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Analysis of Local Diagnostic Reference Levels for Pediatric Patients Undergoing ^{18}F-FDG PET/CT Imaging for Oncology

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Abstract

Background: The PET/CT imaging studies have two doses components the dose from the PET radiopharmaceutical and the other from the low dose CT used for PET images attenuation correction. We have one PET/CT scanner at our institution a Philips Time of Flight scanner. Our local patient's radiation protection rules requires continuous assessment of radiation doses delivered to our patients. **Purposes:** The objectives of this study are to develop a weight-based facility DRLs for paediatric F-18-FDG PET-CT imaging for oncology in a large tertiary hospital and to determine whether the calculated DRLs compares with internationally published DRLs. **Materials & Methods:** Radiation dose data and patient demographics of two-hundreds and sixteen paediatric PET-CT oncology patients imaging procedures from one large tertiary hospital were selected and analysed in order to establish a facility paediatric DRLs. Statistical analysis was performed. **Results:** The PET dose reference levels ranged between [62 - 525] MBq of injected activity for a range of pediatric age groups. The $CTDI_{vol}$ values were between 3.5 and 16.5 mGy for all age groups. Comparison with current EANM and SNMMI recommendations of patient's dose are discussed. **Conclusion:** Our pediatric PET/CT reference levels are higher than the ones reported internationally with notable variations.

Keywords

Diagnostic Reference Levels, PET/CT, 18-F-FDG, Pediatric Radiation Dose, $CTDI_{vol}$, Oncology

1. Introduction

The role of paediatric PET/CT in oncology is expanding and the number of imaging procedures is increasing therefore a review of the actual delivered radiation doses to paediatric patients is justified and required by radiation protection standards applied to medical imaging.

For patient radiation protection, the principles of justification, optimization and dose limitation should be implemented and followed. Therefore, each radiologic procedure should be justified and the radiation exposures should be kept as low as reasonably achievable (ALARA). The procedure also should be optimized and avoid excessive radiation exposure. Optimization must balance image quality and patient absorbed dose.

Diagnostic Reference levels are not individual dose limits or dose constraints for exposure or patients. The levels can be used as an investigation indicator to ensure that the radiation optimization is applied and to obtain the required medical information while using the lowest achievable radiation dose.

DRLs are introduced by the ICRP publication 60 and 37 for supporting and monitoring the optimisation of radiation dose of investigation [1] [2] [3]. DRLs should be set in terms of the practical dose quantities used to monitor the practice. Local DRLs could be higher or lower than international DRLs depending on the imaging equipment available.

However, there is a lack of national and international DRLs for many examinations, especially for paediatric interventional and nuclear medicine procedures. Therefore, to advance optimisation of radiation protection for paediatric patients, the establishment and use of DRLs in paediatric radio diagnostic imaging and nuclear medicine practice should be promoted and established [4]. On the other hand they should be used to complement the clinician decision not to replace it and it should not be used to judge clinical practice as good or bad [5]. Nuclear medicine imaging is different than other diagnostic modality in terms of equipment sensitivity related to image formation where more variations is expected than in other modalities. It is natural to find wider variation in administered activity among equipment because the associated image quality will differ between imaging systems used in nuclear medicine particularly due to geometries and collimation systems. Therefore same level of administered activity will not equate to same image quality among different systems in nuclear medicine and this will limit the role of administered activity based reference levels in nuclear medicine [5].

Published studies involving paediatric DRLs in Nuclear Medicine especially 18-F-FDG PET/CT imaging are quite scarce [6] [7] [8].

Therefore we have decided to contribute to these studies by sharing our paediatric oncology population radiation dose date with the international community. Furthermore there are no international agreement on RDLs in paediatric 18-F-FDG PET/CT imaging yet. In the absence of such agreement the levels of administered activities are expected to vary quite broadly.

The objectives of this study are to analyse the radiation doses received by the paediatric oncology patients subjected to PET/CT imaging, to propose a facility preliminary diagnostic reference level (DRL) for paediatric PET-CT diagnostic oncology imaging and to compare the obtained values with internationally published DRLs.

