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Diagnostic Reference Levels for Adult Nuclear Medicine Imaging Established from the National Survey in Korea

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Abstract

Purpose There is substantial need for optimizing radiation protection in nuclear medicine imaging studies. However, the diagnostic reference levels (DRLs) have not yet been established for nuclear medicine imaging studies in Korea.

Materials and Methods The data of administered activity in 32 nuclear medicine imaging studies were collected from the Korean Society of Nuclear Medicine (KSNM) dose survey database from 2013 and 2014. Through the expert discussions and statistical analyses, the 75th quartile value (Q3) was suggested as the preliminary DRL values. Preliminary DRLs were subjected to approval process by the KSNM Board of Directors and KSNM Council, followed by clinical applications and performance rating by domestic institutes.

Results DRLs were determined through 32 nuclear medicine imaging studies. The Q3 value was considered as appropriate selection as it was generally consistent with the most commonly administered activity. In the present study, the final version of initial DRL values for nuclear medicine imaging in Korean adults is described including various protocols of the brain and myocardial perfusion imaging.

Conclusion The first DRLs for nuclear medicine imaging in Korean adults were confirmed. The DRLs will enable optimized radiation protection in the field of nuclear medicine imaging in Korea.

Keywords Diagnostic reference level · Radiopharmaceutical · Dose optimization · Nuclear medicine imaging

Introduction

There is substantial need to establish diagnostic reference levels (DRLs) in nuclear medicine imaging studies to reduce unjustified medical radiation exposure and social concerns, as well as to optimize radiation protection. DRL was first introduced in the International Commission on Radiation Protection (ICRP) Publication 73 [1]. It is a form of investigation level, which applies to an easily measured quantity, usually the administered activity (MBq) in nuclear medicine imaging studies. However, as DRL is recommended to avoid excessive radiation exposure to patients while maintaining sufficient image quality, it should not be applied as a dose constraint or dose limit [2]. In 1999, the European Commission published the Radiation Protection 109 [3] and stated that DRLs should be set by member states under consideration of individual national or regional circumstances such as the availability of equipment and training under the Radiation Protection 180 [4]. ICRP supported the establishment of DRL through publications following ICRP 73, including a practical supporting guidance [5] and the ICRP 105 [6] in 2001 and 2007, respectively. The most recent publication, ICRP 135 [7], specifies existing guidelines and various aspects of DRL establishment such as considerations for conducting national survey, clinical applications of DRLs, and appropriate intervals for DRL's updates. Following these instructions, DRLs have been established in many countries [8–14].

In Korea, the first national radiation dose survey was conducted in patients undergoing chest radiography and mammography

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in 2008, and a second national survey was conducted in 2016 to update the DRL. However, since DRLs were not established for nuclear medicine imaging, the International Atomic Energy Agency (IAEA) suggested that the Nuclear Safety and Security Commission (NSSC) of Korea establish DRLs in nuclear medicine imaging studies via the Integrated Regulatory Review Service (IRRS). Therefore, the Medical Radiation Safety Research Center (MRSRC) and Korean Society of Nuclear Medicine (KSNM) collected and analyzed the data of administered activity for nuclear medicine imaging in Korea. The KSNM DRL Task Force was founded and established confirmative DRL values through 32 nuclear medicine imaging studies in Korean adults. In this study, the establishment process of the first DRLs for nuclear medicine imaging studies in Korea is presented.

Materials and Methods

Data Collection

The data of administered activity in nuclear medicine imaging studies were collected from the KSNM dose survey database of two consecutive years, 2013 and 2014. The administered activity of each nuclear medicine imaging study was reported by the departmental representative of each institute using the on-line nuclear medicine protocol information network (http://www.ksnm.or.kr/stats) created by the KSNM. In total, 144/148 (97.3%) and 142/148 (95.9%) hospitals provided dose data in 2013 and 2014, respectively. The data for 2013 were entered between April 11, 2014, and January 30, 2015, while the data for 2014 were entered between August 10, 2015, and January 30, 2016. The four centers which did not respond to the 2013 survey were those with nuclear medicine blood sample studies only. Two centers had closed nuclear medicine services in 2014 which led to the decreased number of total nuclear medicine centers and those with responses.

