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Diagnostic reference levels in PC

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Percutaneous coronary intervention (PCI)

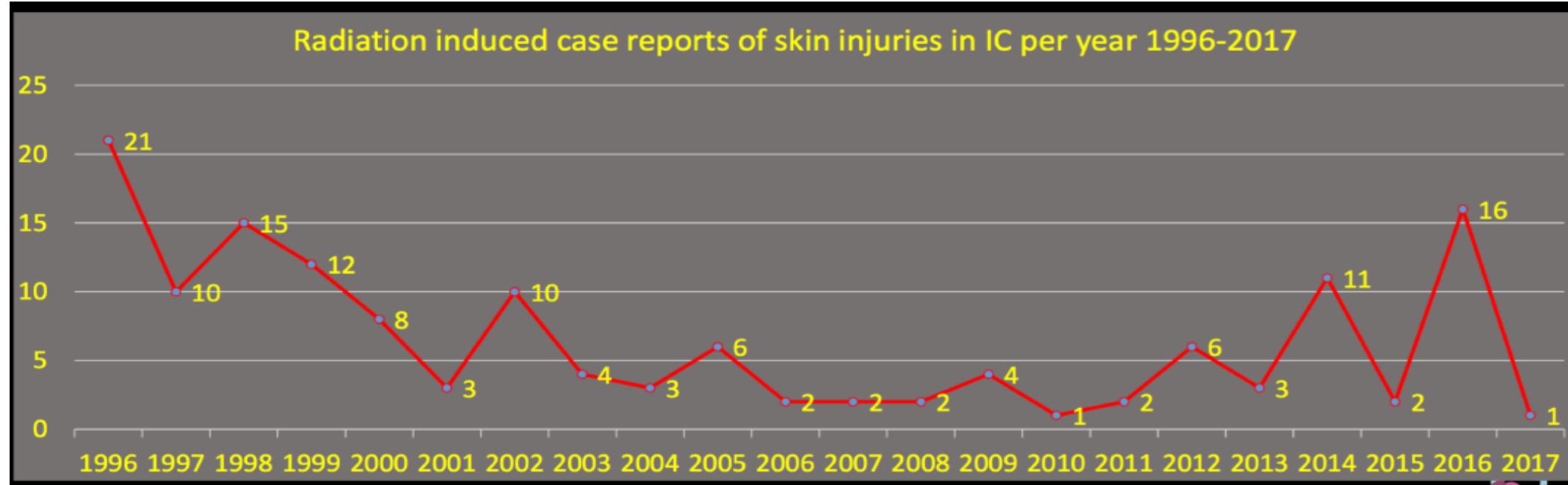
- PCI is now the standard treatment for coronary revascularization in patients who had symptomatic significant CAD.
- The complex PCI particularly chronic total occlusion (CTO) lesion may increase the radiation dose in both cath lab staffs and patients.
- High dose radiation exposure can cause radiation skin injury to the patients and chronic exposure may increase the incidence of premature lens opacity / cataracts as well as stochastic effect.



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Reports of skin reaction due to cardiac fluoroscopy guided





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Radiation & Cataract



- Lens are now sensitive tissue
- Dot Opacities
- Latency depends on rate at which **damaged** epithelial cells undergo fibrogenesis and accumulate.
- **ICRP Publication 118 (2012)** decreased the dose limit of the eye lens from 150 to 20 mSv per year, average over 5 year period, due to the epidemiology of cataract and eye lens opacity.



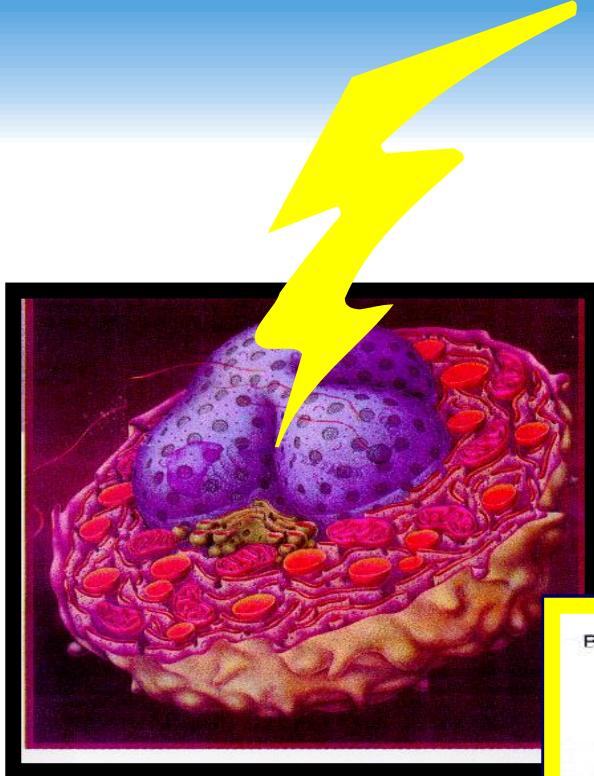
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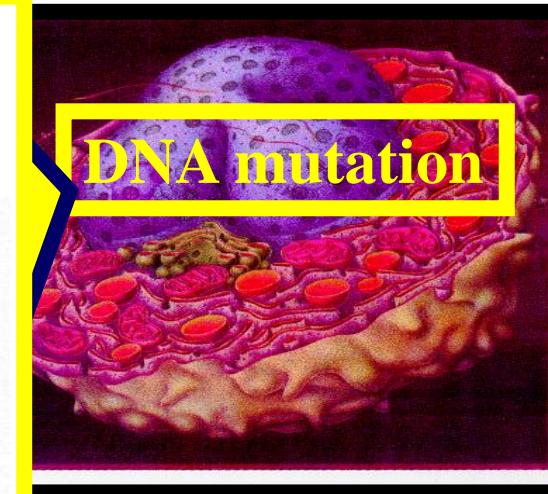
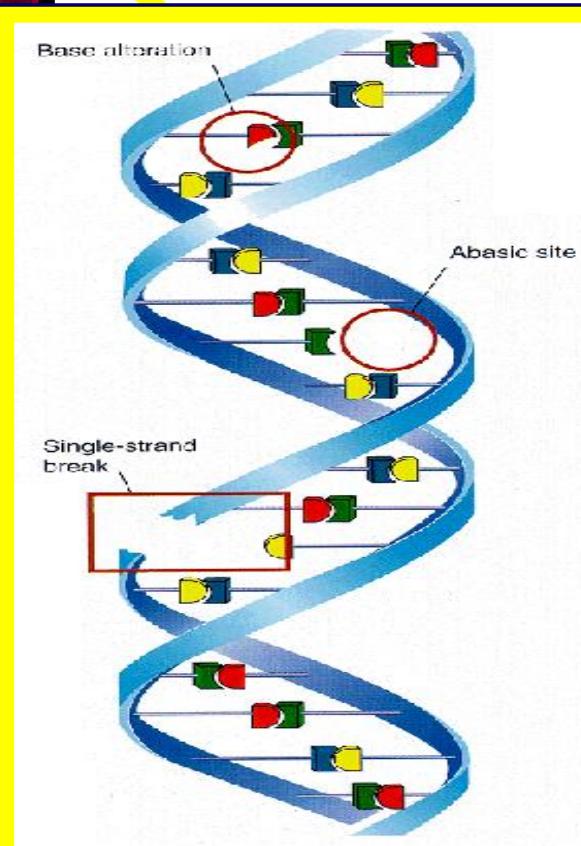
Posterior Subcapsular Lens Opacities

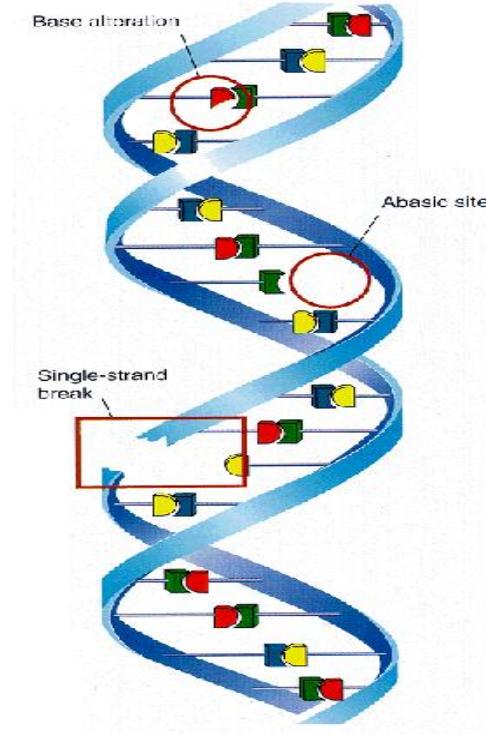
Subject (N)	Posterior lens opacities in one or both eyes (%) *	Relative risk	P value
Interventional Cardiologist (7)	2 (28.6%)	14.4	0.013
Nurses and Technicians (41)	8 (19.5%)	8.73	0.020
All Interventional cardiology staffs (48)	10 (20.8 %)	9.47	0.014
Control (37)	1 (2.7%)	1	

