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Contrast Administration in Pediatric Cardiac Catheterization: Dose and Adverse Events

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Abstract

Background—In pediatrics, contrast-related AE such as allergic reactions, seizures, and nephropathy have been reported to occur after cardiac catheterization, but their incidence remains unknown.

Objective—We sought to report adverse event (AE) rates attributed to contrast administration in a pediatric cardiac catheterization lab and identify characteristics related to higher doses.

Methods—A single institution prospective cardiac catheterization AE database identified AE in children <18 years old exposed to contrast. All AE were reviewed and classified by relationship to contrast. Medical records for the 50 cases who received highest contrast doses were retrospectively reviewed for AE. Patient and procedural characteristics were compared in the top quartile of contrast dose versus remaining cases.

Results—Over 3 years, 2,321 consecutive cases required median 3.9 cm³/kg [IQR: 2.0, 6.0] of contrast. Patients receiving high dose contrast (top quartile) were more likely to be <1 year (51% vs. 24%), weigh <10 kg (66% vs. 29%), have complex 2 ventricle disease (56% vs. 35%), be in a high procedure type risk group (57% vs. 26%), and undergo procedures >2 h (67% vs. 28%), all $P < 0.001$. Only 2 of 2,321 cases (0.09%, 95% CI 0.01–0.31%) had AE possibly related to contrast. These events were an acute neurological change and transient nephropathy. In 50 cases receiving the most contrast, no AE were attributed to contrast.

Conclusion—A large volume pediatric cardiac catheterization lab administered 6 cm³/kg of contrast in a quarter of cases; however, AE related to contrast exposure were exceedingly rare.

BACKGROUND

The development of newer, safer, contrast agents, and the advent of more complex interventional catheter procedures has changed the profile of contrast use in pediatric catheterization laboratories. In the earliest era of pediatric catheterization, hyperosmolar

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ionic, contrast agents were associated with arrhythmias, pulmonary edema, hemodynamic alterations, cerebral and renal complications [1–3]. Later in the 1980s nonionic, less hypertonic, contrast agents were widely adopted after demonstrating equivalent angiographic results with less hemodynamic response following contrast administration [4–7]. Using these agents, adverse consequences related to contrast appear uncommon [8–12]. Only small series and individual case descriptions address complications such as seizures and contrast induced nephropathy [13–18]. Thus, we sought to identify contrast related adverse events in a large cohort and for the first time describe the characteristics of patients and procedures receiving higher doses of contrast in a pediatric population.

METHODS

Database Review

Using a prospectively collected catheterization adverse events database initiated in January 2004 for the purposes of quality improvement, all cases performed at Children's Hospital Boston between January 2004 and December 2006 were available for analysis. The start date was chosen based on the initiation time of the database, prior to which insufficient and varied methods of adverse events capture precluded use in data analysis. The data set was limited to children under the age of 18 years at the time of the procedure. Cases not utilizing contrast, and electrophysiology procedures were not included. IRB approval was obtained for this retrospective analysis of the prospectively collected data.

Patient and Procedural Characteristics

Patient characteristics recorded at the time of the procedure included age, weight, and one of five underlying physiological diagnoses (no structural heart disease after heart transplant or cardiomyopathy, isolated defect, pulmonary hypertension, complex two ventricle physiology, or single ventricle physiology). Procedure types were broadly categorized as (1) hemodynamic, if angiography was obtained but no interventions were performed, (2) interventional, if in addition to angiography, an angioplasty, valvuloplasty, or device placement was performed, and (3) biopsy, if no other intervention was performed regardless of whether coronary angiography was obtained. Procedure type risk categories were developed in previous work based on anticipated risk of a high severity adverse event using judgment and empiric methods [8]. Cases were categorized according to the highest procedure type risk category. Duration of case was calculated based on the time vascular access sheaths were placed until removal. Contrast dose was recorded by the catheterization technicians at the time of the procedure for all cases and reported as cm³/kg. Optiray 350® (Mallinkrodt, St Louis, Missouri) contrast was used in all cases.

