

SAFETY OF CONTRAST ADMINISTRATION IN COMPUTED TOMOGRAPHY ANGIOGRAPHY IN PEDIATRIC CONGENITAL HEART DISEASE: A 9-YEAR SINGLE CENTER COHORT OF 697 EXAMS

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SAFETY OF CONTRAST ADMINISTRATION IN COMPUTED TOMOGRAPHY ANGIOGRAPHY IN PEDIATRIC CONGENITAL HEART DISEASE: A 9-YEAR SINGLE CENTER COHORT OF 697 EXAMS (Abstract): Pediatric cardiovascular congenital disease (CHD) diagnosis benefits greatly from thoracic computed tomography angiography (CTA), with an increasing number of referrals. **The aim** of this study was to evaluate the safety of CTA examinations in pediatric patients with congenital cardiovascular malformations. **Materials and methods:** A 9-year retrospective analysis of pediatric CTA reports was performed. 697 consecutive examinations were included, with recorded data consisting of demographic data of the patient and procedure-related information (cannulation type, site of venous access, type and volume of contrast agents, injection flow rate, dose and adverse events). **Results:** The median patient age was 199 days (interquartile range IQR [15,1714.5]), with a male: female ratio of 1.29. The most frequent peripheral cannulation site was the left antecubital fossa 265 cases (38.02%), and the most frequently used cannula size was 24-gauge (331 cases); a central line was used in 101 cases (14.49%). The flow rates for peripheral and central venous catheters were 0.3 to 5 mL/s, median 1.00, [0.8, 2.0] and 0.5 to 4 mL/s, median 0.9 [0.8, 1.0] respectively. Nine cases of contrast media extravasation (1.29%), four minor allergic reactions (0.6%), two cases of placement of the central venous catheter in the artery (0.29%), one case of air embolus (0.14 %) and one anaphylactic shock (0.14%) were recorded. **Conclusions:** In a single-center cohort of 697 pediatric CTAs for congenital heart disease over 9 years, complication rates related to contrast and venous access were low (extravasation ~1.3%; allergic reactions ~0.6%; anaphylaxis ~0.14%), all resolved favorably. Central line incidents were rare. The results support the safety of contrast administration in pediatric CTA of congenital heart disease, with the recommendation to verify the prescan and standardize protocols. **Keywords:** CONGENITAL HEART DISEASE, CT ANGIOGRAPHY, CONTRAST MEDIA, PEDIATRIC.

INTRODUCTION

CT Angiography (CTA) has become a vital non-invasive diagnostic tool with extremely high clinical value for cardiovascular pathology due to recent advancements in

multidetector CT scanner technology that have enabled faster anatomical coverage and high submillimeter spatial resolution for larger body scan volumes(1, 2).

Formerly considered in the context of

pediatric use due to associated exposure to ionizing radiation, CTA has recently become a robust imaging modality, providing excellent input for pre and post-therapeutic management of congenital heart disease (CHD)(3-6).

Including a broad spectrum of indications, in the context of CHD, CTA mainly focuses on the anatomical mapping of normal and variant cardiac chambers and the great vessel arrangements, proximal and distal pulmonary arteries, the imaging of normal and abnormal venous anatomy, the detailed analysis of coronary vessels (especially important for surgical planning to treat Tetralogy of Fallot (TOF)), congenital or acquired arterial stenosis, and assessment of aortopulmonary collateral arteries in patients with pulmonary atresia(4, 7-10).

Pediatric cardiovascular CT imaging is performed after intravenous contrast medium injection, with multiple techniques available for contrast agent administration(11). The main challenge in CTA for pediatric CHD is the use of small-bore angiocatheters, which sometimes must be placed in unusual and minute access sites to deliver small volumes of contrast medium while obtaining the appropriate vascular enhancement(12-14).

Due to the possibility of contrast extravasation, volume, maximum flow rate, contrast type, and osmolarity (15-17), must be considered. Pediatric patients, especially those with preexisting cardiac dysfunction, have lower tolerance to intravascular fluid changes, which can be triggered if a hyperosmotic contrast medium is provided, so non-ionic, low- or iso-osmotic iodinated contrast material is preferred(18-20) even if it could provide less enhancement(21).

For children undergoing CTA, contrast material is delivered by a power injection

through small peripheral angiocatheters (22-26 gauge) placed in antecubital veins (preferably the right arm, to avoid hardening artifacts in the innominate vein) or in feet, as well as central venous catheters (jugular or femoral). A high viscosity contrast agent increases the pressure associated with intravascular injection, ultimately limiting the maximum injection rate. This can cause failure to obtain the desired flow rate or even catheter failure and extravasation of contrast material with possible vessel injury. The use of power injectors has become the most common method for delivering contrast media for CTA(12, 22-25).

