

PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Quality Metrics in Cardiac Catheterization for Congenital Heart Disease: Utility of 30-Day Mortality

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Objectives: To characterize the frequency and attributability of death among patients who died within 30 days of their cardiac catheterization (30-day mortality). **Background:** 30-day postprocedure mortality is commonly used as a quality outcome metric in national cardiac catheterization registries. It is unclear if this parameter is sufficiently specific to meaningfully capture mortality attributable to cardiac catheterization in patients with congenital heart disease (CHD). **Methods:** Multicenter cohort study with 3 participating centers. Records were retrospectively reviewed for patients who died within 30 days of catheterization (06/2007–06/2012). Attributability of death was assigned to each case. **Results:** A total of 14,707 cardiac catheterization procedures were performed during the study period. Death occurred within 30 days in 279/14,707 (1.9%) of cases. Among the patients who died, 53% of cases were emergent or urgent cases. The median age was 4 mos (1 day–45 years). Death was attributable to the catheterization procedure in 29/279 (10%) of cases. Death was attributable to cardiac surgery in 14%, precatheterization clinical status in 34%, postcatheterization clinical status in 22%, and noncardiac comorbidity in 19%. In 1%, death attributability could not be established. **Conclusions:** While valuable in adult settings, 30-day mortality is inadequate as a quality metric among patients with CHD undergoing cardiac catheterization. To derive the optimal benefit from catheterization registry data, more robust methodologies to capture procedure-related mortality are needed. © 2014 Wiley Periodicals, Inc.

Key words: PEDS; CATH; pediatric interventions; complications; quality

INTRODUCTION

As the indications and use of catheter-based procedures in pediatric cardiology continues to increase, the development of meaningful and interpretable quality indicators becomes paramount [1–3]. In adult cardiac catheterization, death within 30 days following cardiac catheterization (30-day mortality) is a well-accepted marker for the quality of care provided by individual physicians and centers [4]. Similarly, in pediatric cardiac catheterization, national cardiac catheterization registries have used 30-day mortality in quality care assessment [5]. However, among pediatric patients, where one care process is linked with and dependent on the outcomes of prior care processes (i.e., previous surgical intervention) the efficacy of 30-day mortality

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Conflict of interest: Lisa Bergersen, Jack Rome, and Ralf Holzer are members of the IMPACT registry steering committee. Andy Glatz is a member of the R&P committee.

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Received 23 April 2014; Revision accepted 19 September 2014

DOI: 10.1002/ccd.25683

Published online 26 September 2014 in Wiley Online Library (wileyonlinelibrary.com)

as a quality metric in pediatric cardiac catheterization remains unknown.

In an effort to appropriately characterize adverse events in pediatric cardiac catheterization, including attributability of those events, a rigorous assessment of 30-day mortality as quality metric in pediatric interventional cardiology is needed. This study is the first to explore the utility of this quality metric in the field of pediatric cardiology.

Specific Aims and Objectives

Primary Aim. To characterize the frequency and attributability of death among patients who died within 30 days of their cardiac catheterization (30-day mortality).

Secondary Aim. To describe patient and procedural characteristics among catheterizations attributable to the death of the patient.

MATERIALS AND METHODS

Data were retrospectively collected by three academic institutions with pediatric cardiac interventional programs. All physicians participating in this study reviewed and approved the content of this manuscript. All variables were collected into an Access Database that was password-protected and maintained at each institution. Patient information was then deidentified and combined into a single database for the purposes of this manuscript.

Inclusion and Exclusion Criteria

All patients with congenital or acquired heart disease who died within 30 days of cardiac catheterization, regardless of cause, over a 5-year study period (June 2007 to June 2012) were eligible for inclusion. Cases were not eligible if cardiac surgery and cardiac catheterization were performed in the same procedure (Hybrid procedure) or if the catheterization procedure was performed outside the catheterization laboratory.