The analysis subjects included 28 nuclear medicine imaging studies as major categories. However, final DRL was calculated through 32 nuclear medicine imaging studies due to diverse protocols for brain and myocardial perfusion imaging. They comprise three positron emission tomography (PET) studies and 29 general nuclear medicine imaging studies (musculoskeletal [$n = 1$], infection and inflammation [$n = 1$], endocrine [$n = 4$], brain/nervous system [$n = 3$, excluding PET], genitourinary [$n = 4$], cardiovascular [$n = 9$], respiratory [$n = 1$], digestive system [$n = 4$], and oncologic [$n = 2$, excluding PET]). The DRL for brain perfusion single-photon emission computed tomography (SPECT) was calculated for each of baseline and acetazolamide challenge image. The DRL for myocardial perfusion SPECT was calculated for each of rest and stress images, respectively, for both myocardial perfusion imaging (MPI)-1-day rest (^{99m}Tc)/stress (^{99m}Tc) and MPI-1-day rest (^{201}Tl)/stress (^{99m}Tc). Regarding gated cardiac blood pool scan, DRL was calculated for both the planar and SPECT images. Although the majority of PET studies were performed using hybrid PET/computed tomography (CT) images, the survey was limited to the administered activity of radiopharmaceuticals independent of CT dose. Nuclear medicine imaging studies included in the survey are presented in Table 1.

Final Establishment of DRL

After completion of the data collection, the KSNM DRL Task Force members (21 nuclear medicine physicians) were selected from the board of the KSNM Radiation Safety Committee on February 24, 2016. The preliminary DRL values were reviewed by the Task Force members at the first (March 31, 2016) and second (May 31, 2016) meetings. The draft of the DRL for nuclear medicine imaging studies in Korea was confirmed at the third meeting, which was convened on September 12, 2016. The Task Force suggested the third quartile value (Q3) as the DRL as for CT images [15] and many previous nuclear medicine imaging studies [10, 16–18]. The DRL draft underwent the approval process of the KSNM Board of Trustees on October 10, 2018, and was reported to the KSNM Council on October 28, 2018. It was announced to the members of the KSNM as a draft on October 29, 2018.

DRL values from the announced draft were reviewed by domestic institutes performing nuclear medicine imaging studies in the clinical field for 3 months (January 2017 to March 2017). Opinions and suggestions were collected via questionnaires sent to the institutes and reflected in the revised version of the DRL draft. Additional survey for diverse study protocols of the brain and myocardial perfusion SPECT was conducted between August and September 2017 to confirm the final version of the DRL.

Statistical Analyses

Minimum (min), maximum (max), mode, median, median, first quartile (Q1), Q3, range (max–min), and standard deviation (SD) were calculated as descriptive statistics. The trends of changes in the values were examined by comparing individual descriptive statistics between 2013 and 2014. In case of outliers, the exact value was confirmed via phone interview by the department representative. All statistical analyses were performed with SPSS ver. 21.0 (SPSS Inc., USA) and R version 3.1.2 (The R Foundation for Statistical Computing, Austria) for Windows.

Results

Data were collected from 32 nuclear medicine imaging studies according to the radiopharmaceuticals and protocols used. Dose distribution (min, max, Q1, Q2, Q3, mean ± SD) of the 32

Table 1 National survey results and diagnostic reference levels for adult PET/CT and nuclear medicine imaging procedures commonly performed in Korea

