Patient Doses in Interventional Cardiology

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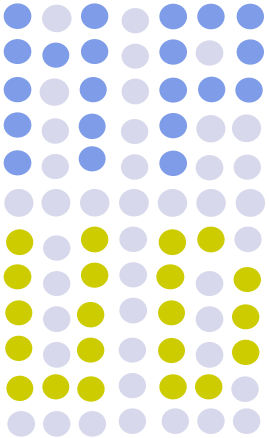

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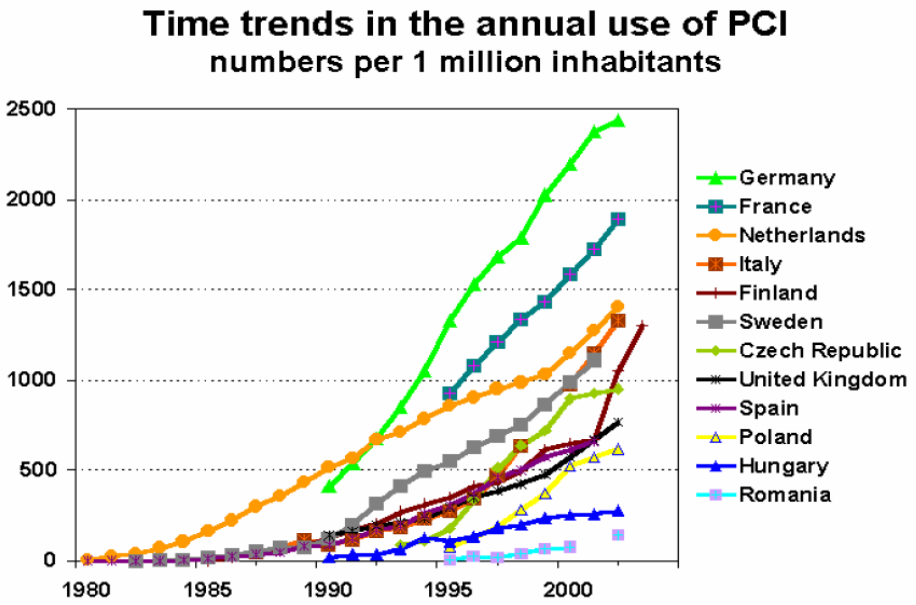
Content

- To introduce the need of radiation protection in interventional cardiology
- To describe the importance of equipment performance assessment and proper set-up; to describe the importance of reference values for equipment set-up
- To describe the benefit of assessing reference levels for patient exposure and dose constraints for staff exposure
- To describe the methods for staff and patient exposure assessment
- To describe need and content of staff education and training and staff involvement in patient/staff dosimetry and image quality assessment

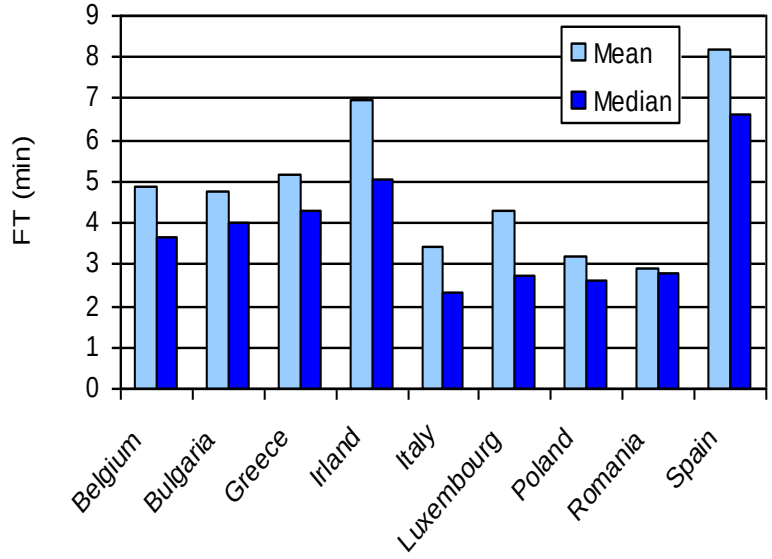
The frequency of cardiac procedures in Europe

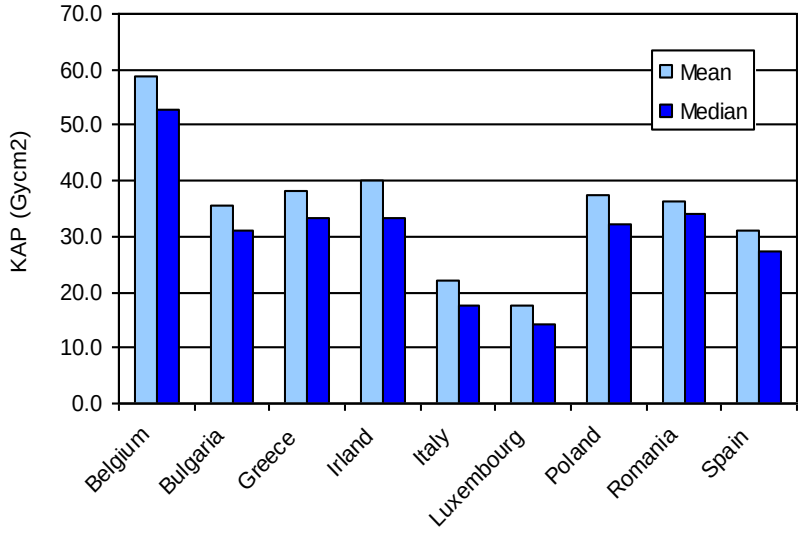
- Number of diagnostic and interventional haemodynamic procedures (PCI) per million inhabitants in European countries is continuously increasing
- Practice is not uniform across Europe



Patient dose: coronary angiography procedures

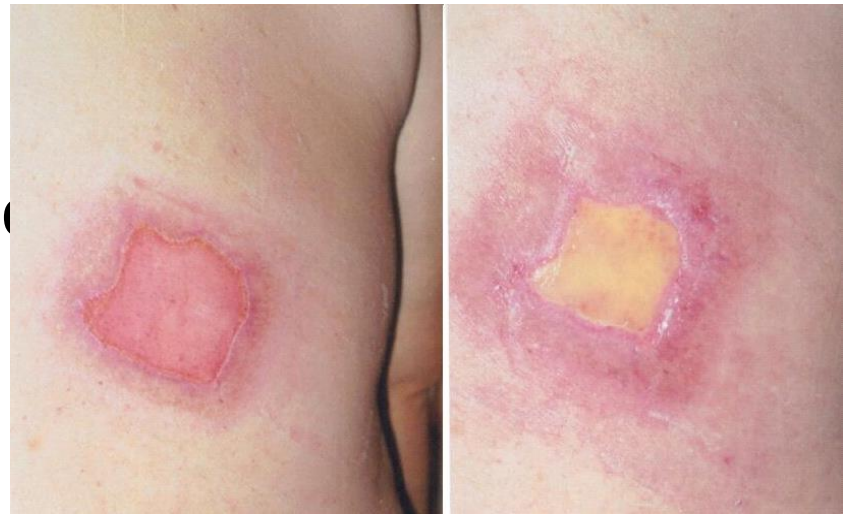
- CA:
  - FT: median values in a range from 2.3 to 6.6 (factor 3)
  - KAP: median values in a range from 15 to 53 (factor 3.5)



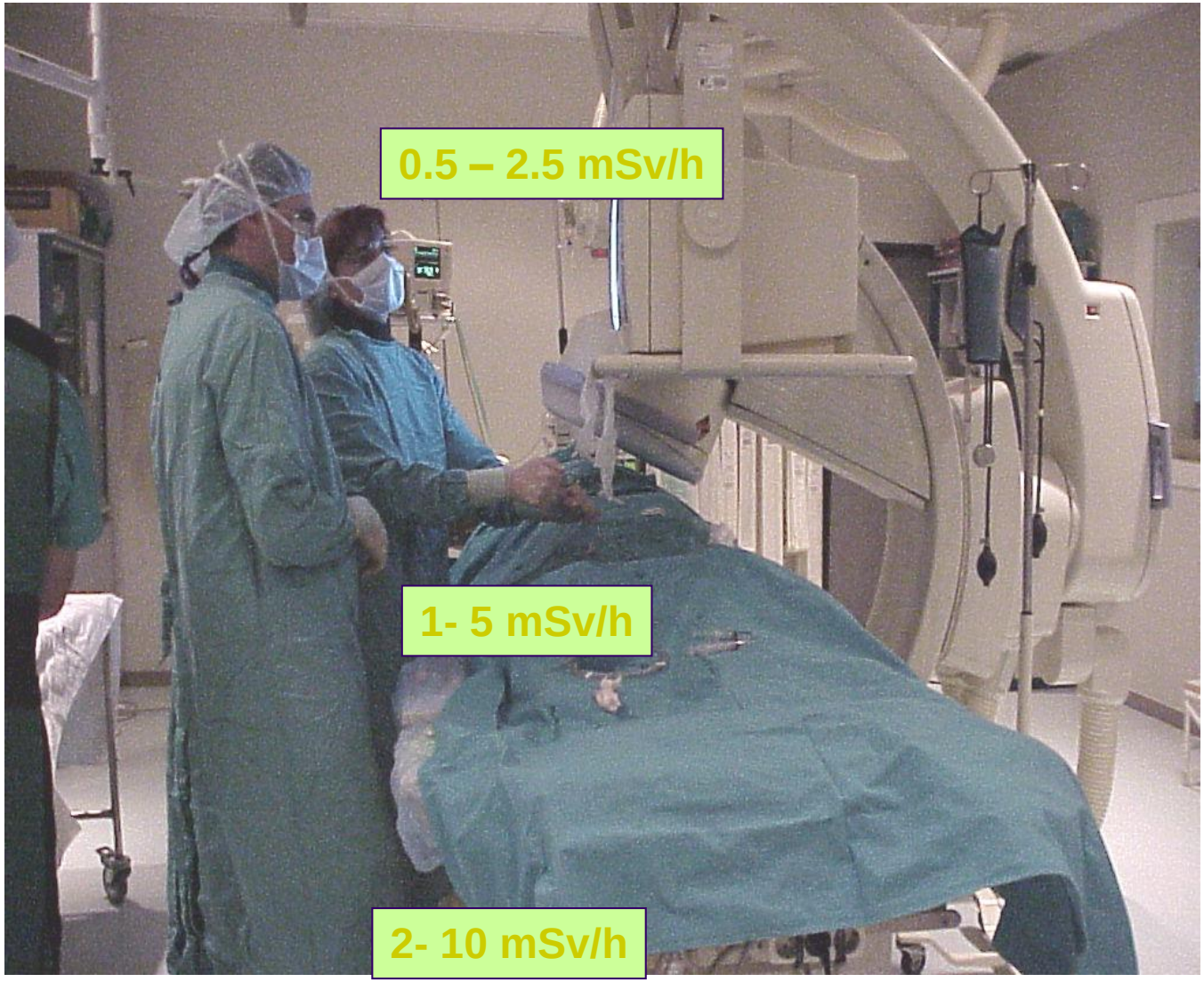


Lessons from injured patients

Cumulative buildup of dose for steeply angled high-dose beam through large patient not recognized.



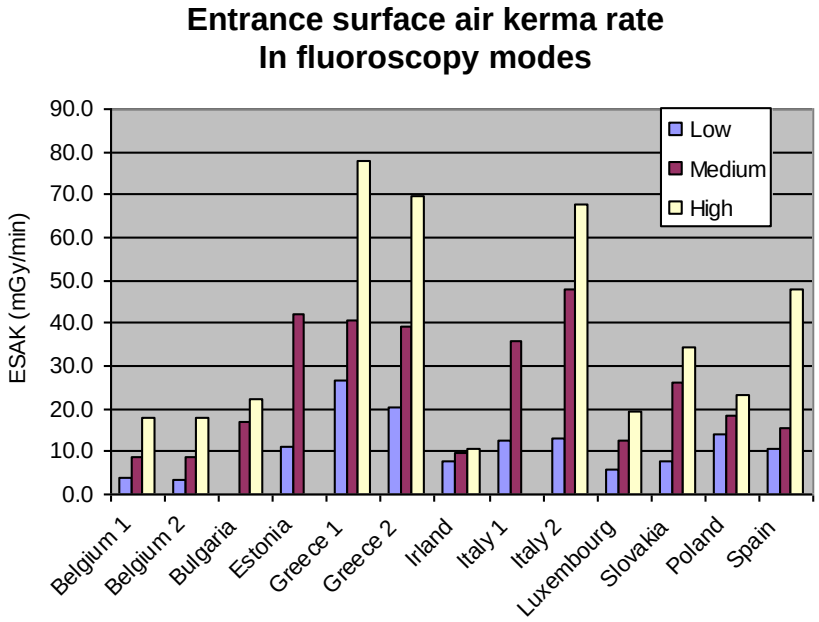
Lesion required grafting.

