

## **Digital subtraction neuroangiography in the pediatric population: Quantification of radiation dose reduction following implementation of an optimized low exposure technique with enhanced image post-processing.**

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## **Abstract**

**Introduction:** Pediatric neuroangiography has an indispensable role in modern pediatric neurosurgical care in both diagnosis and therapeutic interventions. Advances in digital flat panel detector technology and image post-processing have enabled significant radiation dose reduction in adults undergoing neuroangiography. We sought to quantify clinical radiation dose reduction afforded to pediatric patients undergoing cerebral digital subtraction angiography (DSA) by an optimized low exposure angiographic technique with enhanced image post-processing.

**Methods:** Angiographic and clinical records of all patients undergoing diagnostic cerebral DSA studies over a five-year period were retrospectively reviewed. Dose area product (DAP) and cumulative air Kerma (CAK) per frame were the primary outcome measures. DSA studies performed using an optimized “new” technique (Allura Clarity®) were compared to DSA studies obtained using standard “reference” angiographic technique (Allura XPER®). DSA studies performed using a combination of both techniques were classified as “training cases” to assess physician behavior as a real-time workflow assessment of image quality. Cases with incomplete radiation exposure data

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were excluded. Differences between groups concerning patient age, sex and specific vessels examined were evaluated. Analysis of variance was calculated between comparison groups to assess the primary outcome. Fluoroscopy time and number of angiographic frames acquired were analyzed as surrogate markers of physician behavior during the “training phase”.

**Results:** A total of 209 cerebral DSA studies met study criteria; 58 training, 116 reference studies and 35 new studies. Average mGy\*cm<sup>2</sup> comparative radiation dose was 283.08 for new studies and 409.87 for reference studies ( $p < 0.05$ ). Both groups had similar demographic and index vessel distribution. Surrogate measures of physician behavior were similar across all groups.

**Conclusion:** The Allura Clarity which incorporates new technologies to reduce radiation dose can produce high quality imaging with a 31% lower radiation dose than the XPER system in pediatric patients undergoing diagnostic cerebral DSA studies. Implementation of this new technique had no discernable impact on real – time workflow assessment of image quality in physician behavior during the training phase or in clinical use.

## **Introduction**

Cranio cervical digital subtraction angiography (DSA) remains a frequently used imaging modality in modern neurosurgical pediatric clinical practice. Despite major progress in the development of non-invasive imaging technologies, DSA continues to be an indispensable tool for both diagnosis and image guided therapy of numerous conditions encountered in children, particularly hemorrhagic and ischemic stroke, and neoplastic or vascular lesions above the clavicle [1]. Advantages of DSA relative to other imaging modalities include high speed image acquisition with superior spatial, temporal and contrast resolution that is relatively insensitive to artifacts produced by metal implants.[2]

However, radiation induced damages such as skin reactions and tumor induction are well documented in literature in both patients and operators and it is thus imperative to intensify effort to reduce the risk of radiation related pathologies [3, 4, 5, 6, 7, 8, 9]. This is especially relevant considering that DSA imaging procedures are often associated with the highest exposure to ionizing radiation when compared to other imaging modalities [10].

In neurotrauma patients, protocols to limit radiation exposure to the patient and staff, in accordance with the “As Low As Reasonably Achievable” ALARA principle, have demonstrated up to 80% dose reduction to thyroid tissue in pediatric patients undergoing computed tomography scan (CT) for cervical spine clearance[11], and significant decreases in dose length product and CT dose index for head CT after their implementation.[12] Weight based CT imaging protocols in the pediatric population have also been demonstrated to reduce radiation exposure.[13] Similarly, low-dose CT protocols have successfully limited radiation dose for craniosynostosis,[14] hydrocephalus,[15], and non-neurosurgical patients when implemented focused on the disease rather than anatomically focused, i.e. cystic fibrosis.[16–18] and congenital heart disease[19].

Recent progress in DSA and fluoroscopic imaging technology and increased experience of operators has enabled significant reductions in patient exposure to ionizing radiation. Previous studies have demonstrated that these advances may enable a 60-75% radiation dose reduction without loss of image quality or alteration of physician work habits in adults undergoing neuroangiographic DSA studies.[20,21] Nevertheless, there is a paucity of data on this issue

regarding the pediatric population. The purpose of this study is to quantify the radiation dose reduction achieved by implementation of an optimized low exposure angiography technique combined with enhanced image post-processing technology in a cohort of pediatric patients undergoing diagnostic neuroangiography studies, without altering physician work habits.