*Posterior lens opacities if modified Merriam-Focht score is more than 1.0

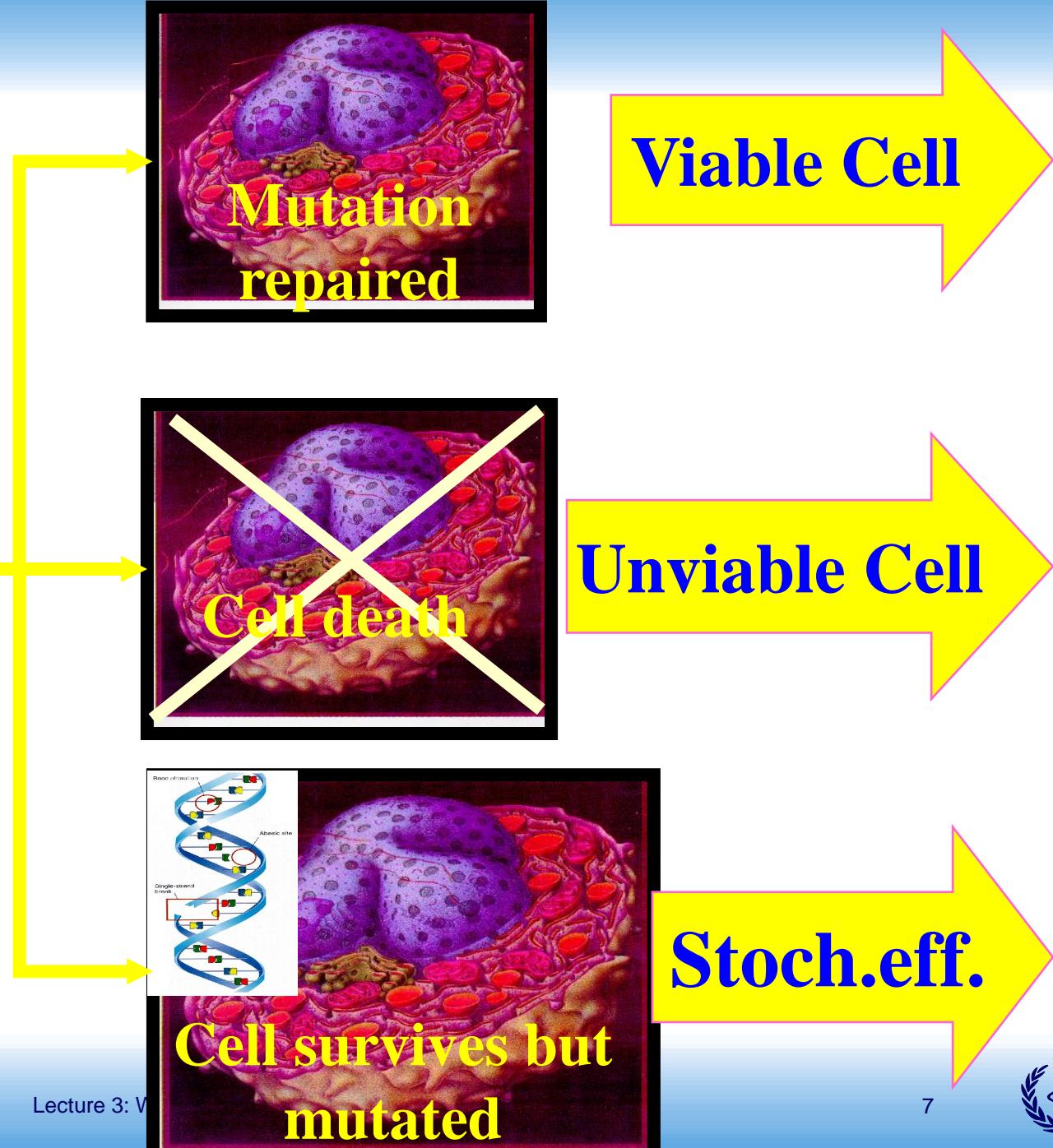


radiation
hits
nucleus!





DNA Mutation
 $p \cong a D$





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To minimize the radiation exposure, ICRP established the radiation protection system for humans.

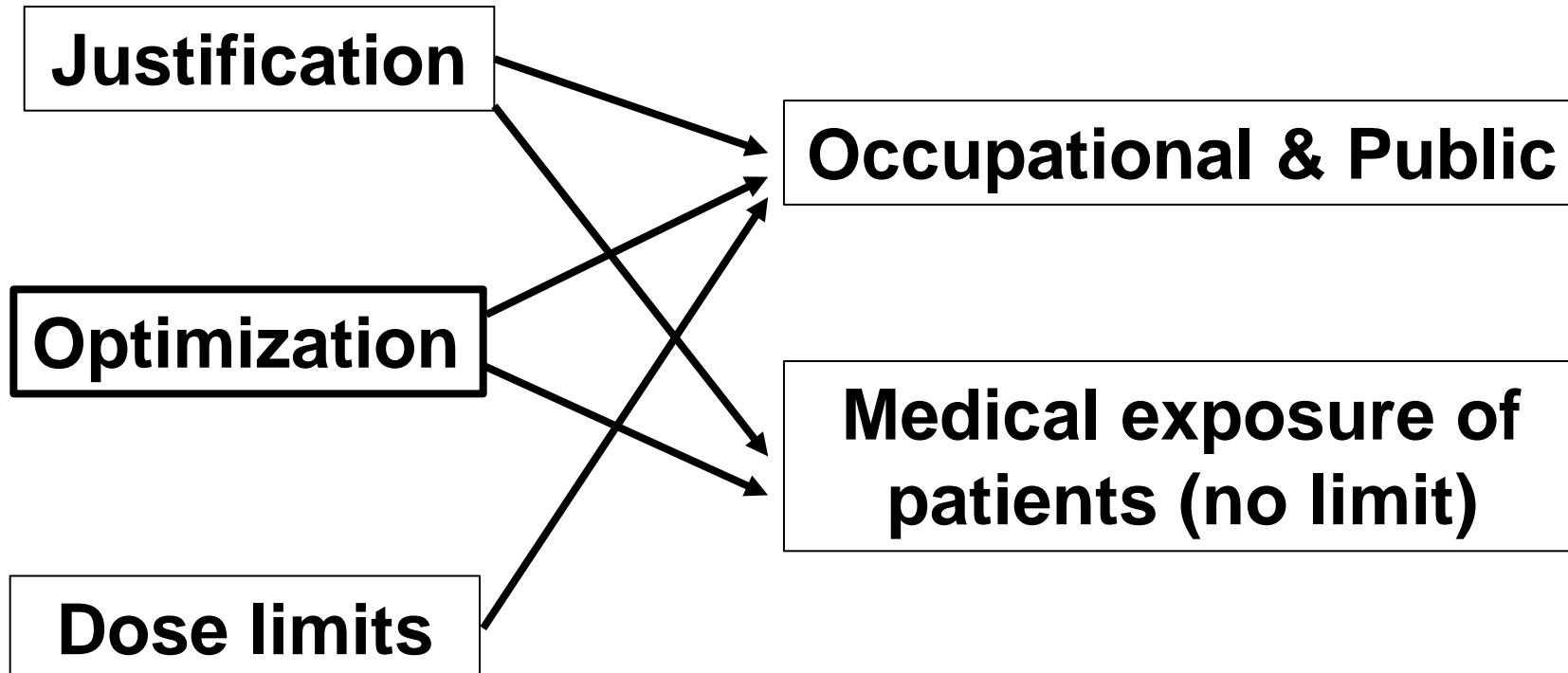
- **Occupational exposures**
- **Public exposures**
- **Medical exposures of patients (the exposure is intentional and for the direct benefit of the patient)**
 - : Diagnostic
 - : Interventional
 - : Therapeutic procedures



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The radiation protection system of ICRP for humans





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What is optimization in Medical exposure?

- The process requiring a **diagnostic outcome** for a patient from an imaging procedure while **minimizing patient dose**.
- **The Diagnostic reference levels (DRLs) have been proven to be an effective tool** that aid in **optimization** of protection in the medical exposure of patients for diagnostic and interventional procedures.
- DRL is calculated by P75 of median value of KAP (or AK) all cath lab sites.



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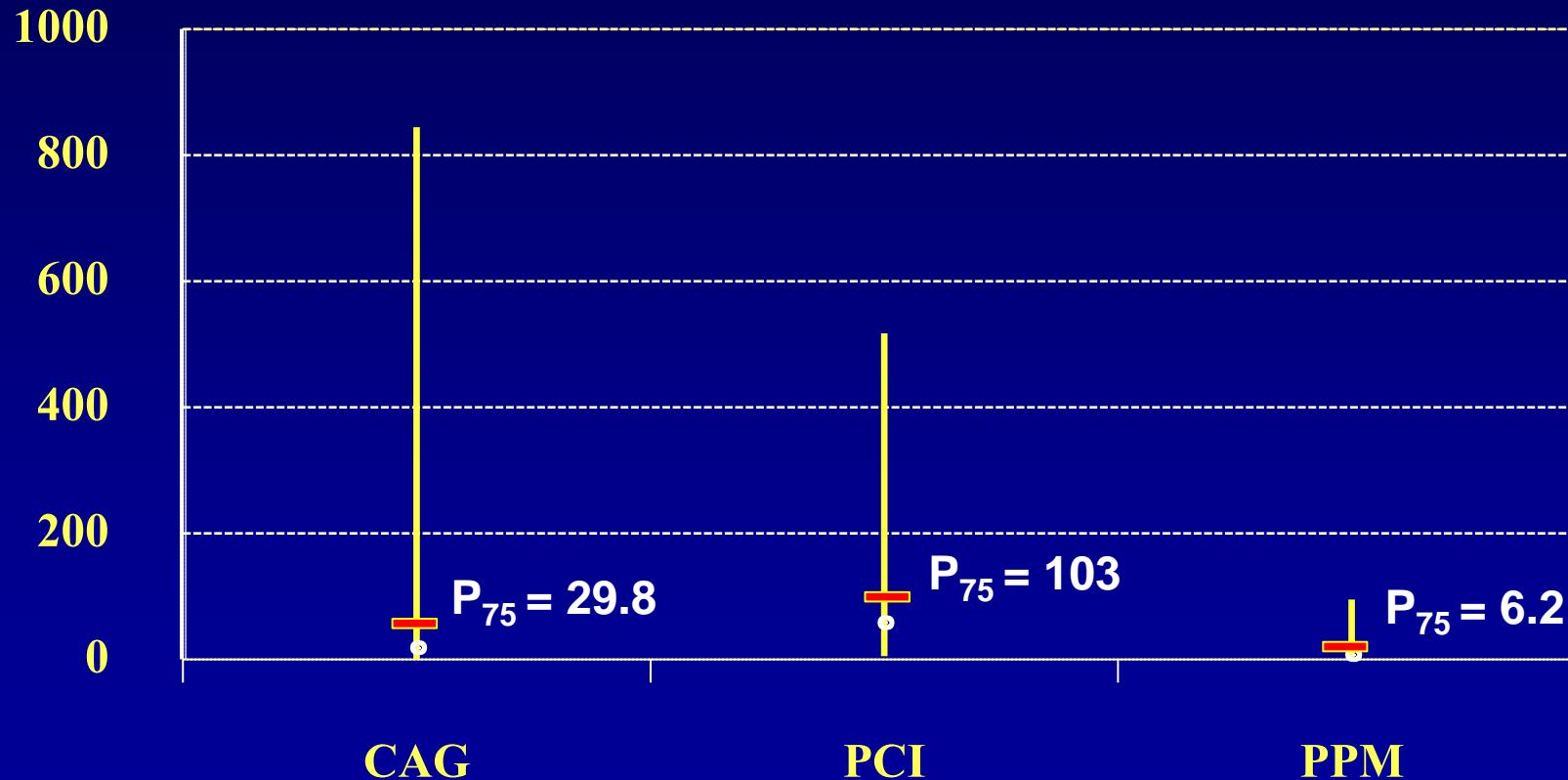
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DRLs for cardiac procedure in Europe: KAP (Gycm²)

