Development of Diagnostic Reference Levels Using a Real-Time Radiation Dose Monitoring System at a Cardiovascular Center in Korea

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Abstract Digital cardiovascular angiography accounts for a major portion of the radiation dose among the examinations performed at cardiovascular centres. However, dose-related information is neither monitored nor recorded systemically. This report concerns the construction of a radiation dose monitoring system based on digital imaging and communications

in medicine (DICOM) data and its use at the cardiovascular centre of the University Hospitals in Korea. The dose information was analysed according to DICOM standards for a series of procedures, and the formulation of diagnostic reference levels (DRLs) at our cardiovascular centre represents the first of its kind in Korea. We determined a dose area product

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(DAP) DRL for coronary angiography of 75.6 Gy cm^2 and a fluoroscopic time DRL of 318.0 s. The DAP DRL for percutaneous transluminal coronary intervention was 213.3 Gy cm^2 , and the DRL for fluoroscopic time was 1207.5 s.

Keywords DICOM MPPS · Radiation dose monitoring · Cardiovascular centre · Diagnostic reference levels · Order communication system

Introduction

Digital radiographic imaging technology can reduce the potential risk of radiation exposure in patients and increase the utility of images. However, concerns have been raised regarding unnecessary radiation exposure that may result from operator inexperience or misinformation. The International Commission on Radiological Protection (ICRP) indicated in Publication 93 that the ease of obtaining and deleting images during digital angiography was accompanied by a tendency among clinical users to take greater numbers of images. Consequently, concern about the likelihood of radiation exposure exceeding the necessary dose has also been raised [1]. In light of this, the Ministry of Food and Drug Safety (MFDS) has implemented a project as a 2011 outsourced task in Korea to establish a recommended diagnostic reference level (DRL) for exposure doses in patients undergoing interventional radiological procedures.

Diagnostic reference levels were first recommended by the ICRP in 1990 [2] and subsequently revised in 1996 [3]. Reference levels are typically set at the 75th percentile of the dose distribution based on a survey conducted across a broad user base (i.e. large and small facilities, public and private, hospital and out-patient) using a specified dose measurement protocol and phantom [4].

Digital cardiovascular angiography and interventional radiological procedures have become essential diagnostic and treatment tools in cases of patients with critical cardiovascular diseases, and the frequency of those procedures continues to increase. The interventional radiological procedures are accompanied by the second largest radiation dose after computed tomography (CT) in diagnostic radiology. In the USA, the Food and Drug Administration (FDA) has issued a regulation requiring manufacturers of fluoroscopic equipment produced since 2006 to attach a patient radiation dose-monitoring device [5]. This radiation-monitoring device records information during patient examinations, including the dose area product (DAP), the total radio-fluoroscopic time and the cumulative radiation dose, which is available within the digital imaging and communications in medicine (DICOM) images. In particular, the DAP value can provide an important index for

predicting radiation injury and stochastic radiation effects in the patient [6].

Korea has previously been without a separate system for dose monitoring in interventional radiological procedures, and data regarding radiation doses in patients undergoing cardiovascular interventional procedures have not been reported. The purpose of the present study was to develop DRLs for cardiovascular interventional procedures in Korea and to introduce the first real-time radiation dose monitoring system at a Korean cardiovascular centre.

Medical Radiation Injury

The ICRP has previously issued warnings about the hazards of interventional radiological procedures (ICRP Publication 85). To minimize the radiation hazard for patients and providers, the ICRP has also issued recommendations for preventing skin injury that may be incurred by interventional radiological procedures (ICRP Publication 103). A number of previous studies have reported radiation doses incurred during coronary interventional procedures and during radiological cine-scanning that have exceeded the acceptable limits for skin doses, which are 2–6 Gy for skin edema, 3 Gy for alopecia and 18 Gy for tissue necrosis [7, 8]. These types of radiation injuries are closely associated with DAP values recorded during interventional radiological procedures. Therefore, recording total fluoroscopic time and DAP during such procedures is very important for the assessment of radiation injuries.

