ORIGINAL ARTICLE

DIAGNOSTIC REFERENCE LEVELS (DRLs) FOR CONTRAST RADIOGRAPHY EXAMINATIONS IN NORTH EASTERN NIGERIA

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ABSTRACT

BACKGROUND: Diagnostic reference levels (DRLs) is an essential optimization tool in radiation medicine. This study was carried out as part of a comprehensive project to establish DRLs for radiological examinations for the first time in North Eastern Nigeria. **OBJECTIVE OF THE STUDY:** To establish DRL for contrast radiography examinations in north eastern Nigeria and to compare it with other established work. **METHODOLOGY:** This study is a prospective cross- sectional study conducted in two university teaching hospitals in north eastern Nigeria. Three hundred and Sixty (360) patients were recruited for the study. Thermoluminiscent dosimeter (TLD) chips were exposed for each examination while Dose area product (DAP) meter was used in fluoroscopy examination. TLD readings (entrance skin dose) were obtained at the Centre for Energy Research and Training Zaria, Kaduna state, Nigeria. Student T-test was used to determine the relationship between the mean ESD obtained in the two centers and Pearson's correlation was used to determine the relationship between the dose and anthropotechnical parameters. Statistical significance was set at $P<0.05$. **RESULTS:** DRLs for this study are 6.68 mGy ,10.66 mGy.cm^2 for IVU, 2.31 mGy, 3.6723 mGy.cm^2 for HSG, 2.66 mGy ,8.98 mGy.cm^2 for barium meal, 12.78 mGy, 20.64 mGy.cm^2 for barium enema, 2.73 mGy and 6.56 mGy.cm^2 for barium swallow and 2.05 mGy, 7.77 mGy.cm^2 for RUG respectively. However, ESD and DAP show statistical significant relationship for barium enema while mAs and kVp showed statistical significant relationship for barium swallow and barium meal respectively. The remaining study showed no statistical significance $p>0.05$. **CONCLUSION:** DRLs in this work recorded lower values compared to international established work. However, regular dose optimization technique and etiquette are required to ensure good practice in North Eastern Nigeria.

Introduction

Diagnostic reference level (DRL) is defined as an investigation level used to identify unusually high radiation doses for radiological examinations.[1,2] They are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses.[3] DRLs is an optimization tool to ensure patients are adequately protected and it is deemed to be an important mechanism for the management of patient dose to ensure it is commensurate with the medical purpose of x-ray examination.[4] In the recommendation of international commission of Radiological protection (Report 103), the principle for setting DRLs are enumerated, the local, regional and national objectives is clearly defined, including the degree of the specification of clinical and technical conditions for

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medical imaging task, the selected value of the DRL is based on the relevant regional, national and local data, the quantity used for the DRLs can be obtained in practical way.[5,6,7] The concept of investigation levels for diagnostic medical exposures was first proposed by the International Commission of Radiological protection (ICRP) in its 1990 recommendations, and further developed into diagnostic reference levels (DRL) in 1996 in ICRP publication 73.[8] The numerical values of diagnostic reference levels are advisory however; implementation of the DRLs concept may be required by regulatory and professional bodies.[3,7] Diagnostic reference levels (DRLs) are optimization tools used as special type of dose constraints above which doses must be reviewed and considered above acceptable levels, especially if acceptable image quality can be achieved at lower doses.[9] Optimizing the protection of patients, and maintaining appropriate good practice is a priority for all diagnostic radiological examinations.[9] Many studies carried out to measure entrance surface dose (ESD) in different countries and their results were compared with dose levels recommended by relevant organizations. Also, organizations such as the National Radiological Protection Board (NRPB) and International Atomic Energy Agency (IAEA) recommended the use of dose constraints or investigation levels to provide guidance for medical exposures.[10] In the United States, Greece, Brazil and Bangladesh, investigations showed that patients dose from common x-ray examinations were below the reference levels set by International Commission on Radiological Protection.[11] In contrast, in China and Tanzania researchers reported that the average ESDs were comparatively high for x-ray examinations.[12]

