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Original paper

Organ and effective doses detriment to paediatric patients undergoing multiple interventional cardiology procedures

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ABSTRACT

The aims of the present study were to present the frequency of multiple interventional cardiac procedures for a certain group of patients obtained at one of the largest paediatric hospitals in Chile. In addition it has been analysed cumulative kerma area product (KAP) and cumulative air kerma (CAK), and calculated organ doses for the patient groups undergoing 2, 3 and ≥ 4 procedures, using Monte Carlo software. Effective doses were also estimated for epidemiological purposes and to permit comparison with other imaging procedures.

The sample used corresponds to the last 9 years and refers to a total of 1521 paediatric patients and 1824 interventional cardiac procedures. The results for frequency were: 13.7% of patients underwent 2 procedures, 4.1% underwent 3 procedures and 1.4% underwent 4 or more procedures. The median KAP and CAK values measured for the cumulative procedures in these three groups of patients were 3.7, 5.4 and 10.8 Gy·cm^2 and 59.9, 83.2 and 147.6 mGy, respectively.

In terms of the most irradiated organs during interventional cardiac procedures, the highest median values (for the group of ≥4 procedures) were: active bone marrow 5.0 mGy, lungs 23.5 mGy, oesophagus 15.2 mGy, thyroid 7.8 mGy and breast 11.0 mGy. Median dose value to the heart (for the group of ≥4 procedures) was 12.7 mGy. Median values in terms of calculated effective dose for the three patient groups (with 2, 3 and ≥4 procedures) were 3.4, 5.9 and 8.7 mSv, respectively.

1. Introduction

Paediatric patients with congenital and acquired heart disease represent a vulnerable patient population, many of whom will require life-long medical care [1]. For these patients, interventional cardiac procedures are essential for accurate diagnosis and safe therapeutic actions. Coronary angiographies currently represent 4% of all the medical imaging examinations performed on infants and children (0–15 years old) in well-developed countries [2]. As life expectancy in children with heart disease increases, often as a positive result of the fluoroscopically guided interventional cardiology (FGIC) procedures themselves, these children may be subject to repeated catheterizations and hence to a higher cumulative radiation dose over their lifetimes [3–5].

Exposure to ionizing radiation during FGIC procedures produces additional risks, including the potential development in the long term of stochastic effects (i.e. cancer) and mortality [6–8]. Some epidemiological studies suggest that exposure to ionizing radiation increases the risk of some cancers at organ dose ranges of approximately 50–100 mSv [9–12], values that are unlikely to occur in a single FGIC procedure for children, where the estimated effective dose and organ dose values are generally between 3 and 15 mSv and less than 20 mGy, respectively [13,14]. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) recognised that areas of future research should include evaluation of potential radiation effects on children in medical interventional fluoroscopy procedures [2].

According to the UNSCEAR 2013 report, “radiogenic tumour occurrence in children is more variable than in adults and depends on tumour type, and on the child’s sex and age at exposure. The differences in radiosensitivity between children and adults have found that children are more sensitive for the development of thyroid, brain, skin and breast cancer and leukaemia, but the available data are insufficient for a number of other cancer sites to determine whether or not children are more sensitive to those cancer types” [2].

Several papers have been published reporting effective doses to paediatric patients during FGIC procedures [3,13–21], with others

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reporting organ doses [13–17,19–22]. However, published cumulative organ and effective dose values for paediatric patients undergoing several interventional cardiac procedures (and the frequency of multiple procedures on the same patient) remain non-existent to our knowledge.

The aims of this study were: a) to determine the frequency of multiple interventional cardiac procedures in paediatric patients for three groups (patients with 2, 3 and ≥4 procedures); b) to calculate the cumulative kerma area product (KAP), the cumulative air kerma (CAK) at the patient entrance reference point, the organ doses in the most irradiated organs that are hence more sensitive for the development of cancer (active bone marrow, breast, lung, oesophagus and thyroid) and other organs with significant irradiation (heart and skin) for tissue reactions (deterministic effects); and c) to estimate the cumulative effective dose in these groups of patients, for epidemiological purposes and purposes of comparison with other imaging procedures.

