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Relationship Between Procedural Adverse Events Associated With Cardiac Catheterization for Congenital Heart Disease and Operator Factors: Results of a Multi-Institutional Registry (C3PO)

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Background: Data examining the effect of operator years in practice and volume on adverse events (AE) after cardiac catheterization in patients with congenital heart disease is limited. Methods and Results: Data were prospectively collected using a multicenter registry (C3PO). 10,885 catheterizations performed between 02/07 and 06/10 at eight institutions were included. AE rates were risk-adjusted for hemodynamic vulnerability, procedure type risk group, and age and compared between operators with different years in practice (YIP) and volume. AE occurred in 13% of procedures. Operators with less than five YIP had higher adjusted odds of any AE (OR 1.42, 95% CI 1.14–1.77) or a high severity AE (OR 1.35, 95% CI 1.04–1.75), when compared with operators with 5 to less than 25 YIP (5<25), while operators with ≥25 YIP had higher odds of a high severity (but not any) AE (OR 1.39, 95% CI 1.08–1.80). Operators with <5 YIP had a higher percentage of preventable AE (out of all AE, 16% vs. 8%, $P<0.001$) as well as higher odds of vascular or cardiac trauma (OR 1.81, 95% CI 1.11–2.97), or technical AE (OR 1.98, 95% CI 1.31–2.99) when compared with operators with 5<25 YIP. There was no consistent relationship between operator volume, and incidence of AE. Conclusions: Operators with less than 5 years in practice have higher risk-adjusted AE rates. While an important consideration in guiding and mentoring operators with fewer years in practice, it is important to emphasize that reporting adverse events does not take into account procedural efficacy. © 2013 Wiley Periodicals, Inc.

Key words: congenital heart disease; operator years in practice; cardiac catheterization; adverse events

INTRODUCTION

Operators and hospitals constantly strive to improve outcomes of children born with congenital heart disease. Prospective registries such as C3PO, CCISC and IMPACT are being used to collect outcome data on patients undergoing catheter-based interventions for congenital cardiac lesions [1–3]. Comparing results that are adjusted for risk is an important tool to facilitate this quality improvement process. Bergersen et al. recently reported on the Congenital Cardiac Catheterizations Outcome Project (C3PO), a multicenter registry prospectively collecting outcome data on a variety of cardiac catheterization procedures [1]. As part of this registry, the "Catheterization for Congenital Heart Disease Adjustment for Risk Method" (CHARM) was

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developed [4], with its main purpose being to adjust for differences in risk based on patient characteristics, or as a consequence of performing different types of procedures. The CHARM model therefore included procedure type risk category [5], age, as well hemodynamic vulnerability criteria to risk adjust and facilitate comparison of adverse event rates between operators and institutions.

Through population and procedure based risk adjustment, the CHARM model has provided the prerequisite to evaluate for other important factors that may have an effect on the incidence of adverse events, such as operator years in practice, operator volume, and hospital volume. However, even though the importance of operator years in practice, operator volume, and hospital volume on procedural outcome has been documented for a variety of medical specialties, including percutaneous coronary interventions [6], no studies have so far comprehensively evaluated the effect of these parameters in the realm of congenital cardiac interventions. The only report on this topic thus far presents limited data from the C3PO registry on pulmonary artery rehabilitation, suggesting that operator years in practice may indeed have a relationship with the incidence of procedure-related adverse events [7]. This study therefore was designed to evaluate the effect of operator experience and case volume on the incidence of adverse events in congenital cardiac catheterization. In particular, the study thought to identify whether operators with less than 5 years in practice have a higher incidence of risk-adjusted adverse events.

METHODS

Data were prospectively collected using the "Congenital Cardiac Catheterization Outcomes Project" (C3PO), a multi-institutional interventional registry with eight participating institutions. Details pertaining to registry design have recently been reported by Bergersen et al. [1]. All physicians participating in the C3PO registry reviewed and approved the content of this manuscript.