	Radiopharmaceuticals	Min	Percentile			Max	Mean	SD	DRLs
			25th	50th	75th				
Tumor PET (130/130)*	^{18}F-FDG	250	370	370	370	414	356.1	35.9	370
Brain PET (109/109)	^{18}F-FDG	185	185	270	370	380	282.9	83.3	370
Brain PET (73/71)	^{18}F-FP-CIT	180	185	185	185	296	186.4	12.1	185
Bone scan (109/111)	^{99m}Tc-diphosphonate (MDP, HDP, DPD)	555	740	740	925	1110	822.4	130.9	925
Leukocyte scan (30/28)	^{99m}Tc-HMPAO-WBC	74	648	740	888	1110	725.6	219.7	888
Thyroid scan (103/108)	^{99m}Tc-pertechnetate	111	185	185	217	444	214.6	78.5	217
Thyroid cancer WBS (66/67)	^{123}I-NaI	111	185	185	185	370	179.7	38.3	185
Thyroid cancer WBS (66/67)	^{131}I-NaI	74	111	111	185	370	137.7	52.3	185
Parathyroid scan (84/84)	^{99m}Tc-MIBI	185	555	740	740	1110	691.2	220.1	740
Gated cardiac blood pool scan (53/53)	^{99m}Tc-RBC (planar)	370	740	740	740	1100	730.7	115.8	740
	^{99m}Tc-RBC (SPECT)	740	740	740	851	1110	811.7	119.0	851
Lung perfusion scan (87/88)	^{99m}Tc-MAA	111	185	185	222	370	215.2	79.1	222
Lymphangioscintigraphy (62/62)	^{99m}Tc-phytate	37	74	148	148	444	137.6	81.5	148
Raynaud's scan (71/70)	^{99m}Tc-RBC	185	555	740	740	1110	661.3	200.2	740
Liver scan (56/56)	^{99m}Tc-phytate	148	185	185	185	740	200.9	79.7	185
Hepatobiliary scan (88/88)	^{99m}Tc-mebrofenin	148	185	259	370	1110	287.5	136.9	370
Salivary scan (89/89)	^{99m}Tc-pertechnetate	111	185	370	370	740	321.2	132.2	370
Gastric emptying scan (78/78)	^{99m}Tc-DTPA or -pertechnetate	37	37	74	111	740	92.8	112.6	111
Renal scan (dynamic) (82/82)	^{99m}Tc-DTPA	111	370	370	555	740	438.7	169.6	555
Renal scan (dynamic) (62/62)	^{99m}Tc-MAG3	74	185	370	500	740	368.5	172.9	500
Renal scan (static) (98/100)	^{99m}Tc-DMSA	37	185	185	185	740	203.7	109.7	185
Radionuclide cystography (23/21)	^{99m}Tc-pertechnetate	35	37	74	74	370	76.4	67.3	74
Sentinel lymphangiography (53/53)	^{99m}Tc-phytate	7.4	37	37	74	185	55.6	43.1	74
Neuroendocrine tumor scan (43/41)	^{123}I-MIBG	111	111	111	222	370	171.2	85.7	222

*Indicates the number of institutes with available data of administered activity (2013/2014)

PET, positron emission tomography; *Min*, minimal values; *Max*, maximal values; *SD*, standard deviation; *DRL*, diagnostic reference level; *FDG*, fluorodeoxyglucose; *FP-CIT*, F-18-fluorinated-*N*-3-fluoropropyl-2β-carboxymethoxy-3β-(4-iodophenyl)-nortropane; *MDP*, methyl diphosphonate; *HDP*, hydroxydiphosphonate; *DPD*, diphosphono-1,2-propanodicarboxylic acid; *HMPAO*, hexamethylpropyleneamine oxime; *WBC*, white blood cell; *WBS*, whole body scan; *MIBI*, methoxy-isobutyl-isonitrile; *ECD*, ethyl cysteinate dimer; *MPI*, myocardial perfusion imaging; *TF*, tetrofosmin; *RBC*, red blood cell; *SPECT*, single-photon emission computed tomography; *MAA*, macroaggregated albumin; *DTPA*, diethylenetriamine pentaacetic acid; *MAG3*, mercaptoacetyltriglycine; *DMSA*, dimercaptosuccinic acid; *MIBG*, methyliodobenzylguanidine

The routes of administration of radiopharmaceuticals are intravenous injection in most of PET/CT and NM imaging procedures, except oral administration in thyroid cancer WBS, ingestion in gastric emptying scan, and bladder administration in radionuclide cystography

All radioactivity values are in MBq

nuclear medicine imaging studies in adults is shown in Table 1. DRLs for diverse protocols of the brain and myocardial perfusion SPECT are shown in Tables 2 and 3, respectively.

