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RADIATION EXPOSURE IN INTERVENTIONAL PROCEDURES

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The aim of this study was to estimate radiation doses patients and staff are exposed to during interventional procedures (IPs), compare them with the international diagnostic reference levels and to develop initial National Diagnostic Reference Levels. The IP survey was undertaken as the initial task of which, retrospective data were collected from the only four Kenyan hospitals carrying out interventional radiology and cardiology procedures at the time of the study. Real-time measurement of radiation dose to patients and staff during these procedures was done. To the patients, kerma-area product (KAP) and fluoroscopy time measurements were done using an in-built KAP meter, while peak skin dose (PSD) was measured using slow Extended Dose Range (EDR2[®]) radiographic films. The staff occupational doses were measured using individual thermoluminescence dosimeters. The maximum and minimum KAP values were found to be 137.1 and 4.2 Gy cm², while the measured PSD values were 740 and 52 mGy, respectively. The fluoroscopic time range was between 3.3 and 70 min. The staff doses per procedure ranged between 0.05 and 1.41 mSv for medical doctors, 0.03 and 1.16 mSv for nurses, 0.04 and 0.78 mSv for radiographers and 0.04 and 0.88 mSv for clinical staff. The measured patient PSDs were within the threshold limit for skin injuries. However, with the current few IP specialists, an annual increase in workload as determined in the study will result in the International Commission on Radiation Protection annual eye lens dose limit being exceeded by 10 %. A concerted effort is required to contain these dose levels through use of protective gear, optimisation of practice and justification.

INTRODUCTION

Interventional fluoroscopy procedures are medical procedures in which potentially high dose rate X-ray fluoroscopy with high temporal resolution may be used to guide the navigation, placement or manipulation of medical devices inside the human body. Although originally developed for radiologists, interventional radiology (IR) is now being used also by many other medical specialists—cardiologists, urologists, gastroenterologists, orthopaedic surgeons, cardiovascular surgeons, neurosurgeons, traumatologists, anaesthesiologists and paediatricians. Interventional procedures (IPs) are therefore divided into many categories, such as IR and interventional cardiology (IC). In most countries, irrespective of the level of healthcare provision, IPs offer the opportunity to diagnose and treat more patients with a wide range of pathological issues at a relatively lower cost. Compared with conventional surgery, interventional techniques do not require an expensive operating room, space for in-patient hospital admissions and risk associated with the use of local anaesthetics. The disadvantages of local anaesthesia are excessively high concentration of the anaesthetic in the blood, injury from the needle used to inject the drug and discomfort due to inadequate

anaesthetic. Additionally, IPs allow biopsy of lesions that were previously inaccessible via other available means, at a relatively lower cost but with concomitantly greater risks⁽¹⁾.

IPs have been extensively developed and may be classified into different types such as drainage, coil embolisation, filter placement, stenting and foreign-body retrieval, or into anatomical systems such as vascular, gastro-intestinal and urological procedures. Modern fluoroscopic systems that use image intensifiers coupled to closed-circuit television unit have encouraged the rise in the frequency of IPs over the years. Originally, fluoroscopy was carried out in a dark room with the radiologist viewing the faint scintillations from a thick fluorescent screen⁽²⁾.

Many modern catheterisation laboratories have improved in-built radiological protection measures and reduced scatter radiation. In addition, the inclusion of radiation protection training for interventional radiologists and cardiologists has played a role in the reduction of the risk of radiation exposure, even though the complexity and the number of procedures have increased⁽³⁾. Therefore, evaluation and follow-up of occupational doses should be considered an aspect of extra importance of the quality

assurance programme. In a study of radiation-associated posterior lens opacities carried out in Serbia, a strong dose-response was found between occupational exposure and the prevalence of radiation-associated posterior lens changes⁽⁴⁾. Occupational exposure risk in IPs is higher than in other specialties that involve the use of X-ray. This is because the specialists performing the interventions monitor the procedures on a real-time basis by staying close to the patients who are being exposed to radiation. Radiation exposure is, therefore, a significant concern in this type of IPs and is aggravated further by the low number of specialists, who thus experience large workloads and associated complex procedures⁽⁵⁾.