The aim of this study was to evaluate the safety of CTA exams in pediatric patients with congenital cardiovascular malformations. Our hypothesis was that CTA examinations performed in a pediatric congenital cardiovascular population represent a rather safe procedure, with a rate of incidents similar to that in the general population.

MATERIALS AND METHODS

A retrospective review of data collected from computed tomography angiography examinations reports of a single center- a tertiary cardiovascular teaching hospital was performed, following Ethics Committee retrospective approval (5718/08.07.2024), with exemption from informed consent for the file analysis. For minor patients, consent for the medical procedure/imaging was obtained from the legal guardian, in accordance with institutional policy.

Patient and procedural data were collected from consecutively performed CTA. All patients under 18 years of age underwent computed tomography angiography to evaluate cardiovascular anatomy or function between February 2015 and July 2024.

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Examinations were considered and included in the database if they were ordered for a patient with congenital cardiovascular disease to evaluate anatomy or function.

Exclusion criteria included CTA examinations performed for evaluation of non-cardiovascular indication, incomplete demographic or reporting records, and reports mentioning non-diagnostic scans. Acquisition protocols have been developed according to multi-society recommendations, considering the available infrastructure.

Relevant information was collected from radiological records, including patient demographics (age, gender, weight, height, indication), procedure-related data (cannulation type, site of venous access, type and volume of contrast agents used, injection flow rate), and adverse events (erythema, nausea, vomiting, anaphylactic shock) or technical issues (extravasation, line misplacement). Examinations in which any of the above-mentioned data were missing were excluded from the study.

In pediatric cardiac CT imaging using the Mallinckrodt OptiVantage system, it is essential to balance image quality and radiation exposure. For children, 80-100 kVp is typically used to minimize radiation, with mAs adjusted according to the patient's weight: 1-30 mAs for infants and 30-60 mAs for older children. The CARE dose system optimizes the mAs automatically based on body size and anatomical area. Collimation is set tightly around the heart to reduce unnecessary radiation, and the pitch is typically 1.0-1.5, ensuring optimal resolution while maintaining scan speed. ECG gating is used to synchronize the scan with the cardiac cycle, usually capturing the 50%-75% phase to reduce motion artifacts. Contrast is administered at 1.5-2.5 mL/kg of body weight, with concentrations

of 300-370 mg/mL, and followed by 0.5-30 mL saline to flush the contrast from the system. The contrast temperature is maintained at 37°C to prevent reactions and ensure smooth injection. These settings are carefully adjusted to provide high-quality cardiac imaging while minimizing risks, such as radiation exposure and contrast-related issues, especially in pediatric patients.

The flow rate used in each case was established according to the local protocol, depending on the cannula size, ranging from 0.3 mL/s in the case of central lines and 26-gauge cannula up to 5 mL/s in case of large-bore 16-gauge cannula.

The amount of contrast medium used varied depending on the patient's weight and body height ranging from 3 to 100 mL. In all cases, a bolus tracking technique was used, with a threshold of 150 Hounsfield units and a region of interest determined by clinical indication.

Until approximately 2019, none of the patients underwent pre-medication for contrast agent reaction prophylaxis. Starting in that year, all patients capable of receiving oral medication were treated with Medrol 32 mg (in general between 0.5-1 mg/kg) 12 hours before examination and Medrol 32mg + Loratadine 5/10 mg one hour before. If the patients were unable to take oral medication, we replaced each corticoid with 4-8 mg/kg of hydrocortisone IV. Premedication was introduced not only for patients with a history of contrast reactions but also to minimize the risk of adverse reactions, even in the absence of prior tests, given the underlying cardiac conditions of the patients. For those already under treatment, their medication remained unchanged prior to CTA.

Adverse events (AE) were defined as

contrast-related and technical- related.

AE related to contrast included bitter taste, erythema, nausea, vomiting, and anaphylactic shock. To reduce bias, warming sensation and bitter taste were considered physiological and were not included. They were evaluated after contrast administration and up to 24 hours following the examination since all patients were represented by hospitalized patients.

The technical related events were assessed immediately after contrast agent administration. The presence of extravasation of the contrast agent, misplacement of the catheter and air embolus were recorded.

Data normality was evaluated using a Kolmogorov-Smirnov test.