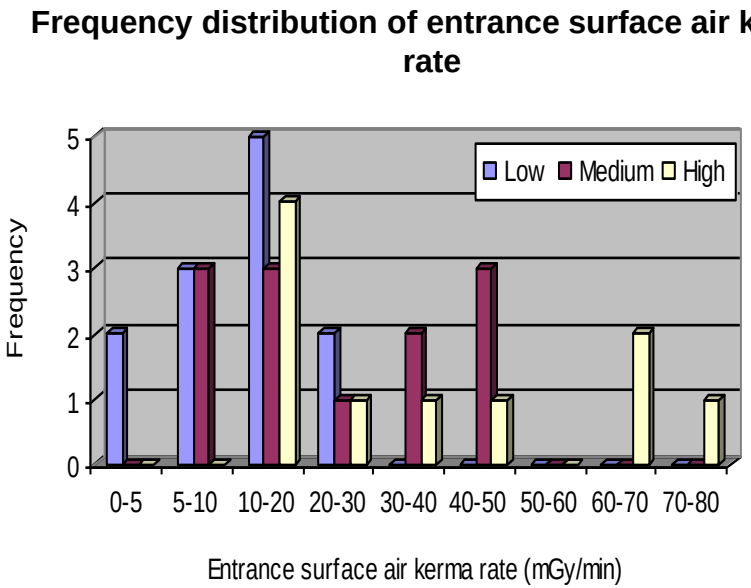


Interventionalsts are working in high dose field:
staff and patient dose are correlated

Equipment performance

Equipment performance (I)



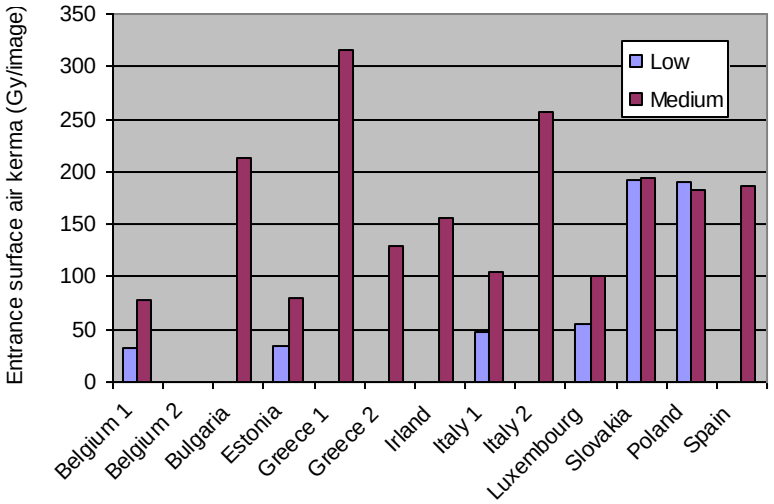


Large variability in equipment set-up and performances:

- dose rates:
  - fluoro low: ratio max/min 7
  - fluoro medium: ratio max/min 5
  - fluoro high: ratio max/min 7

Equipment performance (II)

Entrance surface air kerma rate
In image acquisition (cine) modes



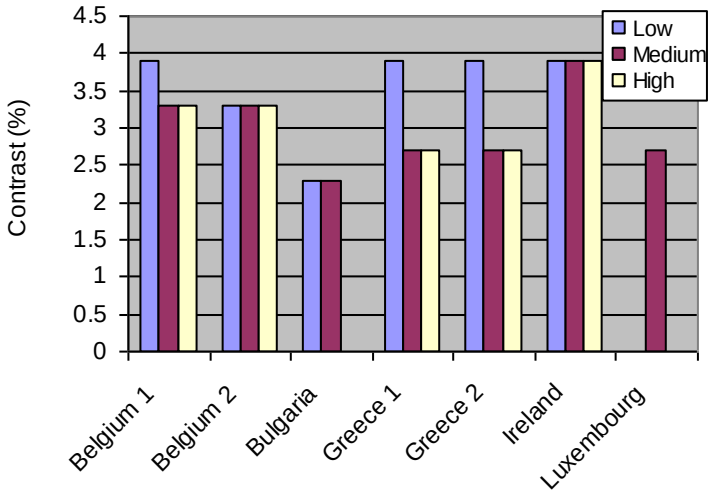
Large variability in equipment set-up and performances:

-dose rates:

- cine low: ratio max/min 4
- cine normal : ratio max/min 4

Equipment performance (III)

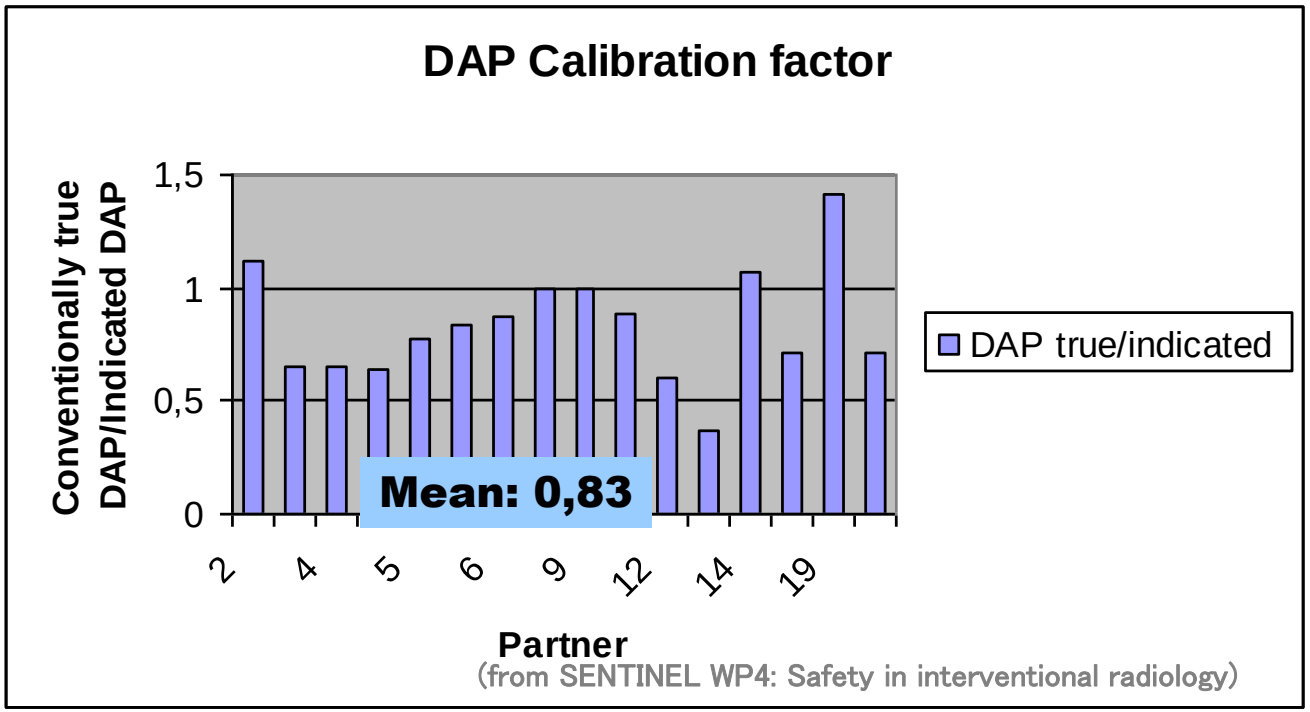
- Image quality: identified poor image quality on some old systems
- Results contribute to explain patient dose variability in angiographic cardiac procedures
- **Reference levels for key performance parameters are proposed:**



(from SENTINEL WP4: Safety in interventional radiology)

Entrance surface air kerma rate (20 cm PMMA; FOV ≈ 18 cm)	**Fluoroscopy low: 13 (mGy/min)** **Image acquisition: 100 (μGy/fr)**

Equipment: KAP calibration



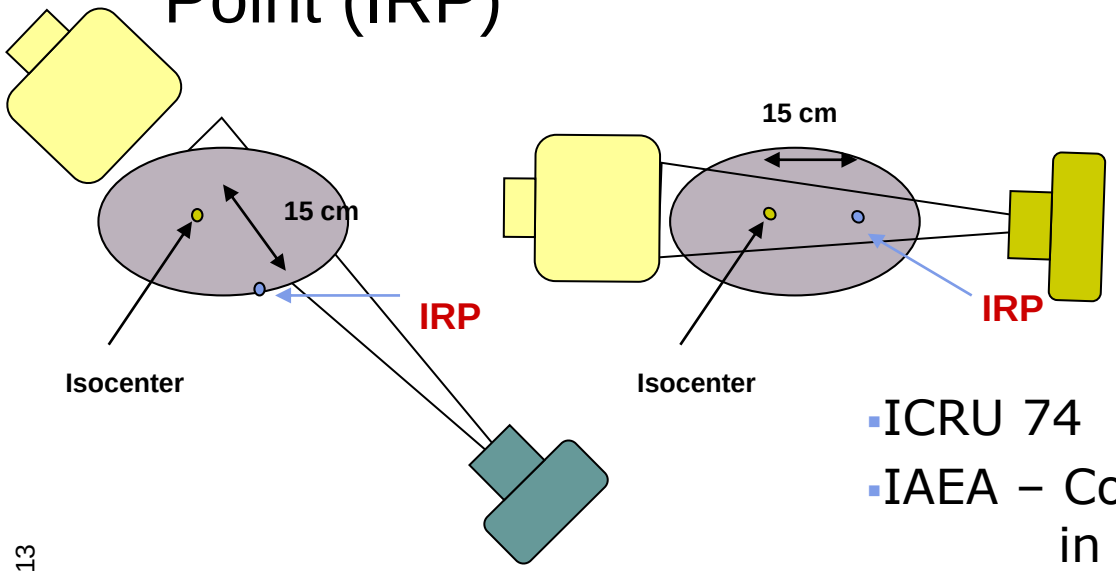
- Calibration should take in to account table and mattress attenuation at typical kV and added filtration
- Periodic checks can be performed without table in the beam
- KAP values provided by the equipment has to be corrected for table/mattress attenuation

Patient doses

Operational quantities for patient dosimetry in FGP

- Air kerma area product KAP or P_{KA} (ICRU 75)
- Cumulative Dose to Interventional Radiology Point (IRP)

- Organ and effective dose D_T and E
- Maximum (peak) skin dose



- ICRU 74
- IAEA – Code of practice for Dosimetry in Diagnostic Radiology

Dose quantities for stochastic risk

Effective dose, E

The equivalent doses to organs and tissues weighted by the relative w_T are summed over the whole body to give the effective dose **E**

$$E = \Sigma_T \, w_T . H_T$$

w_T : weighting factor for organ or tissue T

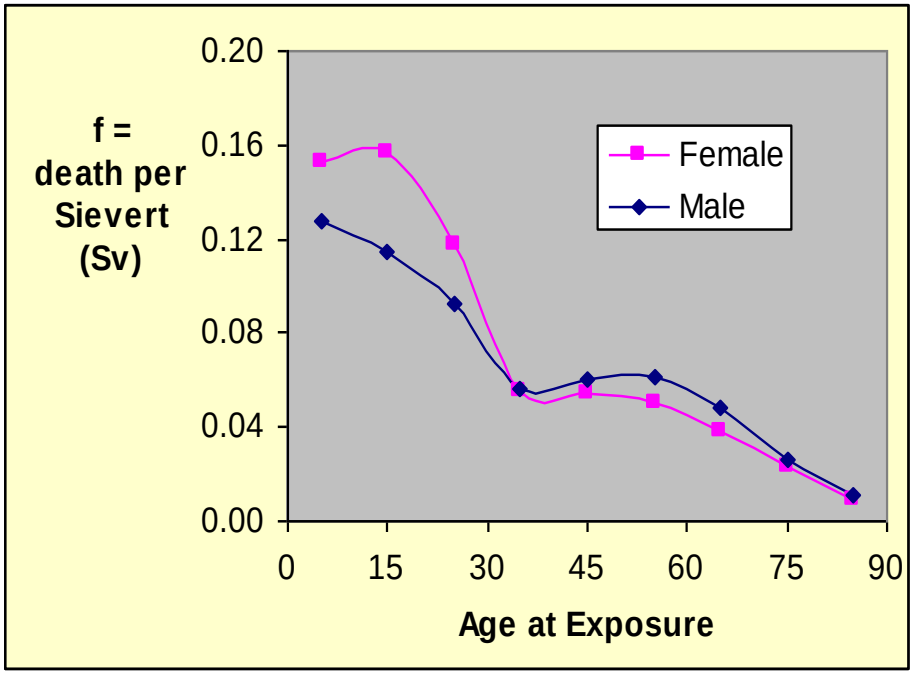
H_T : equivalent dose in organ or tissue T