Medical radiation may have both stochastic effects and deterministic effects in humans. Koenig [6] has published the details of 13 cases of radiation injury incurred during cardiac angiography and coronary intervention procedures. The report includes detailed descriptions of patient demographics and of the examinations, locations of skin injuries and associated clinical findings [9].

Radiation Dose Monitoring

Radiation exposures incurred by patients during interventional radiological procedures at a cardiovascular centre are classified by type and are measured in terms of total fluoroscopy time, peak skin dose, reference dose and DAP. These measurement methods present values of different profiles. Total fluoroscopy time is defined as the total length of time of fluoroscopic radiation exposure as measured during the course of an interventional radiological procedure. The US FDA regulations have also stated that fluoroscopic times should be recorded by all types of angiography equipment [6]. Furthermore, the US FDA requires that all angiographic equipment that has been sold in the USA after June 2006 must measure, indicate and record reference doses including air kerma rate and cumulative air kerma [10]. The cumulative dose is an especially useful index for evaluating risk of deterministic

radiation effect in patients [11]. The cumulative data represent the total entrance dose from the angiography equipment to patients. The DAP is measured through an ionization chamber located in the front of the collimator, and the measured values are transferred via DICOM. In Europe, The DAP is considered the reference value and is compared with the measured radiation exposures of patients undergoing interventional radiological procedures [12].

Digital Imaging and Communications in Medicine Modality Performed Procedure Step

In order to resolve the problem of hospital workflow, DICOM 3.0 was introduced by the American College of Radiology (ACR) and the National Electrical Manufacturer Association (NEMA). DICOM 3.0 is currently used in conjunction with the contents of the DICOM modality work list (DICOM MWL, 1995) and the DICOM modality performed procedure step (DICOM MPPS, 1998). The DICOM MPPS is a protocol for transferring data from radiologic examinations to the picture archiving and communication system (PACS) or the radiologic information system (RIS) [13].

DICOM MPPS contains various data including patient information, the order information for the IR procedure, MPPS information, result information and radiation exposure information [14]. Patient information includes the name and age of the patient. The order information for the IR procedure contains an access number and the study instance unique identifiers (UID). The MPPS information includes location performed, starting date and time performed, ending date and time performed, name of procedure, status, and reason for discontinuation. Lastly, the radiation exposure result contains the anatomic region exposed, exposure time and exposure dose. However, many Korean hospitals use an order communication system (OCS) that is tailored to the needs of each hospital, rather than an RIS, which is regulated by the Integrating the Healthcare Enterprise (IHE) organisation, and therefore, most hospitals in Korea do not record or store DICOM MPPS data in particular.

Order Communication System

As noted, most hospitals in Korea use an OCS. The system has been installed from 1990 and is customized to each hospital [15]. The OCS was established before the introduction of DICOM MWL and DICOM MPPS. Thus, it does not follow any specific standard. Furthermore, as OCS focuses on the delivery of physician orders and application of medical insurance fees, it is not utilized for or does not store information such as MPPS. Therefore, so far, there are no reports concerning the use of MPPS through OCS.

Workflow of Interventional Radiological Procedures

In the past, most cardiovascular centres in Korea did not prescribe before interventional procedures but entered the order information into the OCS after the procedure was completed. This custom in Korean hospitals has been a major hindrance to the implementation of a DICOM MPPS that includes the characteristics of interventional procedures, and the OCS did not support DICOM MWL. However, when the cardiovascular information system (CVIS) and cardiovascular PACS (CV PACS) were simultaneously introduced into cardiovascular centres in Korea, the method of the order information was changed to comply with the IHE regulation. However, PACS and electronic medical records (EMR) that are used widely in Korean hospitals cannot record or store the DICOM MPPS information defined in DICOM 3.0. Because most hospitals in Korea use OCS, a standard communication protocol is essential for incorporating DICOM MPPS according to the workflow recommended by IHE. Therefore, a Health Level 7 (HL7) converter has been introduced to allow interlocking of the order information database from OCS with the order information database from CVIS in this study. HL7 was designated as the standard for interlocking information by the American National Standards Institute (ANSI) in 1994. Whether or not an interventional procedure is prescribed depends on the result of diagnostic cardiovascular angiography. Thus, it is difficult to transmit DICOM MWL to radiologic equipment before entering the order information in OCS. Also, as there were many tasks that had to be performed manually, such as entering patient information and matching order information to the images, the digitalization of hospital information has been completed slowly (Figs. 1 and 2).