2. Materials and methods

This study was conducted at the paediatric cardiovascular service at Luis Calvo Mackenna Hospital in Santiago, Chile. This hospital performs approximately 50% of all paediatric FGIC procedures in Santiago (the capital of the country). The Chilean population was 18 million in 2017 (of whom 20.1% were children aged between 0 and 14) [23]. The estimated number of FGIC procedures carried out among the Chilean paediatric population is around 40 per million inhabitants per year [14].

The paediatric cardiovascular service at Luis Calvo Mackenna Hospital has a cardiac catheterization laboratory with a biplane X-ray system (Siemens Axiom Artis BC, Siemens Inc., Erlangen, Germany) equipped with image intensifiers, installed in 2006 and with a properly calibrated ionization transmission chamber integrated into the collimator housing to measure air kerma-area product (KAP), equivalent to the most commonly used quantity dose-area product [24]. It had a generator of 100 kW at 100 kV. The system has been set by the local Siemens engineers with three exam protocols (newborn, infant, and child), three fluoroscopy modes (low, medium, and high dose) all configured with 10 pulses s^{-1}, and one single mode for cine acquisition configured with 30 frames s^{-1}. There were three fields of view: 16, 22 and 33 cm. Additional filters, from 0.1 to 0.9 mmCu and virtual collimation were available. Distance from isocentre to floor was 106 cm and focus-to-isocentre distance was 75 cm. Four full characterizations in terms of dose and image quality of the angiography system have been carried out since 2008, using the protocols agreed during the DIMOND and SENTINEL European programmes [25]. These protocols were adapted to paediatric procedures and periodically verified as part of the quality assurance programme [26–28].

The study design was retrospective and prospective case series [29]. Paediatric patients who had undergone multiple FGIC procedures were initially grouped into three cumulative procedure ranges (2, 3 and ≥4 procedures).

Data were collected over a nine-year period from January 2008 to September 2017. The following data were recorded from the patient dose reports produced by the Siemens X-ray system at the end of each procedure: procedure identification, patient age, gender, weight, height, KAP, CAK (cumulative air kerma at the patient entrance reference point) [30], number of cine series, total number of cine frames, fluoroscopy time (FT), projection, projection angle, patient number, X-ray tube voltage, filtration (mm Al) and additional filter (mm Cu). KAP values were corrected with the appropriate calibration factor (0.81) for the frontal C-arm (derived from the table and mattress attenuation measured for the X-ray beam qualities in the system used). No correction factor was necessary for the lateral C-arm in our system.

The frontal C-arm calibration factor may have small differences for the fluoroscopy and cine series depending on variables such as kV, added copper filtration and C-arm angulations, but the adopted value (0.81) was a mean value obtained during the commissioning and characterization of the X-ray system for several experimental conditions simulating the clinical practice in paediatrics, using thicknesses of polymethyl methacrylate ranging from 4 to 20 cm [26]. This correction is necessary when estimating organ factors on interventional procedures [31].

The use of the CAK display at the X-ray system (and its inclusion in the patient dose reports) for paediatrics entails significant differences from the real skin dose values depending on patient thickness. The CAK is calculated by the system at 15 cm below isocentre, and patient skin may be at a shorter distance in paediatrics [26]. In our case, KAP was used as the dosimetric quantity for the Monte Carlo calculations to obtain organ doses.

The X-ray system used includes dynamic density optimization (DDO) internal selectable post-processing software, which allows the improvement of image quality using online harmonization of contrast. Spectral shaping copper filters are automatically inserted in the X-ray system depending on patient absorption to reduce skin dose. The information on the filtration used in the different cine runs is included in the patient dose reports and has been taken into account for the Monte Carlo calculations [14].

The three available paediatric specific protocols (newborn, infant, child) customized by the Siemens application specialist at Luis Calvo Mackenna Hospital use different curves for the kV variation and the added filtration, seeking to optimize image quality while minimizing radiation dose. The cardiologist selects the appropriate protocol depending on patient weight.