Adverse Events

It is our practice in the database to record all adverse events. For the purposes of this database, adverse events were defined as including any anticipated or unanticipated event for which injury could have or did occur, potentially or definitely as a consequence of performing the catheterization procedure. Immediately following the case, acute events were recorded by the catheterization fellow. The attending physician recorded any late events at the time of identification, before or after discharge and in follow-up. Symptoms,

interventions, and resolution or follow-up were recorded. Every adverse event description recorded in the database was reviewed for this study and classified as related, possibly related, or not related to contrast administration by two physicians.

Chart Audit

The 50 cases in the cohort with the highest recorded contrast dose in cm³/kg were selected for chart review. Patient medical records, including follow up evaluations in clinic or as an inpatient, were comprehensively reviewed for evidence of any adverse event potentially related to contrast and specifically screened for events such as fever, neurologic events, or nephropathy. The charts were also screened for any blood urea nitrogen (BUN) and creatinine measurements obtained within 30 days pre- and postcatheterization.

Statistical Analysis

Patient and procedural characteristics are reported as frequencies for categorical variables and median with interquartile ranges for continuous variables. Characteristics of cases in the top quartile of contrast dose administration were compared against those in the lower three quartiles combined using χ^2 testing. The proportion of cases experiencing an adverse event definitely or possibly related to contrast was estimated, along with a 95% exact binomial confidence interval. Among cases undergoing chart audit, BUN and creatinine measurements pre- and postcatheterization were compared using the Wilcoxon signed-rank test.

RESULTS

We identified 2,321 hemodynamic, interventional, or biopsy and coronary angiography cases requiring contrast between January 1, 2004 and December 31, 2006. Patient and procedural characteristics are summarized in Table I. The median dose of contrast was 3.9 cm³/kg; 25% of cases were performed with less than 2.0 cm³/kg and 25% of cases required equal to or greater than 6.0 cm³/kg (Fig. 1).

Significant differences emerged when comparing cases in which high dose contrast (top quartile; ≥ 6 cm³/kg) was required to the rest of the cohort (Table II). Patients receiving high dose contrast were younger, age < 1 -year-old (51% vs. 24%), weighed less, < 10 kg (66% vs. 29%) and were more likely to have complex two ventricle physiology (56% vs. 35%), all $P < 0.001$. Procedures involving high dose contrast were more likely to be in a higher procedure type risk group (57% vs. 26%) and to require procedure times greater than 2 h (67% vs. 28%), both $P < 0.001$.

Adverse Events

Two of 650 adverse events documented at the time of the procedure or in follow-up were classified as definitely or possibly related to contrast. These events, occurred in 2 of 2,321 cases (0.09%, 95% CI 0.01–0.31%). The remaining events had no plausible relationship to contrast administration.

Adverse Events Possibly Related to Contrast

A total of three events affecting the central nervous system were recorded and in one of these contrast may have contributed to the event. In this event, a 13-year-old with Tetralogy of Fallot with pulmonary atresia presented for balloon dilation of a right ventricle to pulmonary artery conduit. The procedure was uncomplicated and required 4.1 cm³/kg of contrast. A few hours after the procedure the patient experienced dizziness, slurred speech, and amnesia with a non focal neurological examination. The consulting neurologist concluded the acute neurological changes were likely related to sedation medication effects rather than a transient ischemic attack, cerebrovascular accident, or atypical seizure. Complete resolution of symptoms was observed prior to discharge the next day and brain imaging was not pursued. We included this case as possibly related to contrast since contrast exposure cannot be excluded as a potential etiology for the symptoms observed. In the two other cases involving the central nervous system frontal embolic strokes were confirmed by neuroimaging, and were classified as not related to contrast.

One case of transient nephropathy was also possibly related to contrast administration. A 1-day-old infant who underwent balloon valvotomy for critical pulmonary valve stenosis requiring 4.2 cm³/kg experienced a transient increase in BUN and creatinine after the catheterization. BUN and creatinine peaked at 27 and 1.7 mg/dL, respectively, and normalized over the next 3 days. Other contributing factors to the renal dysfunction may have included gentamicin administration and intravascular fluid depletion on diuretics. One other case of nephropathy was recorded in the database but attributed to hemolysis rather than contrast.