Procedure	BE	HR	CZ	FI	FR	GR	IR	LB	PL	RS	ES	SE	CH	3rd quartile
CA	35.6		35.5	21.2	22.0	-	35.3	12.8	14.1	42.2	34.2	17.5	65.7	35.5
PCI	87.3	35.9	89.8	45.7	57.6	44.5	73.0	37.7	28.5	98.1	63.4	31.7	135	87.3
CTO	-	-	-	-	120	-	(271)	-	-	-	-	143	-	137
TAVI	(305.4)	(55.4)	130	89.4	134	193	87.1	99.2	-	-	25.9	87.2	96.8	130
PI SCH	-	-	2.18	1.86	-	5.60	2.63	2.40	-	2.97	-	1.43	-	2.80
PI DCH	-	-	2.28	3.20	-	(25)	2.53	3.84	-	5.16	-	0.86	-	3.65
PI CRT	-	-	18.4	31.4	14	6.63	15.8	4.96	-	19.2	5.82	4.13	-	18.4
EF AVNRT	-	-	0.97	3.67	-	-	(2.26)	-	-	-	-	2.73	-	3.2
EF FL	-	-	0.96	14.5	-	-	-	-	-	-	-	6.58	-	10.5
EF AF	-	-	2.51	29.2	-	-	4.84	-	-	-	-	8.41	-	13.6
EF ALL	-	-	1.09	14.5	3.5	5.28	3.5	109.1*	-	-	13.7	6.53	-	14.1 (11.9)

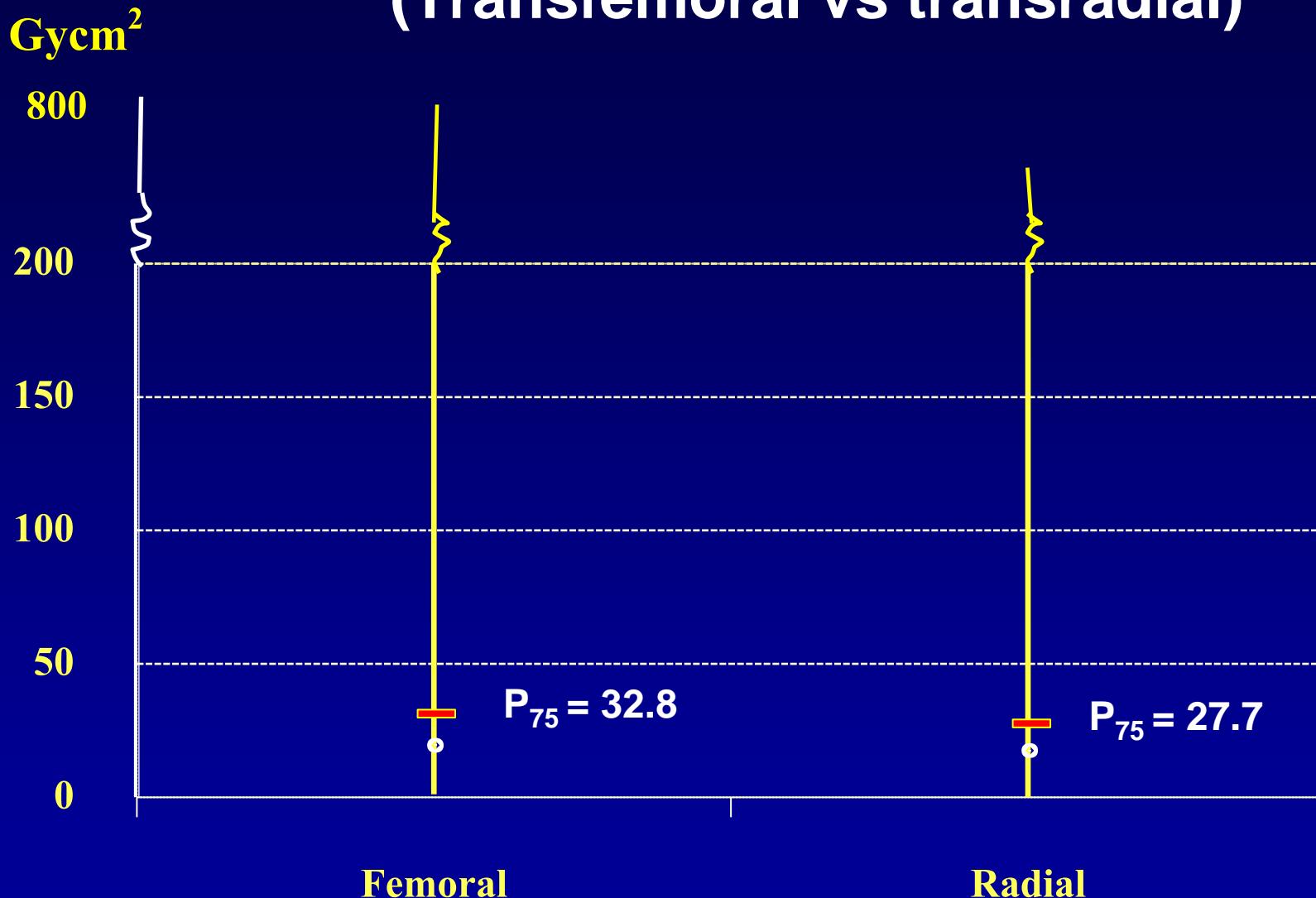


DRLs in common cardiac procedures: KAP (Gy cm^2)