Contrast radiography examination is a special radiographic investigation that employs the use of contrast media to outline certain anatomical structures in the body. These study includes hysterosalpingography (HSG) for the uterus and fallopian tubes, intravenous Urography (IVU) for kidneys ureter and bladder, retrograte urethrography (RUG) and micturating urethrogram (MCUG) for the urethra, barium meal for the stomach, barium swallow for the oesophagus, barium enema for the bowels, venography for the veins mostly lower limbs, fistulogram for an opening connecting structures (fistula) and genitogram to check for reproductive organs.

Diagnostic reference levels are usually established along with image quality.[14] Quality control (QC) is normally part of the QA program and key in ensuring the accuracy of data obtained in DRLs investigations. QC techniques are those techniques used in the monitoring (or testing) and maintenance of the technical elements or components of an x-ray system. The quality control techniques thus are concerned directly with the equipment that can affect the quality of the image.[12] An X-ray system refers to an assemblage of components for the controlled production of diagnostic images with x-rays. It includes minimally an x-ray high voltage generator, an x-ray control device, a tube-housing assembly, a beam-limiting device and the necessary supporting structures.[10,13] Other components that function with the system, such as image receptors, image processors, automatic exposure control devices, viewing boxes and darkrooms, are also parts of the system. The main goal of a QC program is to ensure the accuracy of the diagnosis or the intervention (optimizing the outcome) while minimizing the radiation dose to achieve that objective.[10,14]

Increasing concerns over radiation doses received by patients and the associated radiation risks have become a major issue in recent years.[13,14] Reducing radiation dose in radiological examination is of utmost importance particularly in the light of continued increase in the number of new modalities and examinations performed annually.[14] In Nigeria, in spite of the large number of examinations carried out yearly, the dose information available is grossly inadequate. In addition, there are no evidence of published data indicating the establishment of diagnostic reference levels for common radiographic examination in Nigeria.[15,16]

Diagnostic Reference Levels (DRLs), which is the recommended tool in achieving optimization of doses, is yet to be set or unavailable for radiology examinations and procedures in Nigeria.[17] Practices are presently referenced to United Kingdom radiological practice standards, European commission and Australian Radiation Protection and Nuclear Safety Agency. More so, IPEM (2004) recommends that every country and or facility should have or set its DRLs, because practices and advancement in technology varies from one country to another and hence one country's DRLs cannot be a good representation of another.[16] The aim of this study was to establish DRL for contrast

radiography examinations in north eastern Nigeria and to compare it with other established work.

Materials and Methods

Method

The study is prospective cross sectional study carried out in Radiology departments of two University Teaching Hospitals located in North Eastern part of Nigeria. Three hundred and sixty patients were recruited for the study. The data in this study were collected from October 2015 to January 2016. The centers were chosen because they met the eligibility criteria for the study; having all the imaging modalities for the study and Nigerian Nuclear Regulatory Authority's Requirement for Authorization and Practice (Licensing) involving ionizing radiation. The exposed TLDs were labeled for proper identification and kept in black nylon away from radiation. A dose data capture was drafted, the template sort for information such as patients age, gender, sex, weight, height, Body mass index, focus to film distance and technical parameters. Data were entered by the researcher assisted by two senior Radiographers in each facility and then checked by a medical physicist. The information obtained for the study includes:

(i) Age, to make sure that only adult patients are recruited in the study.

(ii) Gender of the patients.

(iii) Patients body region examined

(iv) Technical Parameters such as tube potential (kVp), tube current (mAs), scan length, Field of view, angle of rotation, focus to film distance, anterior posterior thickness and fluoroscopy time for each examination and procedure where applicable.