Continuous variables are expressed as mean +/- standard deviation (SD) if data has normal distribution or as median and interquartile range (IQR) if data is skewed.

Comparison of medians was made using Mann-Whitney tests, and correlation strength analysis was assessed using Spearman test.

All statistical calculations were performed using IBM SPSS Statistics 26, with a p-value <0.05 considered statistically significant.

RESULTS

Data from 697 examinations performed at one institution were retrospectively included in the study. The median patient age at the time of the scan was 199.00 days (range: 0 days to 17 years; IQR [15,1714.5]). Females accounted for 44.5% of the study population (n=310), while males were 55.5%, resulting in a male-to-female ratio of 1.29. The median male age was 245 days, IQR [15,2102]; was statistically significantly different ($P = 0.045$) from the median female age, which was

153 days, IQR [15,1097].

The median weight was 6.0 kilograms, IQR [3.4,15], while the median height was 65.00 centimeters, IQR [53,105].

The most common primary indications for the studies were vascular abnormalities - including aortic coarctation, ascending aortic ectasia, and aortic arch hypoplasia — as well as complex congenital heart malformations such as TOF (including double outlet right ventricle), transposition of the great arteries, and total anomalous pulmonary venous return.

Before surgical or interventional treatment, aortic coarctation, complex congenital heart malformations, and TOF accounted for 55.73% of all cases, representing 306 examinations of a total of 549. Following surgical correction, the most frequent indications remained similar, with aortic coarctation, Tetralogy of Fallot, and transposition of the great arteries comprising 60.81% of all cases (90 examinations out of 148).

When using peripheral access, the most frequent cannulation site was the left upper limb antecubital fossa, 265 cases (38.02%) followed by the right upper limb, 242 cases (34.72%). Scalp veins and inferior limb peripheral cannulas were used less frequently, representing less than 12.19% of the total sites (fig. 1).

A central line was used in 101 cases (14.49%), placed in the superior vena cava (72 cases), inferior cava vein tributaries (25 cases) or umbilical veins (4 cases).

Figure 1 illustrates the distribution of venous access sites and the size (gauge) of the devices used in patients. The x-axis indicates the location of the venous access. The y-axis shows the number of patients who received access to that site. The colors within the bars represent the size (gauge) and the type of catheter / cannula used.

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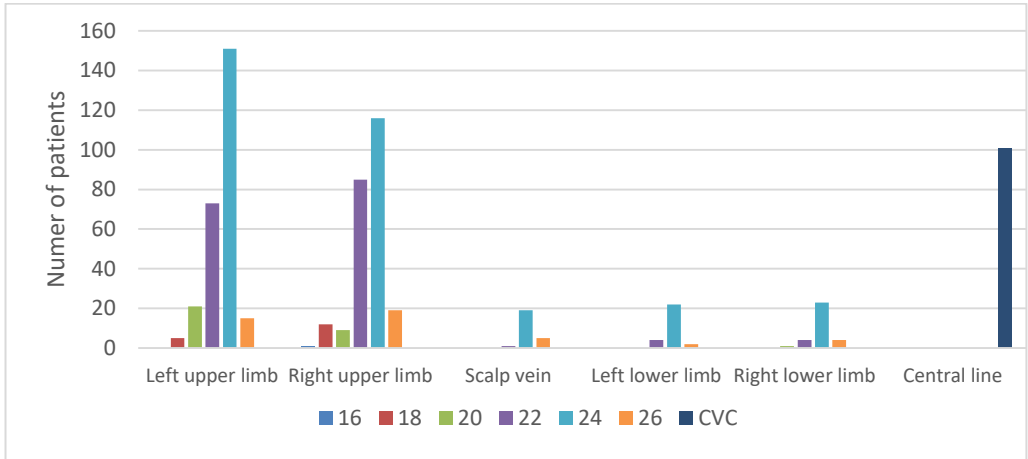


Fig. 1. Venous access sites and size (gauge)

As the gauge number increases (moving from a 16 gauge up to a 26 gauge and then a central line), the median flow rate consistently and significantly decreases, confirming that larger cannulas (lower gauge numbers) permit much higher flow rates. For example, the 18-gauge cannula shows the highest median flow-rate 2.5 and the

largest range, IQR [0.9, 3.5], while the 24- and 26-gauge cannulas have the lowest median flow rate 0.8 and the least variability, IQR [0.8,1.0], demonstrating the critical impact of catheter diameter on intravenous fluid delivery speed. The central line is comparable with 24- and 26-gauge cannulas (fig. 2).