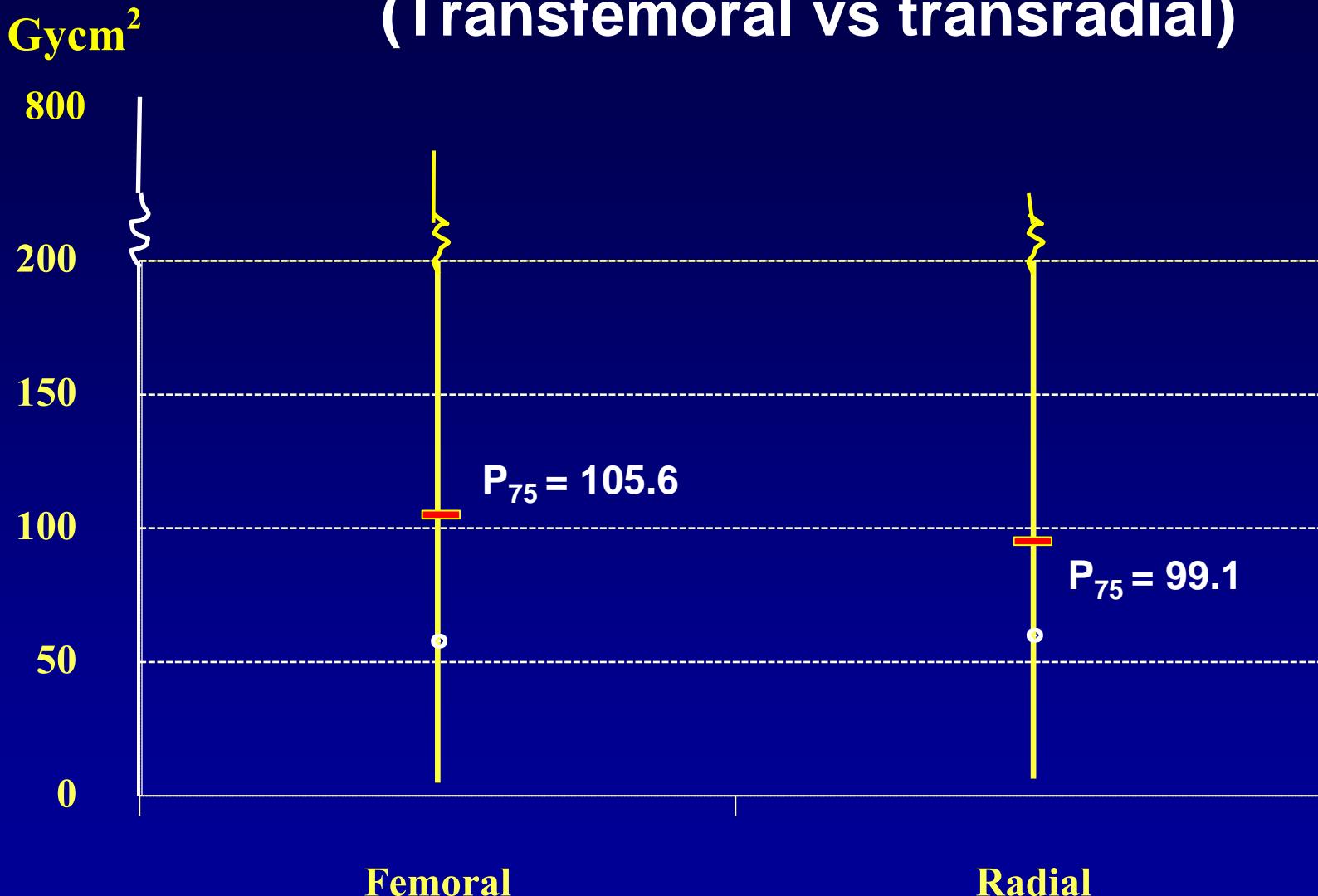


DRLs in CAG: KAP (Gycm²) (Transfemoral vs transradial)



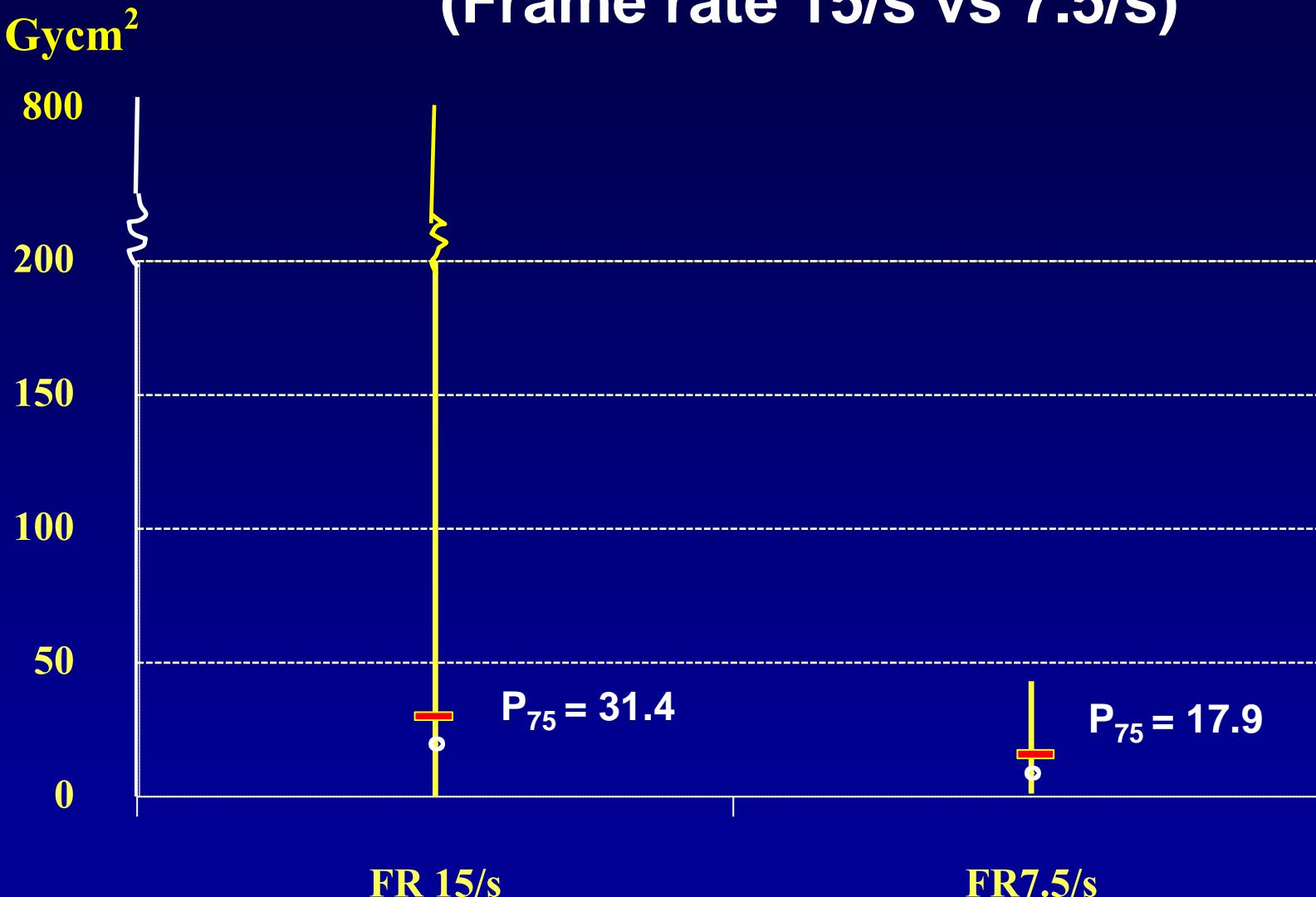


DRLs in PCI: KAP (Gycm^2) (Transfemoral vs transradial)



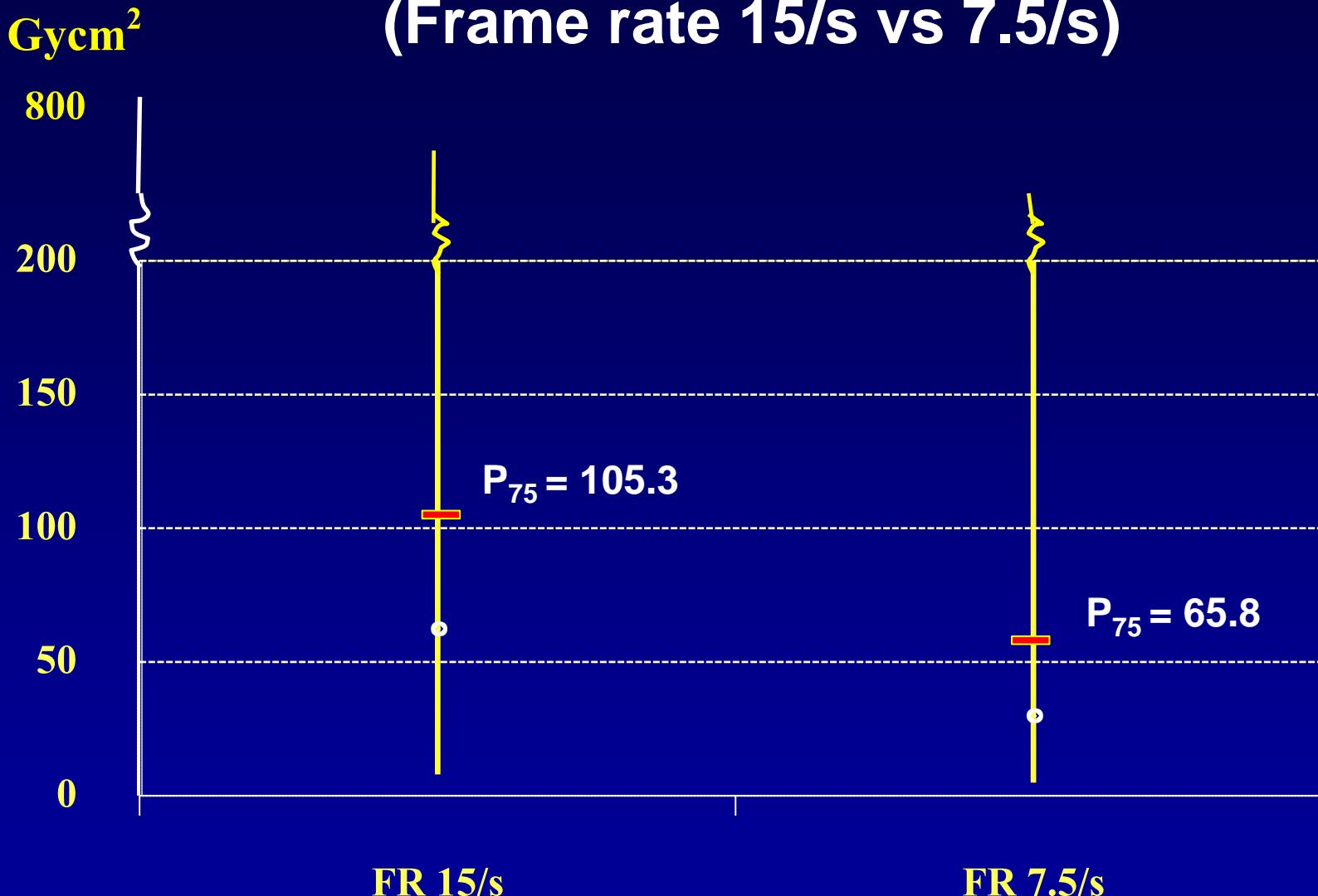


DRLs in CAG: KAP (Gycm^2) (Frame rate 15/s vs 7.5/s)





DRLs in PCI: KAP (Gycm²) (Frame rate 15/s vs 7.5/s)