Data Collected

The data reviewed included surgical and catheterization reports, clinical charts, and autopsy records. Patient and procedural characteristics included admission status (urgent/emergent vs. elective), if the procedure was performed on extracorporeal membrane oxygenation (ECMO) or inotropic support (milrinone, norepinephrine, vasopressin, dopamine, dobutamine, and epinephrine), the types of procedure performed (diagnostic-only, balloon angioplasty/stent, device coil/occlusion, pulmonary or aortic valvuloplasty, or atrial

septum dilation/stent) and the procedural type risk group (Level 1–4), according to previous work by Bergersen et al. [6] The timing of cardiac surgery (if applicable), relative to the cardiac catheterization, was reviewed and a description of adverse events during the surgery was recorded. The collected data also included the number of days between cardiac catheterization and death (0–30).

Following review of the patient's medical and autopsy record, the primary cause of the patient's death (attributability) was assigned. Death attributability categories, with corresponding examples for each category, were defined as follows:

- **Cardiac catheterization:** Cardiac catheterization was the main factor leading to death of a patient (e.g., an infant with tetralogy of Fallot/pulmonary atresia who underwent pulmonary artery balloon angioplasty resulting in vessel perforation, massive bleeding, and death in catheterization suite).
- **Cardiac surgery:** Cardiac surgery was the main factor leading to death of a patient (e.g., an infant with d-transposition of the great arteries with intact ventricular septum who underwent primary arterial switch operation and developed postoperative LV failure requiring ECMO, with catheterization being performed for hemodynamic evaluation).
- **Precatheterization cardiac status:** A patient who was moribund prior to catheterization with very little chance of survival and died of the underlying disease unrelated to the catheterization procedure (e.g., an infant with obstructed, supracardiac total anomalous pulmonary venous return and intact atrial septum who was admitted to the catheterization laboratory with severe acidosis (pH of 6.6) and subsequently died following balloon atrial septostomy [without any catheter related injury]).
- **Postcatheterization cardiac status:** A postprocedural deterioration of cardiac function not directly related to cardiac catheterization or cardiac surgery resulting in death of the patient (e.g., an patient with cardiomyopathy and poor cardiac function who had been "chronically stable" but who's cardiac function deteriorated within 30 days following a routine biopsy, resulting in death of the patient).
- **Noncardiac comorbidity:** A noncardiac comorbidity was the main cause of death (e.g., an infant with congenital diaphragmatic hernia who underwent hemodynamic catheterization and died at day of life 24 in the pediatric intensive care unit following surgical repair of the diaphragmatic hernia).
- **Other/unknown attributability:** No clear cause of death could be established after reviewing the medical chart.

TABLE I. Basic Demographic and Clinical Data

	Overall	Death attributability		P-value
		Cath	Non Cath	
Number (N)	279	29	250	
Age (months)	4 (0–556)	4 (0–45)	4 (0–556)	0.26
Weight (kg)	4.5 (1.2–133.5)	4.5 (1.2–82)	4.6 (1.2–133.45)	0.17
Diagnosis, N (%)				
Single ventricle,	117 (42)	15 (52)	102 (41)	0.72
Complex 2 ventricle	98 (35)	8 (28)	90 (36)	
Isolated defects	20 (7)	2 (7)	18 (7)	
Normal-structure heart	44 (16)	4 (14)	40 (16)	
Antecedent procedure(s) within 30 d, n (%)				
Cardiac surgery	106 (38)	10 (34)	93 (37)	0.34
Cardiac catheterization	78 (28)	5 (17)	68 (27)	
Cardiac surgery + catheterization	44 (16)	1 (3)	38 (15)	

The attributability assignment was initially performed by two local investigators, including one pediatric cardiologist or noninterventionalist. Differences in the categorization of death attributability between the local-investigators were resolved by reviewing the events surrounding the patient's death with a third investigator (independent cardiologist) and the final determination was agreed on by consensus.

