Abstract

Local patient diagnostic reference levels and impact of a commercial dose reduction system on dosimetric quantities in paediatric interventional cardiology

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Interventional cardiology procedures performed at the Paediatric Cardiology Unit of the University-Hospital of Padua between January 2016 and June 2019 were retrospectively analysed. The study protocol was approved by the Institute's Ethics Committee and informed consent was not required. IC were conducted by five experienced interventional cardiologists in the same catheterization room using a digital single plane Philips Allura Xper FD10 installed in 2008. Three paediatrics protocols (newborn, infant, child) with three pulsed fluoroscopy modes (low, medium, high dose) were available. The lowest value of 7.5 fps was almost always used for fluoroscopy, while for cine-acquisition both 15 and 30 fps were selected. Additional copper filtration was within the range of 0.1-0.4 mm. Fields of view were properly adapted to clinical cases switching between 15, 20 and 25 cm. The accuracy of DAP (Dose-Area Product) meter was assured by routine quality controls (<10% in the range 60-120 kV). In December 2017 the device was upgraded with ClarityIQ software (Philips). While the new AlluraClarity has the same hardware, Clarity noise reduction technology (NRT) provides three protocols ("flavors") for fluoroscopy and two for stationary acquisition and performs image reconstruction. Demographic data and dose-related quantities were automatically extracted from the DICOM Radiation Structured Dose Report (RDSR) by means of the open source dose tracking software OpenRem, modified by the author of this study to interact with the in facility IT hardware. Dose readings were corrected for table and mattress attenuation: from analysis of irradiation events stored in the RDSR, the actual kV values were derived and a kV-specific transmission factor was used.

The first part of this study deals with the comparison of dosimetric indexes in paediatric interventional cardiology before and after the equipment of an Allura Xper FD10 angiography device with ClarityIQ noise reduction technology (NTR). Populations of the study are of 360 interventions with reference device and 286 with NRT. The procedures have been divided into diagnostic and interventional, and interventional further subset in four categories (angioplasty, ASD, PDA, and valvuloplasty) (Fig.1). Diagnostic procedures dose area product has been compared

in the reference and NRT case. A statistically significant ($p < 10^{-3}$) decrease in total DAP has been found for an overall sparing of -75.05%. This is in line with the literature on the subject (Halls et al, 2015). An interesting result here is the difference in DAP sparing for the fluoroscopy component (-55.25%) and the stationary acquisition one (-92.63%). This difference between the two components is to be expected because of the different algorithms applied by ClarityIQ technology in dealing with fluoroscopy and stationary acquisition. Interventional procedures have been compared as well, as a whole at first and then by each category. Even as a whole, they exploit significant dose reduction of total DAP, namely -86.27%, -35.96% for fluoroscopy and -52.96% for stationary acquisition. Once again the stationary acquisition component displays a greater impact on dose sparing. Considering the procedures separately, it can be noted that ClarityIQ total DAP sparing is procedure dependent, ranging from -19.66% in ASD to -71.08% in angioplasty (again stationary acquisition contribution is leading). This might aid in explaining why in literature very different values for ClarityIQ overall dose reduction are proposed by different authors: the ratio of kind of procedures performed in each center greatly varies.

