Diagnostic Reference Levels in Cardiology and Interventional Radiology

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Abstract—**The purpose of this paper is to present a strategy to define diagnostic reference levels DRL for fluoroscopic, dose-intensive examinations in cardiology and interventional radiology. This work is part of the project of the Federal Office of Public Health of Switzerland to translate the guidelines of the ICRP and the EU into action. After the 2002 survey in all University Hospitals in Switzerland this work will present the results of the 2006-2007 survey performed in small and medium sized hospitals. The data of the small and medium sized hospitals are analyzed to establish DRL. They are corrected to patient size and analyzed in respect to the difficulty of the examination, the experience of the operator and the type of image detection system. The results of the study will be compared to those of the former study in the University Hospitals.**

Keywords— **Diagnostic Reference Level DRL, Cardiology, Interventional Radiology**

I. Introduction

X-ray examinations involving fluoroscopy, particularly those of the digestive system, angiography and interventional examinations contribute significantly to the total collective dose due to medical exposure even if their frequency is relatively low. A survey on the exposure of the Swiss population by X-ray imaging indicated that this contribution amounts up to 29% [1]. Moreover, these types of examinations, which deliver effective doses to the patient of the order of few mSv to few tens of mSv, can lead to extremely high entrance surface doses, up to a few Gy, leading to a significant risk of deterministic effects.

Several international bodies address seriously the issue of radiation protection of the patient and the radiologist for dose-intensive examinations. The International Commission on Radiological Protection (ICRP) dedicated one of its publications to the means and methods to set up in order to prevent the lesions that may be induced by interventional radiology [2]. Similarly, the European Directive 97/43 Euratom states in its article 9 that "Member States shall ensure that appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure […] involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy." [3]

In Switzerland the Federal Office of Public Health set up in early 2000 with the collaboration of the University Institute of Applied Radiation Physics a working group on the optimization of radiation protection in the case of dose-intensive X-ray examinations (Optimierung des Strahlenschutzes bei dosisintensiven Untersuchungen in der Radiologie – OSUR). Several medical associations concerned by the issue were invited to take part in this working group: general practitioners, radiologists, cardiologists, radiographers, medical physicists. One of the main issues addressed by the working group relates to diagnostic reference levels (DRLs), whose definition, establishment and implementation have become in recent years of central importance in the management of radiation doses delivered to the patient in diagnostic and interventional radiology. In fact, several international, regional and national bodies showed an increasing interest for this subject [3-6], a great number of papers were dedicated to DRLs and several scientific meetings and journals included DRLs in their priority topics [7].

The International Commission on Radiological Protection (ICRP) introduced the term "DRL" for the first time in 1996 [8], specifying that it is advisory, set by professional bodies, apply to dose to patients or intake of pharmaceutical, and call for local review if consistently exceeded.

The ICRP compiled in 2001 different sets of DRLs proposed at the international level [4]. The data presented in the ICRP report covers fifteen radiographic views for adult patients, and for pediatrics in a few cases, three fluoroscopy examinations, ten CT examinations, mammography and five dental examinations.

In 2002 a survey was organized by the OSUR group with aim to study the patient exposure due to dose intensive applications of fluoroscopy in Switzerland [9]. This survey was performed in the university hospitals of Switzerland to study the clinical practice of 8 fluoroscopic examinations and to collect dose values to determine the corresponding DRL.

Even if it is difficult to deal with DRLs in the case of complex X-ray examinations, their use is important for such dose-intensive examinations since it provides guidance for proper dose management.

II. Material and Method

A. Participating Centers and chosen examinations

In the beginning, 84 hospitals were asked to participate in the survey and give a list of the examinations in cardiology, interventional radiology and fluoroscopy of the digestive system, which they perform frequently. 65 hospitals (77%) answered the questionnaire and were willing to participate.