Methods

System Configuration

Although PACS was used in the cardiovascular centre described in this study, images related to cardiac angiographic procedures were previously not stored or recorded at storage because of problems with transmission speed and the storage device. In 2010, this cardiovascular centre was appointed as a regional cardiovascular centre and was provided with a CVIS and a cardiac PACS. However, the connection between the DICOM MWL and the CVIS equipment remained unavailable because of the OCS interface until the EMR system was constructed in 2011. The CVIS connection for DICOM MPPS became available after that, and using this system, a monitoring system for radiation dose (radiation exposure monitoring system) could be established based on MPPS (Centricity CARDDAS, GE Healthcare, USA). Figure 3 shows the

Fig. 1 Legacy workflow for cardiovascular angiography

configuration of the cardiac information system that was constructed.

An Intel Xeon 20-GHz processor and 4 GB of CPU memory were used for construction of the CVIS. A dual hard disk drive

(HDD) system was chosen to minimize the risk of data loss due to physical loss of one HDD. The database used was Gupta SQL 9.01 (Unify Corporation, California, USA), and a Microsoft Server 2008 R2 standard operating system was used

Fig. 2 DICOM MPPS workflow for cardiovascular angiography

Fig. 3 Configuration of the dose quality monitoring system

(Microsoft Corporation, USA). In addition, in order to apply the OCS, Smart Gap was used to convert order information to HL7 on a Microsoft Windows Server 2008 R2 standard system (Microsoft Corporation, USA) that had an Intel Xeon 2.1 3-GHz processor with 2 GB of CPU memory. A modality for generation of MPPS has been installed and has been in operation with INOVA2000 (GE Healthcare, Milwaukee, WI, USA) angiography equipment since 2006. On this system, the MPPS information about the examination could be transmitted to the CVIS when cardiovascular angiography was performed, and after transmission, the data were recorded on the database and could be checked by the viewer software shown in Fig. 4.

The system that was constructed can provide information such as total fluoroscopic time and sum of DAP values from acquisition of images, exposure time of each run, total number of frames, direction of exposure, tube voltage, tube current, angle of projection and field of view.

Data Analysis

Data related to patient radiation exposures during coronary angiography from 875 interventional procedures conducted at a cardiovascular centre located in the Gyeongsang-do area of Korea were collected from March 1 to December 31, 2012.

Fig. 4 Radiation dose quality monitoring software

Run	Time	Frames	Plane	kV	mA	ms	RAO / LAO	CRA / CAU	SID (cm)	FOV (cm)
1	08:05	84	FR	80	729	5	7	40	18	101
2	08:05	113	FR	70	630	4	7	-5	19	101
3	08:08	54	FR	109	573	5	9	57	-38	117
4	08:08	97	FR	106	478	4	9	0	42	117
5	08:13	66	FR	78	701	5	7	-6	39	116
6	08:16	4	FR	111	357	3	9	-6	39	116
7	08:16	4	FR	111	449	4	9	-6	39	116
8	08:17	58	FR	111	458	4	9	-6	39	116
9	08:22	3	FR	103	302	3	9	-8	38	116
10	08:22	49	FR	91	579	4	7	-8	38	116
11	08:22	63	FR	120	411	4	10	-8	38	116
12	08:25	3	FR	120	419	4	10	-8	38	116
13	08:25	1	FR	112	250	2	9	-8	38	116
14	08:26	56	FR	120	464	5	10	-8	38	116
15	08:29	76	FR	115	397	4	10	-8	38	112
16	08:30	1	FR	116	426	4	10	-8	38	112
17	08:30	2	FR	116	393	4	10	-8	38	112
18	08:31	70	FR	117	382	4	10	-8	38	112
19	08:34	58	FR	113	420	4	9	-8	38	112
20	08:34	23	FR	102	545	5	8	-8	38	112
21	08:38	31	FR	112	460	4	9	0	38	115
22	08:38	4	FR	111	404	4	9	0	38	115
23	08:39	69	FR	120	459	5	10	-8	38	116
24	08:41	130	FR	104	488	4	9	38	29	109
25	08:41	59	FR	110	539	5	9	-2	41	117
26	08:59	4	FR	98	418	3	8	-3	37	117
27	08:59	4	FR	98	549	4	8	-3	37	117
28	09:01	2	FR	98	551	4	8	-3	37	111
29	09:02	13	FR	106	473	4	9	-3	37	111
30	09:03	52	FR	118	398	4	10	-3	37	111
31	09:04	131	FR	120	459	5	10	20	37	114
32	09:04	54	FR	119	385	4	10	-33	30	111
33	09:04	60	FR	120	533	5	10	-7	39	117

