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Establishing diagnostic reference levels for interventional procedures in Kenya

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ABSTRACT

Purpose: To quantify ionizing radiation exposure to patients during interventional procedures and establish national diagnostic reference levels (NDRLs) for clinical radiation exposure management.
Methods: The cumulative reference point air kerma, kerma area product, fluoroscopy time and other operational parameters were monitored for 50 children and 261 adult patient procedures in five catheterization medical laboratories in Kenya. To estimate the risk associated with the exposure, effective doses were derived from the kerma area product using conversion factors from Monte Carlo models.
Results: About 3% of the measured cumulative reference point air kerma for the interventional procedures approached the threshold dose limit with the potential to cause deterministic effects such as skin injuries. In interventional cardiology, the results obtained for both children and adults indicated 33% were below the diagnostic reference levels (DRLs). In adult interventional radiology, 29% for cumulative reference point air kerma, and 43% for kerma area product and fluoroscopy time respectively were below the diagnostic reference levels. NDRLs were proposed for routine use in the procedures considered and for the non-existent DRLs situations in paediatric interventional cardiology.
Conclusion: The measured patient doses were above the DRLs available in the literature indicating a need for radiation optimization through, continuous monitoring and recording of patient dose. To promote radiation safety, facilities performing interventional procedures need to establish a radiation monitoring notification threshold for possible deterministic effects, in addition to the use of the newly established national diagnostic reference levels, as a quality assurance measure.

Introduction

Medical applications of X-rays play a critical role in patient management for disease diagnosis and treatment follow-up. General radiography, dental, fluoroscopy, interventional procedures (IPs), mammography, and computed tomography are the major categories of X-ray imaging clinical practices. The IPs data in the literature indicates 34 procedures per million inhabitants in Kenya, a 1.36-fold increase since 2007.[1] However, the number of catheterization laboratories per million population is 21 times higher in Europe than in Kenya.[2] IPs are on the increase all over the world because they are performed with minimal invasiveness as compared to conventional surgery. However, radiation burden to the patient can be important factor due to long procedure time and high dose rates involved. Appreciation of the new diagnostic and therapeutic techniques is clear, but as there is a growing concern of detrimental effects of radiation more studies and quality assurance measures are needed. There has been significant increase in deterministic effects including transient erythema due to radiation exposure arising from complicated interventional procedures and the IPs being performed by non-radiologists.[2–5]

Several patient radiation exposure measurements have been done in interventional procedures using thermoluminescent dosimeters, entrance surface dose, peak skin dose, kerma area product, cumulative reference point air kerma, but few investigations of effective dose estimates have been done.[1,4–15] Effective dose derived from the kerma area product conversion factors which are calculated from Monte Carlo methods[16] can be used in the assessment of risk and benefits in interventional procedures. This is because IPs have benefits including no general anaesthesia risk,

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short recovery time, a short stay in the hospital and a reduced risk for the patient during treatment of coronary artery stenosis. To facilitate routine assessment of radiation burden to patients, comparison between hospitals and identification of bad practices, this study aimed at establishing the NDRL for the kerma area product, cumulative reference point air kerma, fluoroscopic time and effective dose respectively.

Materials and methods

Examination frequency and patient dose assessment

The examination frequency for IPs was derived from the annual patient records information registries kept by the participating hospital. The multinational manufacturers of the fluoroscopy equipment in the study were two Philips Allura Xper FD20, one Philips MultiDiagnost Eleva and two Siemens AXIOM Artis installed between 2006 and 2008. The two major categories of IPs studied were interventional radiology (IR) and interventional cardiology (IC). The IR examinations were performed by radiologists while IC by cardiologists. Dosimetry information was generated for each examination using the equipment integrated measuring system that corrects for table attenuation, and displayed kerma area product (KAP) (in units of Gy cm^2), cumulative reference point air kerma ($K_{a,r}$ in mGy) at the interventional reference point, and fluoroscopic time (minutes). The third quartile value for each type of examination was considered the NDRLs. For each examination, the following additional parameters were recorded age, number of images acquired, field of view (FOV), kVp, and mAs. The dosimetry systems are designed to be compliant with the dosimetry requirements set by the International Electrotechnical Commission (IEC).[17] The $K_{a,r}$ indicated the total air kerma delivered to the interventional reference point (IRP), located at a point along the central ray 15 cm from the system isocenter toward the X-ray focal spot.[17] Calibration verification of the KAP meter was done using measurements obtained from an Unfors Xi (Unfors Instruments AB, Billdal, Sweden) external detector. The cumulative KAP values were used with effective dose conversion factors to obtain effective dose for full examinations.[15] In the study, the mean dose parameters were compared with the lowest DRL value available in the literature and the percentage of procedures below the DRLs was calculated.