Statistical Methods

Descriptive patient and case characteristics were calculated for all cases. Median and range were calculated for all continuous variables and frequency with percentages for categorical variables. Patient and case characteristics among cardiac catheterizations directly attributable to the death of the patient, relative to those attributable to other causes (surgery, pre/post cardiac status, noncardiac morbidity) were compared. For categorical variables, comparison between two groups was done using Pearson's Chi-square test or Fisher's exact test if there were cells with counts less than 5. For continuous variables, the Mann-Whitney test was used. All tests were performed at $\alpha < 0.05$.

RESULTS

Demographic, Clinical, and Procedural Data

A total of 14,707 cardiac catheterization procedures were performed during the study period; 279 patients died within 30 days of cardiac catheterization (1.9%). Basic clinical and demographic data among cases are shown in Table I. Among patients who died, the median weight at the time of catheterization was 4.5 kg (range, 1.2–133.5 kg). The median age at the time of death was 4 months (range 1 day–45 years). The median interval between cardiac catheterization and death was 9 days (0–30 days; mean \pm SD = 11.2 \pm 9.0 days). We observed no differences in the age at the time of

death between the 3 participating institutions. The underlying physiologic diagnosis was single ventricle in 117 (42%), complex 2-ventricle in 98 (35%), isolated cardiac defect in 20 (7%), and structurally normal heart (i.e., cardiomyopathy) in 44 (16%). Recent cardiac procedures performed within 30 days preceding cardiac catheterization included cardiac surgery in 106 (38%), cardiac catheterization in 78 (28%), or both in 44 (16%).

We observed no significant differences in the incidence of antecedent cardiac surgery, cardiac catheterization, or both among cases where death was attributed to cardiac catheterization compared to cases where death was attributed to other causes ($P = 0.34$). Equally, there was no significant difference in the underlying diagnosis between those two groups ($P = 0.72$, Table I).

Cardiac Catheterization Details

Procedural data are shown in Table II. The majority of cases were performed urgently or emergently ($n = 147$, 53%), while 132 (47%) were performed electively. A total of 91 (32%) patients arrived to the catheterization laboratory on inotropic support. Seventy-three (26%) required ECMO support during their hospitalization. The median procedure time was 55 min (5–423 min). Procedures performed in the catheterization laboratory included exclusively diagnostic procedures in 102 (37%), balloon angioplasty or stent placement in 32 (11%), device or vascular occlusions in 91 (32%), balloon valvuloplasty in 19 (7%), atrial septum dilation or stent placement in 10 (4%), and other/multiple interventions in 25 (9%). The procedures type risk group was level 1 in 42 (15%), level 2 in 76 (27%), level 3 in 92 (33%), and level 4 in 66 (24%). Three patients (1%) were not assigned a procedure level risk group due to incomplete medical records.

TABLE II. Procedural Data

Case type number (N)	N = 279 N (%)	Death attributability		P-value
		Cath = 29 N (%)	Non Cath = 250 N (%)	
Admission status				<0.001
Urgent/emergent	147 (53)	24 (83)	123 (49)	
Elective	132 (47)	5 (17)	127 (51)	
Inotropic support (at start)	91 (32)	10 (34)	81 (32)	0.81
ECMO during hospitalization	73 (26)	8 (28)	65 (26)	0.84
Procedure time (min) ^a	55 (5–423)	74 (58–301)	32 (5–423)	<0.01
Procedures performed				
Diagnostic only	102 (37)	5 (17)	97 (39)	<0.001
Balloon angioplasty/stent	32 (11)	7 (24)	25 (10)	
Device/coil occlusion	91 (32)	5 (17)	86 (34)	
Valvuloplasty	19 (7)	1 (3)	18 (7)	
Atrial septal dilation/stent	10 (4)	8 (28)	2 (1)	
Other/multiple intervent.	25 (9)	2 (7)	23 (9)	
Procedure type risk group				0.02
Level 1	42 (15)	1 (3)	41 (16)	
Level 2	76 (27)	7 (24)	69 (28)	
Level 3	92 (33)	10 (34)	82 (33)	
Level 4	66 (24)	11 (38)	55 (22)	
Unassigned	3 (1)	0 (0)	3 (1)	

^aMedian (range).