Fig. 5 The sex distribution of patients according to procedure

These data were used in analysis of frequency by SPSS v20.0 (IBM Corporation, New York, USA), and third quartile values were obtained.

This retrospective study complied with the Health Insurance and Portability and Accountability Act and was approved by our respective institutional review boards; the need for informed consent was waived.

Results

The data included information about the procedures such as total fluoroscopic time, total DAP, DAP for acquisition of radiographic images, DAP for fluoroscopy, number of frames, frame rate, total number of runs, and kilovolts, milliamperes, projection angle and FOV (field of view) size for each run. The 875 procedures were divided into coronary angiography (CAG, $n=361$, 41.3 %) and coronary

angiography with percutaneous transluminal coronary intervention (PCI; $n=514$, 58.7 %) (Fig. 5).

Patient age range was from 18 to 87 years in the CAG group and 35 to 97 years in the PCI group. The average age of all patients was 63.3 years and the standard deviation was 11.9 years. The age distribution is shown in Fig. 6. The maximum DAP values for CAG and DPI were 853.9 and 1384.9 Gy cm², respectively. The range of fluoroscopy times was 54 to 3948 s, average of 283.3 s, for CAG and 94 s to 5520 s, average of 984.3 s, for PCI (Fig. 5).

In frequency analysis for CAG (Table 1), total fluoroscopy time for the third quartile diagnostic reference level (DRL) was 318 s, total DAP was 75.6 Gy cm², X-ray exam DAP was 39.9 Gy cm², X-ray exam fluoro DAP was 36.3 Gy cm² and number of X-ray frames was 731.

The DRL values for PCI (Table 2) were total fluoroscopy time of 1207.5 s, total DAP of 213.3 Gy cm², X-ray DAP of 74.3 Gy cm², X-ray fluoro DAP of 135.6 Gy cm² and number of X-ray frames of 1489. The DRL values for all patients were

Fig. 6 Age distribution of patients

Table 1 CAG results

	Fluoro time	Total exam DAP (Gy cm ²)	Exam exposure DAP (Gy cm ²)	Exam fluoro DAP (Gy cm ²)	X-ray (runs)	X-ray (frames)	X-ray (frames sec ⁻¹)	X-ray (kV)	X-ray (mA)	X-ray (mAs)	X-ray (SID cm)	X-ray (FOV cm)	Age (years)
<i>N</i>	361.00	361.00	361.00	361.00	361.00	361.00	361.00	361.00	361.00	361.00	361.00	361.00	361.00
Mean	283.33	67.60	34.64	32.96	9.91	664.96	15.04	95.94	575.80	4.53	110.41	14.17	61.72
Median	198.00	54.67	32.32	20.85	9.00	637.00	15.00	94.00	559.38	4.43	108.31	13.67	63.00
Mode	114.00	43.21	24.97 ^a	4.80 ^a	8.00	628.00	15.00	97.00000000 ^a	450.5555556 ^a	4.38	110.00	13.25	63.00
SD	309.52	59.36	13.81	51.28	4.05	228.04	0.87	47.20	212.51	1.90	47.04	5.85	12.56
S2	95803.03	3523.56	190.64	2629.96	16.39	52001.72	0.75	2227.79	45162.10	3.62	2212.34	34.18	157.67
Min	54.00	13.81	0.18	3.75	1.00	9.00	5.00	34.00	234.20	1.80	41.53	5.47	18.00
Max	3942.00	853.95	115.05	738.90	49.00	1813.00	19.09	973.00	4410.00	40.00	998.00	123.00	87.00