(v) Weight (kg), height (m^2) and body mass index BMI (kg/m^2)

Procedure

Dosimetric Measurements

Thermoluminiscent dosimeters and Dose Area Product meters were used for dose measurement for conventional x-ray, dental x-ray, and mammography and fluoroscopy examinations. The TLDs were annealed and read at Center for Energy Research and Training Zaria, Kaduna State, Nigeria after exposure. The TLDs were annealed before taking the measurements. The annealing was done at a high temperature of 98 degree centigrade; this process essentially zeroed the Thermo luminescent material by releasing all trapped electrons before the TLD is used. About ten percent (10%) of the TLD chips used were set aside as controls in the various centers to help record background radiation. The control TLD chips are kept in a black nylon away from exposure to irradiation (both primary and secondary beam). Readings were taken directly from the DAP meters because it is an instant dosimeter. After collection of the TLD and DAP readings, the collective values were recorded for each examination. The mean and third quartile (75^{th} percentile) values were obtained from the total received.

Materials

a. Conventional x-ray machine: The machine used were products of Variant medical system manufactured in China and United states for hospital A and B respectively both manufactured 2009. Maximum and minimum kVp and mAs for the machines are 40-150 and 0.5-630 for hospital A and 40-200 and 0.5-400 for hospital B respectively and inherent filtration of 1.5 mmAL and 0.8 mmAL for hospital A and B respectively.

b. Fluoroscopy machine: The equipment is an over couch type manufactured by Philips in February 2010. The inherent filter is 2.5 mmAl with kVp and mAs range of 40-150 and 0.5-850. Fluoroscopy machine used was for hospital A. Hospital B has no fluoroscopy machine.

c. Thermoluminescent dosimeters (TLD): TLD-chips 100 Dosimeters (calibrated) annealed. They are round, small, white in colour and very sensitive. They are enclosed in a black leather and labeled. The Thermoluminiscent dosimeter chips were obtained from a registered Radiation Safety Adviser (RSA), Nigerian Nuclear regulatory Authority (NNRA), Abuja, Nigeria.

d. Dose Area Product (DAP) meters (calibrated): Dose-area product meter is relatively easy to measure radiation dose. DAP meters measure the radiation dose to air, times the area of the x-ray field. DAP is expressed in gray-cm^2 (Gy-cm^2). The

reading from a DAP meter can be changed by altering the x-ray technique factors (kVp, mA, or time), varying the area of the field, or both. If the chamber area is larger than that of the collimators, as the collimators are opened or closed the charge collected will also increase or decrease in proportion to the area of the field.

Data Analysis

Data was obtained and saved on a computer Microsoft excel spread sheet and categorized for each examination and imaging modality respectively. It was independently checked by a statistician and two senior radiographers. Statistical Package for Social Sciences version 21.0 was used to analyze the mean and standard deviation of the anthropometric variables, technical parameters and radiation dose received. Seventy fifth (75th) percentile or (3rd quartile) value of the total mean of the examinations and or procedures were obtained at 95% confidence interval. Using Kolmogorov - Smirnov to test for normality of data distribution it was verified that, for 95% of confidence level, there was a normal distribution. Therefore, we used a parametric test that was suitable for the set of data and analysis. Pearson's correlation was used to determine the relationship between radiation dose and weight at statistical significance of $p<0.05$.

Ethical Clearance

In line with Helsinki declaration 1964 (8), ethical approval was obtained from the research ethics committee of the Faculty of Health Science and Technology, Nnamdi Azikiwe University Nnewi Campus and from each hospital under study. Informed consent form interpreted in Hausa language was filled by each (volunteer, Patient) participant in compliance with the Human Research Ethics Guidelines for patients who do not understand English Language.