Most of the patients who were imaged are cancer patients. The local patient's radiation protection rules requires continuous assessment of radiation doses delivered to the patients. Radiation dose data and patient demographics of two-hundreds and sixteen paediatric PET-CT oncology patients imaging procedures from one large tertiary hospital were selected and analysed in order to establish a facility paediatric DRLs. Statistical analysis was performed.

2. Materials and Methods

The routine PET/CT imaging studies have two radiation dose components the dose from the PET radiopharmaceutical mainly 18-F-FDG and the other from the low dose CT used for PET images attenuation correction. We have one PET/CT scanner at our institution a Philips Time of Flight scanner.

2.1. The FDG Injection Protocol

Most of the patients who are imaged are oncology patients. Our local patient radiation protection rules require continuous assessment of radiation doses delivered to our patients. The routine PET/CT imaging studies have two radiation dose components: the dose from the PET radiopharmaceutical, mainly 18F-FDG, and the low dose of CT used for PET images attenuation correction. One PET/CT scanner was used in this study Philips TOF 16 PET-CT.

The whole examination process takes 2 - 3 hours. This includes 30 minutes to prepare the patient for the scan, 40 - 60 minutes for the uptake phase after the 18F-FDG injection and 15 - 30 minutes for the image acquisition, depending on the heights of the patients and their clinical indications.

The protocol implemented for the PET acquisition time was 1 min per bed position for all of the paediatric categories. The FDG dose was administered to 92% of patients using an automatic dose injector (Intego, by MedRad Inc., Indianola, PA, USA). All of the patients were scanned by TOF 16 PET CT scanner.

The local protocol for dosage of 18F-FDG given to paediatric patients in a PET-CT at our hospital is to stay within the range of 0.15 - 0.30 mCi/kg (5.6 - 11.1 MBq/kg), with a minimum dose of 1 mCi and a maximum of 10 mCi for the whole body. Also, blood glucose levels should be below 11 mmol/ml [9].

It is known that the imaging protocols are institution specific and should take into consideration the clinical question and the type of the tumor it has to comply with the institutional policy. Consequently each institution may have its own unique PET/CT protocols [9].

Local facility DRLs are based on sufficient patient dose data collected from the records of individual paediatric patients. In this retrospective study, data was taken from 216 paediatrics (patients that are 18 years old or younger based on

hospital regulations), including whole body records (from the top of the head down to the middle of the thighs; 82% of the body) and total body measurements (from the top of the head down to the bottom of the feet; 18% of the body), and 18F-FDG PET-CT procedures were selected from one centre only. All patient dose data was retrieved from the Radiology Information System (RIS) and the Picture Archiving and communication System (PACS). The data from the last three years was retrospectively collected and analysed.

Due to the large variation of patient sizes among the paediatric population, several ages, sizes and weight based groups are needed to establish the DRLs, and there has been little consistency in the grouping of the patients. Extensive patient dose surveys are needed to establish DRLs, but there has been no detailed guidance on how to carry out and report these surveys in order to ensure consistent methods and comparability of the DRLs, in particular for the reliable evaluation of DRLs for use at the European level [10].

2.2. The CT Scan Imaging Protocol

Our data shows that the CT scans included in this work have been done using tube potential of 120 - 140 kVp and the mAs values where (50, 100 and 150) depending on the patient, rotation time of 0.5 sec, slice thickness 5 mm, and pitch ratio of 0.8 were fixed for all studies. Only 3 brain CT studies are included and all the CT scans were low dose low resolution for attenuation correction, the CT scanner was Philips 16 slices system.

Table 1 has the patients' demographic data. **Table 2** has the levels of administered activities per age group. **Table 3** and **Table 4** have the DRls per gender. **Table 5** has the CT dose data.

3. Results

From **Figure 1** and **Figure 2** it is clear that the administered activity doesn't follow activity per kg regime or at least it doesn't observe the regime all the time.

Table 1. Patients demographics.