DAP dose area product, SID X-ray source to image receptor distance, FOV field of view

^a Smallest median values

Table 2 PCI results

	Fluoro time	Total exam DAP (Gy cm ²)	Exam exposure DAP (Gy cm ²)	Exam fluoro DAP (Gy cm ²)	X-ray (runs)	X-ray (frames)	X-ray (frames sec ⁻¹)	X-ray (kV)	X-ray (mA)	X-ray (mAs)	X-ray (SID cm)	X-ray (FOV cm)	Age (years)
<i>N</i>	514.00	514.00	514.00	514.00	514.00	514.00	514.00	514.00	514.00	514.00	514.00	514.00	514.00
Mean	984.26	187.63	64.84	122.79	28.18	1289.68	15.03	100.15	524.39	4.30	109.02	12.85	64.37
Median	720.00	143.51	57.71	83.07	25.00	1164.00	15.00	100.55	512.60	4.25	108.57	12.63	65.00
Mode	768.00	102.95 ^a	63.16	58.37 ^a	19 ^a	950.00	15.00	80.10526316 ^a	518.6666667 ^a	4.00	107.5 ^a	12.50	68.00
SD	855.01	157.86	35.53	127.83	12.59	660.49	0.16	13.31	73.26	0.45	10.44	1.44	11.43
S2	731046.39	24919.27	1262.14	16341.20	158.56	436251.43	0.03	177.09	5367.75	0.20	108.99	2.07	130.69
Min	96.00	25.12	13.92	9.34	5.00	244.00	15.00	74.75	376.91	3.50	99.72	12.00	35.00
Max	5220.00	1384.94	389.47	995.47	116.00	8478.00	17.00	323.53	1505.53	12.47	332.67	42.13	97.00

DAP dose area product, SID X-ray source to image receptor distance, FOV field of view

^a Smallest median values

Fig. 7 Distribution of total fluoroscopy times for CAG (a) and PCI (b)

total fluoroscopy time of 834.0 s, total DAP of 160.2 Gy cm², X-ray DAP of 63.8 Gy cm², X-ray fluoro DAP of 100.3 Gy cm² and number of X-ray frames of 1244. Most exams were performed at 15 frames s⁻¹. The average tube voltage for all exams was 94.4 kV, average tube current was 4.5 mAs, average shooting distance was 109.6 cm and the average field of view (FOV) was 13.4 cm² (Figs. 7 and 8).

Discussion

Coronary angiography and intervention procedures are examinations in which a specific quantity of radiation is delivered to the same area, and injury to this area by radiation exposure has been well documented. While it is essential to monitor and record patient exposure doses to digital angiographic equipment in real time, it is also very difficult to evaluate a patient's risk of radiation exposure during the procedure. Direct measurement by equipment such as a thermoluminescent dosimeter (TLD) requires post-processing in order to evaluate the real dose; therefore, it is not adequate for monitoring at the

clinical site. Furthermore, methods that measure doses directly are inappropriate because the chamber can appear in images as a foreign body. Indirect measurement tools such as a dose-area product meter are the preferred method for producing a DRL in order to prevent radiation injury to patients.

In the present study, the indicated DRLs for DAP were 75.6 Gy cm² for CAG and 213.3 Gy cm² for PCI. These values were higher than those reported in 2013 (57 Gy cm² for CAG and 94 Gy cm² for PCI) Neofotistou et al. [16]. The DRL for CAG in the present study was lower than the first action level of 125 Gy cm² reported by Bogaert et al. [17], but in PCI, the DRL was close to the second action level of 250 Gy cm². A DRL of 125 Gy cm² corresponds to an exposure dose of 2 Gy, and appearance of erythema corresponds to maximum skin dose of 3 Gy, emphasizing that caution is needed to prevent radiation injuries to the skin [4]. In the present study, 6.9 % of CAG patient doses exceeded the first action level and 18.1 % exceeded the second action level.