Results

Examination	Mean ESD (mGy) Hospital A	Mean ESD (mGy) Hospital B	Mean ESD (mGy) Both	DAP (mGy. cm^2)	DRL	
					mGy	mGy.cm^2
IVU	2.17±1.94	4.61±4.58	3.39±3.26	9.25±1.31	6.68	10.66
HSG	1.41±0.66	2.30±1.45	1.85±1.05	2.97±0.55	2.31	3.67
Barium meal	1.66±0.44	2.61±1.31	2.14±0.88	7.33±1.85	2.66	8.98
Barium enema	10.63±1.05	2.62±1.31	6.63±1.18	16.26±3.23	12.78	20.64
Barium swallow	1.62±0.35	2.62±1.45	2.12±0.90	7.62±2.01	2.73	6.56
RUG	1.18±0.65	1.82±1.19	1.50±0.92	5.91±1.24	2.05	7.55

Key: IVU- Intravenous urography, HSG- Hysterosalpingography, RUG- Retrograte-urethrography, ESD- Entrance skin dose, DAP- Dose area product

Table 1: Mean doses received and 75 percentile (DRLs) for contrast radiographic examination

Examination	Technical Parameters	ESD Vs Technical Parameters		DAP Vs Technical Parameters	
		R-value	p-value		
IVU	FSD	0.534	0.002	0.077	0.686
	kVp	-0.317	0.088	-0.209	0.268
	mAs	-0.067	0.726	-0.469**	0.009
HSG	FSD	0.171	0.367	-0.096	0.613
	kVp	0.250	0.183	-0.071	0.708
	mAs	0.012	0.949	-0.132	0.488
RUG	FSD	-0.235	0.211	0.671	0.000
	kVp	-0.153	0.420	0.485	0.007
	mAs	0.213	0.259	-0.010	0.956
BA Enema	FSD	0.386	0.035	0.390*	0.033
	kVp	-0.086	0.650	-0.199	0.292
	mAs	-0.013	0.944	0.230	0.222
BA Swallow	FSD	0.174	0.357	-0.137	0.470
	kVp	0.448	0.013	-0.110	0.562
	mAs	0.678	0.000	-0.056	0.769
BA Meal	FSD	0.139	0.465	0.185	0.327
	kVp	-0.532	0.002	-0.162	0.393
	mAs	-0.437	0.016	-0.246	0.191

**. Correlation is significant at the 0.01 level (2-tailed). *. Correlation is significant at the 0.05 level (2-tailed). IVU- Intravenous urography, HSG- Hysterosalpingography, RUG- Retrograteurethrography, ESD- Entrance skin dose, DAP-Dose area product, kVp- kilo volt peak, mAs- milli ampere seconds, FSD- Focus to skin distance, BA- Barium

Table 2: Relationship between doses received by patients during contrast radiographic examination and technical parameters

Examination	Technical Parameters	Mean±Std (Hospital A)	Mean±Std (Hospital B)	P-value	T-value
IVU	KVp	78.50±9.16	81.50±10.00	p>0.05	0.383
	mAs	32.00±10.00	49.23±10.00	p>0.05	2.110
	ESD	3.17±1.02	6.61±2.00	p>0.05	2.654
	DAP	9.25±0.00	10.26±2.00	p>0.05	0.875
HSG	KVp	66.90±5.00	76.63±4.00	p>0.05	2.632
	mAs	25.67±10.00	40.80±10.00	p>0.05	1.853
	ESD	1.41±0.91	2.30±0.88	p>0.05	1.207
	DAP	2.97±0.00	3.44±0.40	p>0.05	2.035
RUG	KVp	74.67±3.00	79.33±10.00	p>0.05	0.773
	mAs	34.83±10.00	39.60±10.00	p>0.05	0.584
	ESD	1.18±1.00	1.82±0.80	p>0.05	0.866
	DAP	5.91±0.00	7.14±1.00	p>0.05	2.130
BA Enema	KVp	78.50±10.00	86.00±2.00	p>0.05	1.274
	mAs	32.00±10.00	29.67±10.00	p>0.05	0.285
	ESD	10.63±4.00	2.62±0.00*	P<0.05	3.374
	DAP	16.26±0.00	7.90±1.00*	P<0.05	14.480
BA Swallow	KVp	65.67±10.00	80.00±3.50	p>0.05	2.343
	mAs	24.17±4.00	50.00±5.00*	P<0.05	6.987
	ESD	1.62±1.00	2.62±1.00	p>0.05	1.225
	DAP	7.62±1.00	6.24±1.00	p>0.05	2.390
BA Meal	KVp	66.97±6.00	86.00±2.50*	P<0.05	5.071
	mAs	24.42±10.00	29.67±10.00	p>0.05	0.643
	ESD	0.34±0.20	0.55±0.20	p>0.05	1.286
	DAP	7.33±0.00	7.90±1.00	p>0.05	0.987