Audit of Highest Dose Contrast Cases

In the 50 cases where the most contrast was administered, the contrast dose ranged from 10.8 to 16.8 cm³/kg. Thirty adverse events related to the catheterization procedure in 20 patients were identified by chart review. All events were recorded in the database. These 30 adverse events included three life threatening events: heart perforation during a pulmonary vein intervention and two cases of high degree heart block requiring resuscitative actions. In one case, aortic valve injury occurred when attempting to cross the valve retrograde on ECMO support, the patient required surgical intervention. Less severe events caused by catheter based interventions included coil embolization or mal-position [4], stent malposition [1], confined tear after balloon angioplasty [3], balloon rupture with air embolus [2], air embolus with angiography [1], pulmonary edema following dilation [3], decrease in oxygen saturation while pulmonary blood flow was transiently obstructed [2], possible clot formation on a catheter [1], and minor access related complications [2]. In one case, systemic hypotension was related to a pulmonary hypertensive event. Arrhythmias, mostly related to catheter manipulation and some occurring spontaneously occurred in six cases.

Of the 50 cases receiving the most contrast, and thus potentially at highest risk of contrast induced nephropathy, ~50% (n = 26) of the cases had pre- and postprocedure BUN and creatinine measured. In these 26 cases, no significant changes between pre and post catheterization renal function occurred. In 17 cases, the patients had normal pre- and postprocedure renal function (precase median BUN 9 mg/dL [2,19] and creatinine 0.4

mg/dL [0.2,0.7], postcase median BUN 7 mg/dL [2,17] and creatinine 0.4 mg/dL [0.2,0.6]). In the other nine cases, patients had elevated BUN, median 33 mg/dL [24,109] and normal creatinine 0.4 mg/dL [0.1,0.6] before the procedure. None of these patients experienced a significant change in BUN or creatinine following the procedure, median BUN 31 mg/dL [18,103] and creatinine 0.4 mg/dL [0.2,0.6]). Among the remaining 24 cases, four cases had precase BUN and creatinine values measured but no postcatheterization evaluation and five cases had a postprocedure measurement but no preprocedure lab value. In the five cases with only postprocedure values, the median BUN was 14 mg/dL [6,17] and creatinine 0.3 mg/dL [0.3, 0.6]. In the final 15 cases no pre or post procedure renal function blood tests were performed.

DISCUSSION

For the first time, we have been able to identify patient factors associated with the use of high contrast doses in a pediatric cardiac population. In an attempt to understand the risks of routinely administered contrast doses, we analyzed adverse events in a prospectively collected single center database and conducted a medical record audit of all patients receiving the highest doses of contrast. Despite the use of contrast doses frequently exceeding 4 cm³/kg we identified only two cases among 2,321 (0.09%) with an adverse event possibly related to contrast administration. Further when we comprehensively reviewed the medical record of 50 patients exposed to the largest doses of contrast (>10 cm³/kg), none of these patients had evidence of an adverse consequence (e.g. allergic reaction, fever, contrast induced nephropathy, or neurologic sequelae). Thirty years ago investigators claimed that up to 5 cm³/kg of ionic, hyperosmolar, contrast could be administered safely in children based on little objective information [3]. At the same time, recommendations and dose guidelines were established and published by the radiology community based solely on operator experience [19]. As noninvasive imaging modalities have largely replaced cardiac angiography for anatomic delineation of congenital heart disease, the role of angiography has evolved substantially. Angiography is now used primarily to guide catheter based interventions and to assess the effect of these interventions. Catheterization procedures may involve multiple angio- grams, in different angles, of a structure, both before and after intervention. In some cases, multiple interventions are performed in the same procedure. Thus, it is easy to understand how large cumulative doses may be administered during a single procedure. Still, however, the pediatric interventional community has not attempted to define the risk of adverse events associated with these doses of contrast in pediatric patients.