Dose quantities for stochastic risk

Stochastic risk

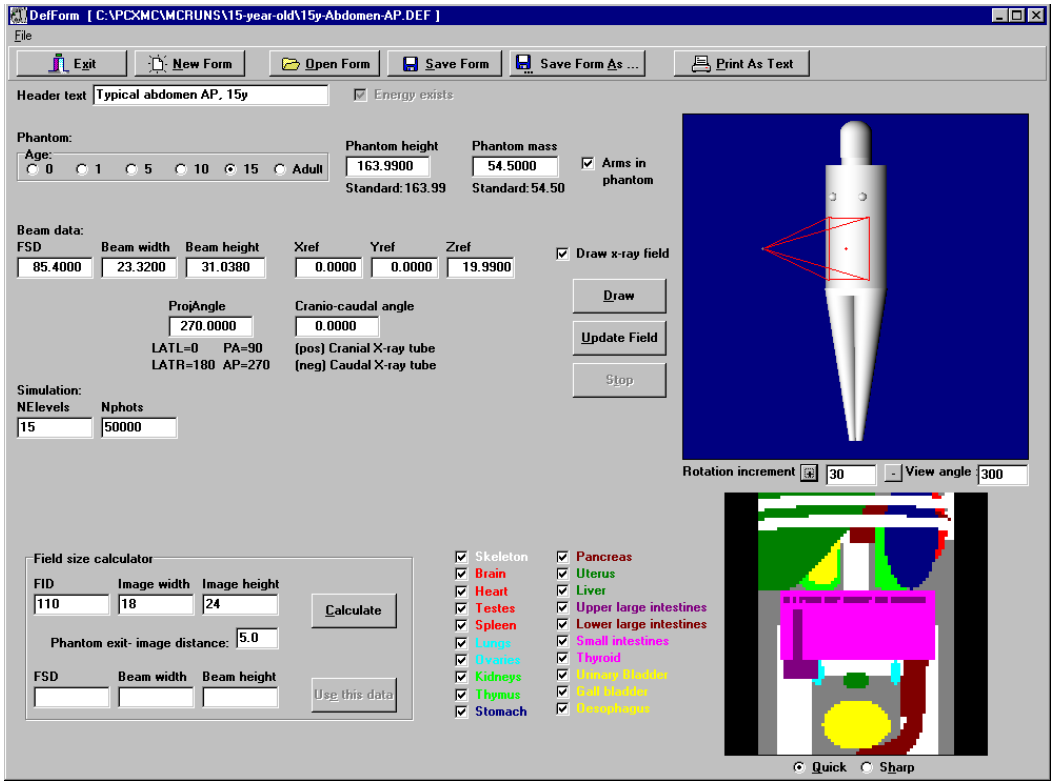
Stochastic risk is calculated multiplying effective dose E by the risk factor specific for sex and age at exposure

Stochastic Risk = E(Sv) * f



Organ and effective dose evaluation

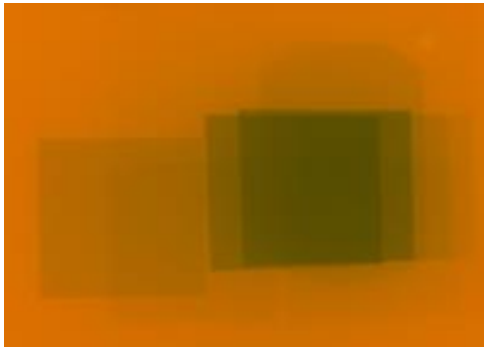
Software tool (STUK, Finland):
PCXMC simulates the interaction of X-rays on a mathematical phantom

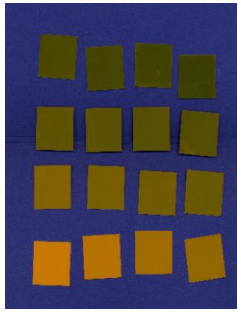


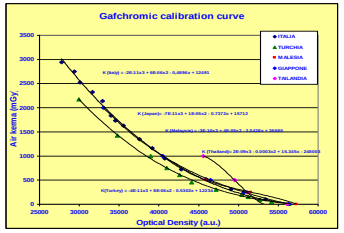
•Tapiovaara M, Lakkisto M and Servomaa A. A PC-based Monte Carlo program for calculating patient doses in medical x-ray examinations, Finnish Centre for Radiation and Nuclear Safety (STUK), Helsinki, 1997. http://www.stuk.fi/pcxmc.

Evaluation of skin dose in high dose procedures

- Periodic monitoring of MSD is necessary in high dose procedures and in frequently repeated procedures
- Dosimetry methods:
  - Cumulative dose at IRP (IEC standard) on DICOM Header
  - Large area detectors (radiochromic films) periodically on sample of patients
  - Relationship between CD or KAP and Peak Skin Dose

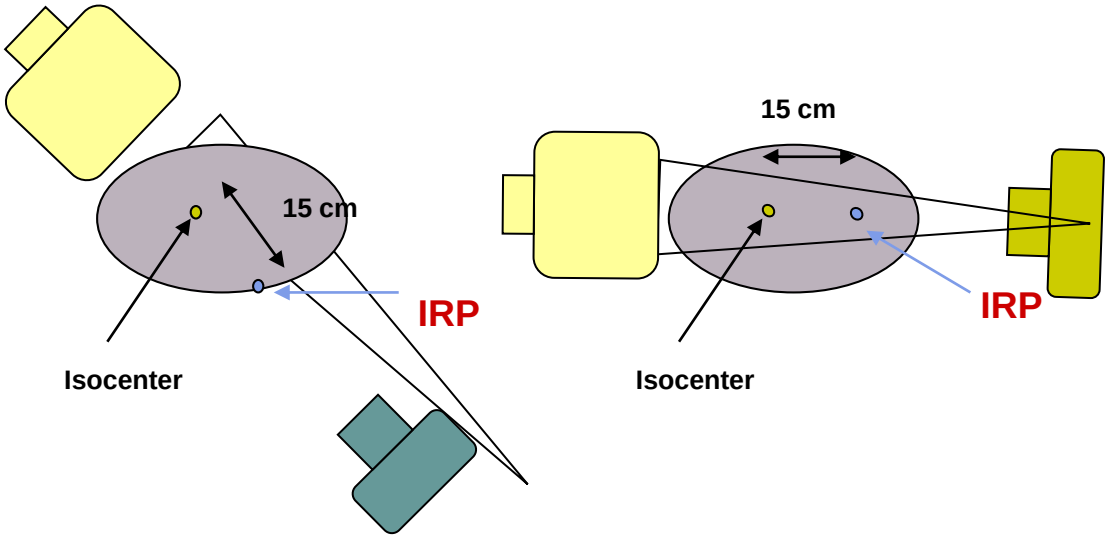


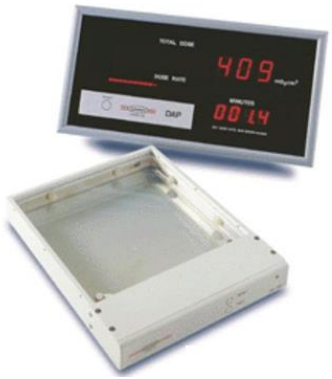




Methods for skin dosimetry: on-line methods (I)

- Point detectors (ion chamber, diode and Mosfet detectors)
- Dose to Interventional Radiology Point (IRP) via ion chamber or calculation

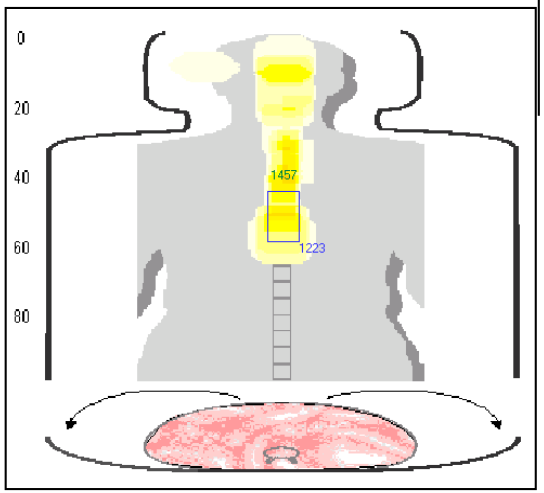


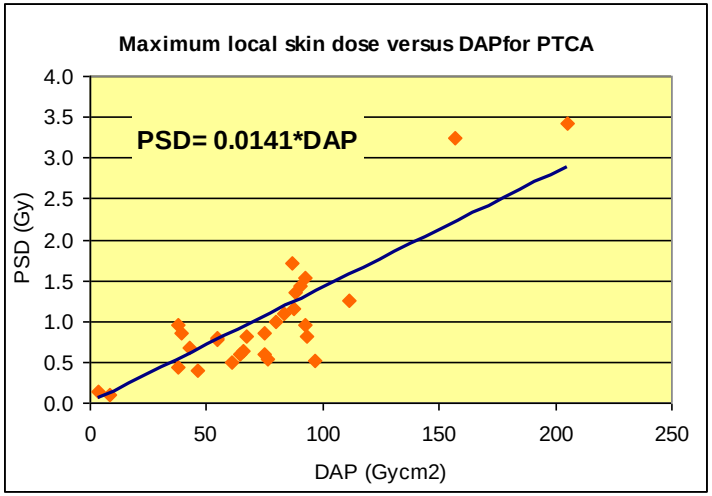


Methods for skin dosimetry: on-line methods (II)

- Dose distribution calculated by the angio unit using all the geometric and radiographic parameters (C-arm angles, collimation, kV, mA, FIID, …)

- Correlation MSD vs. KAP:
  - Maximum local skin dose has a weak correlation with KAP
  - For specific procedure and protocol, installation and operators a better correlation can be obtained and MSD/KAP factors can be adopted for an approximate estimation of the MSD

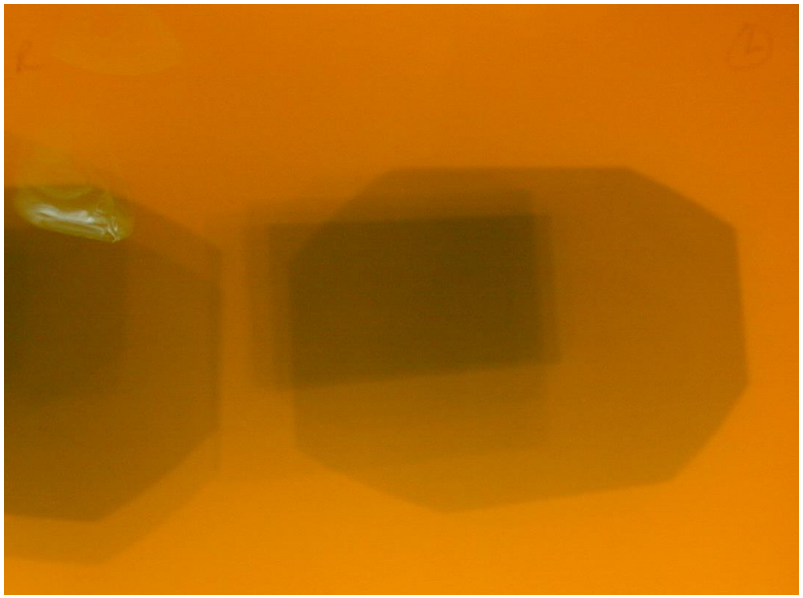




Example of correlation between K_i ESD and KAP for PTCA procedure in the Udine cardiac centre

Methods for skin dosimetry: off-line methods (I)

- Point measurements: thermoluminescent detectors (TLD)
- Area detectors: radiotherapy portal films, radiochromic films, TLD grid
  - Large area detectors exposed during the cardiac procedure: between tabletop and back of the patient