**. Correlation is significant at the 0.01 level (2-tailed), *. Correlation is significant at the 0.05 level (2-tailed).
IVU- Intravenous urography, HSG- Hysterosalpingography, RUG- Retrograteurethrography, ESD- Entrance skin dose, DAP-Dose area product, kVp- kilo volt peak, mAs- milli ampere seconds.

Table 3: Comparison of patient's mean radiation dose and technical parameters for contrast radiographic examination for hospital A and Hospital B

Discussion

The study established diagnostic reference levels for contrast radiographic examination in two selected university teaching hospitals in North eastern Nigeria. The hospitals studied were divided into two A and B respectively. There are three university teaching hospitals in North Eastern Nigeria as at the time of the study. However, hospitals A and B were chosen because they met the inclusion criteria for the study having the necessary functional imaging facility. A

Examination	ARPANSA DRL		EC, DRL		UK, DRL		DRL This work	
	mGy	DAP	mGy	DAP	mGy	DAP	mGy	DAP
IVU	--	16	--	14	10	14	6.68	10.66
HSG	--	4	--	2	2	4	2.31	3.67
Barium meal	--	13	--	12	5.0	12	2.66	8.98
Barium enema	--	31	--	23	15	21	12.78	20.64
Barium swallow	--	11	--	3.4	4	7.5	2.73	6.56
RUG	--	13	--	7	15	7	2.05	7.77

Fluoroscopy time is between 2 - 15 seconds with mean time of 8.12±1.03 minutes. DAP - dose area product in mGy.cm2. EC- European commission, UK- United Kingdom, ARPANSA-Australian radiation protection and nuclear safety agency

Table 4: Comparison of DRLs for contrast radiographic examination in this work with European Commission, United Kingdom and Australian radiation protection and nuclear safety agency DRLs.

total of three hundred and sixty (360) patients were considered in this study. It is recommended that the entrance skin dose measurements be made on statistically significant sample of patients (minimum 10) whose weights are near the standard adult patients of average weight 70±10 kg as a major step to establish standardized patients for our population.[8,18,19] This study complied with the recommendations and therefore the estimate of ESDs for the various examinations could be considered sufficiently as a representative value for specific protocols and examination. This corroborates with other studies by ARPANSA, UK, EC and IPEM, 2005.[8]

The main factors affecting patient's dose in contrast radiographic examination are exposure factors, filtration, and source to skin distance, collimation pathology and patient size. Minor variations were observed among patient's populations in terms of age weight height, BMI and thickness. The established diagnostic reference levels for intravenous urography, hysterosalpingography, barium meal, barium enema, barium swallow and retrograde urethrography are 6.68 mGy and 10.66 mGy.cm^2, 2.31mGy and 3.67 Gy.cm^2, 2.66 mGy and 8.98 Gy.cm^2, 12.78 mGy and 20.64 Gy.cm^2, 2.73 mGy and 6.56 Gy.cm^2, 2.05 mGy and 7.55 Gy.cm^2 respectively. There were variations in the mean doses as noted in (Tab. 2), the variations in the data recorded demonstrate the importance of creating awareness by the radiographic staff on quality assurance and standardization of protocols to ensure satisfactory y standards and optimized radiation dose to patients and staff, this concurs with another study.[4,15] The variations encountered might have arisen

from the differences in sample sizes as well as the inherent variations in patient radiation dose values for different types of examination. The variations in patient dose are relevant in the process of dose optimization.[8]

The inherent variations in doses among the investigated population are expected to be taken into consideration while setting up the tolerance and limiting values to act as trigger levels and guidance mechanism for establishing DRL published by Institute of Physics and Engineering in Medicine.[16]