From this list of 65 hospitals 32 were chosen to be in the survey due to following considerations: existence of dose-area-product meter (DAP), number of examinations performed within the 3 month survey period, balance between the different modalities (radiology, cardiology, urology and gastroenterology) and the geographical distribution with in Switzerland.

The monitored examinations (coronary angiography, PTCA, cerebral angiography, angiography and PTA of lower limbs) were chosen by a panel of radiologists. Each of the 32 centers involved agreed to monitor 20 patients for each examination. Examinations of the digestive system and urology will be analyzed and presented at a later date.

B. Characterization of the installations

To compare the different DAP-meters of the installations and to get a reference point of the dose all installations in the survey have been characterized. In addition the entrance surface dose was determined using a patient equivalent phantom to characterize the skin dose and the image quality using a specific type of automatic exposure control system.

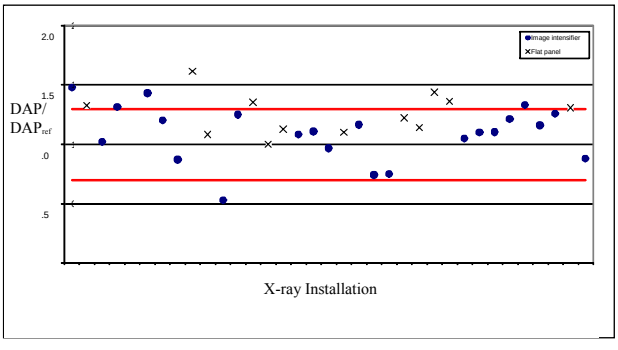

Fig. 1 Characterization of the DAP-meters of the x-ray installations to a reference chamber, red lines indicate ±30% of the reference

C. Determination of diagnostic reference levels DRL

The primary goal of this survey was the establishment of DRL (3. Quartile of the distribution). The DRL are primarily determined in fluoroscopic examinations for the DAP. Because each examinations is set together of a fluoroscopic part (Characterized by the fluoroscopic time: T) and another part of image acquisition (Characterized by the number of images: N), the DRL of these quantities are determined in addition.

D. Analysis of patient collective and patient size

In the questionnaire following data of the patients were collected: age, size, weight and sex. The information was used to determine for each examination the specific distribution of the patient collective.

For the examinations of the trunk, the delivered dose depends essentially on the size of the patient. For the establishment of DRL the measured dose values have to be corrected to a standard patient (height: 1.70m; weight: 70kg). A simple model for a correction factor to modify the measured DAP has been applied:

$$f = DAP_{standard}/DAP_{measured} = e^{\mu(d_a-d_r)}$$

With μ for the average attenuation coefficient ($0.3cm^{-1}$), d_a for diameter of the average patient and d_r the diameter of the real patient; d_r is calculated from the height h and the weight m with the formula

$$d_r = 2(m/\pi h\rho)^{-2}$$

With ρ for the density of the body (set to $1000kg/m^3$).

E. Effect of the complexity of the examination

The complexity of the examination is certainly an important factor for the dose delivered to the patient. The results were analyzed to determine this correlation. Three categories of the complexity were recorded in the questionnaire: simple, normal and difficult examination.

F. Effect of the experience of the operator

On the basis of years of experience of the radiologist or cardiologist, a classification in three groups has been applied: doctor-in-training (<1 year), junior doctor (1-5 years) and senior doctor (>5 years)

G. Influence of the detector type

The efficiency of the detector system has a mayor influence of the primary radiation needed and consequently to

the patient exposure. The survey was also analyzed in respect to the used detector type: flat panel detector or image intensifier.

H. Inter-center comparison

The selected centers represent private radiological institutes and hospitals of small and medium size. Therefore a analysis of the results in respect of the center type can show differences in clinical practice and possible systematic different patient exposure.

III. RESULTS

A. Diagnostic reference values DRL

The survey allowed to the establish DRL for five types of examinations. The values of the present study in small and medium hospitals are shown in the table 1 below and compared to those of the previous study in the university hospitals.