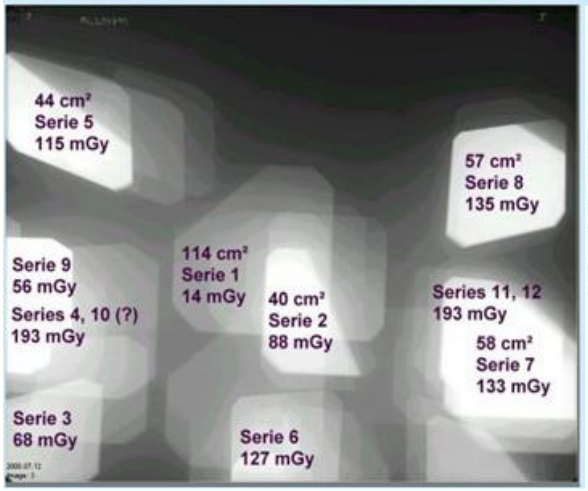


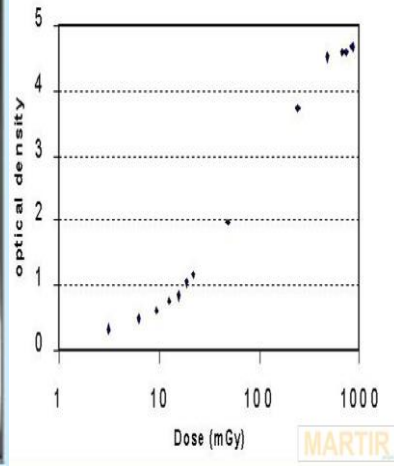
Example of dose distribution in a CA procedure shown on a radiochromic film as a grading of color

Methods for skin dosimetry: off-line methods (II)

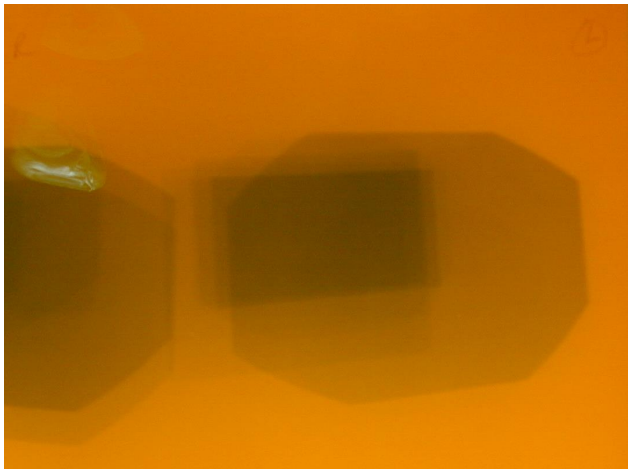
- Area detectors:
  - Air kerma distribution is obtained through a calibration curve of Optical Density vs. air kerma
  - Skin dose distribution is obtained converting air kerma to dose to skin (f=1.06)

Slow film method (Vano E et al. Patient dosimetry in interventional radiology using slow film systems. Br J Radiol 1997; 70: 195-200)





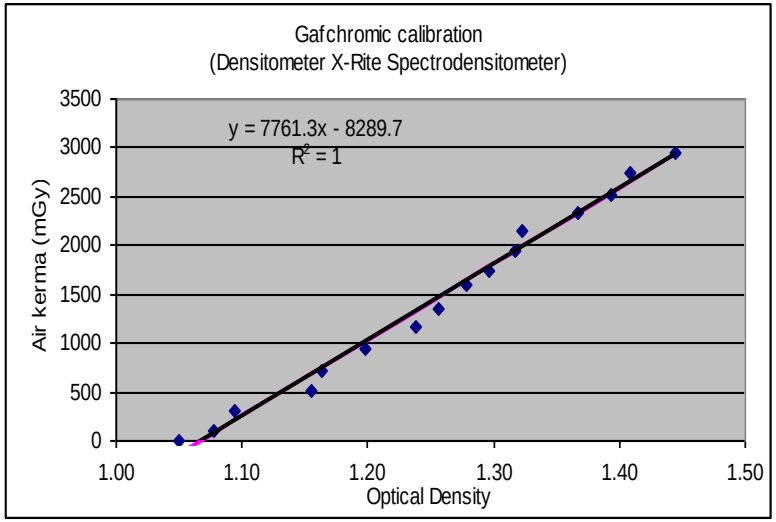
- Radiotherapy films:
  - require chemical processing
  - maximum kerma 0.5-1 Gy
- Radiochromic detectors:
  - do not require film processing
  - immediate visualisation of dose distribution
  - maximum Kerma 15 Gy



Calibration procedure for radiochromic film (I)

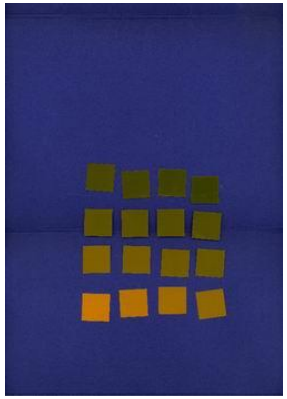
- Each piece of gafchromic is read with the reflection densitometer (typical results are reported in the table)
- Air kerma vs. OD are interpolated in an Excel sheet
- The resulting calibration curve (a straight line in this case) is adopted for the patient dose calculation
- In the example: ESD (mGy) = -8290 + 7771*OD

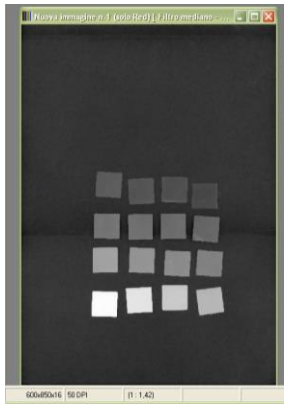
OD	Air kerma (mGy)
1.050	0
1.077	103
1.094	310
1.155	517
1.163	724
1.198	949
1.238	1161
1.256	1346
1.279	1601
1.297	1732
1.317	1936
1.323	2140
1.367	2325
1.393	2521
1.409	2749
1.444	2942

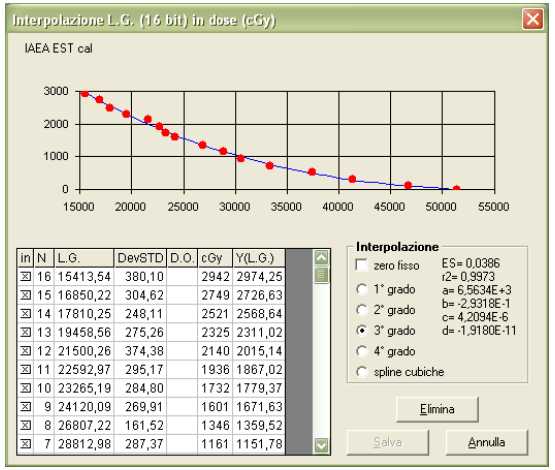


Calibration procedure for radiochromic film (II)

- Flat bed scanner





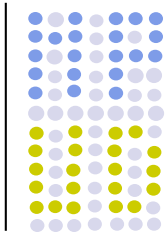


In the example: (i) in the table the grey levels (GL) vs air kerma values (AK) (ii) the coefficients of the cubic interpolating curve: AK= 6.563*10^3+2.282E-GL+4.209*10^-6*GL^2-1.918*10^-9*GL^3

Patient film evaluation

1. According to the estimated calibration curve:
   ESD (mGy) = -8290 + 7771*OD
2. In the reported film exposed during a PTCA procedure on the table under the patient:
   a. the highest exposed area is visually detected and the OD measured: in the example OD_{max}= 1.239
   b. the maximum local skin dose is calculated
   MESD = -8290+7771*1.239 = 1338 mGy

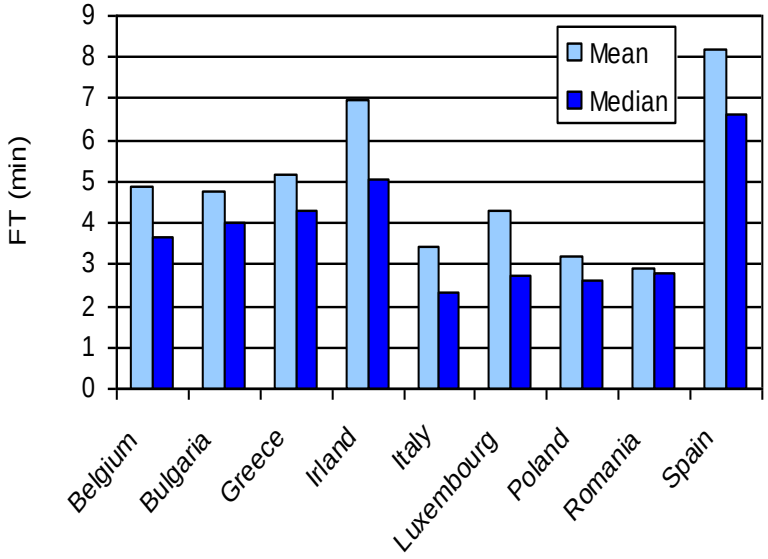
Patient doses in cardiac procedures

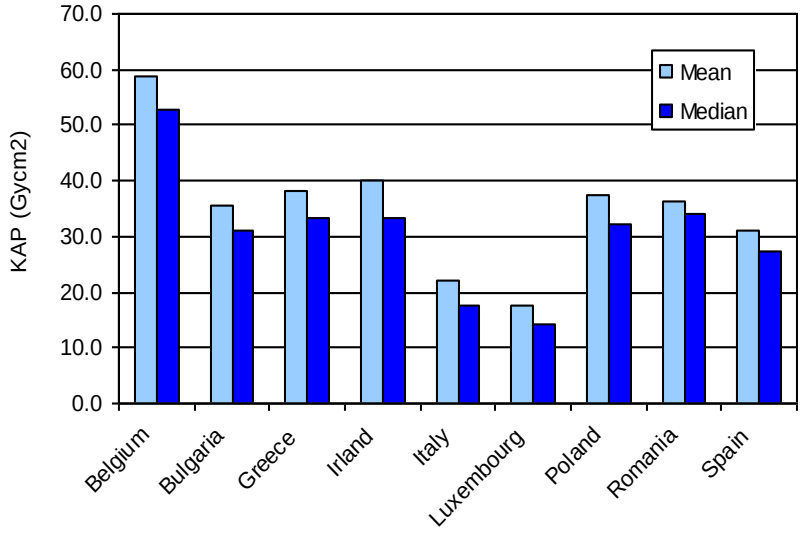


- SENTINEL consortium has investigated doses in selected interventional cardiac procedures to asses reference levels.

Patient dose: coronary angiography procedures

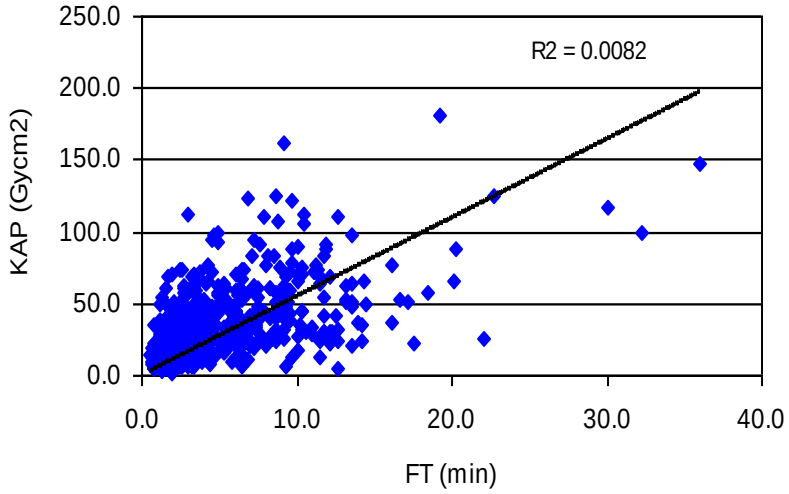
- CA:
  - FT: median values in a range from 2.3 to 6.6 (factor 3)
  - KAP: median values in a range from 15 to 53 (factor 3.5)

