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Preliminary reference levels in interventional cardiology

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Abstract This article describes the European DIMOND approach to defining reference levels (RLs) for radiation doses delivered to patients during two types of invasive cardiology procedures, namely coronary angiography (CA) and percutaneous transluminal coronary angioplasty (PTCA). Representative centres of six European countries recorded patients' doses in terms of dose-area product (DAP), fluoroscopy time and number of radiographic exposures, using X-ray equipment that has been subject to constancy testing. In addition, a DAP trigger level for cardiac procedures which should alert the operator to possible skin injury, was set to 300 Gy×cm^2. The estimation of maximum skin dose was recommended in the event that a DAP trigger level was likely to be exceeded. The proposed RLs for CA and PTCA were for DAP 45 Gy×cm^2 and 75 Gy×cm^2, for fluoroscopy time 7.5 min and 17 min and for number of frames 1250 and 1300, respectively. The proposed RLs should be considered as a first approach to help in the optimisation of these procedures. More studies are required to establish certain "tolerances" from the proposed levels taking into account the complexity of the procedure and the patient's size.

Keywords Reference levels · Interventional cardiology · Radiation dose

Introduction

The growing use of interventional cardiology (IC) procedures, while offering enormous benefits to patients, also contributes significantly to the radiation exposure of patients and personnel [1, 2, 3, 4, 5, 6, 7, 8, 9, 10]. The IC procedures have been known to require radiation doses that in some instances have resulted in deterministic skin injuries to the patient [7, 8, 9, 10, 11, 12, 13, 14]. The main task of radiation protection is not only to minimise the stochastic risks but also to avoid deterministic injuries.

The DAP, a dose quantity that is easily measured by means of a large flat-field ionisation chamber placed at the tube housing, has been proven to correlate reasonably well with the increased probability of stochastic effects [15, 16, 17]. Deterministic injuries can be prevented by measuring patient's skin entrance exposure

[7, 8]. The International Commission on Radiological Protection (ICRP) recommends the establishment of reference levels as method of optimising the radiation exposure [18, 19, 20]. The Council Directive of the European Community 97/43/Euratom (MED) [21] dealing with the health protection of patients against dangers of ionising radiation in relation to medical exposure focuses attention on special procedures (article 9) including interventional radiology. The methodology developed at the European level for the definition of quality criteria and dose reference values can be effectively applied in IC examinations. Image-quality criteria for cineangiographic images, as a function of the level of visibility of important anatomical markers, have been proposed by Bernardi et al. [22, 23]; however, a literature review on the dosimetry data available [24] has shown that the various dose descriptors recorded differences in ways of measurement and variations in the X-ray equipment used, which makes the comparison of patients' doses problematic.

In order to define RLs in IC the European DIMOND (Measures for Optimising Radiological Information and Dose in Digital Imaging and Interventional Radiology) [25] research cardiology group has measured radiation doses in actual medical practice in patients undergoing two types of IC procedures, namely percutaneous transluminal coronary angioplasty (PTCA) and coronary angiography (CA). Although CA is not an interventional procedure as such, CA was also included in the study as it is the most frequent invasive cardiac procedure, and because PTCA is complementary to CA. Moreover, in some cases diagnostic CA is performed at the same time with the interventional PTCA, making the differentiation between the two procedures difficult unless examination data are collected in detail.

Materials and methods

Patient radiation doses have been submitted by six European countries (Greece, Italy, Spain, England, Ireland and Finland) and from centres representative of standard practice during the course of examinations in patients. The doses delivered to patients during CA and PTCA expressed as DAP, fluoroscopic time (FT) and the total number of radiographic exposures (FR) taken have been recorded as suggested during the DIMOND II Concerted Action [26, 27]. The three dose descriptors chosen best illustrate the clinical protocol used and they are available conveniently on all X-ray equipment used in IC. If possible, DAP was recorded separately for the fluoroscopy mode and the radiographic mode. The form for data collection also included hospital and operator's identification as well as the X-ray equipment used. Image quality, fluoroscopy dose rate and dose per image were audited during the regular constancy checks in all the centres and results were considered satisfactory. In the current study, only dosimetric data for patients were reported and a correlation with image quality or diagnostic information obtained in the different centres was not achieved. This is part of the work in progress done by the DIMOND consortium at the time of writing this article.