Q3 values tended to be higher than mode values in six studies including ^{99m}Tc-diphosphonate (bone scan), ^{99m}Tc-HMPAO-WBC (leukocyte scan), ^{99m}Tc-pertechnetate (thyroid scan), ^{99m}Tc-DTPA (dynamic renal scan), ^{99m}Tc-MAG3 (dynamic renal scan), ^{99m}Tc-DTPA or ^{99m}Tc-pertechnetate (gastric emptying scan), and ^{99m}Tc-RBC SPECT (gated cardiac blood pool scan), while the values were equal to the mode values in the remaining studies. These results are probably due to a relatively homogeneous distribution of the administered activity among domestic institutes, which is considered as a good condition for achieving consensus. There was no Q3 value, which was considered impractical or adjusted through expert opinion (Table 1).

Comparison between the confirmed DRLs in Korea and values abroad (Japan, Australia, UK, Brazil, USA

Table 2 DRLs and administered doses for adult brain perfusion SPECT with acetazolamide challenge according to imaging protocols in Korea

Procedure name and protocol		No. of nuclear medicine facilities (%)	Protocol	Min	Percentile			Max	Mean	SD	DRLs
					25th	50th	75th				
Overall		95 (100%)	Baseline	259	555	740	740	1110	642.2	158.1	740
			ACZ	499	740	1110	1110	2035	1027.1	286.9	1110
According to protocols	1-day baseline-ACZ	75 (79%)	Baseline	259	555	555	740	1110	623.5	155.8	
			ACZ	499	925	1110	1295	2035	1098.8	277.8	
	2-day baseline and ACZ	19 (20%)	Baseline	370	740	740	740	925	730.3	130.4	
			ACZ	555	740	740	740	925	759.5	104.9	
	1-day ACZ-baseline	1 (1%)	ACZ 740, baseline 370								

ACZ, acetazolamide

Other abbreviations are as in Table 1

All radioactivity values are in MBq

(NCRP), and EU) is shown in Table 4. The 12 member states of Austria, Finland, France, Germany, Greece, Bulgaria, Czech Republic, Spain, Norway, Italy, Sweden, and Switzerland are included as the EU, while the UK is separately summarized due to its recent withdrawal from the EU. The Korean DRL values tended to be lower than those of Japan: Korean DRLs were lower for 10 of 16 studies (62.5%), higher for five (including F-18 FDG PET), and identical for one study. In addition, Korean DRLs showed trend of similar or lower values than those of other countries, except ^{99m}Tc-HMPAO-WBC (leukocyte scan) and ^{99m}Tc-mebrofenin (hepatobiliary scan) which showed the highest DRL values.

Table 3 DRLs and administered doses for myocardial perfusion imaging according to imaging protocols in Korea

Procedures name and protocol		No. of nuclear medicine facilities (%)	Protocol	Min (MBq)	Percentile (MBq)			Max (MBq)	Mean (MBq)	SD (MBq)	DRLs (MBq)
					25th	50th	75th				
Single isotope											
^{201}Tl stress-redistribution		54 (100%)	Stress-redistribution	74	111	111	111	111	109.6	7.1	111
1-day rest (^{99m}Tc)/stress (^{99m}Tc)	Overall	73 (100%)	Rest	222	370	555	740	1110	579.4	273.0	740
		73 (100%)	Stress	259	555	925	1110	1480	845.2	303.6	1110
	1-day rest-stress	48 (66%)	Rest	222	370	370	555	740	418.7	129.3	
		48 (66%)	Stress	740	925	1110	1110	1480	1031.0	155.2	
	1-day stress-rest	25 (34%)	Stress	259	370	370	555	925	485.4	170.3	
		25 (34%)	Rest	370	740	925	1110	1110	888.0	199.8	
	1-day stress only	1 (1%)	Stress	925							
Dual isotope											
Overall	MPI-1-day ^{201}Tl/^{99m}Tc-MIBI or TF	10 (100%)	Rest (^{201}Tl)	44	69	111	111	111	95.1	26.6	111
			Stress (^{99m}Tc)	194	333	463	648	925	504.1	256.4	648
According to protocols and camera	1-day rest-stress	7 (70%)	Rest (^{201}Tl)	74	111	111	111	111	105.7	13.9	
			Stress (^{99m}Tc)	370	370	555	925	925	581.4	248.9	
	1-day stress-rest	3 (30%)	Stress (^{201}Tl)	44	44	55		111	70.3	35.7	
			Rest (^{99m}Tc)	194	194	222		555	323.8	200.8	
	CZT cardiac SPECT	2 (20%)	Stress (^{201}Tl	44	44	50		56	50.0	7.9	
			Rest (^{99m}Tc)	194	194	208		222	208.1	19.6	