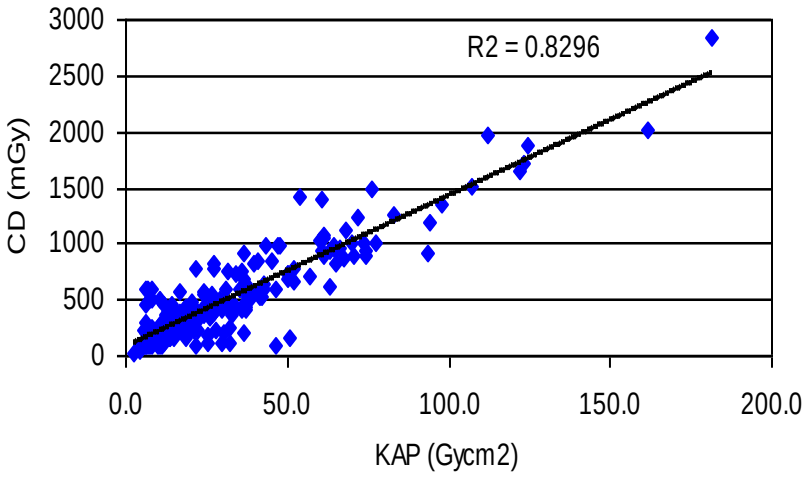




Patient dose: coronary angiography procedures

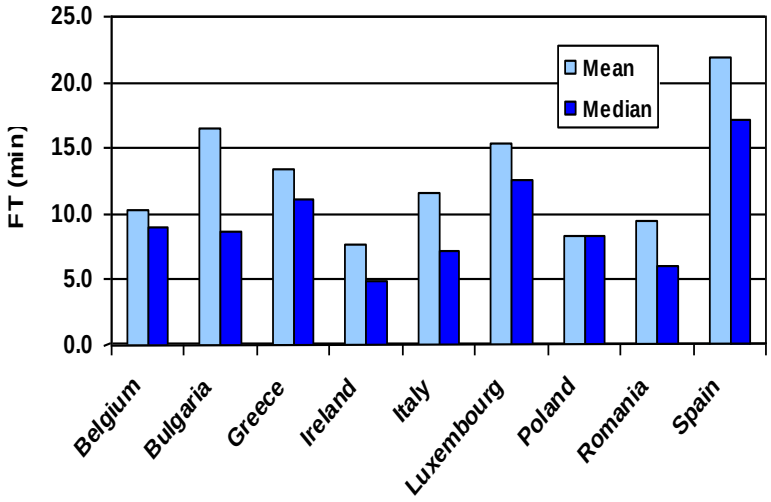
- For CA:
  - Poor correlation between KAP and FT
  - Good correlation between CD and KAP

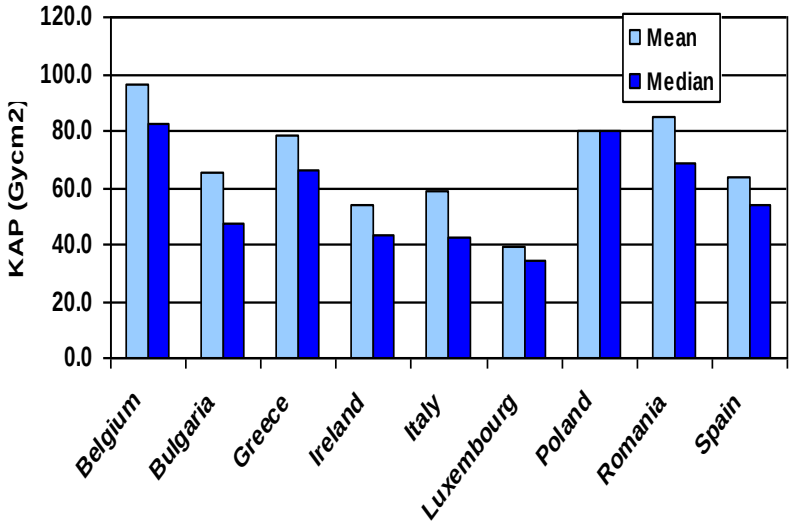




Patient dose: PTCA procedures

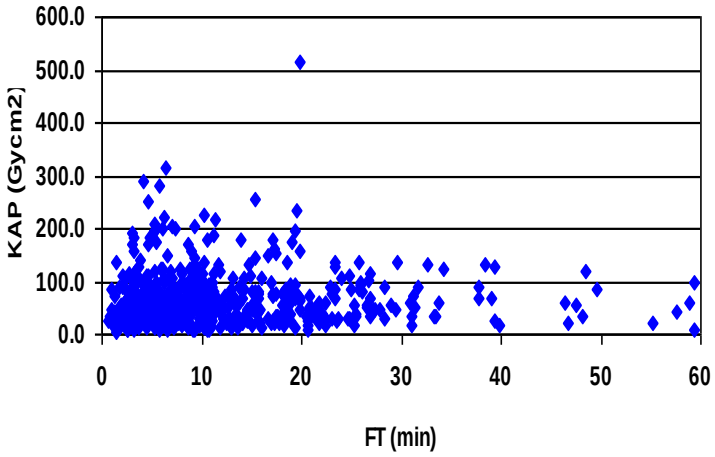
- PTCA:
  - FT: median values in a range from 5 to 13 (factor 2.5)
  - KAP: median values in a range from 35 to 85 (factor 2.5)

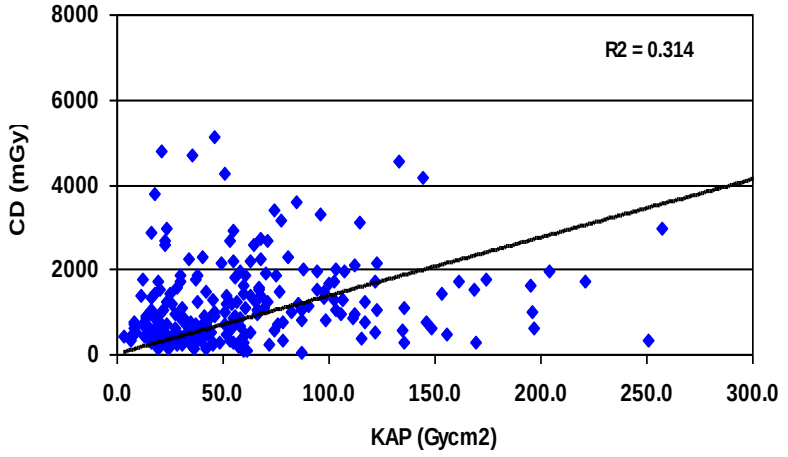




Patient dose: PTCA procedures

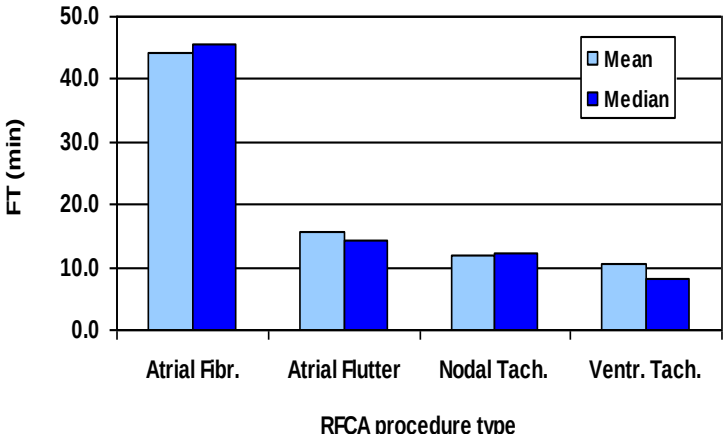
- For PTCA:
  - Poor correlation between KAP and FT
  - Poor correlation between CD and KAP
- Results demonstrate a certain indipendence of FT, KAP and CD quantities

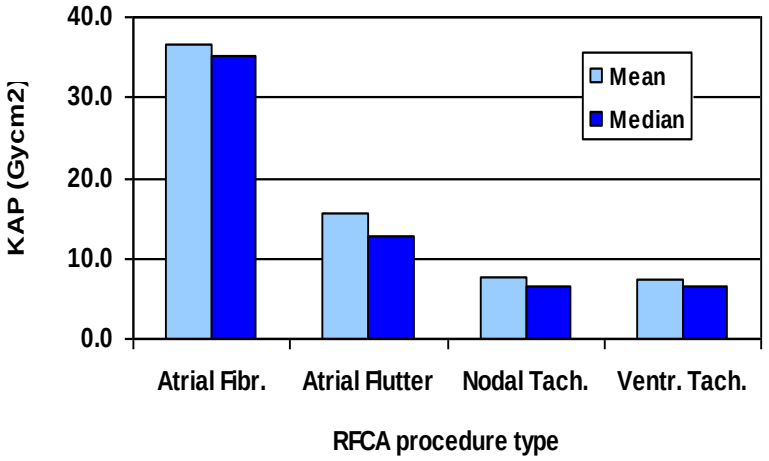




RF cardiac ablation sample

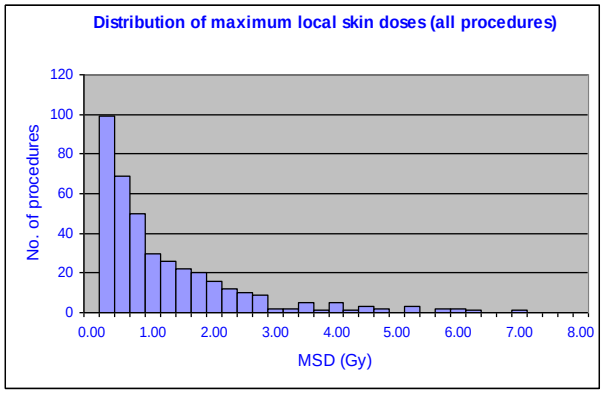
- For RFA it is necessary to share the sample in different types of interventions (only Udine data):
  - atrial fibrillation,
  - atrial flutter,
  - nodal tachycardia,
  - ventricular tachycardia and WPW



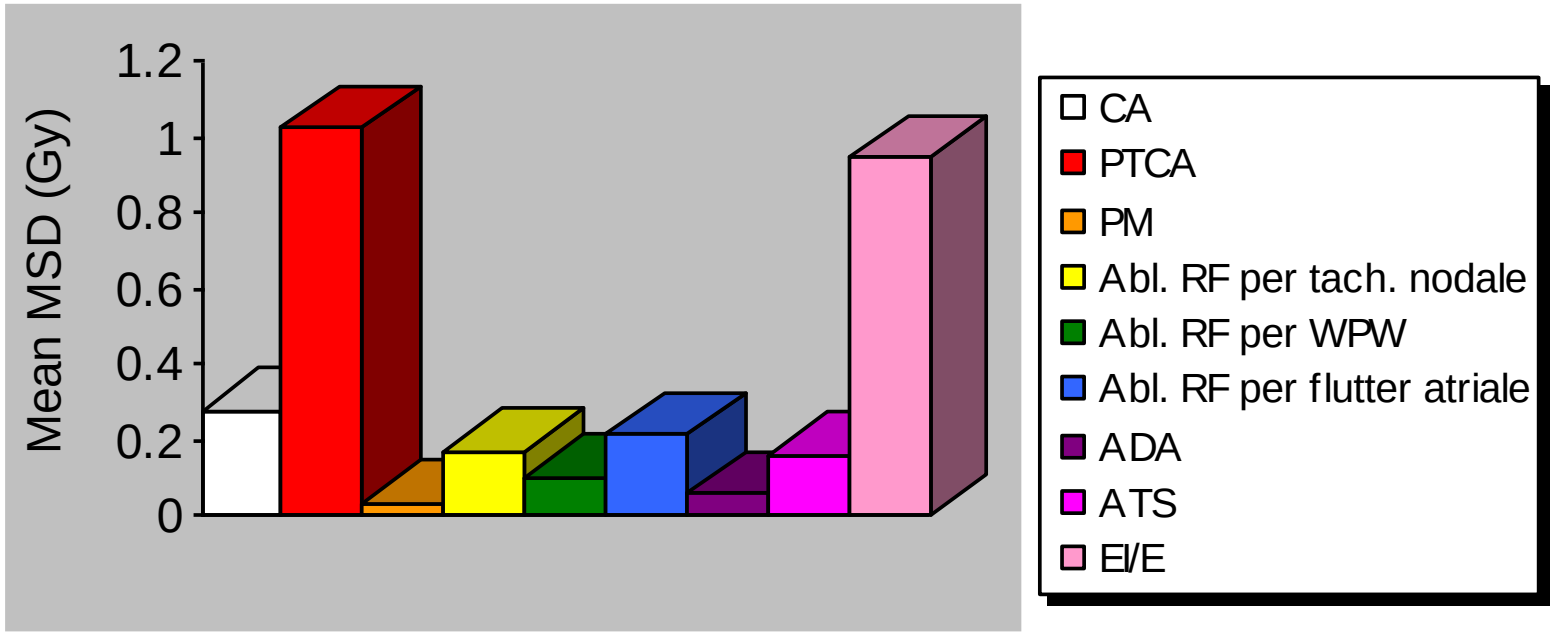


Monitoring of skin dose in high dose procedures (IAEA)

- Radiochromic films used to measure patient skin dose in a sample of 392 intervnetional procedures in a IAEA international study
- In 52 procedures (7.4%) the PSK> 2 Gy, 15 > 4 Gy
- maximum PSK 6.6 Gy; 38 PTCA, 6 RF ablation, 1 neuro-embolisation and 6 hepatic
- 39 occurred at two hospitals !
- The skin dose monitor was shown to underestimate PSK



Monitoring of skin dose in high dose procedures (IAEA)



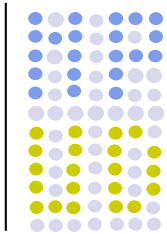
Role of Reference Levels in Interventional Procedures

- Are RLs an optimisation tool applicable in interventional procedures?