Age group [years]	Males (n)	Females (n)	Male average BMI in ($kg \cdot m^{-2}$) [min - max]	Female average BMI in ($kg \cdot m^{-2}$) [min - max]	Male average weight in (kg) [min - max]	Female average Weight in (kg) [min - max]
1 - 5	9	7	14.8 [10.1 - 18.7]	16.2 [12.3 - 21.3]	18.3 [12.2 - 23.0]	11.3 [7.5 - 15.0]
6 - 10	34	13	16.4 [10.9 - 23.9]	15.5 [11.0 - 26.0]	29.1 [14.0 - 51.0]	25.3 [14.9 - 48.0]
11 - 15	35	37	21.6 [11.6 - 35.1]	20.8 [9.4 - 36.7]	56.2 [22.0 - 98.0]	49.8 [22.0 - 78.0]
16 - 20	50	31	23.6 [13.6 - 58.1]	21.8 [11.5 - 34.0]	64.6 [33.0 - 160.0]	56.2 [28.0 - 87.0]

Table 2. Injected activity per age group and gender-averaged.

	All ages				
	1 - 18* years	1 - 5 years	6 - 10 years	11 - 15 years	16 - 20 years
n	216	16	47	72	81
Mean injected 18-F-FDG [MBq]	226	114	164	241	271
Standard deviation [MBq]	80	58	50	63	67
Minimum injected activity [MBq]	62	62	73	109	185
Maximum injected Activity [MBq]	525	220	225	414	525

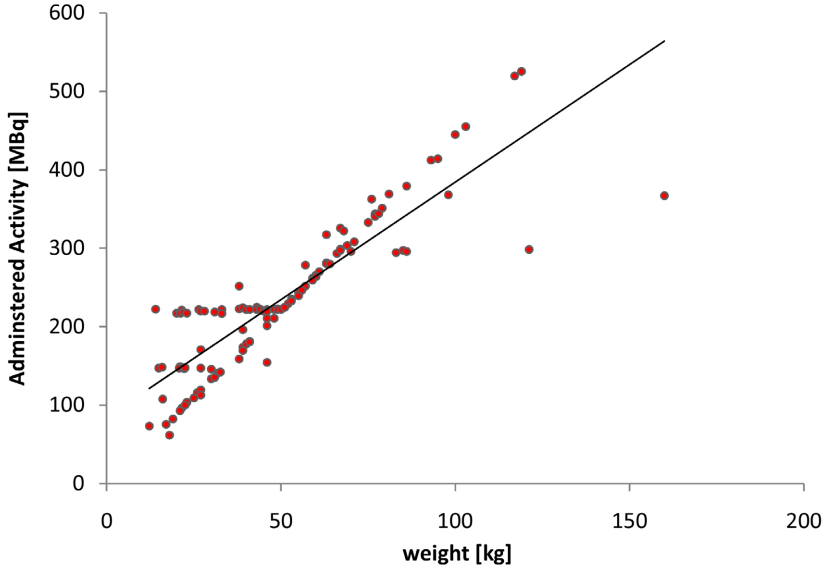
*We had no patient of age more than 18 in this study.

Table 3. Diagnostic Reference Levels (DRLs) for the Male paediatric patients.

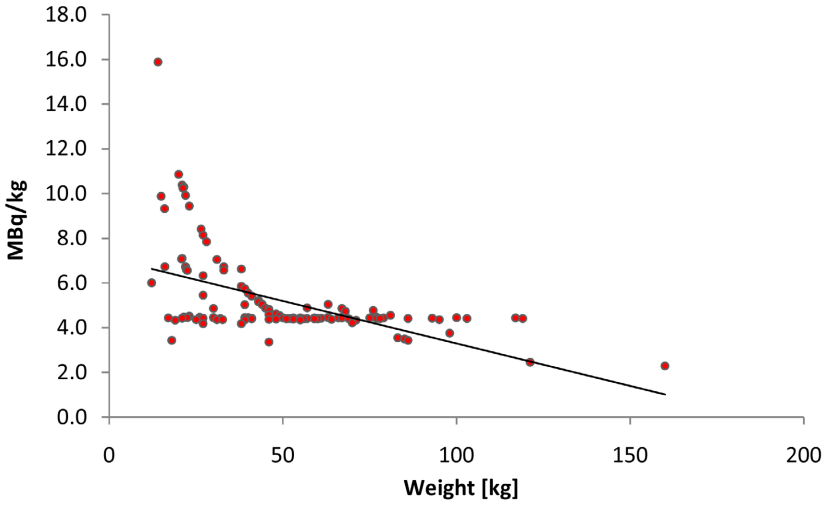
Male Patients (128)	F-18 FDG Activity MBq (mCi)	Activity per weight [MBq/kg]
Maximum	525 (14.2)	15.9
Minimum	63 (1.7)	2.3
Standard Deviation	89 (2.4)	1.8
Skewness	0.68	2.7
Kurtosis	1.01	9.6
Median	222 (6.0)	4.5
75 percentile	281 (7.6)	5.1
50 percentile	222 (6.0)	4.5
25 percentile	174 (4.7)	4.4