Death Attributability by Procedure Type

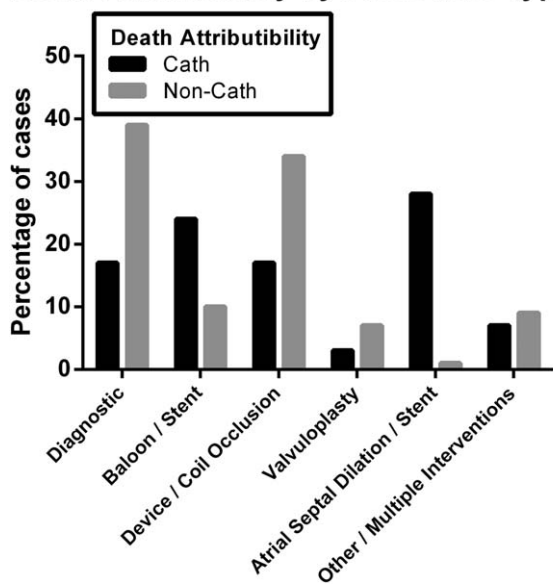


Fig. 1. Percentage of deaths attributed to catheterization and noncatheterization based on type of procedure performed.

Deaths attributed to the catheterization were more likely to be urgent or emergent, compared with noncatheterization attributable deaths (83% vs. 49%, $P < 0.001$). No differences were observed in the need for inotropic support or ECMO support. The overall procedure time was longer among cases where death was attributed to the cardiac catheterization, compared

Death Attributability by Procedure Risk

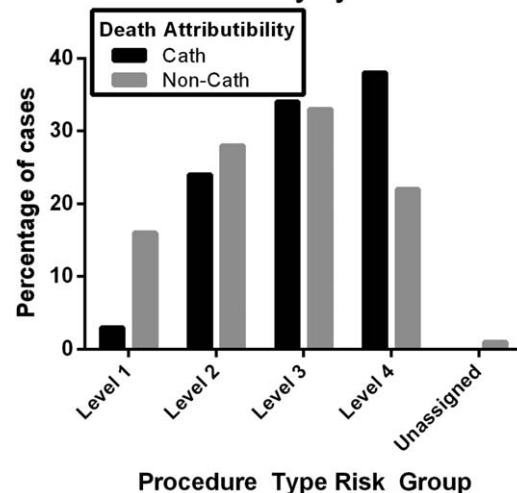


Fig. 2. Percentage of deaths attributed to catheterization and noncatheterization based on procedure-type risk group.

with cases where death was attributed to other causes (74 min vs. 32 min, $P < 0.01$).

Deaths attributed to the cardiac catheterization (Fig. 1) had a lower proportion of purely diagnostic cases, a lower proportion of device/coil occlusion cases, and a higher proportion of interventions at the atrial septum ($P < 0.001$). Among the eight cases where death was attributed to cardiac catheterization on the atrial septum, all involved either transcatheter atrial septoplasty due to cyanosis at birth ($n = 5$) in

neonates with single ventricle physiology or atrial septostomy as palliative therapy for refractory pulmonary hypertension ($n=3$). There was also a significant difference in the relative frequency of procedure type risk groups between deaths attributed to the cardiac catheterization compared to noncatheterization attributable deaths ($P=0.02$). A lower procedure-type risk group of level 1 accounted for just 3% of cases where death was attributed to the cardiac catheterization, but as much as 16% of noncatheterization attributable deaths. Similarly, a high procedure-type risk group of level 4 accounted for 38% of cases where death was attributed to the cardiac catheterization, but only 22% of noncatheterization attributable deaths (Fig. 2).