Patient organ and effective doses were calculated using the PCXMC 2.0 programme (STUK Radiation and Nuclear Safety Authority, Finland) [32]. This program is based on the Monte Carlo code that simulates the doses to five mathematical phantoms (ages 0, 1, 5, 10, and 15 years) using different exposure geometries and X-ray beam spectra. A previous paper has been published in this journal, reporting organ and effective doses for diagnostic and the most frequent therapeutic interventional cardiology procedures in paediatrics for various age and weight bands [14].

Absorbed doses were calculated for all organs and tissues, but presented and analysed in detail in this paper for the most irradiated organs (thyroid, breast, active bone marrow, oesophagus, heart and lungs) and for the groups of patients with multiple procedures. The calculation was performed for each cine series with the technical, geometrical and dosimetric parameters included in the patient dose reports. A proportionality criteria to incorporate the contribution of the fluoroscopy series in the doses calculated using the PCXMC software to allocate the KAP contribution of the fluoroscopy series among the cine series. The patient dose reports in this X-ray system only included detailed data for the cine series and not for the fluoroscopy runs. This represents a limitation on the organ dose calculation results, but it is a reasonable approach. Work was carried out directly using Autocalcsheet.xls, which is a spreadsheet application included in the Excel software package [33]. This application permits the definition of the following parameters: projection angle; patient number; patient height; patient weight; patient age (0, 1, 5, 10, 15); X-ray tube voltage (kV); filtration (mm Al); additional filter (mm Cu); focus-reference point distance (FRD) (cm); X-ray beam width (cm at FRD); X-ray beam height (cm at FRD); coordinates of a point inside the phantom, through which the central axis of the X-ray beam is directed (Xref, Yref and Zref); arms in phantom (1 or 0); and input dose value (KAP was used). The calculation methodology was explained in detail in a previous paper [14].

SPSS software was used [34] to analyse organ and effective dose values for the different groups of procedures.

3. Results

A large sample of interventional cardiology procedures carried out at a paediatric hospital in Santiago, Chile, was analysed. The sample

Table 1
Total frequency by cumulative procedure group and gender [male (M) and female (F)]. Mean, minimum (min), and maximum (max) values for age, weight, height, and body mass index grouped by cumulative procedure.

Cumulative procedure group	Frequency (%)	Frequency by gender		Weight (kg)		Height (cm)		Body mass index (kg/m^2)	
		M	F	Mean	(Min-max)	Mean	(Min-max)	Mean	(Min-max)
2	209 (13.7%)	119	90	17.9	2.5–63.8	94.9	50–167.0	16.6	7.9–42.3
3	63 (4.1%)	41	22	15.7	2.6–55.0	92.2	46.7–154.0	16.0	11.4–23.2
≥4	22 (1.4%)	14	8	16.9	7.1–44.0	99.8	70.8–157.0	15.7	12.3–18.6

corresponded to the last 9 years and contains a total of 1521 patients and 1824 interventional procedures. Our analysis shows that 13.7% of patients underwent 2 procedures, 4.1% underwent 3 procedures and 1.4% underwent 4 or more procedures (see Table 1). This last group with ≥4 procedures contained 14 patients who underwent 4 procedures, 7 who underwent 5 procedures, and only 1 patient who underwent 6 procedures. The vast majority (88.8%) of the patients in our sample only underwent one procedure.

Table 1 summarizes the characteristics of the groups of study subjects (with 2, 3 and ≥4 procedures for the same patient). The initial sample included 1521 patients and 1824 interventional procedures.

There were no significant differences in weight (16–18 kg) or in body mass index (BMI) (15.7–16.6 kg/m^2) between the three groups.

Table 2 summarizes the mean and standard deviation values for age, grouped by cumulative procedure and procedure number. Mean age (and sd) is presented according to procedure number. Again there were no significant differences between the groups of patients with 2, 3 and ≥4 procedures.