The need to control patient dose, as far as possible skin injuries are concerned, led to the establishment of "DAP trigger level". This term was established by the growing requirement to decide the start of a clinical follow-up of certain patients whose DAP value was higher than DAP trigger level. Taking into consideration that skin injuries could be produced if 2–3 Gy are imparted to a specific area of the skin, that cardiology procedures require several angulations of the C-arm and that radiation fields are not fully overlapped, 300 Gy×cm^2 appeared to be a reasonable value to trigger clinical follow-up. This value was also based on previous experimental data of the DIMOND partners [7]. In the event that the DAP trigger level was likely to be exceeded, additional information on the technique used [i.e. exposure parameters, beam projections, Image Intensifier (II) field size] were also recorded for a subsequent indirect estimation of maximum skin dose. Maximum skin dose is a good indicator for the onset of skin deterministic effects [7, 8]. Some trigger DAP values (established for each centre) assist in preventing skin burns by alerting the operator when the limits are about to be reached in which case the projection has to be changed if the procedure has to be continued [7, 8].

All participating centres are equipped with C-arm angiographic units designed for interventional work. Images were acquired at 12.5 frames/s with the exception of three centres (two in Greece and one in Finland that used 25 frames/s). The X-ray equipment used in all countries has been subjected to common quality-control test. Fluoroscopy dose rate and dose per image at the entrance of the image intensifier and at the entrance of a copper absorbent of 2-mm thickness were obtained together with image quality using Leeds test object TOR 18-FG as part of the constancy checks [28, 29].

It is known that the complexity of the procedure also has to be taken into account, since this would justify higher patient exposure [30]; however, for this study the procedures have not been grouped according to their complexity.

Results and discussion

In Tables 1 and 2 the median and mean dose values recorded in six European countries are given for PTCA and CA, respectively.

In Figs. 1 and 2, the third quartile values of DAP, FT and number of frames (FR) recorded during PTCA and CA, respectively, are presented. In all of the centres, some of the PTCAs have been done directly after the CA if the clinical condition of the patient allows doing it. In these cases it is very difficult to split dose values for the diagnostic and therapeutic part of the procedure and therefore the dose is considered as the value for the PTCA procedure.

One may note that for PTCA four of six European countries have similar DAP distributions, although the contribution from fluoroscopy to the DAP varies. For Spain the longer FT and larger FR used can be explained by the fact that San Carlos is a university teaching hospital (with ten training fellows and ten staff cardiologists). It is well demonstrated that patient dose is increased for first-year training fellows due to longer fluoroscopy time [31, 32]. The main factor contributing to the higher doses measured in Greece (CA) and Finland (CA and PTCA) is probably the high value of dose rate in fluoroscopy or the dose per frame. It is also noteworthy that in England only 440 frames per PTCA are mainly used for this patient sample; the interventional procedure (PTCA)

Table 1 Patient doses during percutaneous transluminal coronary angioplasty (PTCA). *DAP* dose-area product, *FT* fluoroscopic time

Country	DAP (Gycm^2)		FT (min)		No. of frames	
	Median	Mean	Median	Mean	Median	Mean
Greece	39.0	46	8.4	11.9	1300	1508
Spain	40.0	53.9	17.2	19.1	975	1085
Italy	42.4	56.1	7.5	10.7	540	621
England	27.1	34.1	13.0	17.4	440	440
Ireland	48.5	54.2	8.3	10.2	449	344
Finland	66.9	84.2	11.8	13.1	1425	1557

Sample size of 100 for each country

Table 2 Patient doses during coronary angiography (CA)

Country	DAP (Gy×cm^2)		FT (min)		No. of frames	
	Median	Mean	Median	Mean	Median	Mean
Greece	38.6	46.7	5.5	7.1	1620	960
Spain	27.8	39.4	6.4	9.4	903	1596
Italy	28.2	33.5	3.0	4.2	570	610
England	19.1	25.7	2.5	6.6	845	479
Ireland	33.3	37.5	3.2	4.4	580	585
Finland	39.6	52.7	4.1	4.8	417	803

Sample size of 100 for each country

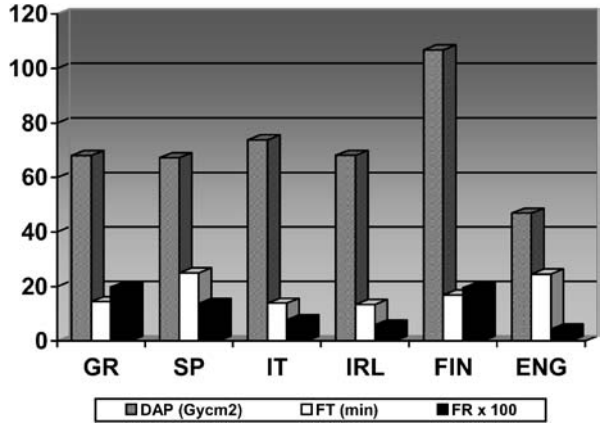

Fig. 1 Dose-area product (*DAP*), fluoroscopic time (*FT*) and number of frames (*FR*) during percutaneous transluminal coronary angioplasty (third-quartile values). *GR* Greece, *SP* Spain, *IT* Italy, *IRL* Ireland, *FIN* Finland, *ENG* England