Inclusion and Exclusion Criteria

All biopsies, diagnostic, or interventional cases performed between 02/2007 and 06/2010 were primarily eligible for inclusion in this study. Interventional cases included balloon angioplasty or stent implantation, balloon valvuloplasty, septostomy/septoplasty, as well as device placements.

Exclusion criteria were the following:

1. Cases that were not classified as either biopsy, diagnostic, or interventional case, such as hybrid procedures, isolated thoracocentesis, primary electrophysiology procedures, and procedures performed outside the catheterization laboratory.
2. Operators with a case volume averaging less than 20 cases per year (2 operators), which was chosen to avoid the possibility that one or two cases influence the overall results for a particular operator. Adverse events are not necessarily occurring equally distributed for each operator, and an operator with a low case volume may just have one or two "extra" cases with adverse events during the study period that would in long-term observations not affect the overall adverse event rate.
3. Operators with a high percentage of biopsies, as this manuscript was intended to focus on interventional cardiologists, rather than transplant physicians that perform mainly biopsies. It was felt that diluting the potential impact of operator volume by including a low-risk high volume procedure, may prevent identifying an important impact of operator volume. Four operators had a percentage of biopsies of 95% or above (all of which were excluded), while the next highest percentage in any operator was 64% of biopsies (this operator was included in the analysis).
4. Cases with no assigned procedure type risk group, as this would prevent appropriate risk adjustment.

Data Collected

Data collected for this study included case-type, admission type, procedural data (procedure date, procedure performed, fluoroscopy time), as well as adverse event (AE) data. C3PO captured data on any adverse event occurring during the procedure, or later, if determined to be related to the procedure. C3PO was not designed as a longitudinal registry and as such does not include long-term outcome data. Adverse events included not only direct procedure-related adverse events, such as technical adverse events, arrhythmias, vascular trauma, or cardiac trauma, but also sedation, anesthesia, or airway-related adverse events and other adverse events such as equipment or X-ray malfunction. Each AE was assigned a severity category from 1 to 5 (none, minor, moderate, major, catastrophic) and preventability designation (not preventable, possibly preventable, preventable), as defined in the International Pediatric Congenital Cardiology Code nomenclature [8] (Supporting Information Tables S1 and S2). Severity level 3–5 adverse events were classified as high severity adverse events (HSAE). All AE were reviewed in a nonblinded fashion by two interventional cardiologists not involved in the case for appropriate and consistent application of seriousness and preventability criteria and where necessary adjusted. This

review was conducted in collaboration, and consensus was sought with the interventional cardiologists when clarification or disagreements required resolving.

Operators were asked to provide the month and year of commencing the first appointment as an independent operator (post fellowship) and years in practice were calculated by using the difference between this date and the procedure date for each individual procedure. Operator volume was calculated using the overall caseload for the entire study period, and deriving a yearly average for each operator.

To facilitate risk adjustment, parameters that have previously been identified within the "Catheterization for congenital heart disease adjustment for risk method (CHARM)" [4] were included in the data collection. These variables were age (below/above 1 year), procedure type risk group (Supporting Information Table S3) [5], as well as hemodynamic vulnerability score [4]. The hemodynamic vulnerability score was calculated based on the number of hemodynamic risk factors present (0, 1, or $\geq$2), as described in the CHARM method, which included threshold values for systemic ventricle enddiastolic pressure ($\geq$18 mm Hg), pulmonary artery pressure (2-ventricle: systolic $\geq$45 mm Hg, single ventricle: mean $\geq$17 mm Hg), systemic saturations (2-ventricle: $<$95%, single ventricle $<$78%), and mixed venous saturations (2-ventricle: $<$60%, single ventricle $<$50%) [4].

Statistical Analysis

Patient and procedure characteristics were summarized for all cases, and also stratified by categories of operator years in practice. The median, range, and interquartile range were calculated for continuous variables, and frequency with percentages for categorical variables. Case characteristics were compared among categories of operator years in practice groups using a mixed effects multinomial logistic regression model to account for the correlation of cases performed by the same operator.