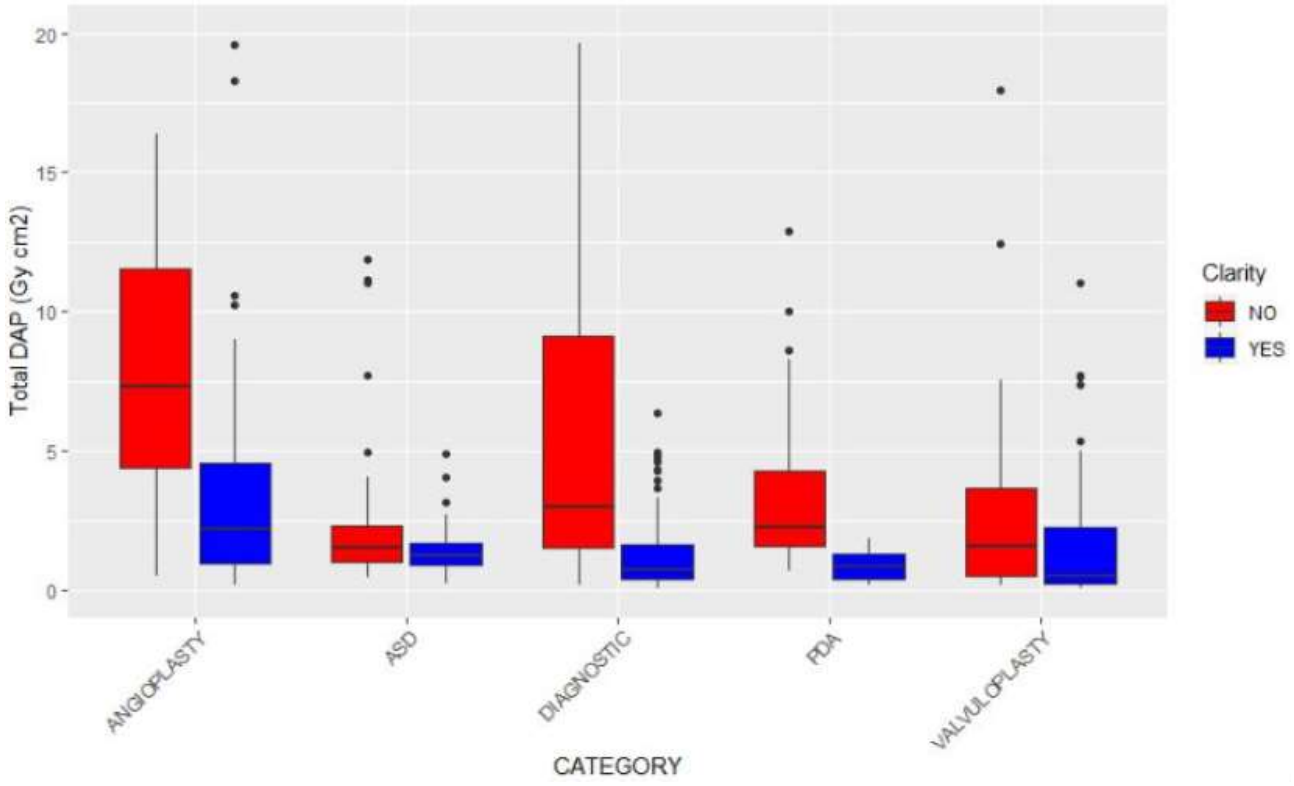

Figura 1: Total DAP values for different kind of procedures.

Some operator impact evaluation has been performed. A total of five operators performed the examinations in the study, but two of them have been excluded from it due to scarcity in numbers. During pre ClarityIQ period, we considered the two most proficient operators (OP1 and OP2). Patient populations have been found out to be comparable. It clearly appears the two operators had

different “styles” in performing their interventions even if there were no size differences in their treated patients. For post-ClarityIQ procedures, the same analysis has been carried out but, since the numbers in each study are even lower, no category but diagnostic examinations was considered. Three operators were compared (again OP1 with OP3 and OP4), to find out no statistical significance to be found in differences apart the number of stationary acquisitions. Statistical significance is found for differences in number of events of stationary acquisition, although this does not impact on the acquisition DAP and much less on the total DAP.

The second part of the study deals in finding robust relationships between dosimetric quantities in order to give estimations for total dose area product, which has been indicated as the preferred candidate for DRLs as displays a strong correlation with risk associated to stochastic dose effects. Since mean based calculations are heavily influenced by the presence of outliers data, a cleaning has been performed (we stress this operation has to be done inside each procedure). To this scope, a method in R package “outlierO3” has been adopted to clean the database consistently. A log-log data transformation approach to put ourselves in conditions of normality and variance homoscedasticity has been used as other authors suggested (Onnasch et al., 2004). In diagnostic procedures relationships among DAP and body weight and DAP/ FT (dose area product over fluoroscopy time) over body weight were investigated. As expected from literature, higher correlation (squared Pearson coefficient) is found when considering fluoroscopy time contribution, going from $r^2 = 0.50(0.62)$ without (with) ClarityIQ to $r^2 = 0.75(0.86)$.

The third part of the study focuses on proposing local DRL. Following ICRP135 recommendations, we divided our procedures into standardized groups on the basis of body weights. Regrettably, most of the groups couldn’t reach the minimum number of examinations needed for calculating DRLs, which is 20. An alternative approach in calculating DRLs when dealing with scarce datasets lies in utilizing quantile regression techniques (Fig.2). RP85 recommends this as an alternate option when possible, (following the lead given by Kiljunen and Jarvinen in CT datasets) and two functional forms (linear and exponential) are indicated to be of preferred usage. However, confidence interval width strongly depends on the number of data; using quantile regression on scarce datasets prevents robust results, especially when using non-linear functions (as the exponential). By performing a log-likelihood goodness of fit analysis, we concluded there are no strong motivations for preferring one function to the other, as differences between the estimators are small and don’t exhibit any uniform trend, not even considering NRT implementation. ICRP135 advice would be that of using the simplest functional form when possible. Comparing the body weight group based DRL calculations (just for the categories meeting ICRP135 requirements) with the regression curves obtained, we get

for both functional forms 95% confidence level compatibility. Results obtained using quantile regression show a good agreement with the ones already published in literature.

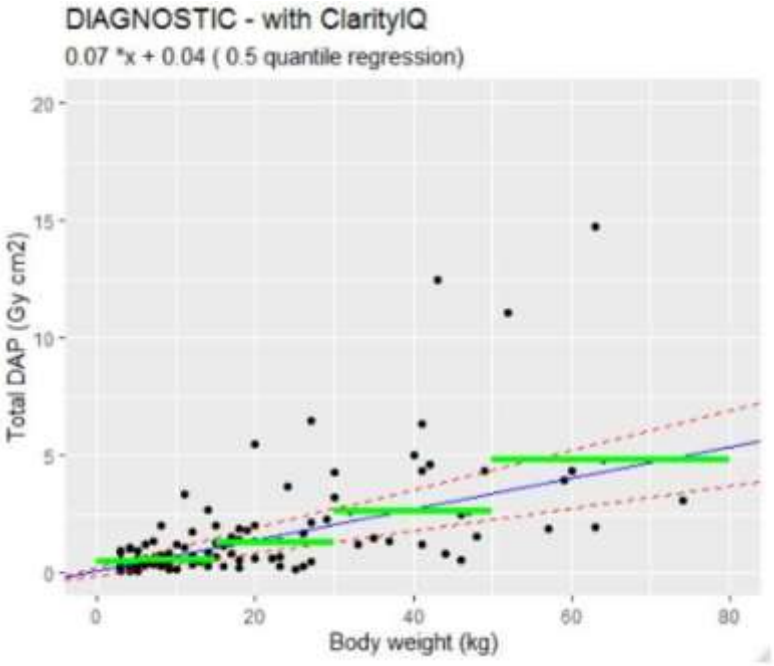

Figura 2: Example of quantile regression (blue) and BW grouping (green) lDRLs calculation approach