The use of interventional fluoroscopy is increasing in Kenya, as evident from the rise in the number of hospitals performing IPs from two in 2000 to five in 2010 as well as from the workload. It is likely that many non-radiologist practitioners will soon join the interventionists' fray, increasing the projected scope of IPs. Most of these interventionists have little or no relevant safety knowledge and experience. Some patient dose studies carried out in the UK have reported the mean peak skin dose (PSD) that exceeds the 2 Gy thresholds for deterministic effects in 2 % of the cases⁽⁶⁾.

Diverse methods of assessing patient dose exist worldwide. Modern fluoroscopic systems have an in-built ion chamber (KAP meter) that measures the total X-ray energy leaving the X-ray tube. Kerma-area product (KAP) gives a reasonable estimate of the dose measurement of any procedure that is used. PSD is the highest radiation dose (entrance surface air kerma) at any portion of a patient's skin during a procedure. As of 2010, the commercially available fluoroscopic unit capable of calculating or displaying PSD was not commonly available⁽⁷⁾; however, use of films was appropriate for this study because of the indication of the likelihood of deterministic effects.

Currently, Kenya has no data on patient dose resulting from IPs as well as dose to the staff involved in the process of carrying out these procedures. Evaluation of risks posed by the radiation that patients and staff in IPs are exposed to is complicated because of diversity in examination and personnel involved. This situation creates a major challenge in implementing radiation safety measures. Consequently, this study was initiated in 2007 to assess the level of radiation exposure at the only four hospitals carrying out IPs in Kenya. The results were compared with the national reference doses for the UK⁽⁸⁾ and the International Commission on Radiation Protection (ICRP) occupational dose limits⁽⁹⁾, thereby providing the baseline data to be used in sensitising IP personnel to the level of radiation they are exposed to in their daily practice and its risks and to how to justify and optimise radiation safety measures.

MATERIALS AND METHODS

IPs statistics

A questionnaire-type form was developed to record patient information, IP statistics and parameters associated with the fluoroscopic equipment.

Patient dose assessment

Slow radiographic films (Kodak EDR2[®]) with a measuring range of 0.01 to ~2 Gy was used for 54 randomly selected IPs and PSD measurements. The films indicate the distribution of dose and skin locations where the dose measurements exceed the limit for deterministic effects. The films were calibrated by segmenting them into four portions and each portion was exposed to a known radiation dose separately while shielding the other three with lead shields. The optical density (OD) was measured using a X-Rite[®] model 341C transmission densitometer (X-Rite Inc., USA) on films exposed to the known dose of 0.01 to ~1 Gy⁽¹⁰⁾. The Kodak EDR2[®] OD calibration curve was then plotted against the known dose to generate a calibration curve. The curve was fitted to generate a second-order polynomial equation as follows

$$y = 1 \times 10^{-8}x^3 - 2 \times 10^{-5}x^2 + 0.0132x + 0.2106 \quad (1)$$

where y and x represent OD and relative dose in mGy, respectively.

Measurements of individual patient doses were carried out using Kodak EDR2[®] films and the machine's in-built KAP meter. The film was placed under the patient table and positioned at the central beam of the patient body's region of interest. The exposed films were processed at least 1 h after exposure to allow the densities to stabilise. The OD values measured were used to obtain PSD, using Equation (1). kVp, tube loading (mAs), KAP reading and fluoroscopic time were all recorded for each procedure. The KAP meter was reset to zero before the commencement of each procedure and the cumulative KAP values were recorded at the end of the procedure. The third quartile values per examination type were considered as the initial National Diagnostic Reference Levels (NDRLs) for KAP and fluoroscopy time, respectively.

Staff dose measurement

A total of 216 personnel were involved in the 54 IPs assessed in the study. All these personnel namely medical doctors (MDs), nurses, radiographers and clinical staff were provided with thermoluminescence dosimeters (TLDs) (lithium fluoride TLD 100;

Harshaw-Filtrol, Cleveland) prior to each procedure. The TLDs were clipped on their collars. These TLDs were in addition to the ones used for routine monthly personal monitoring. After each procedure, the doses recorded by the TLDs were read out using a TLD Reader (Harshaw Model 4500) operating with the WinREMS software. These readings were corrected for the natural background level readings recorded by the control TLDs.