In our review of a single institutional practice, we found that patients receiving high contrast doses (top quartile; 6 cm³/kg) were different than those receiving a lower contrast dose in many respects. These patients had more complex cardiac anatomy and underwent higher risk procedures requiring longer procedure times. In many of these cases, multiple interventions were performed and frequently involved pulmonary, systemic, or venous obstructions. Further many of the patients were infants and small children, in whom the contrast dose required for adequate angiography was relatively greater (on a cm³/kg basis) than is needed in older adult patients. Given the need for these relatively high doses of contrast, it is imperative that we identify the risks associated with the practice.

In concert with the development of newer contrast agents for the use in adult procedures, pediatric cardiac catheterization labs moved toward the sole use of non-ionic contrast medium in the 1990s. This change was supported by studies favoring the use of nonionic contrast [4–6]. In a blinded randomized trial in children, Pelech et al., demonstrated significantly less hemodynamic alterations in heart rate, blood pressure, and left ventricle diastolic pressure using a nonionic contrast agent, Omnipaque-350® [6]. Adverse reactions using the newer agent included one severe allergic reaction and two less severe events. The imaging quality was comparable for the two agents. Studies such as these demonstrated a more favorable safety profile for non-ionic, lower osmolar, contrast agents.

According to the manufacturer's package insert of Optiray 350® (Mallinkrodt, St Louis, Missouri), the agent in use at our institution, nausea and headache were the only adverse reactions reported in >1% of 2,098 patients. Other cardiovascular, nervous, respiratory, and skin reactions occurred in less than 1% of the population. Additional unpublished data on 159 pediatric patients undergoing different contrast imaging studies revealed the following adverse events: fever (1.3%), nausea (0.6%), muscle spasm (0.6%), and LV pressure changes (0.6%).

Among adults, contrast induced nephropathy occurs in 3–16% of patients, and higher dose is clearly a risk factor [20,21]. Additional risk factors include hemodynamic factors such as depressed ejection fraction and congestive heart failure, as well as underlying renal insufficiency. The incidence of nephropathy in the pediatric population is unknown. Certainly a subset of pediatric patients presenting for catheterization are likely to have abnormal renal perfusion in the face of the hemodynamics associated with their anatomic defect. Another subset of patients may be at risk due to chronic cyanosis, which has been shown to alter renal tubular function [15–18]. Fortunately, clinically evident renal insufficiency is relatively rare in the pediatric population. In our study group, with a significant proportion of single ventricle patients (27%) as well as physiologically vulnerable circulations (29%) only one infant had transient renal insufficiency possibly related to contrast. In the 50 cases exposed to the most contrast, and therefore potentially exposed to the most risk, no cases of contrast induced nephropathy were identified even in those with impaired baseline renal function.

The occurrence of a single neurological event that may have been related to contrast raises the issue of central nervous system toxicity. Most reported neurological events, both in pediatrics and adult practice, have been attributed to emboli/ischemia [22]. In 2001, Liu et al., reported on neurologic complications in pediatric cardiac catheterization and found a 0.38% incidence, with the majority of events attributed to cerebral embolism or low cardiac output [23]. However, two recently published cases, neither of which is included in our study, reported contrast retention in the central nervous system following work-up for post catheterization seizures [13,14]. In both cases, the findings were transient and no permanent harm was observed. Although the mechanism is not clear, the neurotoxicity of contrast is implicated, thus, contrast must be considered as a potential etiology for seizures following catheterization, particularly nonfocal or partial-complex seizures.

Limitations

This retrospective review supports the premise that clinically important adverse sequelae related to non-ionic contrast administration are exceedingly rare in pediatrics. However, the study bears a number of inherent limitations. First, the database was not designed specifically for the prospective collection of adverse events related to contrast administration. Thus, some known potential adverse effects of contrast, such as transient hemodynamic alterations, nausea, and fever were not captured. Second, renal function was not routinely monitored following catheterization procedures and both asymptomatic and mildly symptomatic cases of contrast induced nephropathy would not have been identified. But perhaps most importantly, since the time period was limited to 3 years, we do not capture rare, but potentially serious adverse events that may be revealed in a longer time frame. Prior to this time period, insufficient and different methods of adverse event capture limit the scope of data available for analysis. Despite these limitations, the chart review did not identify any contrast dose related adverse events in those children having received the highest contrast doses suggesting that important adverse events related to high contrast dose were not overlooked in this cohort.

