IJC Heart & Vasculature 6 (2015) 101–109

Contents lists available at ScienceDirect

IJC Heart & Vasculature

journal homepage: http://www.journals.elsevier.com/ijc-heart-and-vasculature

Substantial radiation reduction in pediatric and adult congenital heart disease interventions with a novel X-ray imaging technology

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ARTICLE INFO

Article history:
Received 15 September 2014
Received in revised form 10 January 2015
Accepted 13 January 2015
Available online 20 January 2015

Keywords:
X-ray imaging technology
Dose reduction
Congenital heart disease
DAP
Radiation exposure
Interventional therapy

ABSTRACT

Background: Pediatric catheterization exposes patients to varying radiation doses. Concerns over the effects of X-ray radiation dose on the patient population have increased in recent years. This study aims at quantifying the patient radiation dose reduction after the introduction of an X-ray imaging technology using advanced real time image noise reduction algorithms and optimized acquisition chain for fluoroscopy and exposure in a pediatric and adult population with congenital heart disease.
Methods: Patient and radiation dose data was retrospectively collected (July 2012–February 2013) for 338 consecutive patients treated with a system using state of the art image processing and reference acquisition chain (referred as "reference system"). The same data was collected (March–October 2013) for 329 consecutive patients treated with the new imaging technology (Philips AlluraClarity, referred as "new system"). Patients were divided into three weight groups: A) below 10 kg, B) 10–40 kg, and C) over 40 kg. Radiation dose was quantified using dose area product (DAP), while procedure complexity using fluoroscopy time, procedure duration and volume of contrast medium.
Results: The new system provides significant patient dose reduction compared to the reference system. Median DAP values were reduced in group A) from 140.6 $cGy \cdot cm^2$ to 60.7 $cGy \cdot cm^2$, in group B) from 700.0 $cGy \cdot cm^2$ to 202.2 $cGy \cdot cm^2$ and in group C) from 4490.4 $cGy \cdot cm^2$ to 1979.8 $cGy \cdot cm^2$ with reduction of 57%, 71% and 56% respectively ($p < 0.0001$ for all groups).
Conclusions: Despite no other changes in procedural approach, the novel X-ray imaging technology provided substantial radiation dose reduction of 56% or higher.

1. Introduction

Patients with congenital heart defects frequently undergo numerous and repeated diagnostic and interventional catheterization procedures, in addition to other imaging studies such as chest-X-rays and CT studies. The growing number and complexity of interventional cardiology procedures have been significant in the past years as a result of advances made in transcatheter techniques and the armamentarium available (i.e. devices, stents, percutaneous valves, miniaturized balloons, coils, etc.) [1,2]. While their benefits to the patients are undisputable, all these procedures contribute to high accumulated radiation doses to the patient population [3–5]. This is particularly relevant for infants and children and even if the long term consequences of this exposure are not well understood and extremely difficult to estimate, there is now for many decades considerable concern about the possible stochastic effects, such as the incidence of solid tumors and leukemia [6–11]. In fact, growing tissue in children is more radiosensitive than that in adults and, due to their small size, larger body parts are irradiated during cardiac catheterization including radiosensitive organs such as thyroid and eyes which are closer to the heart [12,13]. Moreover, children with complex heart defects often need to undergo increasingly complex procedures many times during their lifetime, resulting in a high cumulative dose acquired [14–16]. Minimizing radiation dose is therefore crucial for this vulnerable population, as children are likely to survive long enough through a possible latent period and develop or manifest late effects of early radiation exposure.

Successful patient radiation dose management can only be achieved by optimization of medical imaging technology together with best control of the equipment by the operator [17,18]. In this respect, best practices are applied in our lab using "ALARA" radiation reduction

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http://dx.doi.org/10.1016/j.ijcha.2015.01.007
2352-9067/

principles in terms of patient radiation safety, such as short imaging time, avoidance of field overlap in repeated acquisitions, low SID, tight collimation, use of intra-procedural echocardiography, and a frame rate for fluoroscopy acquisitions of maximum 15 frames/s [19–24]. Moreover, our cath lab has been recently upgraded to a novel X-ray imaging technology (AlluraClarity; Philips Healthcare, Best, Netherlands) developed for fluoroscopy and cine exposure for interventional cardiology for the entire patient size population, including pediatric. This technology enables significant patient entrance dose reduction achieved by a combination of advanced real-time image noise reduction algorithms with state-of-the-art hardware and an anatomy-specific optimized full acquisition chain (grid switch, beam filtering, pulse width, spot size, detector and image processing engine). Furthermore, image quality is further positively influenced by the use of smaller focal spot sizes and shorter pulses. Radiation dose reduction using this technology has already been investigated in other clinical and investigational domains outside congenital heart disease interventions by comparing state-of-the-art reference to new systems [51,52]. In complex ablation procedures, patient dose and physician dose were reduced by 40% and 50%, respectively [25]. In interventional neuroradiology, 75% patient radiation dose reduction was demonstrated during digital subtraction angiography (DSA) without affecting image quality [26], and 60% procedural patient dose reduction was achieved [27]. However, results that quantify the reduction of patient radiation dose enabled by this technology for congenital heart disease are not available in literature. The study presented here was designed to quantify the procedural patient radiation dose reduction due to the novel X-ray imaging technology in a patient cohort with congenital heart diseases in comparison with our state-of-the-art angiography system.