Table 3 shows mean, standard deviation, median and third quartile values for KAP and CAK for the three cumulative procedure groups. The median KAP values were 3.7, 5.4 and 10.8 Gy cm^2 for the groups of 2, 3 and ≥4 procedures, respectively. The median CAK values for these groups were 59.9, 83.2 and 147.6 mGy, very far below the threshold for potential skin radiation injuries.

At our centre, with a standard quality assurance programme in place and participation in several International Atomic Energy Agency technical cooperation programmes, the typical (median value) dosimetric quantities are relatively low [35–37] in comparison with other published values for paediatric interventional procedures [13,38,39].

Fig. 1 illustrates the first (Q25), second (Q50) and third (Q75) quartiles of the effective dose values grouped by cumulative procedure for the three patient groups. An estimated effective dose (median value) for the group of patients who underwent 2 procedures (14% of the total sample) of 3.4 mSv. In our sample, these procedures were performed for patients ranging from 2 to 4 years of age. For the group of patients who underwent 3 procedures (4% of the total sample) the estimated effective dose (median value) was of 5.9 mSv. These procedures were performed for patients ranging from 2 to 5 years of age. Finally, 8.7 mSv was the estimated effective dose (median value) for the group of patients who underwent ≥4 procedures (1.4% of the total sample). These procedures were performed for patients ranging from 2 to 8 years of age.

Table 2
Mean and standard deviation (sd) values for age, grouped by cumulative procedure and procedure number.

Procedure number	Cumulative procedure group (frequency)		
	2 (209) Age (Mean ± sd)	3 (63) Age (Mean ± sd)	≥4 (22) Age (Mean ± sd)
First	3.4 ± 4.2	2.4 ± 3.1	2.3 ± 3.0
Second	5.2 ± 4.6	3.8 ± 3.7	3.6 ± 3.8
Third		5.4 ± 4.0	5.1 ± 3.6
Fourth			6.5 ± 4.0
Fifth			8.0 ± 4.6

Figs. 2 and 3 illustrate organ dose values (first (Q25), second (Q50) and third (Q75) quartiles) for cumulative procedure groups for the most irradiated organs during cardiac interventional procedures.

4. Discussion

Medical exposure surveys usually collect radiation dose data for different imaging and interventional modalities but there is no previous data regarding cumulative organ and effective doses for paediatric patients as a result of multiple catheterization procedures in cardiology, and this issue may be relevant for further epidemiological studies on radiation risk effects in the paediatric population.

UNSCEAR recognised in one of its most recent reports that "Limited data on the frequency of medical diagnostic radiation procedures on children are available and that fluoroscopically-guided interventional procedures can deliver high doses to various organs of children" [2]. The percentages of various types of medical imaging examinations performed on infants and children (0–15 years old) in well-developed countries are 5% for CT thorax scanning and 4% for cardiac angiography, as reported by UNSCEAR [2]. The aforementioned report did not include data on the frequency for paediatric nuclear medicine procedures.

It was not possible to obtain information on the other imaging procedures (e.g. computed tomography, direct radiography and nuclear medicine imaging) for our sample of patients, due to the lack of automatic record systems at the hospital during the years from which the sample was obtained. It is also possible that a small number of patients may have undergone catheterization procedures at other hospitals. However, this is unlikely as only a few hospitals in Chile currently carry out paediatric interventional cardiology procedures.

Typical (median) effective dose values for the three groups of patients (see Fig. 1) were 3.4, 5.9 and 8.7 mSv, respectively. Despite the limitations in the use of this dosimetric quantity for patients, it remains useful for purposes of comparing paediatric population doses resulting from different imaging procedures (e.g. interventional radiology, diagnostic radiology and nuclear medicine) [8].

For active bone marrow, the highest median value (for the group of ≥4 procedures) was 5.0 mGy. Median values (also for the group of ≥4 procedures) for other organs were: lungs 23.5 mGy, oesophagus 15.2 mGy, thyroid 7.8 mGy, heart 12.7 mGy and breast 11.0 mGy (see Figs. 2 and 3). These are fairly moderate organ dose values in comparison with adult patients, but it would be useful to consider these range of values in cumulative paediatrics cardiac procedures for future epidemiological studies. If the measured KAP values may be higher for other hospitals or countries (due to more complex procedures or a lack of optimization), organ doses should be re-evaluated because they could also be higher.