## Materials and Methods

### Study design and approval

Institutional Review Board approval was obtained for waiver of consent prior to initiation of this study. The study is a single center, retrospective consecutive case series review of all diagnostic cerebral DSA studies performed at a large academic center over a consecutive four-year period. Therapeutic neurointerventional and intra-operative diagnostic cases were excluded. Patients older than 21 years of age were excluded. Cases were also excluded if a complete set of demographics, technical and procedural data could not be obtained from the electronic medical and angiographic records.

### Study Data

Patient demographic data was obtained from the electronic medical record. Technical, procedural and patient dose data were obtained from the archived electronic angiographic record. Technical data included imaging channel (frontal vs lateral plane) and system settings. Patient dose data included dose area product (DAP) and cumulative air Kerma (CAK) per frame. CAK values were collected as a measure of incident radiation dose to a single point in space. Procedural data included number of DSA frames, number of fluoroscopic frames, fluoroscopy times and procedure times. Procedural data was further characterized by imaged vessel: a) internal carotid artery, b) external carotid artery, c) common carotid artery, and d) vertebral artery.

### DSA Image Acquisition

All diagnostic cerebral DSA examinations reviewed in this study were performed by one of two fellowship trained operators using the same *reference* system AlluraXper (FD20/20 biplane; Philips Healthcare, Best, Netherland). Clinical staff, including technologists, and procedural techniques remained consistent throughout the study period. Images were acquired and post-processed using the AlluraXper *reference* or the *new* AlluraClarity

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standard algorithms which applied optimized low exposure angiographic technique with enhanced image post-processing. The *new* system settings achieved enhanced image post-processing with image noise reduction algorithms, real time photon output optimization loops, and motion compensation technologies. Noise reduction algorithms allow for blurring of noise and signal enhancement while recording in real-time, while motion compensation stacks sequential image frames to improve contrast resolution and adjust for patient or table motion. All our patients were under general anesthesia at the time of their procedure hence reducing the need for significant motion compensation related to patient's movements.

### Study groups

DSA studies were divided into three groups; those that used the AlluraXper (FD20/20 biplane; Philips Healthcare, Best, Netherland) *reference* system exclusively, those that implemented the *new* technology (AlluraClarity; Philips Healthcare, Best, Netherland) system settings exclusively, and those that utilized both systems during the same procedure and were classified as "*training cases*" performed during the "*training phase*". The biplane neuroangiography system is equipped with both systems to simply switch between acquired runs such that internal comparisons were able to be performed without additional radiation exposure.

### Statistical Analysis

Patient demographic data and procedural data were characterized by descriptive statistics, with difference between the *reference*, *new*, and "*training phase*" groups analyzed with one-way analysis of variance (ANOVA) at a significance level of  $p=.05$ . Dose exposure differences for CAK/frame and DAP between the *reference* and *the new* groups were evaluated using one-way ANOVA, using an F-test. Differences in number of DSA image frames, and fluoroscopy time were similarly analyzed with one-way ANOVA and an F-test.

## Results

### Pediatric cerebral DSA studies performed during study period

A total of 286 consecutive diagnostic cerebral DSA studies were performed in patients less than 21 years of age during the study period. 77 studies were excluded due to incomplete technical or procedural information. Consequently, 209 cerebral DSA examinations were analyzed.

### Demographic and Procedural Characteristics within comparison groups

The *reference* group comprised 118 diagnostic cerebral DSA studies (66 male, 50 female, mean age  $6.4 \pm 5.5$  years) and the *new* group comprised 35 diagnostic cerebral DSA studies (19 male, 16 female, mean age  $6.2 \pm 6.4$  years). The “training phase” group comprised 58 diagnostic cerebral DSA studies (30 male, 28 female, mean age  $8.6 \pm 6.2$  years).

There were no significant differences in age or gender between groups. In each group, imaging of the internal carotid artery comprised the majority of DSA runs. The difference in number of imaged vessel types using either the *reference* system or the *new* system or a combination of the two was statistically significant. However, our practice is biased to pediatric neurological disorders that may select for vascular territory more commonly associated with specific vascular pathologies. This study is not powered to parcellate variation in disease rather focus on the growing general pediatric neurovascular practice. Demographic and procedural data is further reported in Table 1.

