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Towards the definition of Institutional diagnostic reference levels in paediatric interventional cardiology procedures in Greece

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ABSTRACT

This study aimed to evaluate paediatric radiation doses in a dedicated cardiology hospital, with the objective of characterising patterns in dose variation. The ultimate purpose was to define Local (Institutional) Diagnostic Reference Levels (LDRLs) for different types of paediatric cardiac interventional procedures (IC), according to patient age. From a total of 710 cases performed during three consecutive years, by operators with more than 15 years of experience, the age was noted in only 477 IC procedures. The median values obtained for Fluoroscopy Time (FT), Number of Frames (N) and Kerma Area Product (P_{KA}) by age range were 5.8 min, 1322 and 2.0 Gy.cm^2 for < 1 y; 6.5 min, 1403 and 3.0 Gy.cm^2 for 1 to < 5 y; 5.9 min, 950 and 7.0 Gy.cm^2 for 5 to < 10 y; 5.7 min, 940 and 14.0 Gy.cm^2 for 10 to < 16 y, respectively. A large range of patient dose data is observed, depending greatly on procedure type and patient age. In all age groups the range of median FT, N and P_{KA} values was 3.1–15.8 min, 579–1779 and 1.0–20.8 Gy.cm^2 respectively. Consequently, the definition of LDRLs presents challenges mainly due to the multiple clinical and technical factors affecting the outcome. On the other hand the lack of paediatric IC DRLs makes the identification of good practices more difficult. A consensus is needed on IC procedures nomenclature and grouping in order to allow a common assessment and comparison of doses.

1. Introduction

Interventional cardiology (IC) is a sub-specialty of cardiology, whereby minimally invasive procedures are performed during a heart catheterization. These procedures involve inserting catheters and other devices through transdermal arterial and venous access sites. Interventional cardiology procedures are diagnostic and/or therapeutic medical procedures in which the heart is catheterized under fluoroscopic X-ray guidance to obtain images of the heart chambers, valves and surrounding blood vessels. With improved technology, the role of IC has changed, moving from diagnostic to therapeutic, including dilatation of narrowed vessels and valves and closure of anomalous structures such as arterial ducts or atrial or ventricular septal defects [1]. In recent years, an increasing number of IC procedures have been performed in children [2], offering a relatively non-invasive and low complication alternative to surgery [3]. IC procedures are usually performed in a dedicated cardiac X-ray laboratory with specially trained staff to ensure successful outcome with minimal patient risk. However, due to the complexity of these procedures, radiation doses can be high as a result of the extensive use of fluoroscopy and multiple digital acquisitions. Although IC procedures can result in high skin doses (deterministic risk) in adult patient, stochastic risk is the main concern for children [4–6]. In addition, patients with complex congenital heart disease are now living longer and may need several IC procedures throughout their lifetime, thus the cumulative effective dose can become very high [4–8]. Paediatric IC procedures are very different from adult IC procedures not only because of patient age but also because of the diversity of structural anomalies in heart diseases. Paediatric IC procedures are in general longer and more complex than adult procedures [9,10] at the same time that radiological imaging of children has been shown to be among the fastest growing areas in the last few years. The number, types and complexity of interventional cardiac procedures (in adults and minors) have increased dramatically in recent years due to increased reliability and advancing technology [11–13]. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [14], 4% of all cardiac angiography is carried out in paediatric patients.

Children are more sensitive to radiation induced cancer because of the higher organ specific risk factor together with the fact that the X-ray beam collimation is centered in the region of the heart and more critical

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radiosensitive organs are being irradiated simultaneously due to their close proximity to one another [14,15]. The increased risk of developing a malignancy highlights the importance of establishing DRLs, as a basic tool for optimisation in paediatric IC. Radiation protection issues in IC has recently been addressed by the International Commission on Radiological Protection (ICRP) [16], including the need for DRLs. However, dose data concerning exposures from paediatric IC procedures are still very scarce. Only local or institutional DRLs are provided by certain studies with limited patient samples. The last 10 years have seen a large number of studies published in this area, the conclusions of which are sometimes contradictory as their methodology and information provided differ considerably, making the setting and comparison of national DRLs a challenging procedure [2,17–40].

The physical quantity used to establish DRLs should be an easy to measure quantity, usually directly obtainable from the X-ray equipment console, obtained either by manual recording or preferably by automatic recording and analysis. Organ doses and effective dose are not considered feasible as an DRL quantity because these cannot be easily determined. The quantities recommended are (i) kerma-area product (P_{KA}) (primary quantity), (ii) Fluoroscopy Time and (iii) number of images (useful additional quantities) [35,41,42]. P_{KA} value is generally accepted as a stochastic risk indicator (related to effective dose), whereas the cumulative air kerma ($K_{a,r}$) value is a deterministic risk (skin) indicator of lower importance for children.