The dose to the heart is of particular interest due to the new threshold of 0.5 Gy recommended by the International Commission on Radiological Protection [40] for tissue reactions in the cardiovascular system. In our study, the highest median value (for the group of ≥4 procedures) was 12.7 mGy (and 18.4 mGy for the third quartile) as shown in Fig. 3. This is very far below the threshold for tissue reactions in the cardiovascular system.

Table 3
Mean, standard deviation (sd), median and third quartile values for KAP and CAK for each cumulative procedure group and its frequencies.

Cumulative procedure group	Frequency	KAP (Gy cm^2) Mean – Sd – Median (Q75)	CAK (mGy) Mean – Sd – Median (Q75)
2	208	6.1–7.4–3.7 (6.8)	85.4–151.1–59.9 (86.7)
3	63	8.3–11.8–5.4 (8.5)	132.7–244.9–83.2 (126.7)
≥4	22	12.4–10.8–10.2 (12.2)	234.9–388.4–147.6 (188.1)

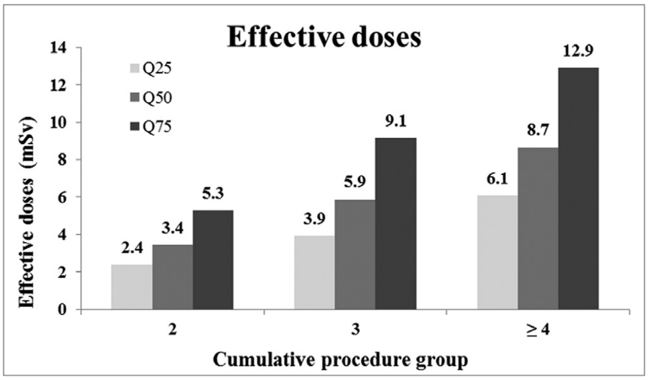

Fig. 1. First (Q25), second (Q50) and third (Q75) quartile effective dose values grouped by cumulative procedure.

Concerning the risk of potential skin radiation injuries in paediatric cardiology, the median CAK values for the groups of 2, 3 and ≥4 procedures are in the range from 60 to 150 mGy (see Table 3), very far below the threshold for potential skin radiation injuries. It should be noted that the differences in CAK between the indication in the patient dose reports as opposed to the real values may be important in paediatrics (as mentioned in the materials and methods section). This may only require consideration for certain patients when the CAK value in multiple procedures could be more than 2–3 Gy, for purposes of deciding on a clinical follow-up for potential skin radiation injuries. CAK values transferred by the X-ray system to patient dose reports (calculated at 15 cm below isocentre) naturally have significant differences (from 25 to 45% higher, with larger differences for smaller children) from the real cumulative skin dose values depending on patient thickness [14]. Peak skin doses are generally lower than CAK. Radiation skin injuries are hence not considered a relevant risk for our standard paediatric patients with the dosimetric values measured in our sample.

In a recent review, Harbron et al., reported typical KAP values for paediatric interventional cardiology of 0.6–10 Gy·cm^2 (< 1 year/10 kg), 1.5–30 Gy·cm^2 (1–5 years), 2–40 Gy·cm^2 (5–10 years), 5–100 Gy·cm^2 (10–16 years) and 10–200 Gy·cm^2 (> 16 years) [13]. The authors note in this review that few studies exist with estimations of organ dose. From these data, and with the large range in patient doses, it seems clear that there remains much room for optimization in paediatric interventional cardiology. The estimation of cumulative doses from several procedures on the same paediatric patients should take into account not only the frequency but also the KAP values measured in the different hospitals.