Results

Examination relative distribution

Fig. 1 indicates the types and the annual interventional procedure workload that constituted paediatric intervention cardiology 17%, adult intervention cardiology 66%, and adult Intervention Radiology 17%. The IR procedures were adult cases only. In interventional procedures 13% of the paediatric examinations were paediatric cardiac catheterization (cardiac cath.) while in adults coronary angiography (CA) procedures were 38% of the IPs. The distribution of patients in interventional procedures was generally skewed towards older patients (mean 55 yrs; median 58 yrs) with 60% male and 40% female.

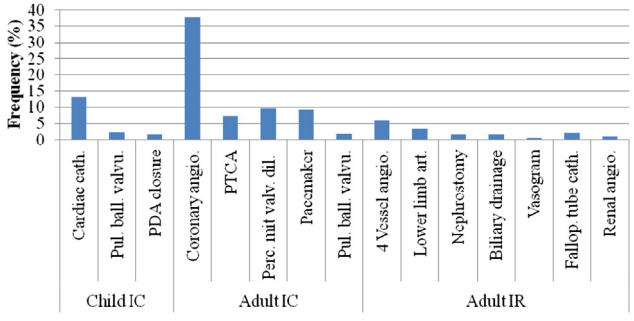

Figure 1. Frequency distribution of interventional procedures considered in the study.

Assessment of patient dose

Table 1 contains the patient age, overall imaging parameters and exposure factors for complete interventional procedures. The examinations with the largest number of runs, number of images, and mAs were cardiac catheterisation and patent ductus arteriosus (PDA) closure in paediatric interventional cardiology; arterial chemo embolization (art. chemo embol.), percutaneous mitral valve dilatation (perc. mitral valv. dilat.), and coronary angiography in adult interventional cardiology.

Table 2 contains the distribution of $K_{a,r}$, KAP, and fluoroscopy time for the IPs considered. There were no DRLs available in literature for the paediatric interventional procedures. In adult cases, interventional cardiology DRLs are currently available for 33% of the procedures in the study, whereas in interventional radiology there was 29% coverage. In interventional cardiology, the results obtained indicated that 33% were below the DRLs for each of the following $K_{a,r}$, KAP, and fluoroscopy time. The respective figures for adult IR were 29%, 43%, and 43%. In adult cases, the IR effective dose DRLs that were available currently covered 50% of the procedures considered in the study. The three examinations with the largest radiation exposure to patients in decreasing order were found to be renal angiography investigations, four vessel angiography, and lower limb arteriography. Most of these procedures demonstrate blood flow and require a lower frame-rate that should result in low radiation dose to the patient. However, the high patient dose obtained in this study indicates slow contrast flow, effects of the body region under investigation, operator skills, and inadvertent use of high dose rates.

The largest cumulative $K_{a,r}$ were detected for adult examinations namely coronary angiography, percutaneous mitral valve dilatation, arterial chemo embolization, four vessel angiography, and renal angiography. The overall fluoroscopic time in paediatric interventional cardiology was moderately long and narrow in range irrespective of examination type. The fluoroscopy time in adult interventional cardiology procedures was long and broad in range compared to the interventional radiology procedures. The interventional procedures performed with the longest fluoroscopy time, in decreasing order, were arterial chemo embolization, percutaneous mitral valve dilatation, and pulmonary balloon valvuloplasty (pulmo. balloon valvu.) in interventional cardiology. In adult IR the respective examinations were fallopian tube catheterization, four vessel angiography, lower limb arteriogram, renal angiography, and biliary drainage investigations. In children, the average effective dose was significantly larger than the effective doses involved in paediatric patients undergoing radiographic chest examinations.[19]

Discussions

Examination frequency

In this study the 17% of interventional procedures performed in children was larger than the 10% reported for the developed countries and 5% for developing countries.[18] The result raises radiation protection concern because, children are at a greater lifetime risk of radiation-induced cancer. The 83% adult interventional procedures was smaller than the 90% and 95% reported in the same reference for the