This study aims to evaluate paediatric IC radiation doses related to the stochastic risk, in a dedicated cardiology center in the context of optimisation, with the objective of characterising patterns in dose variation. The ultimate purpose of this effort was to define Local (Institutional) DRLs for different types of paediatric IC procedures based on outcomes of a retrospective study. The final complete draft for PiDRL Workshop held on 30 September 2015, with the title "European Guidelines on DRLs for Paediatric Imaging" [42], suggests that in general, the patient dose depends on the size of the patient's body, because more radiation is needed for a thicker patient to attain the same image quality compared with a thinner patient. Therefore, and due to the large variation of patient size at any given age, the weight or size is generally more relevant as a parameter for patient grouping for DRLs in body examinations [42]. However, if the aim is to ensure comparisons and trend analysis, age could be used as an additional parameter in a transition phase [42]. Further, for retrospective collection of data, age may be the only parameter available and can then be used [42]. As this study design was retrospective, the classification was accomplished according to age range. Classification by patient age has also been used in several papers to define groups of children for the purpose of establishing paediatric DRLs [9,12,21,23,29,34–36,43–45].

2. Materials and methods

Seven hundred and ten IC paediatric procedures were performed in Onassis Cardiac Surgery Center, (which is a dedicated cardiac hospital for both adults and minors), during three consecutive years, by operators with more than 15 years of experience. The study design was retrospective. Patient age annotation was hard to assess for one third of all cases (a bigger percentage applies to patient weight) due to a number of reasons mainly related to patient clinical emergency; therefore, only four hundred and seventy-seven cases were divided into four age groups. Sample sizes by age group were 118 for < 1 y; 123 for 1 to < 5 y; 135 for 5 to < 10 y; and 101 for 10 to < 16 y. Concerning radiation, the median and third quartile values obtained were for Fluoroscopy Time (FT) in minutes, total Number of Frames (N) and Kerma Area Product (P_{KA}) in $Gy.cm^2$, for diagnostic and therapeutic procedures by age range, as well as for the total (477 cases).

Eleven types of diagnostic and therapeutic IC procedures were carried out in our medical center:

(1) Simple and Complex Diagnostic Catheterization
(2) Aortic Angioplasty
(3) Pulmonary Artery Angioplasty
(4) Pulmonary Artery Angioplasty and Stent Placement
(5) Atrial Septal Defect (ASD) Occlusion
(6) Aortic Valve Dilatation
(7) Pulmonary Valve Dilatation
(8) Patent Ductus Arteriosus (PDA) Occlusion
(9) Electrophysiology study
(10) Radiofrequency Ablation
(11) Pacemaker Implantation

The information concerning procedure nomenclature available from the few published articles on paediatric cardiology dosimetry is limited. We worked with the above eleven categories as the most commonly used internationally [19,20,23,24,26,27,36,45]. However, the data for examination types 4 and 6, during this study, were considered inadequate (less than two cases in each specific age group), because the type of these examinations was rarely noted in the archive file. Moreover, procedures 9 and 10 were grouped together into a single category. As a result, 312 IC procedures (181 diagnostic and 131 therapeutic) have been further analysed.

Details of equipment used in this study are presented in Table 1. The Flat Panel Angiography machine (SIEMENS Zee Biplane) comes up with 3 protocols for paediatric patients, based on patient's body weight: < 6 kg, 6 to < 20 kg and 20 to < 40 kg. The first two protocols make no use of the antiscatter grid. The values of Acquisition Frames per Second and Fluoroscopy Pulses per Second are indicative, as in practice the operator chose any, depending on the needs of each procedure. The same applies for the antiscatter grid use. Settings may be changed even during procedure.

3. Results

The sample which was divided in the age groups included 477 diagnostic and therapeutic paediatric IC procedures. The number of cases per age group per 'predominant' type of procedure (the first four-out of 11-types of examinations concerning the number of patients per age group) and the corresponding percentage of males are presented in Table 2. 'Predominant' procedure types are not the same in each age group. Diagnostic examinations are found to be the most common for the < 1 y and 1 to < 5 y age groups (54 and 66 respectively), whereas for age groups 5 to < 10 y and 10 to < 16 y therapeutic examinations (51 and 33 respectively) are more frequent. Examination types 9 and 10 are not scarce for ages 5 to < 16 (two groups) and raise the average of patient dose values. Median and range for P_{KA} values are presented in the 5th column of Table 2. Maximum P_{KA} value was found to be

Table 1
Details on settings for equipment used (Flat Panel Angiography system SIEMENS Zee Biplane).

Pediatric Protocol	Patient weight	Antiscatter grid	Acquisition kVp	Fluoroscopy kVp	Acquisition frames per second	Fluoroscopy pulses per second
1	< 6 kg	No	70	57/70	15/30	7.5/10
2	6 to < 20 kg	No	70	70	15/30	7.5/10
3	20 to < 40 kg	Yes	73	70	15/30	7.5/10