CZT, cadmium-zinc-telluride

Other abbreviations are as in Table 1

All radioactivity values are in MBq

Discussion

The first DRLs for nuclear medicine imaging studies in Korean adults were established through the process presented in our study. The values were derived through a 4-year research proposed in the IAEA IRRS review in 2014. DRLs can be used to optimize radiation protection by setting the appropriate level of administered activity in adult patients undergoing nuclear medicine imaging. Application of Q3, which is the same standard as in other studies to establish the DRLs of nuclear medicine imaging, was confirmed as appropriate for domestic nuclear medicine imaging studies. This value was consistent with the actual prescribed dose in majority domestic institutions reported in the KSNM dose survey and enabled consensus on the DRL in Korea.

In case the value of any DRL is exceeded, possible reasons should immediately be investigated and if corrective action is required, a plan should be implemented (and documented) without undue delay [7]. Nevertheless, DRL

Table 4 Diagnostic reference levels of Korea compared with those of Japan, Australia, the UK, Brazil, NCRP, and EU

Radiopharmaceuticals (procedures)	Korea	Japan [12]	Australia [11]	UK [8]	Brazil [13]	NCRP [14]	EU [4]
^{18}F-FDG (tumor)	370	240	310	400	370	461–710	200–400
^{18}F-FDG (brain)	370	240	250	250	350		
^{99m}Tc-diphosphonate (bone)	925	950	920	600	1110	848–1185	500–1110
^{99m}Tc-HMPAO-WBC (leukocyte)	888		800	200			300–600
^{99m}Tc-pertechnetate (thyroid)	217	300	215	80	444		75–222
^{123}I-NaI (thyroid cancer)	185		400	400	167		
^{131}I-NaI (thyroid cancer)	185		185	400	185		90–400
^{99m}Tc-MIBI (parathyroid)	740	800	900	900	740		400–900
^{99m}Tc-HMPAO or ECD (brain)	925	800	750	750	1203[a]	887–1294* 733–1193**	500–1110**
^{201}Tl-Cl (MPI, stress-redistribution)	111	180	120	80	130	133–172	75–150
^{99m}Tc-MIBI or TF (MPI, rest)	555	900	620	800	444	519–1153† 590–1089‡	
^{99m}Tc-MIBI or TF (MPI, stress)	1110	1200§	1520§	800	1110	945-1402† 1007–1459‡	
^{99m}Tc-RBC (gated cardiac blood pool, planar)	740		1030	800		916–1301	600–1000
^{99m}Tc-MAA (lung perfusion)	222	260	240	100	333	147–226	100–296
^{99m}Tc-phytate (lymphangioscintigraphy)	148		52	40	74		74–150
^{99m}Tc-phytate (liver)	185	200	200	80	370		110–259
^{99m}Tc-mebrofenin (hepatobiliary scan)	370		210	150	370	189–282	
^{99m}Tc-pertechnetate (salivary)	370	370	200	80	555		
^{99m}Tc-DTPA or pertechnetate (gastric emptying)	111		44	12		31–50	150–540
^{99m}Tc-DTPA (renal dynamic)	555	400	500	300	449	407–587	
^{99m}Tc-MAG3 (renal dynamic)	500	400	305	100		283–379	100–370
^{99m}Tc-DMSA (renal static)	185	210	200	80	185	189–289	70–183
^{99m}Tc-pertechnetate (radionuclide cystography)	74		94	25			
^{123}I-MIBG (neuroendocrine tumor)	222	130	400	400	370	300–391	