CONCLUSIONS

The amount of contrast that can be safely administered to children undergoing cardiac catheterization has not been determined. Reassuringly, even in a large cohort where one quarter of patients received contrast doses exceeding 6 cm³/kg, adverse events related to contrast were exceedingly rare. This is important since dose will limit an operator's ability to obtain adequate diagnostic studies in patients with abnormal anatomy and perform complex therapeutic interventions requiring repeated angiography during cardiac catheterization in the pediatric population. However, we acknowledge that there are potential costs to higher dose contrast administration such as hemodynamic changes, contrast induced nephropathy, and neurologic sequelae. Thus, we continue to recommend administering the minimum contrast dose necessary to successfully complete the case, and only using high dose contrast where the potential risk of additional contrast is superseded by the need for repeated angiography. Modern studies focused on determining a threshold dose for safe contrast administration and on the identification of high risk populations are needed in congenital cardiac catheterization.

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Fig. 1. Contrast dose in cm3/kg versus the number of cases, with number of patients annotated and the arrow separating the top quartile of contrast administration (n = 580).

TABLE I.

Patient and Procedure Characteristics

Patient and procedure characteristics	Number (percent) or median [interquartile range]
Age	
Less than 1 year	713 (31)
1–10 years	1,121 (48)
11–18 years	487 (21)
Weight	
Less than 4 kg	256 (11)
4–9 kg	634 (27)
Greater than or equal to 10 kg	1,431 (62)
Underlying diagnosis	
No structural heart disease	254 (11)
Isolated defects	460 (20)
Pulmonary hypertension	47 (2)
Complex two ventricle physiology	936 (40)
Single ventricle physiology	619 (27)
Type of procedure	
Hemodynamic catheterization	544 (23)
Interventional catheterization	1,618 (70)
Biopsy and coronary angiography	159 (7)
Highest procedure risk group	
1	1,534 (66)
2	422 (18)
3	355 (15)
Duration of case (hours)	
Less than 1	384 (17)
1–1.9	985 (44)
2–2.9	536 (24)
Greater than or equal to 3	311 (14)
Contrast—weight-based dose (cm ³ /kg)	3.9 [2.0;6.0]

TABLE II.

Contrast Dose Relationship to Differences in Patient and Procedural Characteristics

Patient and procedural characteristics	Number (percent)		P-value
	Low dose contrast < 6 cm ³ /kg (n = 1,741)	High dose contrast ≥ 6 cm ³ /kg (n = 580)	
Age			<0.001
Less than 1 year	417 (24)	296 (51)	
1–10 years	851 (49)	270 (47)	
11–18 years	473 (27)	14 (2)	
Weight			<0.001
Less than 4 kg	151 (9)	105 (18)	
4–9 kg	359 (21)	275 (47)	
Greater than or equal to 10 kg	1,231 (71)	200 (34)	
Underlying diagnosis			<0.001
No structural heart disease	251 (14)	3 (1)	
Isolated defects	415 (24)	45 (8)	
Pulmonary hypertension	45 (3)	2 (0)	
Complex two ventricle physiology	611 (35)	325 (56)	
Single ventricle physiology	415 (24)	204 (35)	
Type of Procedure			<0.001
Hemodynamic catheterization	455 (26)	89 (15)	
Interventional catheterization	1,127 (65)	491 (85)	
Biopsy and coronary angiography	159 (9)	0 (0)	
Highest procedure risk group			<0.001
1	1,284 (74)	250 (43)	
2	269 (16)	153 (27)	
3	179 (10)	176 (30)	
Duration of Case (hours)			<0.001
Less than 1	365 (22)	19 (3)	
1–1.9	822 (50)	164 (30)	
2–2.9	334 (20)	202 (36)	
Greater than or equal to 3	140 (8)	171 (31)	