Death Attributability

Death attributability data are shown in Figure 3. Among the 279 patients who died within 30 days of their

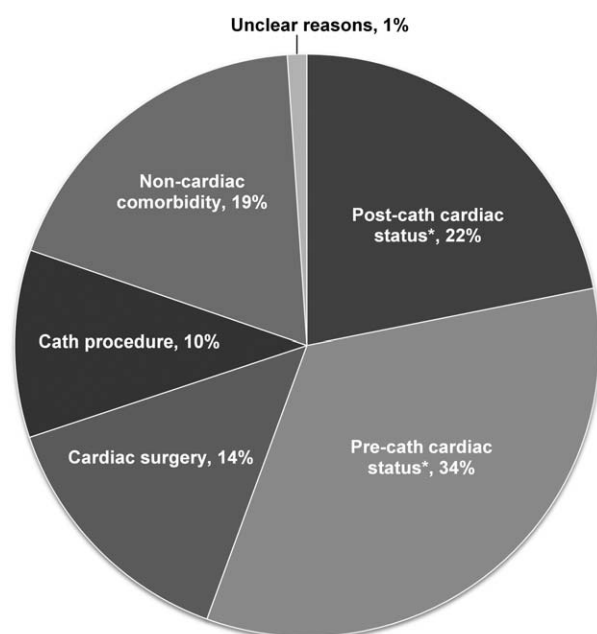


Fig. 3. Death attribution percentages for the entire cohort.

cardiac catheterization, death was likely or probably attributable to the catheterization procedure in 29 cases (10%), cardiac surgery in 40 (14%), precatheterization cardiac morbidity (unrelated to catheterization) in 94 (34%), postprocedure cardiac morbidity (unrelated to catheterization) in 61 (22%), noncardiac morbidity in 52 (19%), and to other or unknown factors in 3 cases (1%).

Among the 29 cases where death was attributed to the cardiac catheterization, the complication resulting in death included: primary arrhythmias ($n=3$), cardiac arrest ($n=6$), vascular or cardiac trauma ($n=9$), device-related problems ($n=1$), neurologic injury ($n=2$), and other AE or hemodynamic compromise within 24 hr following the procedure ($n=8$). Among the deaths attributed to the cardiac catheterization, almost half died in the catheterization laboratory (13/29, 45%). We observed no significant differences between the three centers in the assignment of death attributability (Table III, $P=0.71$), including those catheterizations resulting in the death of the patient (11% vs. 9% vs. 15%, Fig. 4).

DISCUSSION

This study found that, in the field of pediatric interventional cardiology, using 30-day mortality as a marker for quality of care fails to adequately characterize the unique complexity of the pediatric heart patient, wherein outcomes are intimately tied to previous complications or morbidities [7]. Almost half of the deaths were attributed to the patients' cardiac status (34%) or recent cardiac surgery (14%) prior to the cardiac catheterization. This reflects very common practice in pediatric cardiology, that most patients that have shown an unexpected clinical deterioration and/or are very sick usually undergo cardiac catheterization as a diagnostic or therapeutic measure, irrespective of the overall prognosis. This is related to the fact that very often, structural anomalies are identified that are amenable to transcatheter intervention [8], or a hemodynamic assessment is required, including the workup for cardiac transplantation. The prognosis of

TABLE III. Death Attributability

	Overall	Center			P-value
		Center A	Center B	Center C	
Death attributability [n (%)]					0.71
Cardiac catheterization	29 (10)	14 (11)	10 (9)	5 (15)	
Cardiac surgery	40 (14)	23 (17)	14 (12)	3 (9)	
Precath cardiac status ^a	94 (34)	45 (34)	34 (30)	15 (45)	
Postcath cardiac status ^a	61 (22)	25 (19)	31 (27)	5 (15)	
Noncardiac comorbidity	52 (19)	24 (18)	23 (20)	5 (15)	
Unknown	3 (1)	1 (1)	2 (2)	0 (0)	

^aDeath not directly related to cardiac catheterization or cardiac surgery.