For operator years in practice and operator volume, unadjusted, and risk-adjusted event rates for any adverse event as well as higher severity (level 3–5) AE were examined for empirical cut points. For operator years in practice, operators with less than 5 years in practice were considered less experienced operators, and rates for those with at least 5 years in practice was further examined to identify any additional important threshold. Risk adjustment was performed using CHARM, which accounts for procedure type risk group, hemodynamic vulnerability, and age. Generalized estimating equations (GEE) models were used, which account for the correlation among cases performed by the same operator. Odds ratios (OR) and 95% confidence intervals were provided for risk-adjusted models. A sensitivity analysis was performed by removing each operator one at a time and reassessing the results, allowing us to examine the effect of individual operators on the relationships between years in practice or volume and adverse event rates. Once cut points were determined, analyses were repeated for the outcome preventable adverse events, and for specific types of adverse events.

Standardized adverse event ratios (SAERs) were calculated for individual operators to further examine the relationships between risk-adjusted adverse event rates and years in practice and case volume. An observed event rate was calculated for each operator by dividing the number of cases performed by that operator which resulted in an adverse event by the total number of cases performed. The CHARM risk adjustment model was then used to predict the probability of an adverse event for each case in the data set based on procedure type risk group, hemodynamic vulnerability, and age. The expected event rate for an operator was calculated by summing the probabilities of an event (generated from the model) for all cases performed by the operator and dividing by the total number of cases. The SAER for each operator was then generated by dividing his or her observed event rate by the expected event rate; 95% confidence intervals were calculated. An SAER equal to 1.0 indicates that the observed adverse event rate is equal to the expected rate. If the SAER is greater than 1.0, the observed rate is higher than expected; if it is less than 1.0, the observed rate is lower than expected given the operator's case mix complexity. SAS version 9.2 was used for statistical analysis.

RESULTS

Between February 1, 2007 and June 30, 2010, 12,827 cardiac catheterization cases were entered into the C3PO registry, performed in 8 centers by 33 operators. Excluded were 907 cases performed by 6 operators, 2 of which had fewer than 20 eligible cases over the time period while for 4 operators, biopsies accounted for more than 90% of their caseload. Additional cases that were excluded were cases not classified as biopsy, diagnostic catheterization, or interventional catheterization (704 cases, such as combined cath-EP procedures, hybrid procedures, etc), as well as cases, which could not be assigned a procedure type risk category (331 cases). This resulted in 10,885 cases being available for analysis.

Case Characteristics

Case characteristics for the whole study population as well as related to operator years in practice

TABLE I. Operator Years in Practice and Basic Case Characteristics

	Operator years in practice				
	All ($n = 10,885$) *N* (%) or median (IQR)	<5 years ($n = 2,993$) *N* (%) or median (IQR)	5<25years ($n = 6,285$) *N* (%) or median (IQR)	≥25 years ($n = 1,607$) *N* (%) or median (IQR)	*P* Value
Age (years)					
< 1 year	2,811 (26)	889 (30)	1,598 (25)	324 (20)	0.02
≥ 1 year	8,074 (74)	2,104 (70)	4,687 (75)	1,283 (80)	
Admission type					
Elective case	8,676 (80)	2,268 (76)	5,071 (81)	1,337 (83)	0.05
Nonelective or emergent	2,208 (20)	724 (24)	1,214 (19)	270 (17)	
Case type					
Diagnostic	3,139 (29)	840 (28)	1,901 (30)	398 (25)	<0.001
Interventional	5,648 (52)	1,503 (50)	2,967 (47)	1,178 (73)	
Biopsy	2,098 (19)	650 (22)	1,417 (23)	31 (2)	
Fluoroscopy time (minutes)	19 (11–35)	20 (11– 37)	17 (9–30)	31 (17–49)	0.03
Hemodynamic risk factors					
0	6,352 (58)	1,682 (56)	3,800 (60)	870 (54)	0.36
1	2,651 (24)	730 (24)	1,487 (24)	434 (27)	
≥2	1,882 (17)	581 (19)	998 (16)	303 (19)	
Procedure type risk group					
1	4,252 (39)	1,185 (40)	2,720 (43)	347 (22)	<0.001
2	3,304 (30)	904 (30)	1,873 (30)	527 (33)	
3	2,134 (20)	600 (20)	1,072 (17)	462 (29)	
4	1,195 (11)	304 (10)	620 (10)	271 (17)	