All DRL values are in MBq, and blanks stand for non-available values

UK, United Kingdom; *NCRP*, National Council on Radiation Protection and Measurements; *EU*, European Union; *SNMMI*, Society of Nuclear Medicine and Molecular Imaging; *EANM*, European Association of Nuclear Medicine

Other abbreviations are as in Table 1

All radioactivity values are in MBq

* ^{99m}Tc-ECD

** ^{99m}Tc-HMPAO

† ^{99m}Tc-MIBI

‡ ^{99m}Tc-tetrofosmin

§ Rest + stress

should not be regarded as an index of good (or bad) medical practice, but as supplemental data for professional decision-making. Sometimes, it is inevitable to maintain administered activity to achieve adequate image quality due to relatively old SPECT and/or PET cameras. It is not appropriate to adjust the administered activity to the lowest possible level but similar to that of DRL [10]. Moreover, DRL values are not considered as limits, and the highest priority for any diagnostic examination is to achieve sufficient image quality [1, 2, 7]. Therefore, DRLs should not be used as evidences for legal restriction or insurance coverage, which was suggested as a potential concern during the expert discussion.

Some institutes (25%) are expected to show higher level of administered activity than that of DRL since it is defined as the Q3 of domestic administered activity. Therefore, as the medical environment changes, the DRL values should be continuously reviewed and updated at the appropriate interval of 5 years [18]. Ongoing technological advancement in the field of PET and SPECT cameras is expected to lead to decreased levels of administered activity under nuclear medicine imaging and consequently in the DRL. DRL for multi-detector CT has shown decreasing value at periodic review every 5th year in the UK [18]. Since the Korean DRL values may also decline in the future, periodical review and re-establishment are warranted.

Study Limitations

The present study has some limitations. First, the administered activity alone was analyzed without evaluation of the image quality. However, it may be difficult to assess the image quality objectively as it involves not only administered activity but also the use of different hardware and readers' preferences. Improvements in objective/quantitative parameter, such as full-width half maximum, do not guarantee improved diagnostic test accuracy and can be a source of confusion in analyzing the collected data. Second, the administered activity in children was not analyzed. Since children are more sensitive to ionizing radiation, several tools are available for pediatric nuclear medicine imaging studies [19–21]. The European Association of Nuclear Medicine pediatric dosage card [19] is commonly used, which can lead to much lower administered activity than actual pediatric dosing in domestic institutes. DRLs should additionally be established for pediatric nuclear medicine imaging studies in the future. Lastly, DRLs for the CT component of hybrid imaging should be established as the proportion of PET/CT and SPECT/CT is high with trend of further increases [22, 23]. In Korea, DRLs for regional diagnostic CT scans were previously suggested [24, 25]. However, the values are not applicable for the CT component of hybrid nuclear medicine imaging studies, and independent DRL values should be established in the future.

Conclusions

The first DRLs through 32 nuclear medicine imaging studies in Korean adults have been confirmed. The values should be periodically reviewed and updated. The DRLs enable the optimization of radiation protection in the field of nuclear medicine imaging in Korea.

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Compliance with Ethical Standards

Conflict of Interest Ho-Chun Song has received research grants from the Nuclear Safety Research Program through the Korea Radiation Safety Foundation (KORSAFe) and the Nuclear Safety and Security Commission (NSSC), Republic of Korea (Grant No. 1305033).

Myung Hwan Na, Jahae Kim, Sang-Geon Cho, Jin Kyung Park, Keon-Wook Kang, and the other members of the Korean Society of Nuclear Medicine Diagnostic Reference Level Task Force declare that they have no conflict of interest.

Ethical Approval This article does not contain any studies with human participants performed by any of the authors.

Informed Consent The requirement to obtain informed consent was waived in this non-human-subject study.

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