2. Methods

2.1. Patients

All 667 consecutive patients with congenital heart defects referred between July 2012 and October 2013 were retrospectively included in the study. Patients who received catheter investigation with echocardiography only (i.e. Rashkind procedures) or under direct vision of the area to be treated (i.e. intraoperative hybrid procedures) were excluded from the analysis. In March 2013, the biplane flat panel angiography system was upgraded from Allura Xper FD20/10 (installed in 2011) equipped with state-of-the-art image processing ("reference system") to the new AlluraClarity with Clarity IQ technology with advanced real time image noise reduction algorithms and optimized acquisition chain for all exposure techniques (Philips Healthcare, Best, The Netherlands). Patients were therefore assigned to the "reference" or "new" groups, and categorized according to clinical requirements and technical implementation to weight: A) below 10 kg, B) 10–40 kg, and C) over 40 kg.

The study was conducted in accordance with the provisions of the Declaration of Helsinki and was approved by the local ethical committee (approval Ref. No.: 21/2014). Procedure and dose data for all patients admitted with congenital heart disease (CHD) in the period July 2012–February 2013 were collected. As per institutional protocol and enforced by the European legislation, all relevant periprocedural data were continuously monitored and documented as part of the hospital quality assurance program. The data reported here include radiation dose, fluoroscopy time, procedure time, weight, height, BMI, and contrast medium use. After upgrading to the new system, procedure and dose data information for all consecutive patients were collected during March–October 2013. During the procedures the anti-scatter grid was not removed. The same cardiologists were employed and the same procedural techniques were used. All our catheter interventions were performed under deep conscious sedation and without general anesthesia as described in detail elsewhere [28].

2.2. Imaging technology

ClarityIQ is a novel X-ray imaging technology that combines advanced real-time image noise reduction algorithms, with state-of-the-art hardware to reduce patient entrance dose significantly. This is realized by anatomy-specific optimization of the full acquisition chain (grid switch, beam filtering, pulse width, spot size, detector and image processing engine) for every clinical task individually. The system has been optimized for all major disease areas using over a 1000 patients. In addition to patient entrance dose reduction, the image quality is improved through the use of the smaller focal spot sizes, and shorter pulses and the introduction of automatic real-time motion compensation in subtraction imaging.

One of the features of ClarityIQ, temporal noise reduction, is implemented by averaging consecutive images. However, in interventional cardiology, cardiac and respiratory motion result in the appearance of "ghost images" of moving tissues or devices. This used to limit the number of images that could be averaged, hence requiring higher doses per frame. The implementation of a motion compensation algorithm in this technology enables alignment of moving objects before averaging, such that more consecutive images can be averaged to reduce noise more significantly.

In addition, a spatial noise reduction algorithm uses the random nature of noise to discern between noise and useful clinical information in a single image. When a pixel is identified as noise, its intensity is averaged with surrounding pixels in order to filter it out. Thanks to the powerful computational power, a larger neighborhood of pixels can be averaged, providing more noise reduction and increasing the confidence in the clinical information to maintain in the image [26, 27]. Finally, image enhancement processing reduces low frequency over- and under-exposed areas and enhances high frequency edges in order to sharpen contrast. The image enhancement enabled by these features made possible a further optimization of the X-ray acquisition chain; this was modified to achieve patient radiation dose reduction for both pediatric and adult population for fluoroscopy and cine exposure. The maximum patient entrance dose for fluoroscopy was reduced from 22 mGy/min, 44 mGy/min and 44 mGy/min in the reference system to 7 mGy/min, 12 mGy/min and 22 mGy/min in the new system for the fluoroscopy modes I, II and III respectively, with the same relative reduction over the entire patient thickness range. For the pediatric group, two cine applications are introduced based on patient weight: a) below 40 kg and b) above 40 kg. The below 40 kg group uses a small focal spot (0.4) to increase the sharpness of images. In addition, increase in copper filtration was implemented (0.4 mm Cu and 1.0 mm Al) compared to the reference pediatric cine acquisition chain (0.0 mm Cu and 0.0 mm Al). The practical aspects of adding copper filtration to reduce patient radiation dose have been already studied by other authors [13,52]. Photons with lower energy do not contribute to the image quality, as they can't penetrate the patient's body, but add needless radiation dose to the patient. Additional copper filtration enables the reduction of these photons, with consequent patient radiation dose reduction.

In conclusion, hardware imaging components such as copper filtration, power, pulse width and duration, and focal spot size enter a virtuous cycle with advanced and real-time image processing features in order to optimize the dose to image quality relationship for each clinical application.

2.3. Statistical analysis

Patient radiation dose was quantified as (cumulative) dose area product (DAP), measured by the internal transmission ionization chamber (KermaX plus; IBADosimetry, Schwarzenbruck, Germany) and displayed on the equipment as $mGy \cdot cm^2$; this was automatically converted into $cGy \cdot cm^2$ for documentation purposes. In addition, acquisition parameters, such as fluoroscopy time, procedure time, and