RESULTS

IPs statistics

The total annual IP workload for all the four facilities combined was found to be 1029 patients, which consisted of 75 % adults and 25 % children. The adult procedures were predominantly coronary angioplasty (CA) and aortic lesion for diagnostic procedures, while the therapeutic IPs were CA and stenting. The most common paediatric cardiology procedures include diagnostic cardiac catheterisations for shunt assessment such as ventricular-septal defects associated with pulmonary hypertension, tetralogy of Fallot and its clinical variants and other complex congenital cardiac catheterisations such as transposition of great vessels and the dextrocardia. Therapeutic paediatric IPs which were done included pulmonary vasculature for congenital heart disease, patent ductus arteriosus, embolisation and mitral valvoplasty for acquired heart disease. The increasing rates per annum were roughly 30 and 40 % for adult and paediatric patients, respectively. The IPs were distributed as follows: diagnostic procedures 49 %, therapeutic procedures 21 % and combined diagnostic and therapeutic procedures 30 %. The average annual workload per medical specialist was 130 IPs (10 %) with the leading specialist performing 330 IPs (25 %). IC comprised 87 % with adult CA accounting for 33 %, paediatric CA 12 % and paediatric valvoplasty 42 %. Interventional neuro-radiology comprised 13 %; most of which were four-vessel angiography. While 1029 indicated the total annual number of IPs obtained retrospectively, the data points in Figures 1–5 reflect empirical values obtained by the actual measurements of patient and occupational doses. Figure 1 shows the distribution of the 54 randomly selected adult and paediatric patients who underwent IPs and the study parameters measured. There were 25 % of complex procedures carried out in >30 min. The fluoroscopic time in IC procedures was distributed as follows: 3 % took <10 min, 27 % took between 10 and 20 min and 21 % >20 min. In interventional neuro-radiology procedures, 10 % took <10 min, 2 % between 10 and 20 min, while 4 % took <20 min.

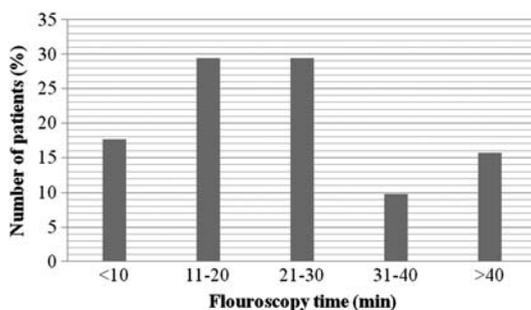


Figure 1. Distribution of the complexity of procedures according to time spent.

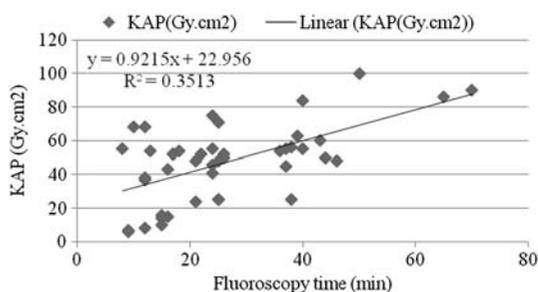


Figure 2. Distribution of the correlation between KAP and fluoroscopy time measurements for the examinations considered.

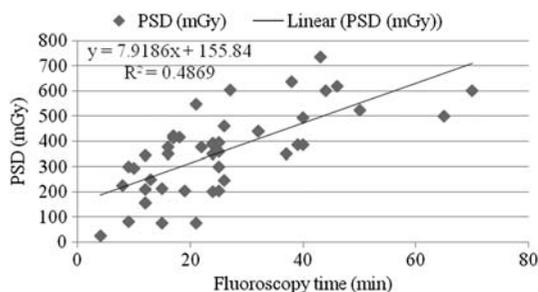


Figure 3. Measurement correlation between PSD and fluoroscopic time.