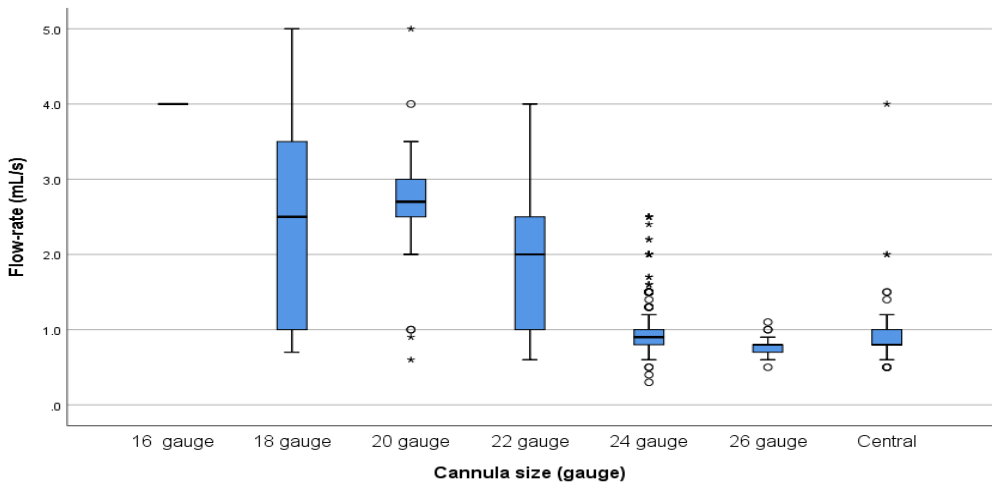


Fig. 2. Relation between flow-rate (mL/s) and cannula size (gauge)

In the second figure the asterisks indicate far out values, the central box repre-

sents the values from the lower to upper quartile (25 to 75 percentile) and the mid-

dle line represents the median. The vertical line extends from the minimum to the maximum value, excluding outside and far-out values, which are displayed as separate points (fig. 2).

Four allergic reactions and an anaphylactic shock with Iodixanol 320 were recorded. All cases are resolved favorably after medical treatment.

With peripheral cannulation, nine cases of subcutaneous extravasation of contrast media occurred (1.29%) with a 95% confi-

dence interval ranging from 0.68%-2.44%. This narrow confidence interval suggests a low and stable rate of extravasation in the study population, indicating that the procedure was performed safely and consistently. They occurred while using 22 to 26 gauge, eight being placed in the upper limb and one in the lower limb, and without connection to the injection flow rate (between 0.6 mL/s and 2.5 mL/s) or the administered media (Iopromide 370, Iomeron 350 and Iodixanol 320) (tab. I).

TABLE I.
Extravasation cases, including injection site, cannula gauge, flow rate, and type of contrast agent used.

Extravasation	Place	Gauge	Flow mL/s	Agent
Extravasation 1	Left upper limb	26 gauge	0.6	Iopromide 370
Extravasation 2	Right lower limb	24 gauge	0.8	Iomeprol 350
Extravasation 3	Left upper limb	22 gauge	0.8	Iomeprol 350
Extravasation 4	Left upper limb	24 gauge	0.8	Iomeprol 350
Extravasation 5	Left upper limb	24 gauge	0.8	Iomeprol 350
Extravasation 6	Left upper limb	24 gauge	1	Iomeprol 350
Extravasation 7	Left upper limb	22 gauge	1	Iomeprol 350
Extravasation 8	Left upper limb	22 gauge	2.3	Iodixanol 320
Extravasation 9	Right upper limb	22 gauge	2.5	Iodixanol 320

The use of central line was not associated with incidents due to contrast medium injection, however, we report two cases of central venous catheter misplacement into the artery, which were detected immediately prior to the exam (2/101= 1.98% with a Wilson CI of 0.55%- 6.98%) and an injection incident, one air embolus (1/101= 1.01% with a Wilson CI of 0.19%-5.43%).

The Mann-Whitney U test showed no significant differences in injection flow rate between examinations with and with-

out extravasation (1.18 mL/s vs 1.31 mL/s, U = 2648.00, p = 0.447), indicating no association between flow rate and extravasation occurrence.

Reactions were evaluated using the ACR-ESUR classification. Three cases of erythema and one case of nausea were observed, both classified as Grade 1 (minor reactions), as they were mild and self-limiting. A case of anaphylactic shock occurred, classified as Grade 3 (severe reaction), requiring immediate medical intervention (tab. II).