Table 1 Results for the DRL for the DAP (Gy·cm^2), the fluoroscopic time T (min) and the number of images N

Type		Small and medium hospitals	University hospitals	Ratio
coronary angiography	DAP	110	80	1.38
	T	10	7	1.43
	N	1500	1400	1.07
PTCA	DAP	150	110	1.36
	T	20	20	1.00
	N	1800	1500	1.20
cerebral angiography	DAP	160	125	1.28
	T	8	15	0.53
	N	240	480	0.50
angiography of lower limbs	DAP	70	210	0.33
	T	8	8	1.00
	N	150	150	1.00
PTA of lower limbs	DAP	70	460	0.15
	T	22	25	0.88
	N	180	200	0.9

In terms of the DAP, the values obtained for the DRL in the small and medium sized hospitals are 30-40% higher than the values of the university hospitals in the case of coronary angiography, PTCA and cerebral angiography. In contrary the values are 3 to 7 times smaller in the case of angiography ant PTA of the lower limbs.

B. Influence of the difficulty of the examination

The analysis of the data in respect of the difficulty of the examination has shown a clear dependency of the complexity of the case in all 5 examinations selected. In table 2 the results of the analysis for coronary angiography is shown:

Table 2 Influence of the complexity of the case in coronary angiography

Category of complexity of the case	Number of cases	DAP [Gy·cm^2] Average	DAP [Gy·cm^2] 3. Quartile
simple	47	49±6	69
normal	140	71±6	95
complex	69	200±9	233
all	256	94±6	110

The increase in patient exposure with the complexity of the examination is seen in all 5 examinations.

C. Influence of the experience of the operator

An effect of the experience of the radiologist or cardiologist is seen in coronary angiography, PTCA and the PTA of the lower limbs, while for the cerebral angiography and the angiography of the lower limbs the distribution of the cases were not sufficient enough to see any evidence. In table 3 the results of the analysis for coronary angiography is shown:

Table 3 Influence of the experience in coronary angiography

Experience of the medical doctor	Number of cases	DAP [Gy·cm^2] Average	DAP [Gy·cm^2] 3. Quartile
In-training	8	64±3	97
Junior	28	60±4	91
Senior	204	93±6	112
all	240	84±6	109

Due to the fact, that the more complex examinations are manly handled be senior doctors, the values for the average DAP ant the 3. quartile is higher than for juniors and trainees.

D. Influence of the detector type

The analysis of the effect of the detector type (flat panel or image intensifier) did not show a significant difference between the average DAP of the tow cases. In table 4 the results of the PTCA are shown:

Table 4 Influence of the type of detector in PTCA

Type of detector	Number of cases	DAP [Gy·cm^2] Average	DAP [Gy·cm^2] 3. Quartile
Flat panel	41	124±12	156
Image intensifier	48	108±13	166
all	89	115±9	109

The analysis with the Mann an Whitney test shows no significant difference for the PTCA examinations in the survey using flat panel detectors or image intensifier (p-value=0.14). An explanation could be that in the flat panel cases the radiation field is not optimized in a proper manner.

E. Inter-center comparison

To compare the different centers with each other, the average DAP of the centers were put in relation. The results are widely spread (up to a factor of 3) and indicate a high potential of optimization of the clinical practice. A significant higher average DAP (factor of 2) has been observed in private hospitals than in public hospitals.

IV. CONCLUSIONS

A strict control concerning the denomination of the examinations involved in such a study is mandatory to obtain reliable data. This can only be done through a close collaboration between physicians, radiographers and medical physicists. The values obtained in the study differ partly strongly from the study performed in the University Hospitals due to the different difficulty of the examinations and the due to degree of experience of the operator. The clinical practice in many hospitals seems to have a high potential to optimize patient exposure. Expertise of medical physics is needed in the hospitals as well as professional clinical audits.

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