ICRP 73

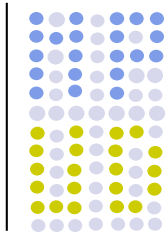
- The concept of DRL was introduced in 1996 by ICRP in its recommendation 73
  - DRL is not a dose limit
  - It does not apply to a single patient

From EC Guideline 109: Guidance on Diagnostic Reference Levels



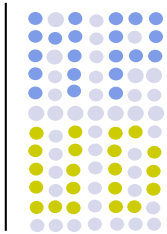
- According to Article 4 of the MED, Member States shall promote the establishment and the use of diagnostic reference levels (DRLs) …
- DRLs are applicable for standard procedures in all areas of diagnostic radiology. They are particularly useful in those areas where a considerable reduction in individual or collective doses may be achieved or where a reduction in absorbed dose means a relatively high reduction in risk:
  - frequent examinations, including health screening;
  - high-dose examinations: CT, procedures requiring long fluoroscopy times, such as for interventional radiology;
  - examinations with more radiosensitive patients, such as children.
- However, it should be recognised that it is rather more difficult to establish DRLs for CT, interventional radiology and groups of children than it is for more frequent, less complex exposures.

On the assessment and use of DRLs



- National DRLs: the third quartile of the distribution of the mean doses to representative groups of standard sized patients at each hospital.
- If patient dose data are available from only one or two hospitals, they can only be used to monitor local trends in patient dose with time.
- Such local data are a valuable tool for local dose audit and optimisation initiatives but they cannot, by themselves, be used to set a reference level
- Mean or median values, used as dose audit standards to monitor local trends, are not the same as third quartile values used to indicate abnormally high doses on a national scale. It is consequently rather misleading to refer to such values as DRLs, as originally defined by the ICRP and the MED, and perhaps an alternative name such as "local audit standards" would be more suitable. (B. Wall BJR 74 (2001) 785-788)

RL in interventional procedures



- Also in interventional procedure there are some experiences to assess RL for the more common procedures.
- When examinations become more complicated there is much greater individual variation in the patient doses. Unavoidable complications frequently arise with the positioning of catheters and guidewires.
- Uncertainties in the median (mean) values on small (realistic) samples of procedures will be high and comparisons with national/international RLs difficult.
- However, as the ICRP stated, RLs have to give a indication of situations that do not appear to be providing the best radiation protection for patients.
- They provide just the first step in the optimisation process by most effectively directing corrective action to where doses and risks are highest.

Reference levels in cardiac procedures

- SENTINEL Study: from the pooled data, reference levels have been derived as the rounded values of the 3rd quartile of the frequency distributions

Dose or dose analogue	Procedures		
	CA	*PTCA*	*EFO*
KAP ($Gycm^2$)	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
Entrance surface air kerma rate	Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (μGy/frame)		

Reference levels in cardiac procedures

- CD, available on new equipment, is added to RLs to help in preventing skin injuries;
- Relationship between CD and peak skin dose has to be derived in each installation and for each high dose procedure

Dose or dose analogue	Procedures		
	CA	*PTCA*	*EFO*
KAP ($Gycm^2$)	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
Entrance surface air kerma rate	Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (μGy/frame)		

Reference levels in cardiac procedures

- Effective dose, derived from KAP, is introduced to help comparison of the risk with procedures performed with other modalities (MSCT, PET/CT, SPECT/CT etc)

Dose or dose analogue	Procedures		
	CA	*PTCA*	*EFO*
KAP ($Gycm^2$)	45	85	35
Effective dose (mSv)	8	15	6
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Reference levels in cardiac procedures

- Equipment performance: because of the large variability of doserates in clinical conditions, reference levels are proposed to help optimisation of equipment set-up.

Dose or dose analogue	Procedures		
	CA	*PTCA*	*EFO*
KAP ($Gycm^2$)	45	85	35
Effective dose (mSv)	8	15	6
CD at IRP (mGy)	650	1500	-
Fluoroscopy time (min)	6.5	15.5	21
No. of cine images	700	1000	-
Entrance surface air kerma rate	Fluoroscopy low: 13 (mGy/min) Image acquisition: 100 (μGy/frame)		

Cardiac RL comparisons (I)

- **DIMOND RL**: The new set of reference level are lower (-12%) compared to those proposed in 2003 by the DIMOND group
  CA: KAP = 57; PTCA: KAP=94 Gycm2. The main difference derives from the lower number of cine images today used.
  V. Neofotistou, E. Vano, R. Padovani, J. Kotre, A. Bowling, M. Toivonen, S. Kottou, V. Tsapaki, S. Willis, G. Bernardi, K. Faulkner, Preliminary reference levels in interventional cardiology, Eur Radiol (2003) 13:2259–2263

- **IAEA CRP study:** The reference level proposed are derived from a sample of thousands of procedures collected in 6 centres
  - KAP value for PTCA is higher than SENTINEL (+ 50%) probably reflecting different level of optimisation in centres outside Europe involved in the survey.
  - Evalution of complexity of procedures performed on a sub-sample of PTCA, accounts for a factor of 2 on median KAP for simple and complex PTCAs.

Procedure	**KAP** ($Gycm^2$)	Fluoroscopy Time (minutes)	Number of Images
Coronary Angiography (CA)	50	9	1000
Percutaneous Cardiovascular Intervention (PCI)	125	22	1700

Cardiac RL comparisons (II)

- HPA (NPRB): Doses to Patients from Medical X-ray Examinations in the UK – 2000 Review
  - 2000 survey: 7 hospitals in UK; CA: mean fluoroscopy time: 4.3 min;
    3rd quartile: 36.3 Gycm2
  - KAP comparable to SENTINEL RL for CA (-30%)

- Swiss study:
  - A nationwide survey to investigate the use of fluoroscopy and establish national reference levels (RL) for dose-intensive procedures
  - A wide variation in dose and image quality in fixed geometry was observed.
  - DAP RLs of … 80, …, 110 Gycm2 were established for ..coronary angiography, …, PTCA, respectively.
  - RL values higher than ours for CA (+ 75% for CA)

Complexity of procedures

- The concept of guidance (reference) levels refers to “common examinations” done on large numbers of patients in a relatively standardized manner.
- Extending this concept to fluoroscopically guided interventions raises several problems:
  - In addition to technical variables (patient size, equipment performance and operational technique), procedures are often non-standard for clinical reasons.
  - The complexity of a procedure is affected by factors related to the patient’s anatomy and to the severity of the treated pathology.

Complexity of procedures

- An index related to patient-specific clinical factors affecting an individual procedure could reflect the complexity of the procedure.
- Appropriate scaling of guidance levels provides an additional tool for optimization processes in a facility.
- Since the complexity of the procedure strongly influences patient exposure it is not appropriate to develop a guidance level without taking complexity into account.
- In DIMOND and IAEA studies on PCI, data were analyzed using multiple linear regression to identify predictors of P_{KA}.

R. Padovani, G. Bernardi, M. R. Malisan, E. Vano, G. Morocutti and P. M. Fioretti PATIENT DOSE RELATED O THE COMPLEXIT OF INTERVENTIONAL CARDIOLOGY PROCEDURES Radiat Prot Dos. 94, 1–2, 189–193 (2001)

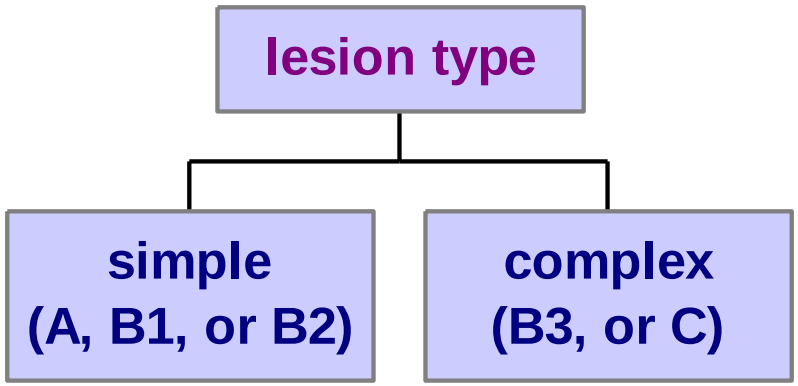
Complexity of procedures

A complexity index (CI) derived:

CI = No.Vessels + No.LesionType*0.51 + No.Occlusion>3Mths*0.73
+ No.SevTortuosity*0.69 + No.BifStenting*0.58

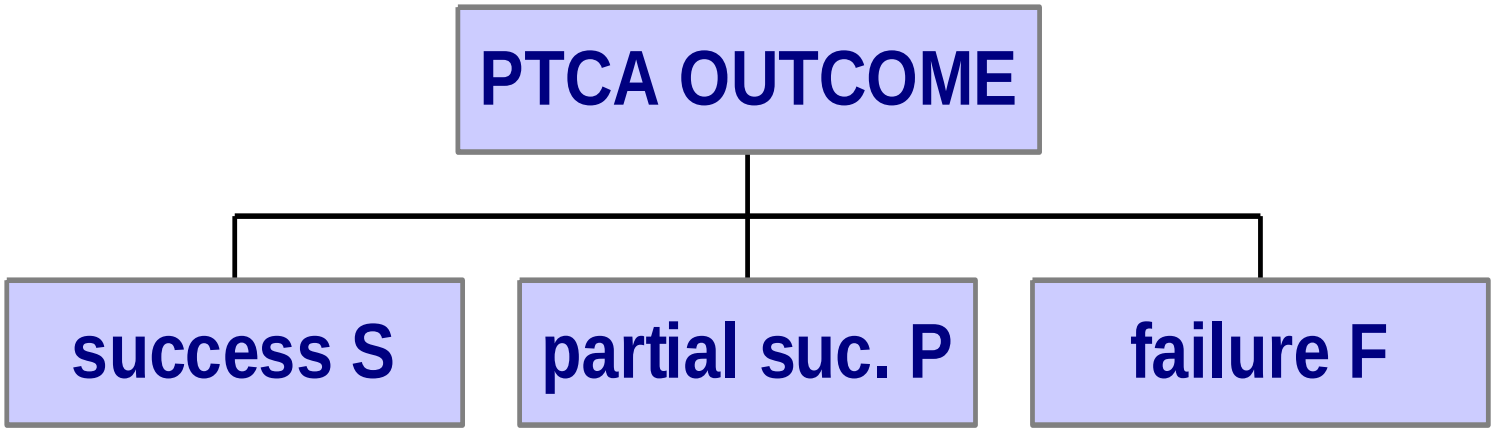
Study on complexity of PTCA

- Experimental data: Fluoroscopy time, No. frames, DAP
- Complexity factors: age, sex, w, h, multi vessel disease, EF, prev AMI, prev CABG, act AMI.
- AFs assessed on AHA/ACC classification:



Study on complexity of PTCA

- Technical factors : multivessel PTCA (No of vessels), No of lesions, the double wire or double balloon technique, simple stenting, ostial stenting, bifurcation stenting, DCA, rotablator, IVUS, EA, laser.



