	17.5 (11.4, 42.6)	290±265	177 (120, 411)	13.4±13.0	9.6 (5.4, 17.6)
H4, n=30	NA	NA	54±60	32 (11, 81)	5.9±3.9	4.7 (3.3, 7.3)
H5, n=30	9.1±8.2	5.8 (5.0, 9.8)	94±84	59 (51, 108)	14.4±7.0	11.7 (10.1, 17.4)
H6, n=90	3.6±7.8	1.9 (0.9, 3.4)	25±49	11 (6, 23)	4.4±3.1	3.5 (2.2, 5.5)
H7, n=30	0.5±0.6	0.3 (0.2, 0.4)	3±4	2 (2, 3)	2.9±2.5	2.2 (1.4, 2.9)
H8, n=14	13.8±13.9	7.3 (6.8, 17.9)	103±101	57 (54, 131)	3.6±3.2	2.3 (1.6, 4.4)
H9, n=30	3.2±2.4	3.0 (1.7, 3.8)	17±13	15 (8, 20)	7.2±3.0	7.1 (5.2, 9.6)
H10, n=25	0.7±0.4	0.7 (0.5, 0.9)	60±36	60 (40, 72)	7.0±7.0	5.6 (2.1, 7.1)
All hospitals, n=339	6.3±12.1	2.4 (1.0, 6.2)	61±118	23 (10, 59)	7.0±6.6	5.2 (2.7, 9.2)
DRLs		5.8		59		7.3

CAG=coronary angiography; PCI=percutaneous coronary intervention; PPM=permanent pacemaker implantation; H1=King Chulalongkorn Memorial Hospital; H2=Queen Sirikit Heart Center of the Northeast; H3=King Prajadhipok Memorial Hospital; H4=Chonburi Hospital; H5=Naresuan University Hospital; H6=Chiang Mai University Hospital; H7=Maharat Nakhon Ratchasima Hospital; H8=Rajavithi Hospital; H9=Ramathibodi Hospital; H10=Suratthani Hospital; DRLs=diagnostic reference levels; SD=standard deviation; IQR=interquartile range cases, and 339 PPM consecutive cases from 10 hospitals of both university hospitals and general hospitals all over Thailand between May 2019 and June 2019. Table 1 shows the X-ray machine manufacturer, type, and year of installation at each hospital. Fluoroscopy and cine acquisition using 15 frames per second were the most common format for undergoing CAG and PCI. The overall baseline basic characteristics of the patients that underwent CAG, PCI, and PPM are shown in Table 2. Mean age for all common cardiac procedures was 65.2±12.9 years old. Overall mean body mass index was 24.0±4.6 kg/m². For CAG procedure, as shown in Table 3, KAP, cumulative AK, and fluoroscopy time significantly varied between hospitals with a median range between 8.1 and 34.3 Gycm² for KAP, and 114 to 486 mGy for cumulative AK). The NDRL of KAP was 29.3 Gycm² and cumulative AK was 395 mGy. PCI also demonstrated the data in the same direction as CAG. Median range of KAP was 21.3 to 157.4 Gycm² and cumulative AK was 344 to 1,842 mGy. NDRL for PCI of KAP was 83.7 Gycm² and cumulative AK was 1,397 mGy. Finally for the PPM procedure, median range of KAP was 0.3 to 7.3 Gycm² and cumulative AK was 2 to 60 mGy. The NDRL for PPM of KAP was 5.8 Gycm² and cumulative AK was 59 mGy. According to access site in which transradial is now the preferable access site for CAG and PCI because of less bleeding complication[8], access site and radiation doses are shown in Table 4. No significant difference of KAP, cumulative AK, and fluoroscopy time between transfemoral or transradial approach for CAG or PCI were observed. Regarding frame rate for fluoroscopy or cine acquisition, lower frame rate at 7.5 frames per second had trend toward to produce lower radiation dose than higher frame rate at 15 frames per second (Table 5). The present study data demonstrated significant difference when using cine acquisition in both CAG and PCI procedures, even when the fluoroscopy time was similar.

Discussion

The present study is the first NDRLs for the common cardiac procedures in Thailand and in the Southeast Asian countries. When compared the NDRLs with European and other Asian countries NDRLs[8-10], Thailand showed the lowest NDRLs in terms of KAP and AK for CAG and the same DRLs as European countries for PCI, and much lower than Japan and Korea NDRLs (Table 6). For PPM, NDRLs Thailand of KAP and AK were higher than twice of NDRLs European countries (Table 6).

Table 4. Access site and radiation doses

	Radial approach; mean±SD	Femoral approach; mean±SD	p-value
CAG	(n=191)	(n=175)	
KAP (Gycm²)	30.0±63.9	23.2±27.9	0.196
Total air kerma (mGy)	362±357	341±406	0.615
Fluoroscopy time (minute)	4.3±4.2	4.1±4.1	0.685
PCI	(n=226)	(n=170)	
KAP (Gycm²)	82.1±71.5	78.9±65.0	0.641
Total air kerma (mGy)	1,270±1,150	1,278±1,169	0.945
Fluoroscopy time (minute)	17.7±13.7	17.9±13.2	0.887

CAG=coronary angiography; PCI=percutaneous coronary intervention; KAP=kerma area product; SD=standard deviation