Walsh et al. published a paper in 2015 [38] regarding cumulative radiation exposure for 70 paediatric patients (mean age of 3.6 ± 1.5 years) undergoing surgery for the most severe forms of congenital heart disease. The authors reported radiation doses from all procedures, including cardiac catheterizations, computed tomography scans, plain film radiography, and nuclear medicine scans. Surprisingly, however, the paper stated that radiation dose was calculated as the dose area product for all imaging modalities, including computed tomography scans and nuclear medicine imaging. For cardiac catheterization

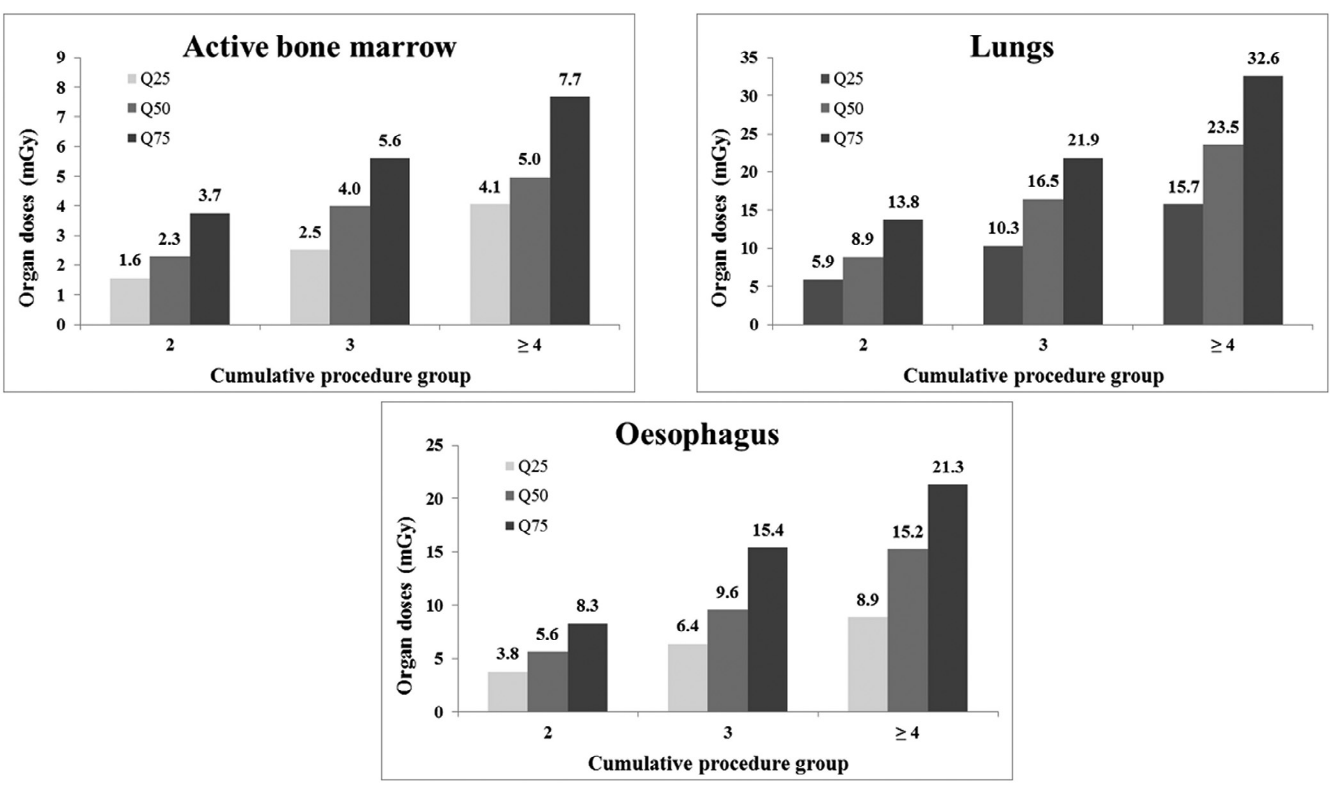

Fig. 2. First (Q25), second (Q50) and third (Q75) quartile values for organ doses (active bone marrow, lungs and oesophagus) grouped by cumulative procedure.