### Dose Area Product

Analysis of DAP values demonstrated a highly skewed distribution with substantial case to case variability. (Fig. 1) DAP was significantly lower for the *new* system (AlluraClarity)

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compared to the reference system (Allura XPER); individual values of DAP demonstrated high variability. In both frontal and lateral channels, the mean DAP per DSA frame was significantly reduced in the *new* group relative to the *reference* group (26% and 40% dose reductions in the frontal and lateral channels respectively, 31% dose reduction in both channels combined based on arithmetic means). In the frontal channel, the mean DAP/frame was 255.9 mGy\*cm<sup>2</sup>/frame for the *reference* group and 190.1 mGy\*cm<sup>2</sup>/frame for the *new* system group ( $p<.05$ ). In the lateral channel, the mean DAP/frame was 154.0 mGy\*cm<sup>2</sup>/frame for the *reference* group and 93.0 mGy\*cm<sup>2</sup>/frame for the *new* group ( $p<.05$ ). Total DAP, which combined the frontal and lateral channels, was 409.87 mGy\*cm<sup>2</sup>/frame in the *reference* group and 283.1 mGy\*cm<sup>2</sup>/frame in the *new* group ( $p<.05$ ). These findings are further detailed in Table 2.

### Cumulative Air Kerma (Total Dose)

Similar to DAP values, analysis of CAK values revealed a highly skewed distribution with considerable case to case variability (Fig. 2). CAK was significantly lower for the *new* system (AlluraClarity) compared to the *reference* system (AlluraXPER); individual values of CAK demonstrated high variability. In both frontal and lateral channels, the mean CAK per DSA frame was significantly reduced in the *new* group relative to the *reference* group (32% and 49% dose reductions in the frontal and lateral channels respectively, 37% dose reduction in both channels combined based on arithmetic means).

In the frontal channel, the mean CAK/frame was 1.5 mGy/frame for the *reference* group and 1.4 mGy/frame for the *new* system ( $p<.05$ ). In the lateral channel, the mean DAP/frame was 0.8 mGy/frame for the *reference* system and 0.4 mGy/frame for the *new* group ( $p<.05$ ). Total DAP, which combined the frontal and lateral channels, was 2.3 mGy/frame in the *reference* group and 1.4 mGy/frame in the *new* group ( $p<.05$ ). These findings are further detailed in Table 3.

## *Technical and Procedural Data*

Technical and procedural data are detailed in Table 4. Across the three groups studied, differences in number DSA images and in fluoroscopy time did not reach statistical significance.

The first 35 diagnostic cerebral DSA studies in each group were further analyzed to determine whether there were significant differences during the “training phase” (Table 5). For both number of DSA images and for fluoroscopy time, the difference between *new* system cases, *reference* cases, and training phase cases did not reach statistical significance.

## **Discussion**

Pediatric neuroangiography is a growing field within neurosurgery, with implications for both diagnosis and treatment of vascular malformations, ischemic stroke, neoplasms, and hemorrhagic strokes granting a superior spatial and temporal resolution compared to the existing non-invasive imaging techniques.

Despite the widespread use of advanced radiation reduction technologies, exposure to ionizing radiation during DSA studies continues to be a significant concern, primarily because of associated long-term and unquantifiable stochastic effects. In adults, it is well documented that adverse effects of exposure to ionizing radiation during radiographic examinations are deterministic and can include alopecia and erythema.[3] Radiation exposure during pediatric neuroangiography rarely reaches the level required to cause those effects.[4] Children on the other hand are considerably more sensitive to the carcinogenic effects of ionizing radiation due to their larger number of rapidly dividing cells[5], and their long life expectancy. As a result, the stochastic effects of medical imaging procedures are of greater concern in the pediatric population due to the higher cumulative risk of developing radiation induced neoplasms.[6-8]

As an effort to reduce radiation exposure in medical imaging, the “As Low As Reasonably Achievable” (ALARA) principle has been widely adopted, with the main aim of reducing radiation exposure to the lowest levels possible required to obtain a clinically acceptable result. This can be achieved through two main methods: 1) choosing an alternative method of imaging without exposure to ionizing radiation, and 2) implementing lower dose image acquisition techniques by favorably adjusting the x-ray tube output. Lowering dose in this manner typically requires some form of image enhancement by augmentation of detector sensitivity to x-ray photons, and/or application of image post-processing methods.

One approach to reducing ionizing radiation exposure during medical imaging is to replace x-ray imaging modalities with magnetic resonance imaging (MRI). While this approach is practical in many cases, diagnostic evaluation of pediatric neurovascular pathologies frequently demands a level of spatial, temporal and contrast resolution that can only be achieved with high quality DSA imaging. Additionally, image artifact produced by metallic implants (i.e. surgical clips and tantalum containing embolic agents) often render magnetic resonance images non-diagnostic in pediatric patients with neurovascular pathology. Consequently, continuing efforts should be focused on protocols incorporating radiation dose-reduction technologies for DSA imaging.