Statistical significance was assessed using a mixed effects multinomial logistic regression model to account for the correlation of cases within operator.

are listed in Table I. There was a significant decrease in the percentage of cases with a patient age below 1 year with increasing operator years in practice (<5 years: 30%, 5 < 25 years: 25%, ≥25 years: 20%, $P = 0.02$). Similarly, the percentage of non-elective or emergent cases decreased significantly with increasing operator years in practice (24% vs. 19% vs. 17%, $P = 0.05$). There was very little difference in the distribution of diagnostic cases, interventional cases, and biopsies when comparing operators with less than 5 years and those with 5 < 25 years in practice. However, operators with 25 or more years in practice had a significantly higher percentage of interventional cases (<5 years: 50%, 5 < 25 years: 47%, ≥25 years: 73%) and a lower percentage of diagnostic cases (<5 years: 28%, 5 < 25 years: 30%, ≥25 years: 25%) and biopsies (<5 years: 22%, 5 < 25 years: 23%, ≥25 years: 2%) when compared with operators with less than 5 or 5 < 25 years in practice ($P < 0.001$).

Operators with ≥25 years in practice had significantly higher median fluoroscopy times (<5 years: 20 min, 5 < 25 years: 17 min, ≥25 years: 31 min, $P = 0.03$) when compared with operators with less than 5 or 5 < 25 years in practice.

There was a significant difference in the distribution of procedure type risk groups between experienced and less experienced operators ($P < 0.001$), with the highest procedure type risk group accounting for 17% of cases of operators with ≥25 years in practice, but only 10% of cases of operators with less than 5 or 5 < 25 years in practice.

Operator Years in Practice and Adverse Events

Table II documents the relationship of incidence of high severity adverse events with age, hemodynamic vulnerability, as well as procedure type risk group, confirming a higher incidence of high severity adverse events in patients with an age below one year, higher hemodynamic vulnerability, as well as higher procedure type risk group (CHARM) [4].

The relationship of operator years in practice with incidence of AE is listed in Table III. When other potential cut points were examined, no significant differences in SAER were identified for: <5 years versus

TABLE II. The Catheterization for Congenital Heart Disease Adjustment for Risk Method (CHARM) for High Severity Adverse Events

	Incidence of level 3–5 AE		Multivariable model	
Risk factor	Total cases n	Cases with level 3–5 AE n (%)	*P*-value	Odds ratio (95% CI)
Age (years)				
< 1 year	2,811	242 (8.6%)	0.04	1.28 (1.01, 1.63)
≥ 1 year	8,074	301 (3.7%)	–	1.00
Hemodynamic risk factors				
0	6,352	207 (3.3%)	–	1.00
1	2,651	163 (6.2%)	<0.001	1.43 (1.16, 1.75)
≥2	1,882	173 (9.2%)	<0.001	1.89 (1.50, 2.39)
Procedure type risk group				
1	4,252	70 (1.7%)	–	1.00
2	3,304	139 (4.2%)	<0.001	2.25 (1.59, 3.20)
3	2,134	186 (8.7%)	<0.001	4.60 (3.16, 6.70)
4	1,195	148 (12.4%)	<0.001	6.31 (4.78, 8.33)

TABLE III. Relation Between Operator Years in Practice on Incidence of Adverse Events