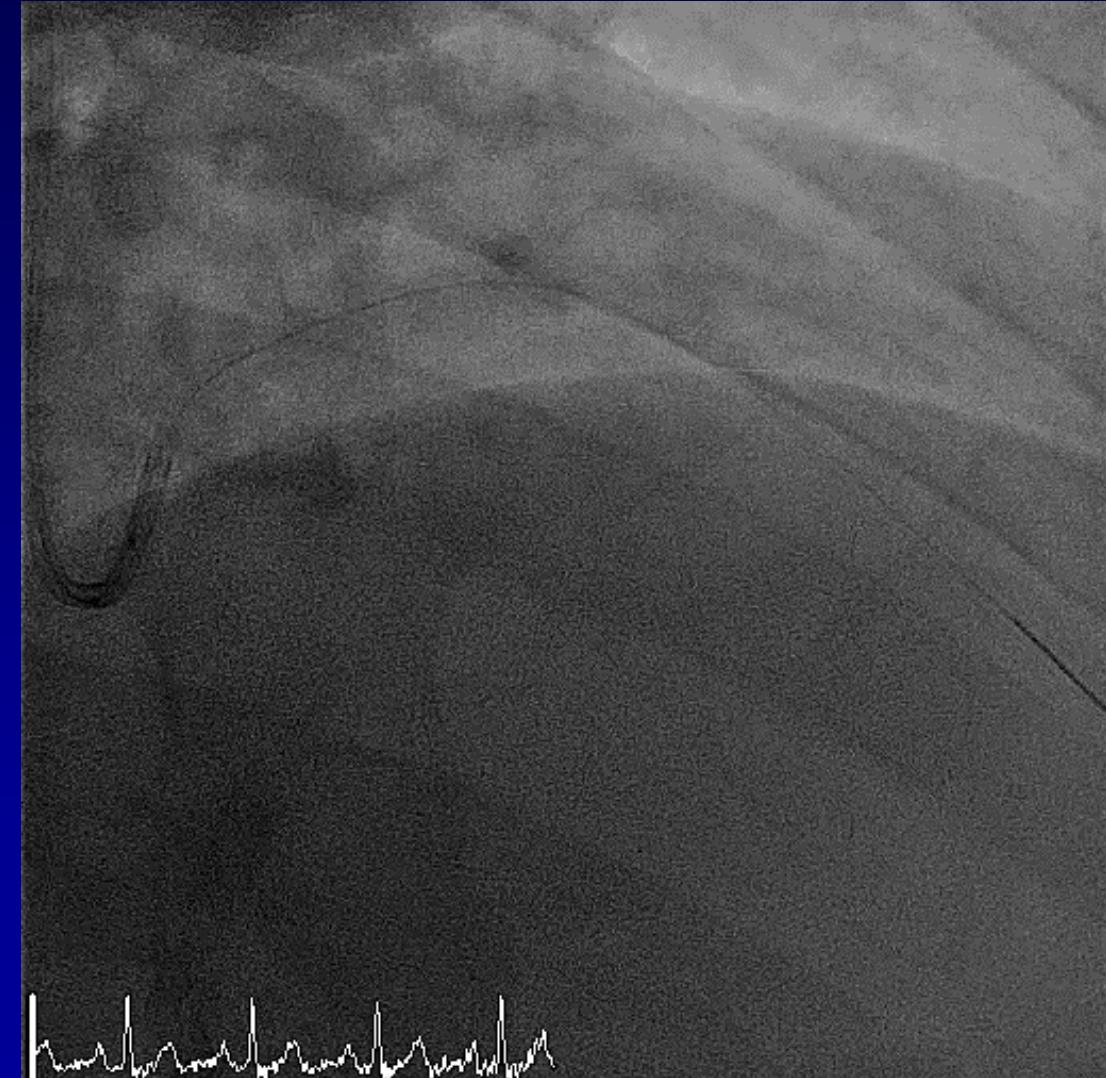
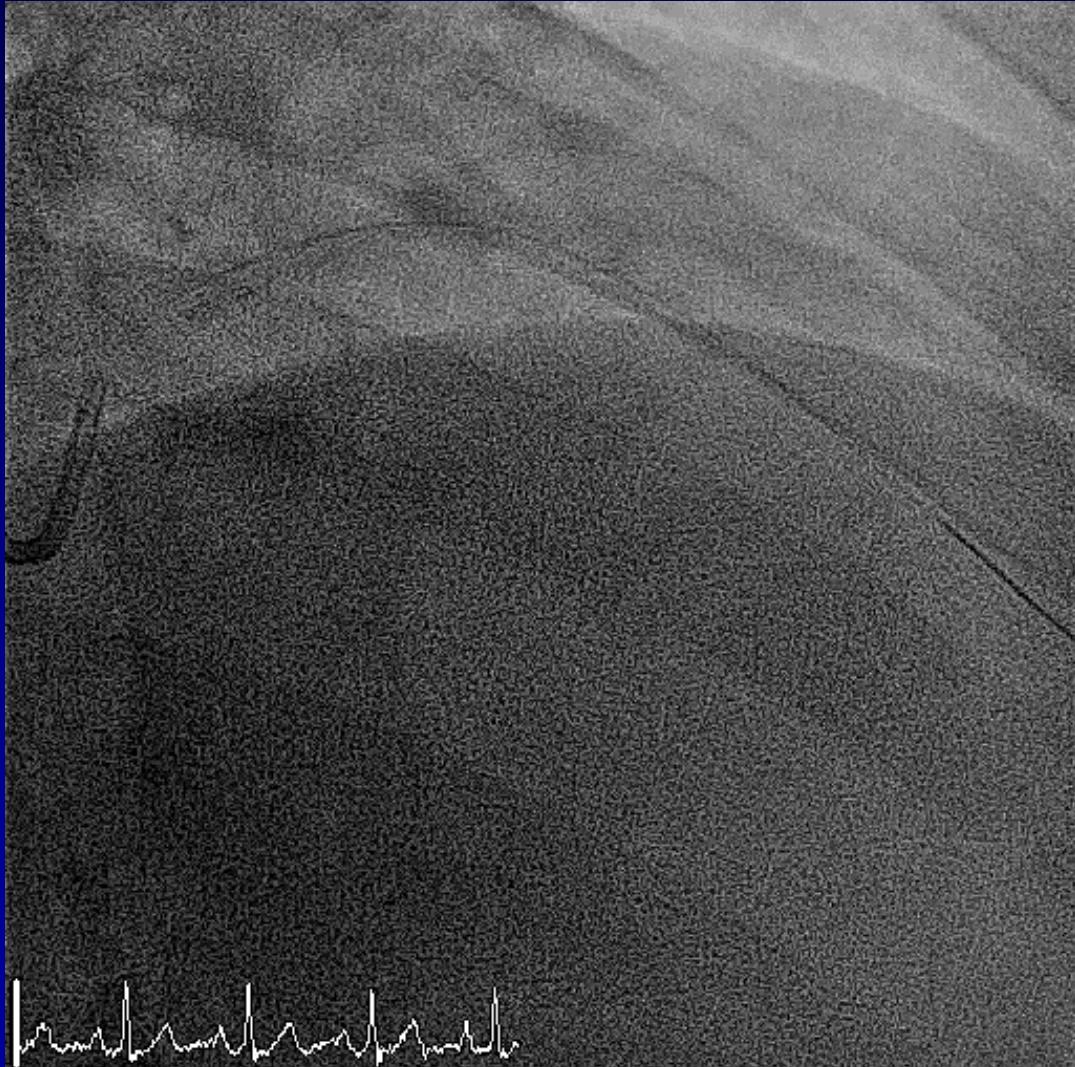




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Fame rate: 15 vs 7.5 f/s



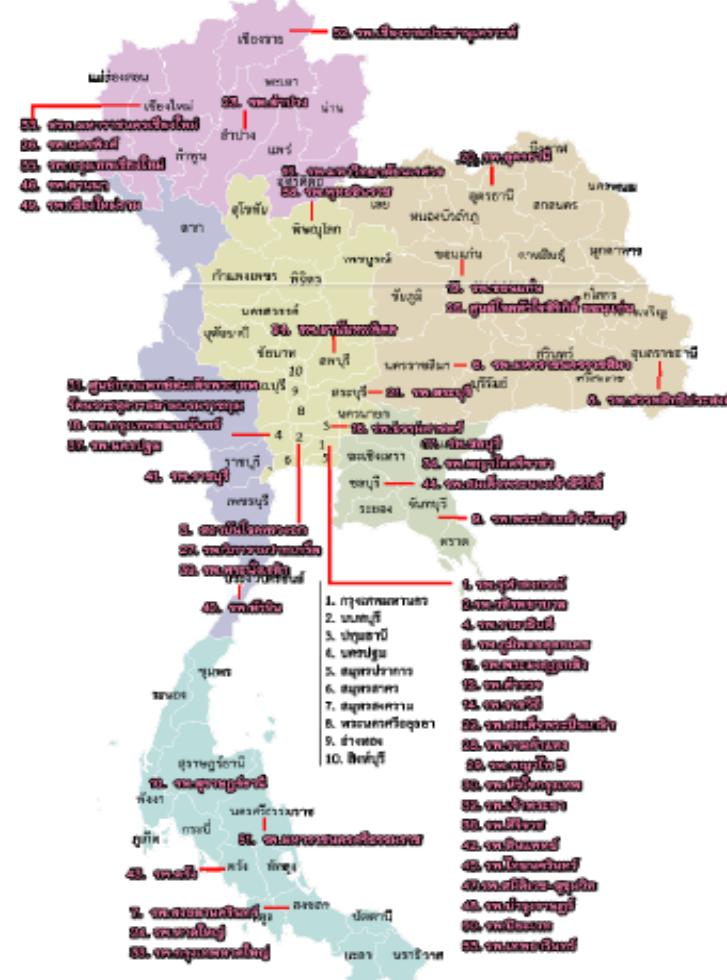
DRL in Thai PCI registry

- Cardiovascular Intervention Association of Thailand initiated the project of the Thai PCI registry.
- 39 hospitals all over Thailand, including academic and non-academic training in cardiology.
- Consecutive cases of PCI were included in the study.
- Data were collected during May 2018 – August 2019.
- Inclusion criteria:
 - The KAP (Kerma area product) from 10 to 3,000 Gy cm²
 - AK (Air Kerma) from 80 to 30,000 mGy
 - Fluoroscopy time from 1 minute to 300 minutes

Thai PCI registry: $n = 22,741$

- Data management using Department of Clinical Epidemiology and Biostatistics, Ramathibodi Hospital.
- The study was approved by Central Research Ethics Committee (CREC) of Thailand.
- The first case enrollment was May 2018 and last case was August 2019
- Auditing 100% of participating sites.
- This study was granted by Health Systems Research Institute (HSRI).