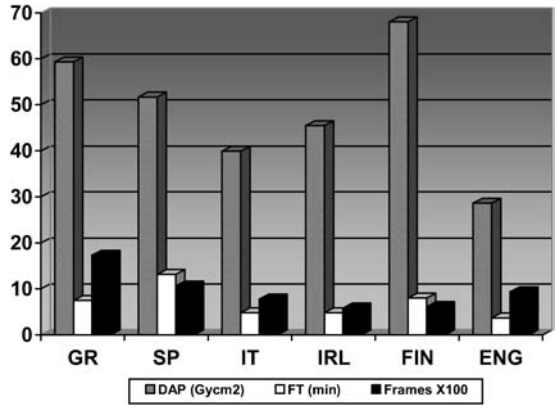

Fig. 2 The DAP, FT and FR during coronary angiography (third-quartile values)

is performed on previously diagnosed cases. Ireland also has a low number of frames in PTCA as does the UK.

In Fig. 2 the third quartile values of DAP, FT and FR measured during CA are presented, with the variations in DAP values being wider than in PTCA. In any case, the reasons why some countries need double the DAP value in order to perform a CA or a PTCA has to be further investigated. Different settings of the image intensifiers (requiring different dose per frame) can cause, as already indicated, these differences, but their reason could also be differences in the operation of the X-ray systems (e.g. lack of collimation, lack of use of the wedge filters, large distances between patient and image intensifier). All these operational parameters have not been investigated in this work. Once reference values are established, centres with higher doses should try to optimise their procedures to decrease their doses.

As far as DAP trigger level is concerned, there are a number of cases where DAP trigger level is exceeded in some centres. These patients are clinically followed for possible skin injuries and results are expected in the near future.

The dilemma inherent to the medical physicists' desire for patient dose reduction is to avoid suboptimal imaging. A thorough discussion between cardiologists and medical physicists on the level of image quality and

number of frames required to make a safe diagnosis would certainly optimise the procedure. It can therefore be tentatively suggested that the 75th percentile of all collected data be used as preliminary reference level (Table 3) until a wider survey can be done.

In theory, RLs are advisory. It is a form of investigation tool to identify unusually high levels of radiation that call for review if consistently exceeded. In principle, there could be a lower level also. It must be kept in mind that RLs are not for regulatory purposes, not a dose constraint, and are not linked to limits or constraints of any kind [21].

The values for RLs proposed by this study are approximately 25% lower than those previously recommended by DIMOND II in 1999 [24]. This could be explained by the higher number of European centres submitting dose data, but also by the continued education and training of all personnel involved in IC procedures and the increase of constancy checks of the X-ray systems. The continuous setting and reviewing of RLs should be seen as a continuing process in order to promote continuous improvement over time.

Table 3 Preliminary reference levels proposed

	PTCA	CA
DAP (Gy×cm^2)	94	57
FT (min)	16	6
No. of frames	1355	1270

Furthermore, one of the benefits of this paper should be that in the future the proposed reference values could be used to establish a reasonable agreement between image quality or diagnostic information required and doses necessary for that.