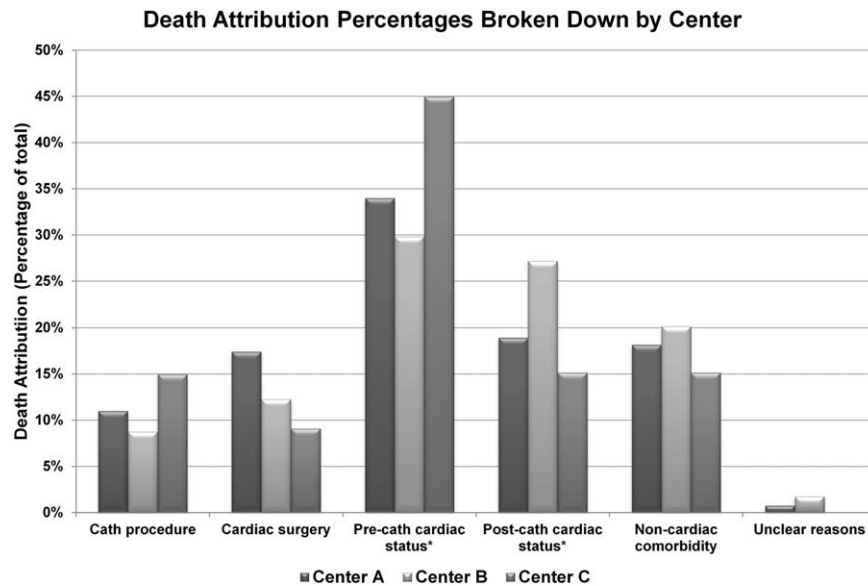


Fig. 4. Comparison of death attribution percentages for the study cohort by participating center.

these patients however remains poor, irrespective of any catheter-related adverse event.

Importantly, an overwhelming majority of the cardiac catheterization cases resulting in the death of the patient were considered nonelective or emergent. While there are risks in any cardiac catheterization, previous authors have shown that emergent cases are associated with greater morbidity and mortality, particularly those following surgery [8]. Thus, our finding that 54% of patients who died following cardiac catheterization had cardiac surgery within the previous 30 days is noteworthy.

Previous investigators have also shown that procedure type risk categories [1–4] are associated with different rates of adverse events, and have been shown to represent important variables in risk-adjustment models in pediatric cardiac catheterization [9]. As expected, among cardiac catheterizations attributed to the death of the patient, the procedure risk category was high risk (level 3 or 4) in 72% of cases. Thus, this study further confirms higher procedure type risk group to be associated with clinically significant adverse events.

The percentage of cases with level 3 or level 4 procedure type risk group was lower (55%) for those cases where death was not attributed to cardiac catheterization, but to other factors, which suggests that for those cases, the procedure performed in the catheterization laboratory may indeed be a less important factor in relation to death of the patient.

LIMITATIONS

While the multicenter study design and the development of a consistent system to effectively determine

the primary cause of death among our patients aided our data analysis, we recognize the potential bias involved in the assignment of death attributability. To address that issue, reviewers had to independently agree on the primary cause of death. In cases of disagreement, an independent cardiologist was included until consensus was reached. We observed no differences between the three academic institutions in the assignment of death attributability. We believe this reflects the consistent manner we used to categorize the primary cause of death, even though it is conceivable that for selected cases death attributability may have been assigned differently by other physicians. Although the catheterization procedure was not the primary cause of mortality in most cases, we recognize that outcomes are intimately tied to a variety of variables [7], and that any adverse event(s) related to the catheterization may contribute (directly or indirectly) to worsened clinical outcomes.

Although categorization of admission status (urgent/emergent vs. elective) was based on previously described criteria [10], we recognize the potential for bias in this determination. As expected in multicenter collaborations, hospital-specific differences in medical record keeping may limit the robustness of data acquisition. We also recognize that this is a retrospective study and our ability to draw cause-effect conclusions from the data is limited. Finally, the participating centers in the present study represent tertiary referral centers, and as such this study may not reflect practice at regional hospitals. Therefore, the applicability of our findings to all pediatric hospitals with cardiac catheterization programs is unknown.

CONCLUSION

While valuable in adult settings, unadjusted 30 day mortality is inadequate as a quality metric among patients with CHD undergoing cardiac catheterization. To derive the optimal benefit from catheterization laboratory registry data it will be important to develop and implement more robust methodologies to capture procedure-related mortality.

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