Table 4. Diagnostic Reference Levels (DRLs) for the female paediatric patients.

Female Patients (n-88)	F-18 FDG Activity MBq (mCi)	Activity per weight [MBq/kg]
Maximum	366 (9.9)	15.7
Minimum	70 (1.9)	3.0
Standard Deviation	63 (1.7)	2.1
Skewness	−0.88	3.3
Kurtosis	0.63	12.6
Median	226 (6.1)	4.4
75 percentile	255 (6.9)	5.2
50 percentile	226 (6.1)	4.4
25 percentile	207 (5.6)	4.4



(a)



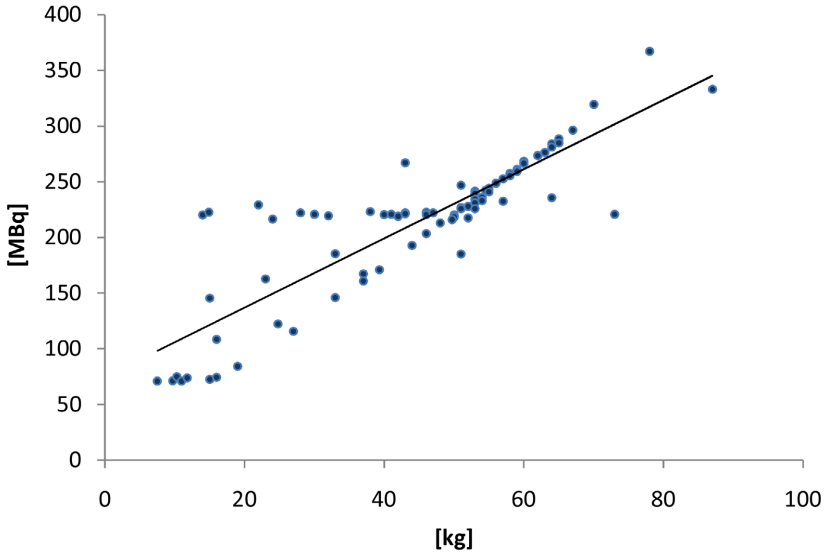
(b)

Figure 1. (a) (b) Pediatric Male patients (n = 128) age (1 - 18 years) PET/CT FDG oncology application).

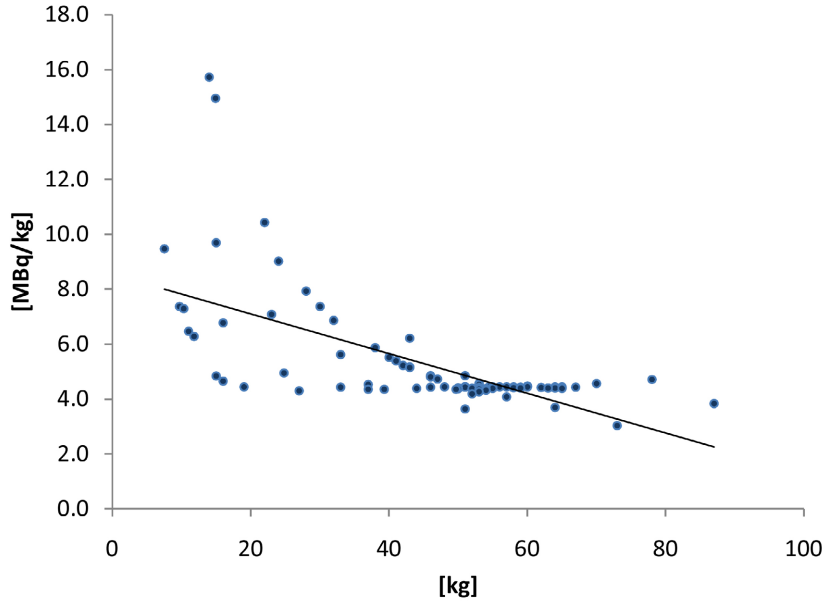
Table 5. The $CTDI_{vol}$ and DLP values per age group for pediatric oncology patient undergoing whole body PET/CT examinations.