Mapping of 39 hospitals participating in Thai PCI Registry



CRF data: part of radiation doses

PROCEDURE INFORMATION

F04: Procedure Date/Time: - - / :

(DD-MM-YYYY (ວ.ສ.))

(24 hr.)

F05: Fluoroscopy Time: . min

F06: Dose (Air Kerma): . mGy

F07: DAP (Dose Area Product): Gy.cm²



Results:

	KAP (Gycm ²)				AK (mGy)				Fluoroscopy time (min)			
	cases	Median (IQR)	Min	Max	cases	Median (IQR)	Min	Max	cases	Median (IQR)	Min	Max
All site	18,368	64.4 (31,129)	10	2890	21,682	955 (491,1832)	80	22318	22,023	12.6 (7.5,22.0)	1.0	220
DRL	91.3 Gycm ²				1360 mGy				16.4 minutes			

Comparative analysis of our DRLs for PCI with European, Asian countries and USA.

	Belgium 2009	Greece 2013	Swiss 2012	USA 2012	European 2018	Korea 2019	Japan 2020	Thai PCI 2022
PCI : KAP (Gy.cm ²)	106	129	125	193	85	171		91
: AK (mGy)					1200	2960		1360
PCI – non-CTO								
: KAP (Gycm ²)							130	83
: AK (mGy)							1800	1302
PCI – CTO								
: KAP (Gycm ²)					137		280	156
: AK (mGy)					2020		3900	2736

Interesting factors effect on KAP/AK

- **Center: university, public or private**
- **Disease complexity (using ACC/AHA classification – A, B1, B2, C)**
- **Chronic total occlusion (CTO) – the most challenging and highest radiation doses procedure.**
- **Access site (transfemoral / transradial approach)**
- **Cine frame rate (7.5 or 15 f/s)**

Multivariate comparison of hospital type according to KAP/AK at reference point

Factors	Number of cases		Median (IQR)	Multivariate		NDRLs		
	n	(%)		Coefficient (95% CI)	P-value			
Kerma Area Product (KAP, Gy·cm²)								
Hospital type								
University	7,599	(41.4)	100.2 (52.2, 184.3)	68.1 (62.8, 73.5)	<0.001	182.1		
Private	1,765	(9.6)	52.4 (28.7, 92.1)	-37.9 (-48.3, 27.6)	<0.001	73.1		
Public	9,004	(49.0)	45.9 (24.0, 90.7)	0		62.0		
Air Kerma (AK, mGy)								
Hospital type								
University	8,206	(37.9)	1433.0 (762.0, 2522.0)	859.9 (800.6, 919.2)	<0.001	1972.0		
Private	1,931	(8.9)	786.0 (408.4, 1456.0)	-337.4 (-451.1, -223.7)	<0.001	1406.7		
Public	11,545	(53.2)	764.0 (406.1, 1360.0)	0		1075.2		

Multivariate comparison of hospital type according to fluoroscopy time

Factors	Number of cases	Median (IQR)	Multivariate		NDRLs		
	n (%)		Coefficient (95% CI)	P-value			
Fluoroscopy time (min)							
Hospital type							
University	8,370 (38.0)	17.0 (10.4, 28.1)	6.6 (5.9, 7.2)	<0.001	19.6		
Private	1,943 (8.8)	10.3 (6.2, 16.6)	-1.2 (-2.5, 0.1)	0.063	16.5		
Public	11,721 (53.2)	10.6 (6.5, 18.1)	0		13.9		

Multivariate comparison of lesion type according to KAP/AK at reference point

Factors	Number of cases		Median (IQR)	Multivariate		NDRLs		
	n (%)			Coefficient (95% CI)	P-value			
Kerma Area Product (KAP, Gy·cm²)								
Lesion type								
C	11,879 (65.0)		74.1 (36.0, 144.3)	51.5 (38.8, 64.3)	<0.001	106.8		
B2	3,173 (17.4)		58.2 (29.0, 116.8)	31.6 (17.9, 45.4)	<0.001	82.6		
B1	2,453 (13.4)		46.8 (24.9, 88.5)	11.7 (-2.4, 25.8)	0.105	67.9		
A	766 (4.2)		35.2 (21.3, 61.8)	0		45.3		
Air Kerma (AK, mGy)								
Lesion type								
C	13,890 (62.4)		1126.0 (584.4, 2121.0)	823.7 (687.3, 960.0)	<0.001	1704.9		
B2	4,118 (18.5)		830.0 (440.0, 1526.0)	441.8 (295.7, 587.9)	<0.001	1246.9		
B1	3,294 (14.8)		699.5 (371.0, 1243.9)	266.0 (116.6, 415.5)	<0.001	962.1		
A	948 (4.3)		542.5 (320.0, 935.7)	0		789.5		

Multivariate comparison of lesion type according to fluoroscopy time

Factors	Number of cases	Median (IQR)	Multivariate		NDRLs		
	n (%)		Coefficient (95% CI)	P-value			
Fluoroscopy time (min)							
Lesion type							
C	14,111 (62.4)	14.9 (8.9, 25.4)	9.6 (8.1, 11.1)	<0.001	21.4		
B2	4,185 (18.5)	11.3 (7.2, 18.2)	5.0 (3.5, 6.6)	<0.001	16.0		
B1	3,349 (14.8)	9.2 (6.1, 14.4)	1.6 (0.0, 3.2)	0.049	13.1		
A	968 (4.3)	8.4 (5.8, 13.0)	0		12.1		

Multivariate comparison of CTO lesion according to KAP/AK at reference point and fluoroscopy time

Factors	Number of cases	Median (IQR)	Multivariate		NDRLs		
	n (%)		Coefficient (95% CI)	P-value			
Kerma Area Product (KAP, Gy·cm²)							
Chronic total occlusion							
Yes	2,014 (11.0)	114.8 (48.8, 222.5)	84.7 (76.1, 93.2)	<0.001	155.8		
No	16,354 (89.0)	61.0 (30.2, 119.1)	0		83.1		
Air Kerma (AK, mGy)							
Chronic total occlusion							
Yes	2,290 (10.2)	1963.5 (888.8, 3503.0)	1629.0 (1534.3, 1723.7)	<0.001	2735.9		
No	20,083 (89.8)	895.9 (469.0, 1662.3)	0		1302.0		
Fluoroscopy time (min)							
Chronic total occlusion							
Yes	2,305 (10.1)	26.0 (15.2, 44.1)	21.3 (20.2, 22.3)	<0.001	34.9		
No	20,433 (89.9)	12.0 (7.3, 19.6)	0		15.9		

Multivariate comparison of **access site** according to KAP/AK at reference point and fluoroscopy time

Factors	Number of cases n (%)	Median (IQR)	Multivariate		NDRLs			
			Coefficient (95% CI)	P-value				
Kerma Area Product (KAP, Gy·cm²)								
Access site								
Radial	7,705 (42.0)	58.1 (28.4, 116.3)	-19.4 (-24.7, -14.1)	<0.001	93.5			
Femoral	10,663 (58.0)	68.7 (33.9, 141.0)	0		98.9			
Air Kerma (AK, mGy)								
Access site								
Radial	9,854 (44.0)	866.0 (452.4, 1583.7)	-393.2 (-450.3, -336.0)	<0.001	1328			
Femoral	12,519 (56.0)	1038.4 (527.3, 2041.0)	0		1460			
Fluoroscopy time (min)								
Access site								
Radial	10,060 (44.3)	11.5 (7.2, 19.3)	-2.1 (-2.7, -1.4)	<0.001	17.8			
Femoral	12,678 (55.7)	13.5 (8.1, 23.7)	0		18.4			

Multivariate comparison of cine frame rate according to KAP/AK at reference point and fluoroscopy time

Factors	Number of cases	Median (IQR)	Multivariate		NDRLs		
	n (%)		Coefficient (95% CI)	P-value			
Kerma Area Product (KAP, Gy·cm²)							
Cine frame rate							
7.5 f/s	3,215 (19.5)	41.8 (23.2, 72.9)	-59.5 (-66.0, -52.9)	<0.001	60.3		
15 f/s	13,287 (80.5)	69.6 (33.5, 144.0)	0		102.3		
Air Kerma (AK, mGy)							
Cine frame rate							
7.5 f/s	5,187 (26.2)	694.9 (379.7, 1272.6)	-495.8 (-559.6, -432.0)	<0.001	1065.7		
15 f/s	14,639 (73.8)	998.0 (502.0, 1922.0)	0		1472.6		
Fluoroscopy time (min)							
Cine frame rate							
7.5 f/s	5,278 (26.2)	12.5 (7.8, 20.6)	-0.8 (-1.4, -0.1)	0.031	14.1		
15 f/s	14,902 (73.8)	12.4 (7.3, 21.5)	0		17.8		



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Establishment of national diagnostic reference levels for percutaneous coronary interventions (PCIs) in Thailand

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Comparative analysis of our DRLs for PCI with European, Asian countries and USA.