Literature addressing radiation exposure in pediatric neuroangiography is limited. On the other hand, this topic has been addressed by several authors in adult neuroangiography highlighting the increased awareness of risks secondary to radiation while focusing on the feasibility of preserving image quality [22,23,24]

A thorough search of the literature revealed only one study focused on dose reduction in pediatric cerebral DSA, which documented a 77% dose reduction over four years as operators became more proficient and decreased fluoroscopy time, number of exposures, and the number of catheterized vessels.[31]

However, we were unable to find any literature discussing implementation of low exposure angiographic technique with enhanced image post-processing technology in the pediatric population. Our study begins to address this gap.

Our results demonstrate that use of a commercially available technology (AlluraClarity; Philips Healthcare, Best, Netherland) achieves significant reductions in total DAP and CAK during pediatric neuroangiography, 37% and 31% respectively. This is similar to estimates from previous pediatric imaging studies estimating dose reductions up to 30%.[25] The overall effect of optimizing system settings in our study is also consistent with what has been reported for neuroangiographic procedures in adults using technology[21] and pediatric abdominal and peripheral fluoroscopically guided procedures that demonstrated a nearly 66% reduction in DAP.[26] Others have shown DAP reductions as high as 65% in children undergoing diagnostic cardiac angiography with novel system settings.[27,28] A very similar and more extensive study has already been performed in adult patients undergoing diagnostic neurointerventional procedures.[29]

One potential disadvantage of reducing exposure during neuroangiographic studies is an unintended degradation of image quality due to decreased contrast resolution and increased image noise. Although we did not evaluate image quality directly in our study, others have reported that image quality is comparable for the two system settings that we compared.[20,30] Instead, we secondarily evaluated the effect of transitioning from the reference (AlluraXper) system to the optimized (AlluraClarity) system through the use of surrogate measures of physician behavior: number of DSA images and fluoroscopy time. We demonstrated that both surrogate markers for physician behavior were similar in all study groups; the *reference* group, the *new system*, “training phase”. Specifically, no difference was observed in number of DSA images or fluoroscopy time during the first 35 encounters for each of the three categorical groups. Similar results were seen in previous studies.[17,30]

Further study will be needed to fully understand the effect of dose reduction on image quality in clinical practice, and how the impact depends on patient anatomy,

pathology and procedural objectives. It is possible that neuroangiographic procedures involving smaller vessels, or with less tolerance for error will demand higher degrees of image quality and suffer more from low exposure angiographic techniques.

The retrospective nature of this study is associated with several limitations. Patients could not be matched for age or gender across comparison groups, and a larger number of patient encounters for specific vessels were unable to be attained. Also, the *new system* group sample size is small. Nonetheless, the reduction in CAK and DAP observed in this study is consistent with results found in previous studies[20,25], as is the minimal impact on physician behavior.[20,21] While DAP and CAK were used as measures of radiation exposure, no direct method of dose measurement to organ systems currently exists. Though this poses a problem, it is generally accepted that DAP is the standard measure of organ system exposure, as it can be used to determine effective radiation dose to organs.[26,32–34] The limitations of this study can be addressed by designing a prospective randomized controlled study that incorporates image quality analysis.

## Conclusion

Optimized low exposure angiographic technique combined with enhanced image post-processing showed a 31-37% radiation dose reduction in a cohort of pediatric patients undergoing diagnostic cerebral DSA studies. Implementation of this new technique had no discernable impact on physician behavior. This technology provides a viable dose-reducing alternative to traditional DSA techniques without compromising physician behavior and can be incorporated into dose-reduction protocols designed for pediatric neuroangiography. A prospective randomized controlled study with image quality analysis could help confirm the advantages of this technique.

## **Statements**

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## **Statement of Ethics**

This study was approved by the Cincinnati Children's Hospital Medical Center IRB no. 2019-0566. The Institutional Review Board of the Cincinnati Children's Hospital Medical Center waived the written informed consent prior to initiation of this study.

## **Conflict of Interest Statement**

The authors have no conflicts of interest to declare and no financial affiliation with the companies developing the technologies discussed in this paper.

## **Data Availability Statement**

All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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## **Author Contributions**

All listed authors contributed to the paper in accordance with ICMJE criteria for authorship and are listed here. Conception and design: Shah, Vadivelu, S; Acquisition of data: Shah,

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Hilvert, Vadivelu, S; Analysis and interpretation of data: Abruzzo, Shah, Hilvert; Drafting the article: Abruzzo, Shah, Zamarano, Richetta, Vadivelu, K, Vadivelu, S; Critically revising the article: all authors; Reviewed submitted version of manuscript: all authors; Approved the final version of the manuscript on behalf of all authors: Shah, Vadivelu; Study supervision: Abruzzo, Vadivelu.

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