Age Group	n	Age Mean (min - max)	weight [kg] Mean (min - max)	BMI [kg·m^2] Mean (min - max)	$CTDI_{vol}$ [mGy] Mean (min - max)	DLP [mGy·cm] Mean (min - max)
1 - 5	16	3.3 (1 - 5)	15 (7.5 - 23)	15 (10.1 - 21)	5.7 (3.5 - 16.5)	519 (223 - 2160)
6 - 10	47	8.4 (6 - 10)	28 (14 - 51)	16 (10.9 - 26)	6.2 (10.9 - 26)	475 (223 - 1715)
11 - 15	72	13.5 (11 - 15)	53 (22 - 98)	21 (9.4 - 37)	8.1 (3.5 - 16.5)	942 (106 - 312)
16 - 20	81	17 (16 - 18)	61 (28 - 160)	23 (11.5 - 58)	9.7 (3.5 - 16.5)	1125 (312 - 3124)

Our data are higher than the ones reported by Abe *et al.* [11] 2020 from Japan.



(a)



(b)

Figure 2. (a) (b) Female patients (n = 88) age (1- 18 years) PET/CT FDG (oncology application).

Patients having the same body weight in [kg] are actually receiving different administered activity in [mCi] or [MBq].

There is a concern about some young or low kg patients that receives higher [MBq/kg] than others from the same weight or age category. Harmonization and optimization of the administered activity practice for these patients is warranted due to their higher risk factor for cancer induction due to absorbed radiation received in their early years of life.

The BMI values of our patients' data are relatively higher than the average reported internationally. This could explain the fact that our average local DRLs

might be higher than others. The difference in DRLs is due to equipment and patient factors including the BMI. Time of flight (TOF), scan mode 2D versus 3D, axial FOV, duration of bed position and amount of bed overlap affect image quality and may affect the dosage chosen by the facility.

The age variable of our patients has higher number of patients with age of more than 15 years old and less than 19. ICRP 135, 2017 recommends to establish the Pediatric Nuclear Medicine DRL based on patient's weight groups: less than 5 kg, from 5 - 15, from 15 - 30, from 30 - 50, from 50 - 80 kg. We will do that and look for observations.

It is clear that our administered activity (AA) in [MBq] is higher than the internationally reported values. The obtained $CTDI_{vol}$ values were higher than the reported studies [12] [13] [14] [15] [16].

Figure 3 and **Figure 4** are showing comparative results with a recently published study from the United States [17].

4. Discussion

It can be seen from **Figure 5** that our administered activities are higher than the ones proposed by the EANM, because we seem to use a weight based dosing system with some variability observed and EANM are using a pharmacokinetics classification system which classifies radiopharmaceuticals in one of three classes according to some pharmacokinetic patterns. On the other hand our data are