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References

1. United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (2000) Sources and effects of ionising radiation. Report to the General Assembly, with Scientific Annexes. United Nations, New York
2. Padovani R, Rodella CA (2001) Staff dosimetry in interventional cardiology. Radiat Prot Dosim 94:99–103
3. Padovani R, Malisan MR, Bernardi G, Vano E, Neofotistou V (2001) Optimisation of patient and staff exposure in interventional cardiology In: Proc Int Conf on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, Malaga, Spain, 26–30 March, IAEA-CN-85–147:338–342
4. Fong RYL, Ryan E, Alonso-Arrizabalaga S (2001) A study on the annual equivalent doses received by cardiologists in a UK hospital. In: Proc Int Conf on Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, Malaga, Spain, 26–30 March, IAEA-CN-85–72:347–351
5. U.S. Food and Drug Administration (1994) Avoidance of serious X-ray-induced skin injuries to patients during fluoroscopically-guided procedures. Med Bull 24:7–17
6. Faulkner K, Vano E (2001) Deterministic effects in interventional radiology. Radiat Prot Dosim 94:95–98
7. Vano E, Gonzalez L, Ten JI, Fernandez JM, Guibelalde E, Macaya C (2001) Skin dose and dose-area product values for interventional cardiology procedures. Br J Radiol 74:48–55
8. Vano E, Goicolea J, Galvan C, Gonzalez L, Meiggs L, Ten J, Macaya C (2001) Skin radiation injuries in patients following repeated coronary angioplasty procedures. Br J Radiol 74:1023–1031
9. Stone M, Robson K, Le Boit P (1998) Subacute radiation dermatitis from fluoroscopy during coronary artery stenting. Evidence of cytotoxic lymphocyte mediated apoptosis. J Am Acad Dermatol 38:333–336
10. Lobotessi H, Karoussou A, Neofotistou V, Louisi A, Tsapaki V (2001) Effective dose to a patient undergoing coronary angiography. Radiat Prot Dosim 94:173–176
11. Broadhead DA, Chapple CL, Faulkner K, Davies ML, McCallum H (1997) The impact of cardiology on the collective effective dose in the north of England. Br J Radiol 70:492–497
12. Leung KC, Martin CJ (1996) Effective doses for coronary angiography. Br J Radiol 69:426–431
13. Koenig TR, Wolff D, Mattler FA, Wagner LK (2001) Skin injuries from fluoroscopically guided procedures. Part 1. Characteristics of radiation injury. Am J Roentgenol 177:3–11
14. Koenig TR, Mattler FA, Wagner LK (2001) Skin injuries from fluoroscopically guided procedures. Part 2. Review of 73 cases and recommendations for minimizing dose delivered to patient. Am J Roentgenol 177:13–20
15. Faulkner K (2001) Dose displays and record keeping. Radiat Prot Dosim 94:143–145
16. Sajben FP (1999) Fluoroscopic-induced radiation dermatitis. Cutis 64:57–59
17. Hansson B, Karambatsakidou A (2000) Relationships between entrance skin dose, effective dose and dose area product for patients in diagnostic and interventional cardiac procedures. Radiat Prot Dosim 90:141–144
18. International Commission on Radiological Protection (1990) Recommendations of the International Commission on Radiological Protection. ICRP Publ 60, Ann ICRP 21 (1–3)
19. International Commission on Radiological Protection (1996) Radiological Protection and Safety in Medicine. ICRP Publ 73, Oxford, Pergamon Press, Ann ICRP 26 (2)
20. International Commission on Radiological Protection (2000) Avoidance of radiation injuries from medical interventional procedures. ICRP Publ 85, Oxford, Pergamon Press, Ann ICRP 30 (2)

21. European Commission (1997) Council Directive of 30 June 1997 (97/43/Euratom) on Health Protection of Individuals against the Dangers of Ionising Radiation in relation to Medical Exposure. Official J Eur Commun L 180:22–27
22. Bernardi G, Padovani R, Morocutti G, Spedicato L, Giannuleas JD, Neofotistou E, Manginas A, Goicolea JC, McNeil J, Vano E, Marzocchi A, Tsapaki V, Fioretti PM, Malone J (2001) Quality criteria for cardiac images in diagnostic and interventional cardiology. Br J Radiol 74:852–855
23. Bernardi G, Padovani R, Morocutti G, Spedicato L, Giannuleas JD, Neofotistou E, Manginas A, Goicolea JC, McNeil J, Vano E (2001) A method based on DIMOND quality criteria to evaluate imaging in diagnostic and interventional cardiology. Radiat Prot Dosim 94:167–172
24. Neofotistou V (2001) Review of patient dosimetry in cardiology. Radiat Prot Dosim 94:177–182
25. Measures for optimising radiological information and dose in digital imaging and interventional radiology. European Commission. Fifth Framework Programme, 1998–2002. Programme Acronym: FP5-EAECTP C. Project Reference: FIGM-2000–00061. Project Acronym: DIMOND III. http://dbs.cordis.lu/fep/FP5/FP5_PROJl_search.html.
26. Toivonen M (2001) Patient dosimetry protocols in digital and interventional radiology. Radiat Prot Dosim 94:105–108
27. Vano E, Gonzalez L (2001) Approaches to establishing reference levels in interventional radiology. Radiat Prot Dosim 94:109–112
28. Faulkner K (2001) Introduction to constancy check protocols in fluoroscopic systems. Radiat Prot Dosim 94:65–68
29. Vano E, Fernandez JM, Lopez L, Ten JI, Gonzalez L, Guibelalde E (2001) The use of constancy checks to optimise patient dose in interventional radiology systems. In: Proc Int Conf Radiological Protection of Patients in Diagnostic and Interventional Radiology, Nuclear Medicine and Radiotherapy, Malaga, Spain, 26–30 March, IAEA-CN-85–196: 320–324
30. Bernardi G, Padovani R, Morocutti G, Vano E, Malisan MR, Rinuncini M, Spedicato L, Fioretti PM (2000) Clinical and technical determinants of the complexity of percutaneous trasnluminal coronary angioplasty procedures: analysis in relation to radiation exposure parameters. Cathet Cardiovasc Interv 51:1–9
31. Watson L (1997) Radiation exposure during cardiology fellowship training. Health Phys 73:690–693
32. Neofotistou V (1995) Illustrating the need for education and training in radiation safety in interventional radiology. In: Proc Joint WHO/ISH Workshop on Efficacy and Radiation Safety in Interventional Radiology, Munich–Neuherberg, Germany, 9–13 October