Result from IVU examination in (Tab. 2) shows that there was statistical significant relationship ($p<0.05$) between FSD and ESD, mAs and DAP while kVp and mAs show no statistical significant relationship ($p>0.05$) with ESD. During HSG examination there was statistical significant relationship ($p<0.05$) between tube current (mAs) and DAP. For RUG examination, ESD and technical parameters (kVp, mAs and FSD) show no statistical significant relationship ($p>0.05$). There was statistical significant relationship ($p<0.05$) between FSD, tube potential (kVp) and DAP. Barium enema showed statistical significant relationship ($p<0.05$) between DAP, ESD and FSD while kVp and mAs show no significant relationship with ESD and DAP. There is statistical significant relationship ($p<0.05$) between kVp, mAs and FSD while DAP showed that there is no significant relationship ($p>0.05$). Similarly, for barium swallow and enema examination, kVp and mAs show statistical significant relationship ($P<0.05$) with ESD while DAP show no statistical significance ($p>0.05$) with kVp, mAs and FSD.

Table 3 shows the T-test comparison of radiation dose and some technical parameters of patients received in the hospitals studied during contrast radiographic examination. Detail result from the table shows that when the mean doses (Entrance skin dose) and technical variables (KVp and mAs) of IVU, HSG, RUG, barium enema, barium swallow and barium meal were compared, they show no statistical significant relationship ($p>0.05$). However, ESD and DAP show statistical significant relationship for barium enema while mAs and kVp showed statistical significant relationship for barium swallow and barium meal respectively.

The DRL for Australian radiation protection and nuclear safety agency (ARPANSA) were 16 mGy.cm^2, 4 mGy.cm^2, 13 mGy.cm^2, 31 mGy.cm^2, 11mGy.cm^2 and 13 mGy.cm^2 for IVU, HSG, barium meal, barium enema and barium swallow and RUG respectively. From the table, European commission (EC) DRL are 14 mGy.cm^2, 2 mGy.cm^2, 12 mGy.cm^2, 23 mGy.cm^2, 3.4 mGy.cm^2 and 7 mGy.cm^2 for IVU, HSG, barium meal, barium enema and barium swallow and RUG respectively. United kingdom DRL are presented as follows 10,2,5,15,4 and 15 mGy and 14,4,12,21,7.5 and 7 in mGy.cm^2 for IVU, HSG, barium meal, barium enema and barium swallow and RUG. DRL for this study are 6.68 mGy ,10.66 mGy.cm^2 for IVU, 2.31 mGy, 3.6723 mGy.cm^2 for HSG, 2.66 mGy,8.98 mGy.cm^2 for barium meal, 12.78 mGy, 20.64 mGy.cm^2 for barium enema, 2.73 mGy and 6.56 mGy.cm^2 for barium swallow and 2.05 mGy, 7.77 mGy.cm^2 for RUG respectively. DRLs for IVU, HSG Barium meal and Barium enema in this work recorded lower values when compared with that of European, UK and ARPANSA respectively a possible explanation for that may be due to the fact that the patient exposure parameters and techniques used in our study differs this agrees with another study.[20] Implementation of DRLs could achieve an ESD reduction between 30% and 60% below the CEC recommendation.[21,22] Several studies show it is possible to achieve a dose reduction of 50% without losing image quality when CEC guidelines are well established.[23]

Conclusion

DRLs for IVU, HSG Barium meal and Barium enema in this work recorded lower values when compared with other international established values. The present work has demonstrated that an efficient and fully integrated radiological dose information system can play an important role, providing data to support radiologist, radiographers, medical physicist, academicians, professional bodies and regulatory bodies in adopting the best strategy in ensuring that radiation doses to patients are adequately optimized. This study has an educational and regulatory function to medical imaging and radiation sciences and furthermore provides a benchmark to assist any statutory organization to establish DRLs for diagnostic radiology practices in Nigeria, Africa and the world entirely.

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