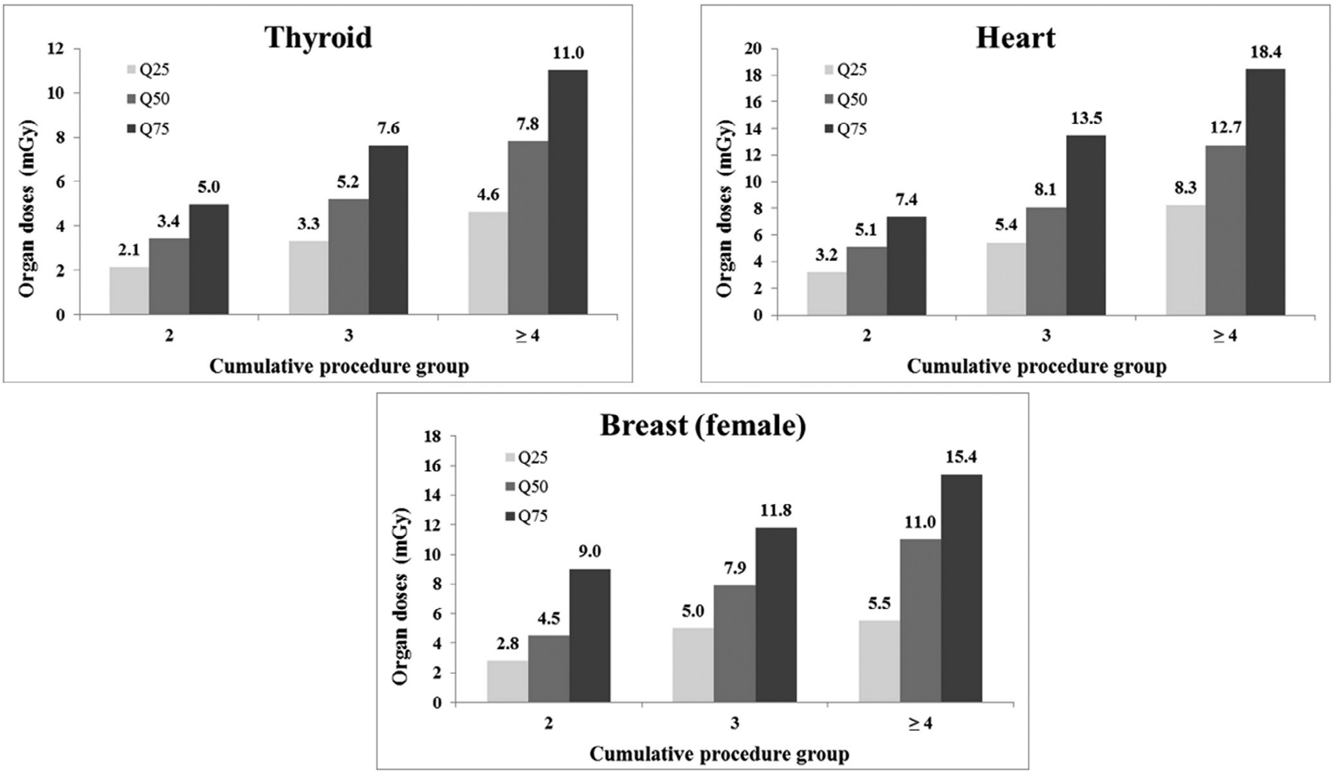

Fig. 3. First (Q25), second (Q50) and third (Q75) quartile values for organ doses (thyroid, heart and breast) grouped by cumulative procedure. Breast doses were reported only for female patients.

data, these authors reported KAP in the range from 20 to 30 Gy cm^2, higher than our values by a factor of two to three. The aforementioned authors concluded that the total cumulative exposure from all imaging modalities was predominantly “from the first and second cardiac catheterizations (48 and 35%, respectively)”, and that “the third catheterization (including subsequent catheterizations) (10%), CT scans (5%), and X-rays (2%) accounted for a much smaller proportion of the radiation exposure”.