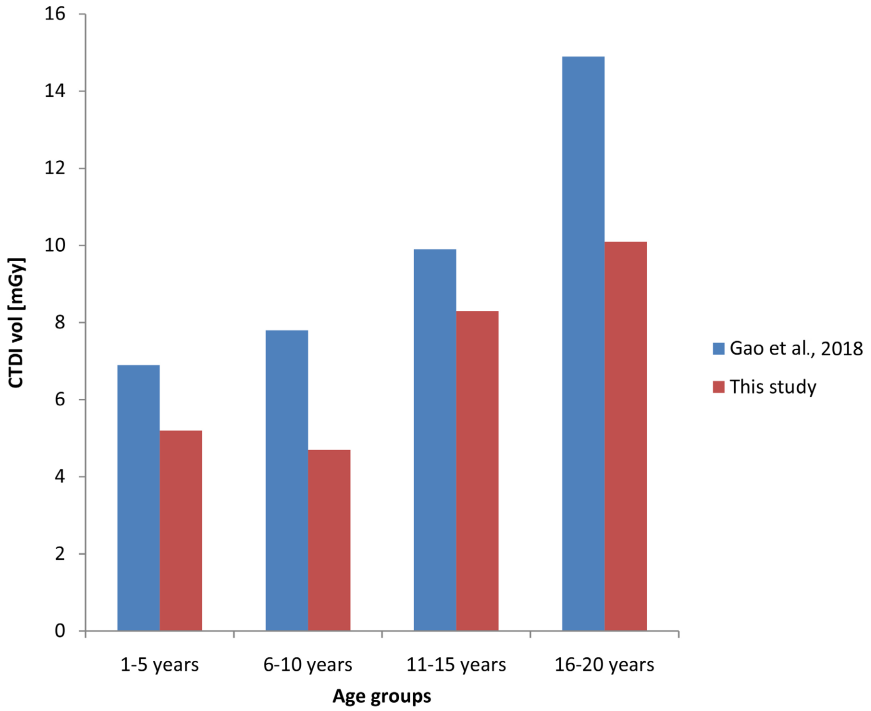


Figure 3. Comparison between this study and the study published by [17]. The reasons for the differences is maybe that our data is reporting Whole body CT scans used for PET/CT attenuation correction and the study by [17] is mentioning Chest-Abdomen-Pelvis CT scans from Pediatric Oncology patients.

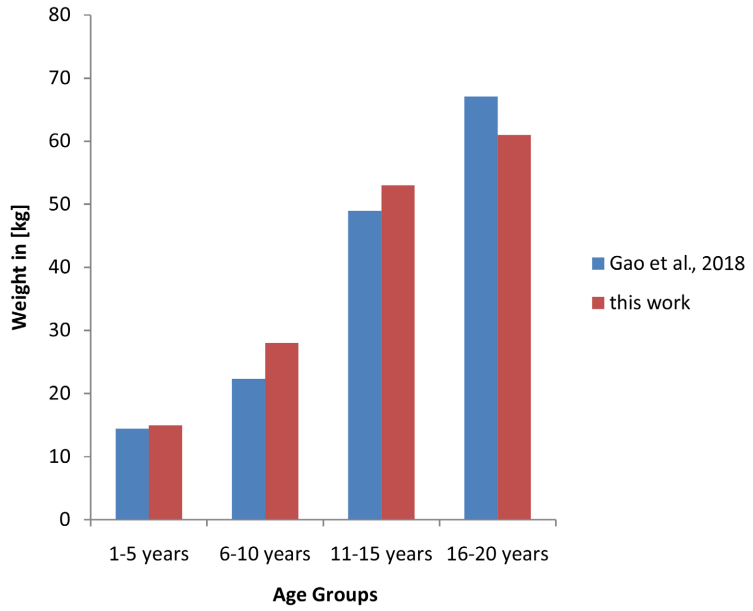


Figure 4. Weights in [kg] of this study patients in comparison with the publication [17], The weights are very comparable.