Patient dose

Figure 2 shows the distribution of KAP and the fluoroscopy time for the examinations considered. The average KAP value was 54 Gy cm², while the maximum and minimum KAP values were 137.1 and 4.2 Gy cm², respectively. The mean KAP values for adult procedures were 65 Gy cm² for coronary angiography and 39 Gy cm² for neuro-angiography, and 36 Gy cm² for paediatric diagnostic cardiac catheterisation and 43 Gy cm² for valvuloplasty. The

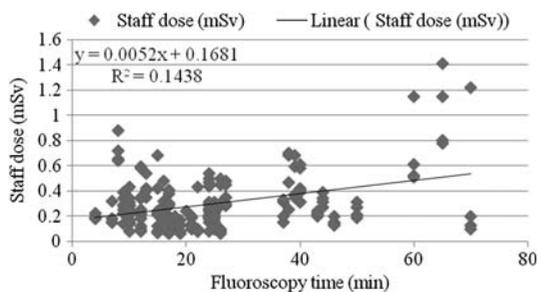


Figure 4. The relation between the occupational (staff) dose and fluoroscopy time.

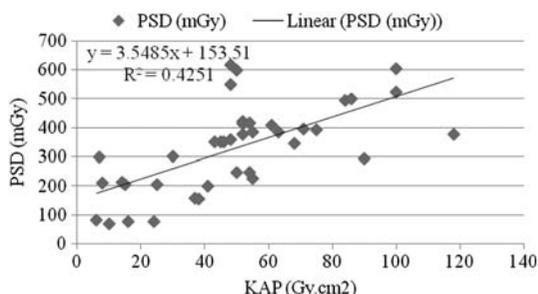


Figure 5. The correlation between PSD and KAP measurements.

fluoroscopic time ranged between 3 and 70 min with a mean of 30 min. There was a KAP and fluoroscopy time correlation of $R^2 = 0.35$. This low correlation is due to the KAP dependence on the additional factors associated with the equipment such as the number of frames, kVp, mA, beam filtration and collimation. The initial KAP NDRLs per examination were 50 Gy cm² for diagnostic cardiac catheterisation and 60 Gy cm² for valvuloplasty in the case of paediatric cases, and 90 Gy cm² for coronary angiography and 105 Gy cm² for neuro-angiography in the case of adults. The respective fluoroscopy time values in minutes were 32 and 40 for paediatric cases, while 26 and 20 were found in adult cases. The only available reference level was the KAP value of 45 Gy cm² for adult coronary angiography⁽¹¹⁾. The mean and third quartile values obtained in this study were above this reference level.

Figure 3 shows the distribution of the PSD and fluoroscopy time for the examinations considered in the study. The measured mean PSD was 347 mGy (range 52–740 mGy). The fluoroscopic time and the patient's PSD were correlated with $R^2 = 0.49$. The mean PSDs per examination were 310 mGy for diagnostic cardiac catheterisation and 397 mGy for valvuloplasty for paediatric cases, and 435 mGy for

coronary angiography and 354 mGy for neuro-angiography for adults.

Occupational (staff) dose

Figure 4 shows the distribution of the occupational dose and fluoroscopic time. The mean occupational dose in decreasing order was found to be as follows: MDs 0.4 mSv, nurses 0.31 mSv, clinical staff 0.27 mSv and technologists 0.25 mSv.

The linear correlation between the PSD and KAP values is shown in Figure 5. The low correlation may improve with fewer angulations (projections) and fewer variations in the image intensifier size.

DISCUSSION

In this study, 25 % of IPs carried out in paediatric patients was higher than the figures reported in the International Atomic Energy Agency studies, where developed countries carried out at 10 % and developing countries at 5 %⁽¹²⁾. The 75 % adult IPs is also lower than 90 %, which has been reported for the developed countries, and 95 %, which has been reported for other developing countries in Africa. This could be due to the increasing number of incidences of heart diseases in paediatric patients and moderately increasing number of heart diseases in adults referred to in the study. One of the hospitals had the highest number and the widest range of procedures. However, the majority were diagnostic procedures, which comparatively, were low-dose procedures. Two other hospitals had the same machine model; hence, the user training given to the staff at the commissioning was likely to have been based on the same curriculum and patient imaging protocols. Three of the four hospitals had similarity in patient workload and average PSD values.