In patients undergoing coronary intervention, the DAP should be checked with the monitor of the angiographic device during the procedure, and the angles of the X-ray tube

Fig. 8 Distribution of total DAP values in CAG (a) and PCI (b)

should be controlled in order to avoid continuous exposure at the same area. However, the DAP value can overestimate the actual skin dose. When a patient completes an exam with a DRL exceeding an action level, in order to monitor for

changes such as skin erythema, it is necessary to register the patient as a high-dose exposure patient and to follow up with trace investigation after 2 weeks. If meaningful changes appear, proper medical treatment should be provided and

Table 3 Mean, median and third quartile DAP values for CAG and PCI

Study		No. of patients	DAP or KAP (Gy cm ²)			
			Mean	Median	Third quartile	Range or upper limit
CAG	Present study 2012	361	67.6	54.7	75.6	13.8 to 853.9
	Sapinn et al. 2004 [19]	176	48.6	37	59.6	6.3 to 452.8
	Van de Putte et al. 2000 [20]	62	60.64	56.82	80.58	144.23
	Betsou et al. 1999 [21]	29	30.4			
	D'Helft et al. 2009 [22]	967	37.86	30.64	41.71	1.36 to 231.01
PCI	Present study 2014	514	187	143	213	96 to 5220
	Sapinn et al. 2004 [19]	70	153	103	189.5	18.8 to 655.0
	Van de Putte et al. 2000 [20]	10	165.95	131.61	185.83	2.0 to 345.72
	Betsou et al. 1999 [21]	7	70.7			
	D'Helft et al. 2009 [22]	463	78.3	58.05	83.56	47.5 to 410.38

DAP dose area product, CAG coronary angiography, PCI percutaneous transluminal coronary intervention

Fig. 9 Diagnostic reference levels for each procedure

continuous trace investigation with hospital consultation is needed. If a patient who has exceeded action levels receives additional radiation exposure within 60 days, the total dose of all exposures should be evaluated [18]. Particular caution is needed in coronary angiography when additional exams to check prognosis are performed because of the additional exposure of the same area.

In the present study, the DRL for fluoroscopic time was 318 s (5.3 min) in CAG and 1207 s (20.1 min) in PCI. These values are quite high, although they are lower than the 30-min range for patients in the first action level in exams using fluoroscopy [11]. This can also come close to the total value in cases of two consecutive exposures, and it is desirable to establish the DRL, record the level of patient radiation exposure and monitor for radiation injury. DRL values established by studies similar to the present study are presented in Table 3. Also see Fig. 9.

Conclusion

Cardiovascular intervention is commonly performed and can be associated with high levels of skin exposure to radiation. Therefore, establishment of DRLs by accurate monitoring of real-time radiation exposure is absolutely necessary to reduce the risk to patients. In the present study, DRL values determined for fluoroscopic times were considerably higher than those reported in previous studies. This was a result of increased diagnostic and interventional procedure times, prior to invasive treatment, in patients with multi-vessel disease. Moreover, this is evidence that the effort to monitor exposure was inadequate and that images may be taken because of the convenience of on-site digital image processing.

The use of diagnostic reference levels has been shown to reduce the overall dose and the range of doses utilized in clinical practice. For example, UK national dose surveys demonstrated a 30 % decrease in typical radiographic doses from 1984 to 1995 and an average drop of about 50 % between 1985 and 2000 [23]. This study is important in that it is the first to identify DRLs to optimize radiation exposure of patients at Korean cardiovascular centres. Continuous monitoring using a real-time radiation dose monitoring system and optimizing DRLs in order to reduce radiation exposure in patients in Korea is necessary. Quality control process from real-time monitoring of exposure condition and dose information such as exposure DAP, fluoroscopic DAP, fluoroscopic time, frame rate and detector focus distance will reduce overall patient dose more.

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