	Belgium 2009	Greece 2013	Swiss 2012	USA 2012	European 2018	Korea 2019	Japan 2020	Thai PCI 2022	Thai 2023 (P75 all)
PCI : KAP (Gy.cm ²) : AK (mGy)	106	129	125	193	85 1200	171 2960		91 1360	90 (94) 1301 (1487)
PCI – non-CTO : KAP (Gycm ²) : AK (mGy)							130 1800	83 1302	69 1062
PCI – CTO : KAP (Gycm ²) : AK (mGy)					137 2020		280 3900	156 2736	105 1739



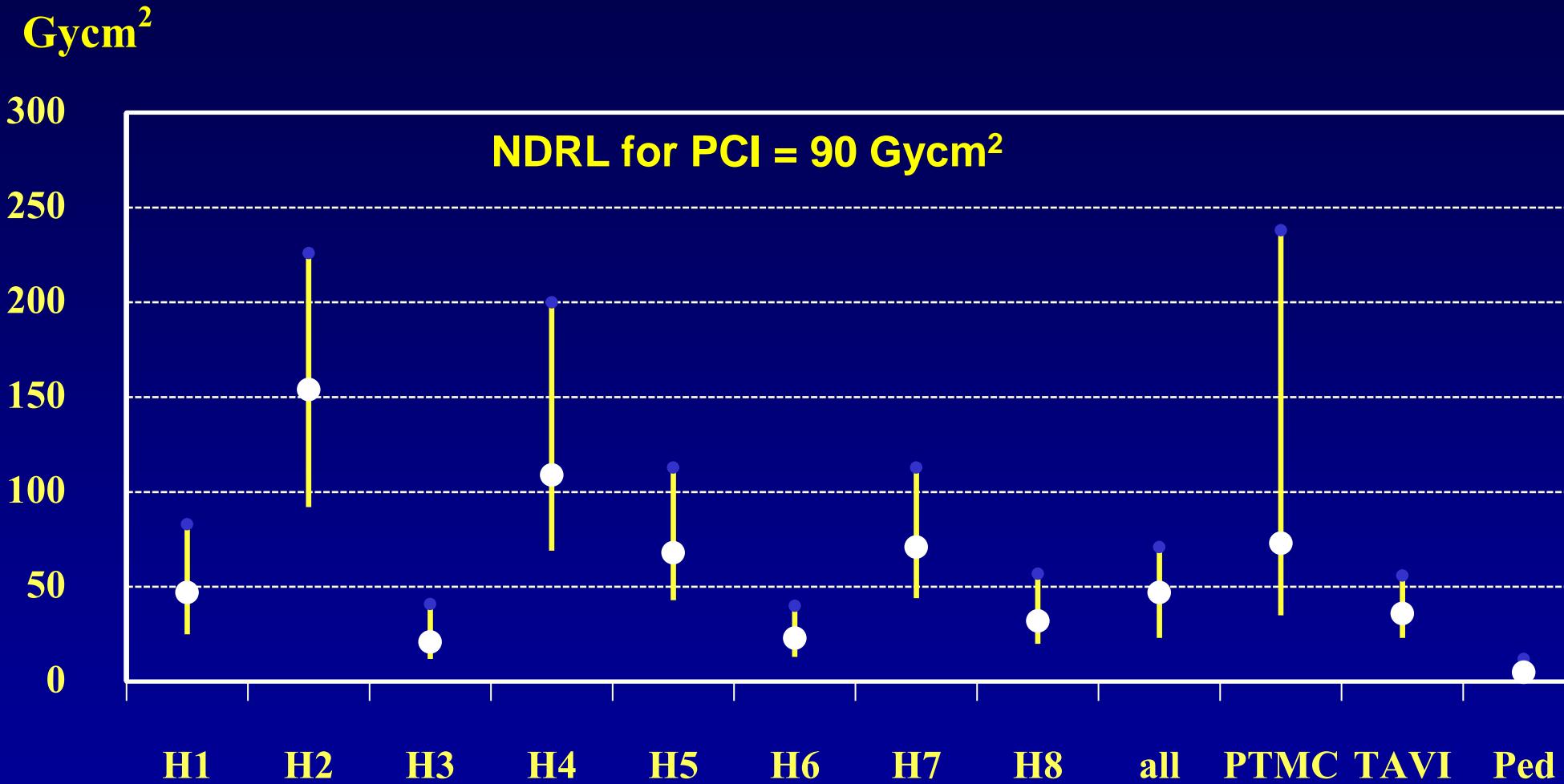


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DRLs for PCI: KAP (Gycm^2)

(9 Hospitals in Thailand – during 2021-2022, n=5185)



CU=1 (flu 7.5/Cine 7.5, EP-3.75), CDI=2 (flu 6/Cine 15), CMU=3 (flu 7.5/Cine 15), มข-4(flu 7.5/Cine 15), มศว-5 (flu 15/Cine 15), รามา-6(flu 7.5/Cine 7.5), ศูนย์สิจิกิติ์ มข=7 (flu 15/Cine 15), สุราษฎร์=8 (flu 7.5/Cine 7.5), Ramathibodi=9 (flu 7.5/Cine 7.5),



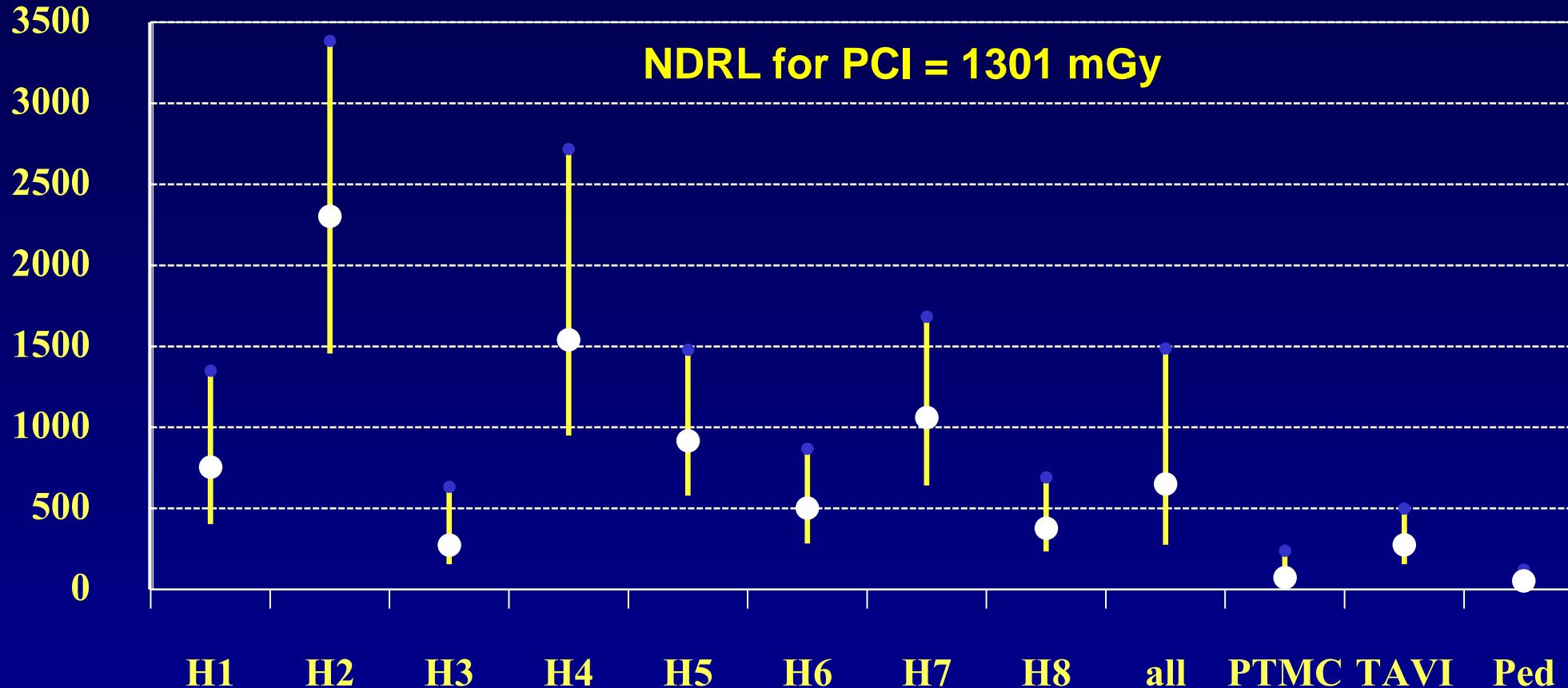
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DRLs for PCI: Air Kerma (mGy)

(9 Hospitals in Thailand – during 2021-2022, n=5185)

mGy



CU=1 (flu 7.5/Cine 7.5, EP-3.75), CDI=2 (flu 6/Cine 15), CMU=3 (flu 7.5/Cine 15), มข-4(flu 7.5/Cine 15), มศว-5 (flu 15/Cine 15), รามคำแหง-6(flu 7.5/Cine 7.5), ศูนย์สิจิกิติ์ มข=7 (flu 15/Cine 15), สุราษฎร์=8 (flu 7.5/Cine 7.5), Ramathibodi=9 (flu 7.5/Cine 7.5),



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% of patients who received radiation > trigger level (DAP > 500 Gy cm², Air Kerma > 5 Gy, Fluoroscopy time > 60 m.)