DRLs for interventional cardiology in paediatrics in Chile are quite low in comparison to other published values. One of the most recently published papers on DRLs for paediatric interventional cardiology in Greece, by Kottou et al. [39], reported values (in Gy·cm^2) of 2.0, 3.0, 7.0 and 14.0 for the age groups of < 1 year, 1–5 years, 5–10 years and 10–16 years, respectively. For diagnostic and therapeutic procedures in Chile [37], these values are respectively 1.17 and 1.11 Gy·cm^2 for < 1 year, 1.74 and 1.90 Gy·cm^2 for 1 to < 5 years, 2.83 and 3.22 Gy·cm^2 for 5 to < 10 years, and 7.34 and 8.68 Gy·cm^2 for 10 to < 16 years, respectively. This represents an approximate factor of 2 between the two countries. Complexity of the procedure was not analysed in any of the centres. As the samples used to derive the local DRLs (data from a single paediatric hospital in each of the countries) were fairly large (477 procedures in Greece and 517 in Chile), however, one would expect the mean complexity of the procedures to be similar.

Patient age is relevant if some approximate factors are used to estimate effective dose from KAP values from cardiac procedures (if the detail of the technical and geometrical factors for the different radiation runs are not known). Note that these factors differ greatly depending on age group. They are 1.70, 0.89, 0.58 and 0.4 mSv/(Gy·cm^2) for the age bands of < 1 year, 1– < 5 years, 5– < 10 years and 10– < 16 years, respectively [14].

5. Limitations

Our study has some limitations. The data analysis was conducted using the interventional cardiology activity database over a nine-year period for a single paediatric hospital in Chile that performs approximately 50% of all paediatric interventional cardiology carried out in the country. The likelihood of some patients having undergone another cardiac procedure in another paediatric hospital cannot be excluded but it is very low considering the Chilean health system and the geographical spread of Chile’s hospitals. Nonetheless, an exhaustive analysis of all patients’ medical records was not conducted.

Concerning uncertainties in terms of organ and effective dose, the estimations in our previous study [14] may also be applicable in the present case. Technical (kVp, mA, ms and added filtration) and geometrical (field of view and C-arm angulations) factors and dosimetric values (KAP and CAK) were available for all the cine series, but not for fluoroscopy runs. The total KAP values for fluoroscopy (included in the patient reports) were distributed proportionally to the KAP of the cine series and assumed the conditions of the cine series. This is one of the main uncertainties in the dosimetric evaluations when DICOM dose structured reports are not available. However, our approach was reasonable. An estimation shows 10% global uncertainty in organ dose as a result of using this approach.

Radiation field sizes were circular in our X-ray system and the square equivalent was calculated for the software, with an estimated uncertainty of 5% in this respect (collimation is not usually applied by paediatric cardiologists at Luis Calvo Mackenna Hospital). The total uncertainty for organ doses may hence be approximately 20%.

6. Conclusions

- From a sample of 1521 paediatric patients and 1824 interventional cardiac procedures, three patient groups were analysed (who had undergone 2, 3 and ≥ 4 procedures): 13.7% of patients underwent 2 procedures, 4.1% underwent 3 procedures and 1.4% underwent 4 or more procedures.
- The main dosimetric quantities (median KAP and CAK values)

measured for the cumulative procedures on these three groups of patients were 3.7, 5.4 and 10.8 Gy.cm^2 and 59.9, 83.2 and 147.6 mGy respectively. These CAK values are very far below the threshold for potential skin radiation injuries.

- For the most irradiated organs during cardiac interventional procedures, the highest median values (for the group of ≥ 4 procedures) were: active bone marrow 5.0 mGy, lungs 23.5 mGy, oesophagus 15.2 mGy, thyroid 7.8 mGy and breast 11.0 mGy.
- The median dose to heart (for the group of ≥ 4 procedures) was 12.7 mGy. This was also very far below the threshold for tissue reactions in the cardiovascular system.
- Median values in terms of calculated effective dose for the three patient groups (with 2, 3 and ≥ 4 procedures and ages between 2 and 8 years) were 3.4, 5.9 and 8.7 mSv, respectively.

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