Table 5. Radiation doses according to fluoroscopy frame rate and cine frame rate

	15 fps; mean±SD	7.5 fps; mean±SD	3.75 fps; mean±SD	p-value
Fluoroscopy frame rate				
CAG	(n=278)	(n=88)		
• KAP (Gycm²)	28.6±56.8	20.9±15.2		0.208
• Air kerma (mGy)	366±417	309±230		0.225
• Fluoroscopy time (minute)	4.0±4.2	5.0±4.0		0.049
PCI	(n=296)	(n=101)		
• KAP (Gycm²)	78.6±66.6	88.5±75.5		0.117
• Air kerma (mGy)	1,275±1,200	1,285±1,030		0.937
• Fluoroscopy time (minute)	16.3±11.5	22.3±17.3		0.000
PPM	(n=68)	(n=174)	(n=67)	
• KAP (Gycm²)	5.8±7.9	8.3±14.9	1.6±1.7	0.001
• Air kerma (mGy)	49±58	77±154	39±50	0.039
• Fluoroscopy time (minute)	6.4±4.4	7.8±7.9	5.6±5.2	0.033
Cine frame rate				
CAG	(n=326)	(n=40)		
• KAP (Gycm²)	28.5±52.7	12.3±9.4		0.052
• Air kerma (mGy)	375±394	170±158		0.001
• Fluoroscopy time (minute)	4.2±4.2	4.5±4.0		0.703
PCI	(n=356)	(n=41)		
• KAP (Gycm²)	84.4±69.8	53.0±54		0.006
• Air kerma (mGy)	1,331±1,184	811±765		0.006
• Fluoroscopy time (minute)	18.1±13.7	15.9±11.2		0.324
PPM	(n=62)	(n=114)	(n=133)	
• KAP (Gycm²)	9.3±9.2	9.4±17.7	2.2±2.1	<0.001
• Air kerma (mGy)	74±74	88±183	29	<0.001
• Fluoroscopy time (minute)	8.1±6.5	6.3±8.2	6.8±4.9	0.138

CAG=coronary angiography; PCI=percutaneous coronary intervention; PPM=permanent pacemaker implantation; KAP=kerma area product; SD=standard deviation

According to access site, there was no difference in DRLs level of CAG and PCI for transfemoral or transradial approach. Nowadays, to avoid bleeding complications due to transfemoral approach, the rate of transradial approach for CAG and PCI are increasing as recommended by ESC guideline for

Table 6. Diagnostic reference levels compared with European and Asian countries

	Thailand	European[9]	Korea[10]	Japan[11]
CAG				
KAP (Gycm²)	29	35	47	59
AK (mGy)	395	460	750	700
PCI				
KAP (Gycm²)	84	85	171	130(NCTO)/280(CTO)
AK (mGy)	1,397	1,200	2,960	1,800(NCTO)/3,900(CTO)
PPM				
KAP (Gycm²)	6	2.5(SC)/3.5(DC)		
AK (mGy)	59	30(SC)/30(DC)		

CAG=coronary angiography; PCI=percutaneous coronary intervention; PPM=permanent pacemaker implantation; KAP=kerma area product; AK=total air kerma; SC=single chamber pacemaker; DC=dual chambers pacemaker; NCTO=non-chronic total occlusion; CTO=chronic total occlusion

myocardial revascularization[11]. From the present data, it could be ensured that transradial approach for coronary procedures do not increase radiation exposure to both patients and medical staffs. The most parameters affecting DRLs were the cine and the fluoroscopy frame rates. The higher frame rate creates higher patient dosage. It is recommended to use 7.5 frames per second rather than 15 frames per second for fluoroscopy and cine acquisitions during coronary procedures to minimize radiation dosages without disturbing the image quality as the data of fluoroscopy have no statistical significance. In Thailand, the cardiac patient doses were varied from center to center, depending on operator's experience, X-ray equipment and parameters set up, and the awareness of the operators in radiation protection. Radiation protection program should be encouraged and refresher courses should be implemented for all cardiac interventionists and catheterization laboratory staffs to create the awareness and culture of radiation protection.

Limitation

The authors had limitations for the present pilot study on DRLs. First, the number of sample size was too small. Second, number of participant hospitals were not much, as only 15% of overall catheterization laboratories participated. Therefore, this may not represent the whole country; however, the authors try to select representative hospitals in each region of Thailand. Third, the authors did not know which data of radiation derived from which machine, single or biplane. Finally, the authors did not have data about the complexity of lesion for PCI, PPM type (single or dual chambers), and site of implantation. More data collection in the future are needed.

Conclusion

The present study is the first study to introduce the NDRLs for common interventional cardiovascular procedures in Thailand. The NDRLs are compared to the Asian and European countries. The results will help the optimization of patient doses in the interventional cardiology procedures at centers in Thailand. The lowest frame rate during fluoroscopy and cine acquisitions for common cardiac procedures should be selected as often as possible.

What is already known about this subject?

DRLs are established to optimize the use of fluoroscopy guided intervention. Many countries demonstrated these levels as a reference for radiation protection for both medical staffs and patients.

What does this study add?

This article shows the first data of DRLs in Southeast Asia. Additional data including transradial compared with transfemoral approach and acquisition frame rate for coronary procedure are also demonstrated in this article.

How might this impact on clinical practice?

This study will increase the awareness of radiation protection for interventionists and electrophysiologists who used the fluoroscopic guidance in both diagnostic and therapeutic procedures.

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Conflicts of interest

The authors declare no conflict of interest.

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