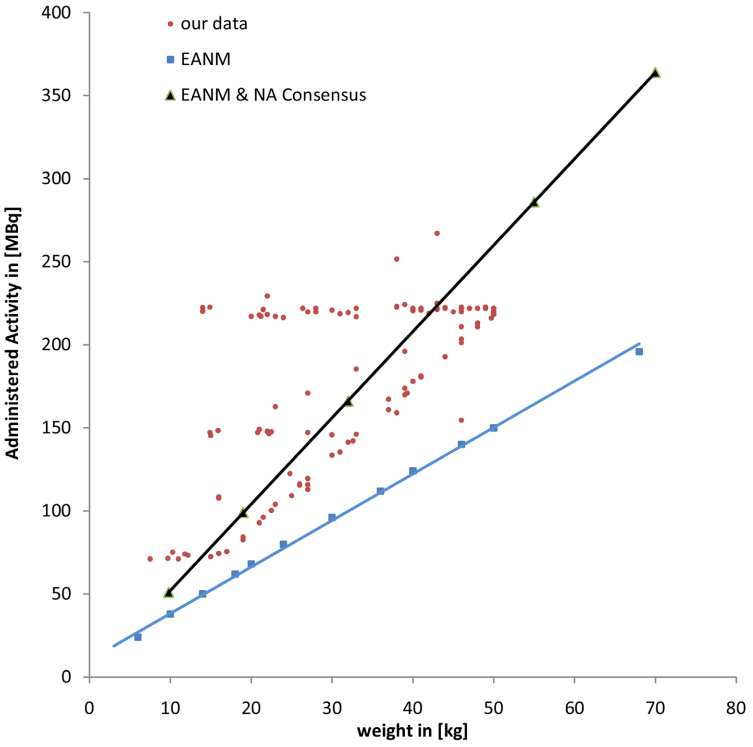


Figure 5. Comparison between EANM proposed 18-F-FDG pediatric oncology dosing schedule (VERSION 1.5.2008) in light blue (square data points). The data in magenta (circle data points) are the data from this study which is showing higher levels of administered activities than the proposed EANM dosage schedule. In black we have the EANM and the North American (NA) consensus guidelines weight-based dosage system (black arrow head points); 5.2 MBq/kg is used for pediatric patients (data taken from reference [19]. Our data distribution is closer to the consensus dosage system with a remarkable variance suggesting establishment of an optimization strategy.

distributed around the EANM and the North American (NA) consensus dosage schedule using 5.2 MBq/kg as described in [18]. Our data distribution show great variations of AA for children having the same weight which certainly requires justification and optimisation efforts.

It is also been noticed that international efforts regarding the standardization of administered activities in paediatric nuclear medicine is actively progressing [20] [21] [22].

A number of studies have been published aiming at finding an optimal AA dosing regimen.

The administered activity should be the lowest possible dose that will produce diagnostic image quality. The administered activity of 18-F-FDG is 3.7 - 5.2 MBq/kg for body PET/CT [18]. The administered dose, however, can be optimized according to the institutional policy and for certain PET systems.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) and The European Association of Nuclear Medicine (EANM) in their Practice Guideline on Pediatric 18-F-FDG PRET/CT for oncology 1.0 stipulate that the standards or guidelines including dosage regimes are educational tools designed to assist practitioners in providing effective patient care and medical practitioners have the freedom to adopt different sequence of action than the ones recommended [6].

It should be expected is that the practitioner follows a reasonable course of action, based on their level of training, the current knowledge, the available resources, and the needs or context of the particular patient being treated [6].

Treves *et al.* [23] mentioned that there are a number of methods used for the selection of the administered activity to children. Harmonization of the existing methods shall reduce the radiation dose received by paediatric patients and reduce the variability of administered activity. In their **Table 1** of this short newsline short paper in the journal of Nuclear medicine they suggested for 18-F-FDG 3.7 to 5.2 MBq/kg for paediatric patients. We use higher values, 5.6 - 11.1 MBq/kg. There are general tendencies among clinicians to reduce the injected activity in order to comply with the proposed North American and European consensus guidelines mentioned by Treves, more dissemination efforts is warranted to achieve larger degree of compliance [23].

Our results indicate a room for administered activity optimization but the facility is in the process of obtaining a new state of the art PET/CT scanner, therefore comparison with the new scanner will be done after the first year of clinical utilisation of the new scanner. It is anticipated that the new scanner will offer better detection sensitivity as a consequence the required 18-F-FDG activity to produce the same clinical image quality will be lower with less radiation doses delivered to our paediatric patients.

5. Conclusion

Establishment of a local facility DRL for paediatric PET-CT procures in a large territory hospital is considered to be the first step toward collaboration between

hospitals in order to establish a national DRL. These local facility DRL will be annually reviewed or after the introduction of new technique or software. The methodology presented in this report can serve as a model for analysing diagnostic reference levels in PET/CT imaging.

Conflicts of Interest

The authors have no conflicts of interst to declare. All co-authors have seen and agree with the contents of the manuscript and there is no financial interest to report. We certify that the submission is original work and is not under review at any other publication.

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