Study on complexity of PTCA

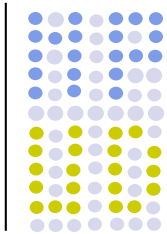
- UNIVARIATE ANALYSIS (SIMPLE CORRELATION)
- MULTIVARIATE STEPWISE LINEAR REGRESSION

  (BOTH FORWARD AND BACKWARD)

$$y = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \ldots + \beta_p x_p$$

- ANOVA TEST
- p VALUE < 0.05 WAS CONSIDERED SIGNIFICANT

Summary: CI determinants



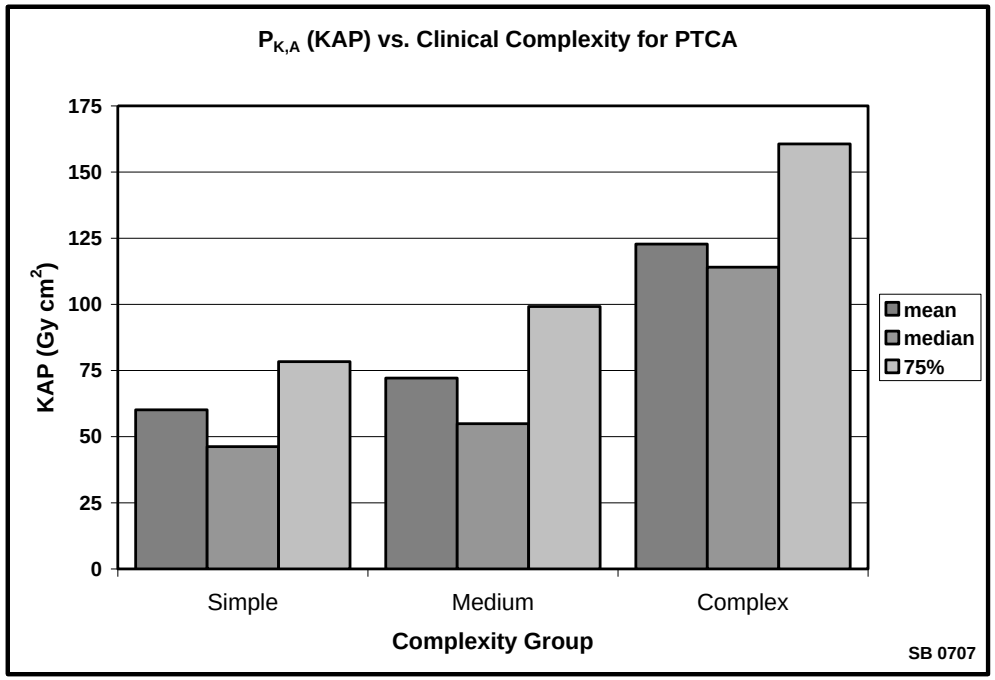
No.	Vessels	Lesion type	Occlus >3mth	Severe tortuos	Ostial st	Bifurc st.
Santiago	X	X	X	X		X
Montevideo (Univ)	X	X				
Montevideo (H.Ital.)	X	X				
Madrid (no brachi)	X		X			
Madrid (new HCSC)	X		X		X	X
Madrid (FP)	X	X		X		X
Udine	X	X		X		X

Weigthing factors for CI determinants

	No. Vessel	Lesion type	Occlus >3mth	Severe tortuos	Ostial st	Bifurc st.
	1	0.51	0.73	0.69		0.58

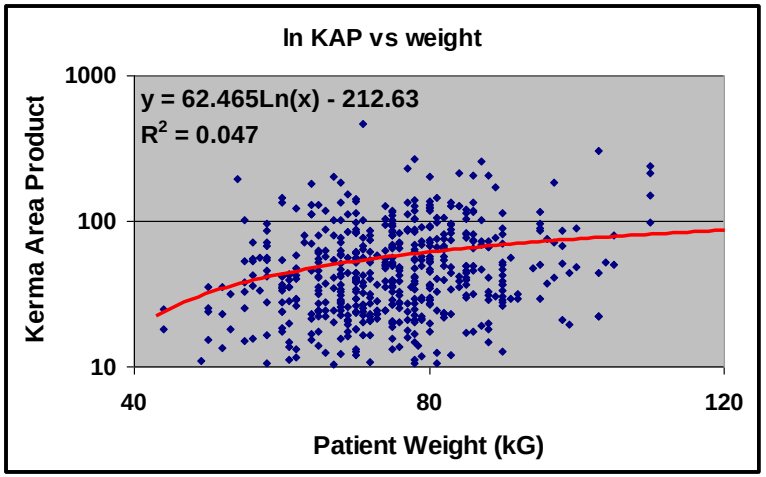
RLs vs complexity of PCI procedures

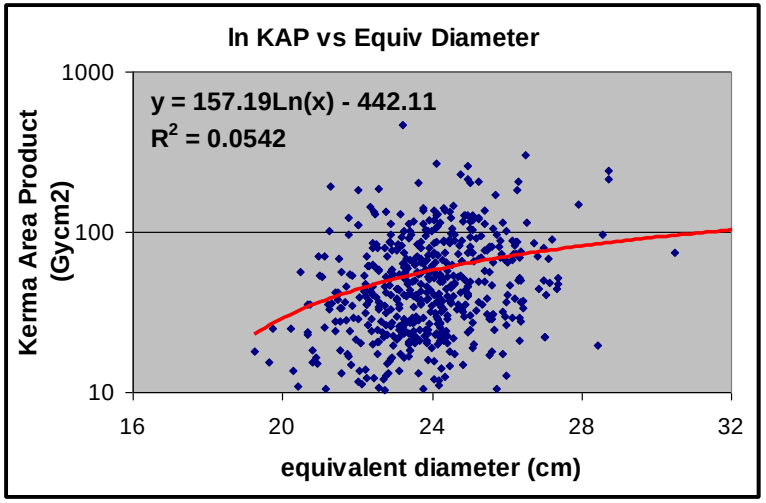
(IAEA CRP study, 2007)



RLs vs complexity of PCI procedures

- To confirm that patient weight/equivalent diameter is not a

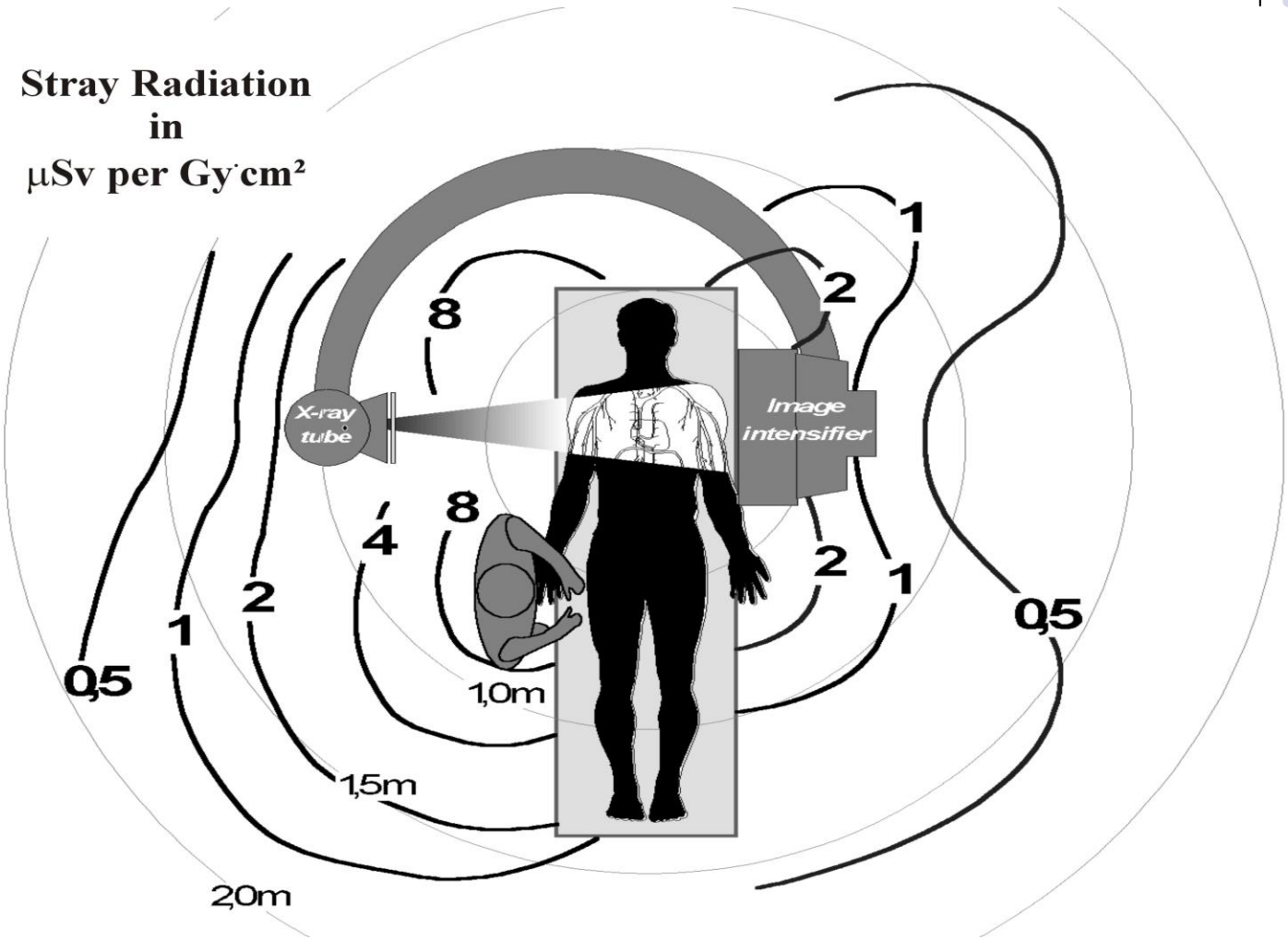




Staff exposure

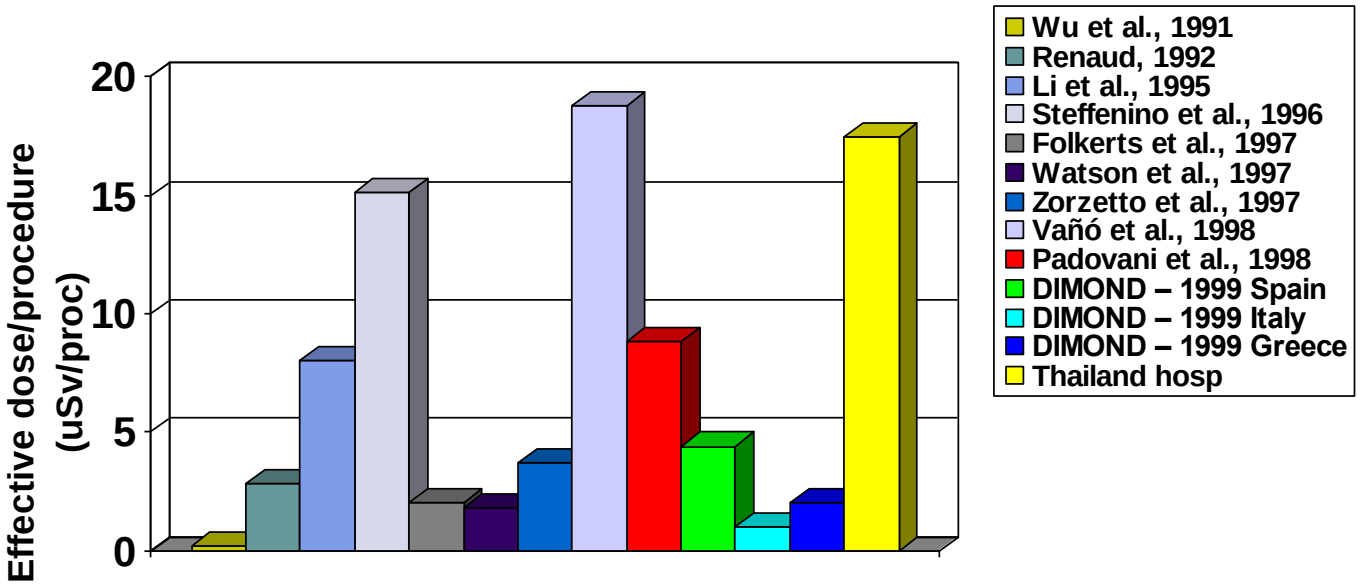
- Evidences of poor monitoring protocols and wide range of exposures
- Dose quantities for staff monitoring
- Individual monitoring and exposure assessment methods
- Optimisation of staff exposure in interventional radiology

Plan view of an interventional operating x-ray unit with isodose curves

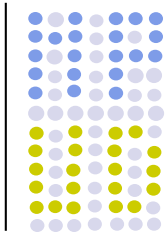


Variability of staff exposure in cardiac procedures

- Interventional cardiologist doses have high variability
- How dosimetry is performed?
- How to know to optimize staff exposure?



Staff dosimetry

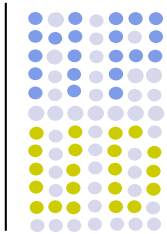


- In practice, dosimeter reading is the only piece of information we have on occupational exposure. This information should be used as effectively as possible.
- Unfortunately, conversion from dosimeter reading to effective dose is prone to large uncertainties (variations).