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**TABLE II.
Types of injected contrast agents and adverse reactions**

Type of contrast agent	Erythema	Nausea/ Vomiting	Anaphylactic shock	Grand Total Cases
lomeprol 350				387 (55.5%)
loversol 350	1			112 (16%)
lopromide 370	1			122 (17.5%)
Iodixanol 320	1	1	1	76 (10.9%)
Total Number of Reactions	3 (0.45%)	1 (0.14%)	1 (0.14%)	697

Following the implementation of the universal premedication protocol in 2019, a distinct cessation of adverse reactions was observed. While the period between 2015 and 2019 showed an incidence of approximately 1.2 reactions per year, no contrast-

related adverse events were recorded in the study population from 2020 onward. Technical events were in total 12 (12/697=1.72% with a 95% CI 0.75%-2.69%) distributed approximately 1.2/year (fig. 3).

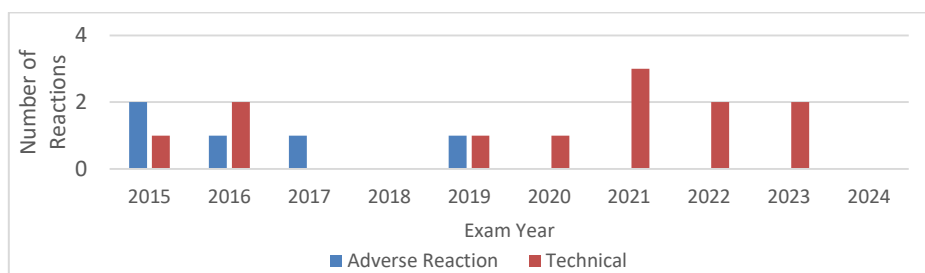


Fig. 3. Total number of incidents per year

Figure 3 presents annual distribution of contrast-related adverse events and technical complications (2015-2024). Technical events occurred at a rate of approximately 1.2 per year. No contrast-related adverse reactions were recorded from 2020 onward, coinciding with the introduction of the universal premedication protocol.

DISCUSSION

Using power injectors with small canulas, especially via non-implanted central venous catheters, is challenging. Catheter type, injection rate, pre-warming, and pressure affect outcomes, and patient factors

must guide decisions.

When the contrast agent was used, tried and adjusted to the size and quality of the vein, neither the extravasation rates nor the contrast reaction frequencies were significantly different from those reported for CT angiography. The extravasation rate was 1.29% (95% CI: 0.68%-2.44%) in our group, 0.36% (95% CI: 0.10%-1.31%) in Amaral et al. and 0.74% (95% CI: 0.47%-1.17%) in Barrera et al. The overlapping 95% CIs (0.68%-2.44%, 0.10%-1.31, 0.47%-1.17) suggest no statistically significant difference between studies. Amaral et al. reported that the risk of extravasation correlated with high

injection rate and pressure. Although, in our examination, the Mann-Whitney U test showed no significant differences in injection flow rate between examinations with and without extravasation (1.18 mL/s vs. 1.31 mL/s, $U = 2648.00$, $p = 0.447$), indicating no association between flow rate and extravasation occurrence (22, 26-30).

Our center's treatment yielded a few minor adverse reactions related to contrast agent (0.6% with a Wilson CI of 0.24%-1.50%) and one anaphylactic shock (0.14% with a Wilson CI of 0.02%-0.80%), when using low-osmolar iodinated contrast media, all which resolved favorably following conservative treatment; in this regard our experience stays in accordance to previously reported data

When speaking about the limitations of the study, one was the relatively small sample size, and all data was collected from a single center. Many examinations were performed under sedation, so some contrast-related incidents may have gone unnoticed. Children may also have difficulty reporting reactions. Due to the retrospective design, only adverse events document-

ed in radiology reports were collected and late complications such as kidney failure or central line infections could not be assessed. Moreover, over the years, the protocol has undergone several modifications; therefore, its heterogeneity may have influenced the results.

CONCLUSIONS

In this nine-year cohort, pediatric congenital heart disease CTA demonstrated low rates of technical and contrast-related complications. Peripheral extravasation was infrequent and self-limited. Central venous access was associated with rare line placement incidents, underscoring the importance of pre-scan verification. Further stratified analyses suggest that universal premedication may contribute to low rates of hypersensitivity. Overall, the procedure is safe for these pediatric CHD patients, as also observed in similar studies (28, 31, 32).

CONFLICT OF INTEREST AND FUNDING

All authors declare no conflict of interest and no funding received.

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