The low correlation between KAP and fluoroscopy time measurements indicates the need to study all the patient dose-dependent factors in radiation protection. The general linear relationship between the PSD and KAP shows that there was less variation in the projections or in the size of the image intensifier. The correlation is affected by differences in either the image intensifier size or the variation in the projections being so great such that increase in PSD did not correspond to that in KAP. Thus, for two similar KAP values obtained by the same staff and X-ray system, the skin dose does not show a similar correlation because of the uneven concentration of radiation fields on the patient's skin. The scatter diagram in Figure 5 shows more correlation towards PSD compared with KAP. Another research study has shown that KAP and PSD are independent quantities in practice, even for a given X-ray system or a specific procedure⁽¹³⁾. While PSD may be an indicator of deterministic effects, KAP may reliably estimate it

with $R^2 = 0.49$. This correlation can be improved by increasing the size of a sample of patients to avoid large statistical variations of the mean value of the measured quantity. This may also improve the estimation of potential stochastic effects. In the same token, a large sample size will improve the accuracy of fluoroscopy time as a measure of radiation dose or an indicator of the potential radiation effects. The larger patient dose as well as initial NDRLs values obtained in this study is associated with the efficiency of the equipment, complexity of the procedure, clinical technique and the operator's experience of using the equipment.

The occupational doses measured for the groups of radiation workers normally present during interventional procedures indicate trends varying from hospital to hospital. In all the participating hospitals, it was evident that the most vulnerable group was the MDs who received an average of 0.34 mSv per procedure. This is because of performing the interventions while standing near the radiation source and next to the patient. The value obtained in this study was above 0.3 μ Sv, which has been reported for cardiologists, but correlated well with the 10–30 mSv month⁻¹ reported in the literature⁽¹⁴⁾. The decreasing trend for the other staff was as follows: the nurses 0.27 mSv, clinical staff 0.23 mSv and the radiographers 0.22 mSv, respectively, per procedure. Considering the workload and the fact that some of the staff work in more than one facility, these values are above those obtained in a study conducted in the UK where interventional radiologists received an average annual dose of 0.35 mSv and cardiologists 0.2 mSv⁽¹⁵⁾. For both of these groups, almost 95 % of the staff receives annual doses of <1 mSv. The other occupational groups receive lower average annual doses. With the average exposure of 125 mSv y⁻¹ and the number of patients increasing as indicated in this study, there is likelihood for the ICRP annual eye lens dose equivalent limit of 150 mSv y⁻¹ to be exceeded, with the prevailing radiation safety practices⁽⁹⁾. The use of lead goggles and ceiling-suspended lead glass to reduce the exposure to the lens of the eye is inevitable. The condition of the machines and the level of training and experience of the staff are some of the likely contributors to both patient and occupational doses. It was also noted that owing to expertise, some cardiologists and radiologists carry out these procedures in more than one hospital but their monthly monitoring is done only at their primary centres. In addition, some staff either did not wear their TLD badges properly, regularly or did not wear them at all.

CONCLUSIONS AND RECOMMENDATIONS

Doctors participating in IPs receive the highest occupational radiation exposure. This external radiation exposure may exceed the ICRP annual eye lens dose

equivalent limit because of the observed and increasing number of patients. This justifies the need for effective radiation safety practices that include adequate use of protective tools such as lead goggles and ceiling-suspended lead glass. Additionally, adequate personnel monitoring programmes relevant to personnel in the catheterisation laboratories should be established. This may include individual monitoring devices being worn, both under the protective apron at the waist and outside the protective apron at the neck.

The measured PSDs were within the threshold limit of 2 Gy per procedure for skin injuries. The patient records in IPs should be updated with patient dose, measurement and appropriate technical factors associated with the equipment. Personnel training on the appropriate use of equipment to practically manage radiation dose exposure levels should be enhanced in order to protect both patients and staff.

A code of practice to govern interventional procedures in the country should be developed with the input of all the hospitals involved, regulatory authorities and other relevant stakeholders to ensure safety in the practice. In addition, a follow-up study is necessary in order to monitor and evaluate the safety status periodically.

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