Introduction: the practice of individual monitoring in IR

- The position of the dosemeter mostly on the chest
- Significant differences in the application of protective devices
  - Mostly lead aprons of wrap-around type
  - Tilted plate thyroid collars
- Effective dose is mainly assessed from single dosemeter measurement as
  - Hp(10) (when the dosemeter is used below the apron)
  - A fraction of Hp(10) (dosemeter above the apron)

Operation dose quantities for staff monitoring



- The ambient dose equivalent - H*(d)
- Directional dose equivalent – H’(d,Ω)
- Personal dose equivalent – Hp(d)

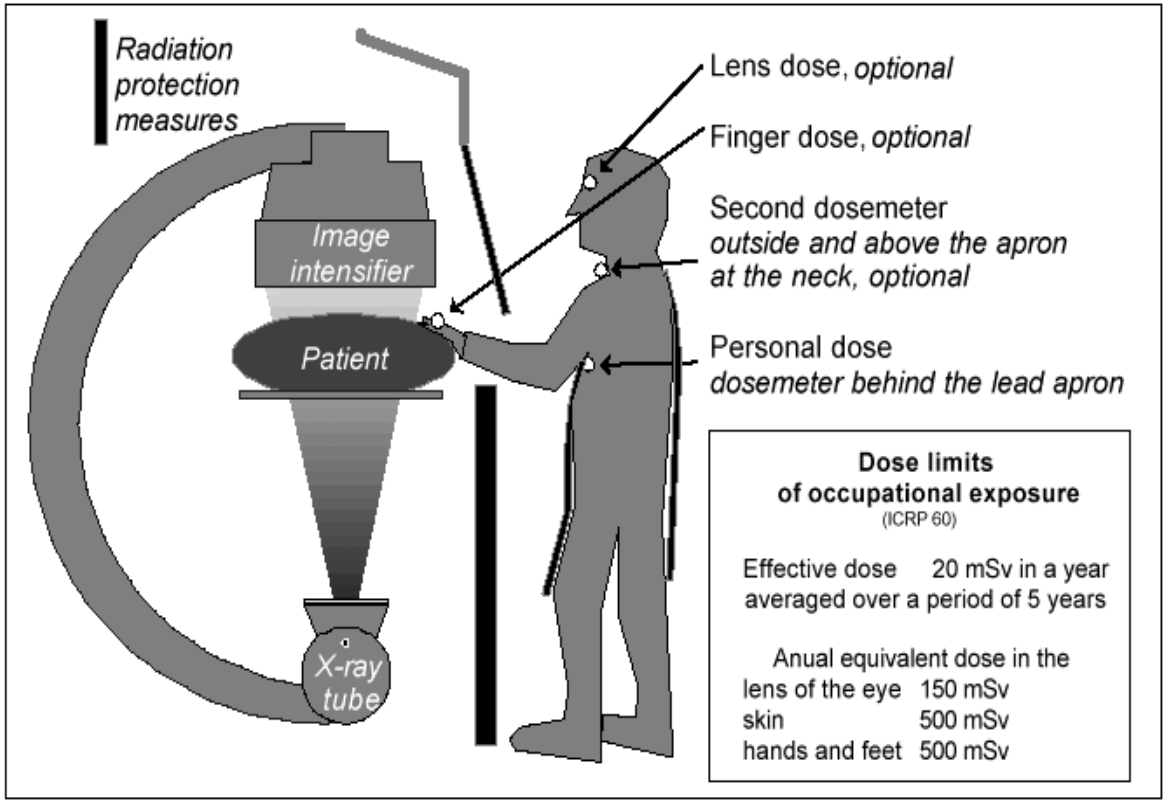
- The latter used for comparing with regulatory requirements such as dose limits, dose constraints, intervention levels.

ICRU Report 47, 51, 57

Personal dosimetry
ICRP Report 85 (2001)

- Paragraph 66: The high occupational exposures in interventional radiology require the use of robust and adequate monitoring arrangements for staff.
- A single dosimeter worn under the lead apron will yield a reasonable estimate of effective dose for most instances.
- Wearing an additional dosimeter at collar level above the lead apron will provide an indication of head (eye) dose.

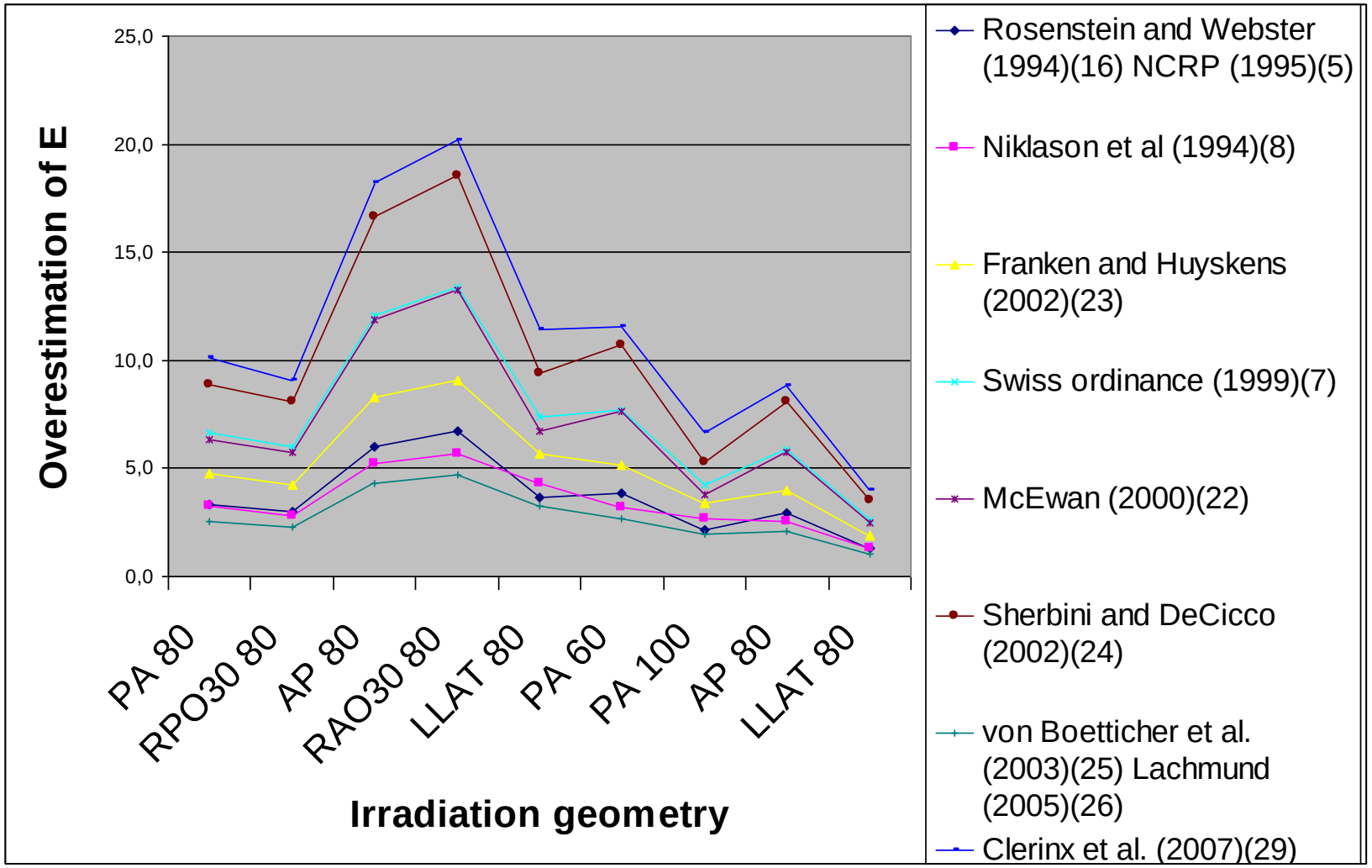
Individual monitoring in IR



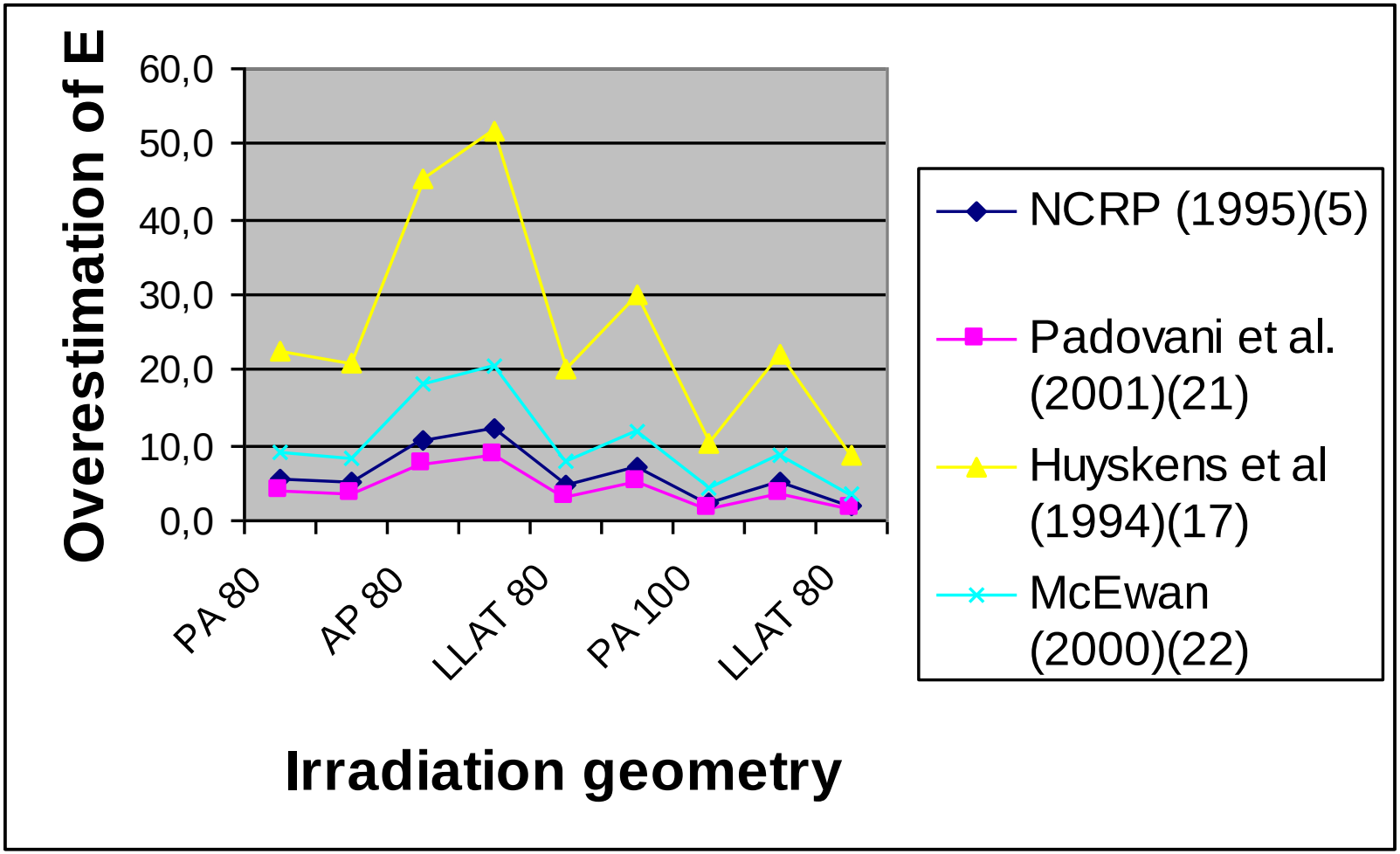
ers are

From: Avoidance of radiation injuries from interventional procedures. ICRP 85

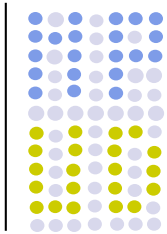
Algorithm comparison (DD)



Algorithm comparison (SD)



Conclusions on personel monitoring



- No harmonized regulations and practices for monitoring workers in IR
- No firm consensus of the best DD algorithm
- Most algorithms overestimate E, at max over a factor of 10
- DD generally recommended, mainly due to the risk of underestimations of E
- No single algorithm optimum for all IR procedures
- Further evaluatons in critical configurations needed

Staff exposure optimisation

- Investigation levels & Dose constraints

SUGGESTED INVESTIGATION LEVELS FOR STAFF DOSE

Body	**0.5**	**mSv/month**
Eyes	**5**	**mSv/month**
Hands/Extremities	**15**	**mSv/month**

Suggested investigation levels in staff exposure in interventional radiology
(Joint WHO/IRH/CE workshop 1995)

Staff exposure optimisation

- Investigation levels & Dose constraints

Annual effective dose	Median	3rd quartile
E (mSv)	1.2	2.0
H_{over} (mSv)	12	14

Suggested **Dose constraints** for cardiac interventionalists assessed as the 3rd quartile of staff doses collected in 13 cardiac centers

(SENTINEL, Delft Workshop, 2007)

Training in RP

- European guideline on training
- MARTIR multimedia training tool
  - Importance of:
    - Optimised procedure:
      - SENTINEL reccommendations for cardiac procedures
  - Equipment performance and proper set-up
  - Factors affecting patient and staff doses
  - Staff dosimetry
  - Patient dosimetry (including skin dosimetry)
  - Potential of deterministic effects in complex procedures

Conclusions

- Equipment set-up and regular constancy checks
- Procedure protocols
- Patient
  - Patient dose monitoring, including skin dosimetry
  - Reference levels
- Staff:
  - Proper protective devices available and used
  - Adoption of proper monitoring method
  - Adoption of constraint/intervention dose levels
- Staff and patient exposure are correlated: patient and staff protection should be part of the same safety programme: implies Qualified Expert and Medical Physics Expert responsibilities
- Training