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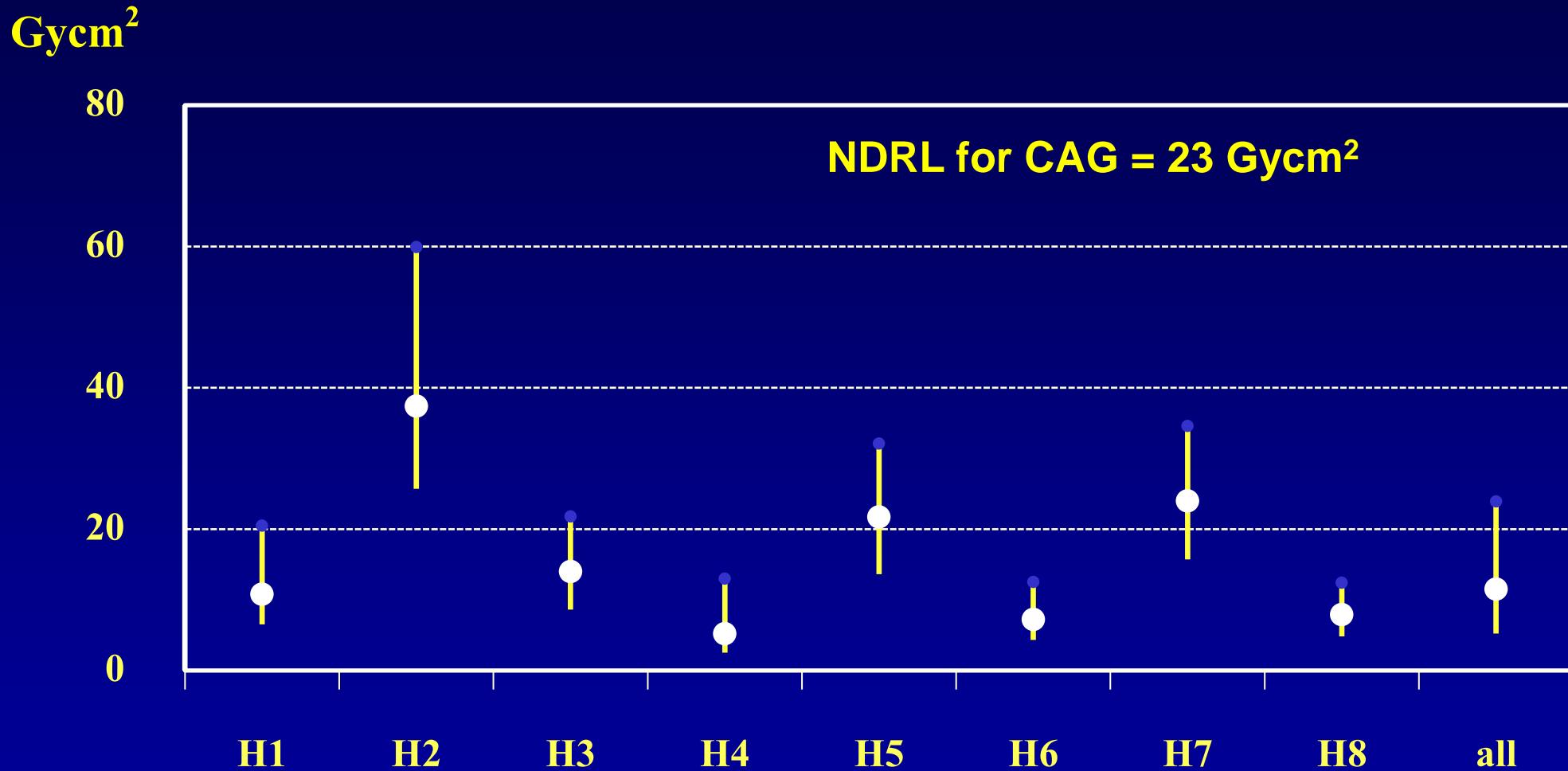


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DRLs for CAG: KAP (Gycm^2)

(9 Hospitals in Thailand – during 2021-2022, n = 5250)



CU=1 (flu 7.5/Cine 7.5, EP-3.75), CDI=2 (flu 6/Cine 15), CMU=3 (flu 7.5/Cine 15), มข-4(flu 7.5/Cine 15), มศว-5 (flu 15/Cine 15), รามา-6(flu 7.5/Cine 7.5), ศูนย์สิจิกิติ์ มข=7 (flu 15/Cine 15), สุราษฎร์=8 (flu 7.5/Cine 7.5), Ramathibodi=9 (flu 7.5/Cine 7.5),

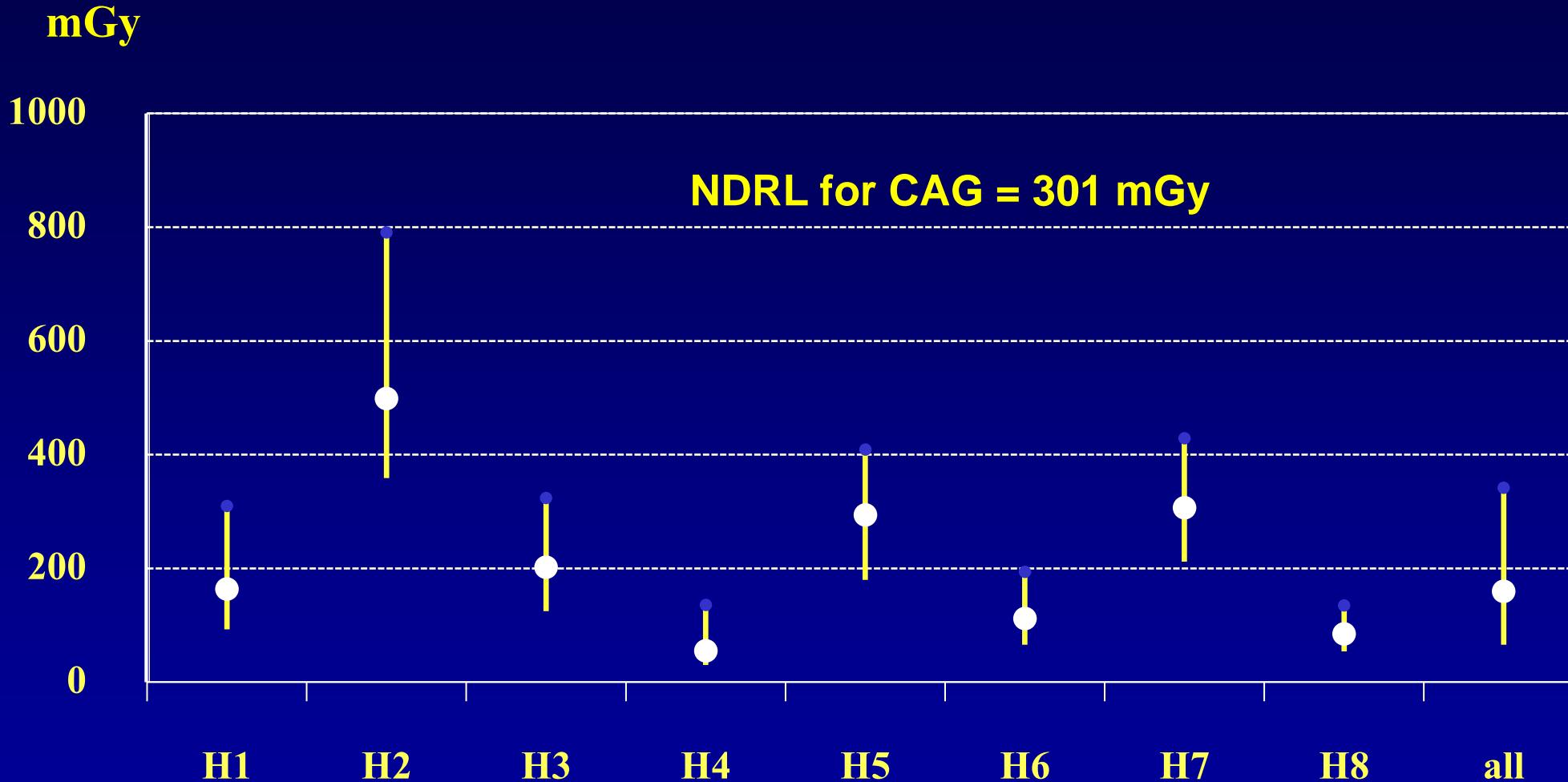


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DRLs for CAG: Air Kerma (mGy)

(9 Hospitals in Thailand – during 2021-2022, n = 5250)



CU=1 (flu 7.5/Cine 7.5, EP-3.75), CDI=2 (flu 6/Cine 15), CMU=3 (flu 7.5/Cine 15), มข-4(flu 7.5/Cine 15), มศว-5 (flu 15/Cine 15), รามา-6(flu 7.5/Cine 7.5), ศูนย์สิจิกิติ์ มข=7 (flu 15/Cine 15), สุราษฎร์=8 (flu 7.5/Cine 7.5), Ramathibodi=9 (flu 7.5/Cine 7.5),



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Summary

- This is the first data available in Thailand (and probable in SEA) for DRL in common cardiac procedures.
- When compared with other countries, our DRL are a bit higher an European countries but lower than Korea.
- We recommended to use lower frame rate (7.5 f/s) acquisition instead of 15 f/s for lower radiation exposure.
- Doses surveys to specialist areas offers important insights to practitioners on dose and image quality.



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Summary

- It is useful to understand the relative patient doses associated with fluoroscopy.
- If the values of DRL quantities for patients are higher than expected, the investigation should start with
 - : evaluation of equipments, then
 - : evaluation of procedure protocols
 - : evaluation of operator technique
- Equipment faults or incorrect set up are easiest to evaluated and correct.
- While operator performance is the most difficult process to analyze and influence.



Thank you for your attention