	Incidence of AE		Univariate	Multivariable model (after risk adjustment[a])	
Risk factor	Total cases *n*	Cases with AE *n* (%)	*P*-value	*P*-value	Odds ratio (95% CI)
Any adverse events					
Operator years in practice					
< 5 years [10 operators]	2,993	462 (15.4)	<0.001	0.002	1.42 (1.14, 1.77)
5 < 25 years [16 operators]	6,285	680 (10.8)		–	1.0
≥25 years [5 operators]	1,607	263 (16.4)		0.09	1.30 (0.96, 1.76)
Level 3–5 Adverse Events					
Operator years in practice					
< 5 years [10 operators]	2,993	174 (5.8)	<0.001	0.03	1.35 (1.04, 1.75)
5 < 25 years [16 operators]	6,285	255 (4.1)		–	1.0
≥25 years [5 operators]	1,607	114 (7.1)		0.01	1.39 (1.08, 1.80)

[a]Risk adjustment was performed using CHARM, adjusting for procedure type risk group, hemodynamic vulnerability, and age.

≥5 years, <10 years versus ≥10 years, <5 years versus 5<15 years versus ≥15 years.

There were 10 operators with less than 5 years in practice, 16 operators with 5<25 years in practice, and 5 operators with ≥25 years in practice. Unadjusted adverse event rates were significantly higher for operators with less than 5 years in practice, as well as those with 25 or more years in practice when compared with operators with 5<25 years in practice for any as well as high severity adverse events. In risk adjusted analyses, operators with less than five years in practice had significantly higher odds of any AE (OR 1.42, 95% CI 1.14–1.77, $P = 0.002$) or a high severity AE (OR 1.35, 95% CI 1.04–1.75, $P = 0.03$), when compared with operators with 5<25 years in practice. Similarly, operators with 25 or more years in practice had significantly higher odds of a high severity AE (OR 1.39, 95% CI 1.08–1.80, $P = 0.01$) than those with 5<25 years in practice, but the relationship did not reach statistical significance when analyzing all AE (OR 1.30, 95% CI 0.96–1.76, $P = 0.09$). When removing a single operator from the ≥25 years in practice group the difference in the incidence of high severity AE of this group relative to operators with 5>25 years in practice did not reach statistical significance (OR1.23, 95% CI 0.86–1.77, $P = 0.25$). In contrast, removing single operators from any of the other two groups (<5 years and 5–25years) did not change the results for any as well as high severity adverse events. Figures 1 and 2 graphically displays standardized adverse event ratios with 95% confidence intervals for individual operators, documenting a wide variability and only very few operators with SAER significantly higher or lower than average.

A similar relationship was identified when looking at the incidence of preventable AE, with operators with <5 years in practice having higher odds of any preventable AE (OR 2.61, 95% CI 1.83–3.72, $P < 0.001$) or a preventable high severity AE (OR 1.95, 95% CI 0.81–4.72, $P = 0.14$), when compared to operators with

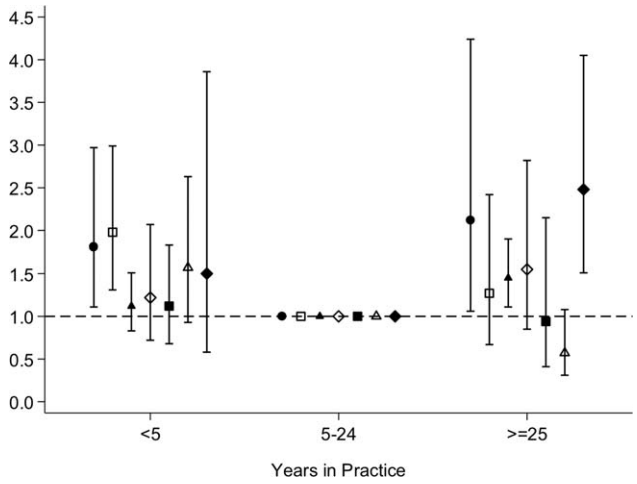

Fig. 1. Any adverse event: SAERs and 95% confidence intervals are shown for individual operators.

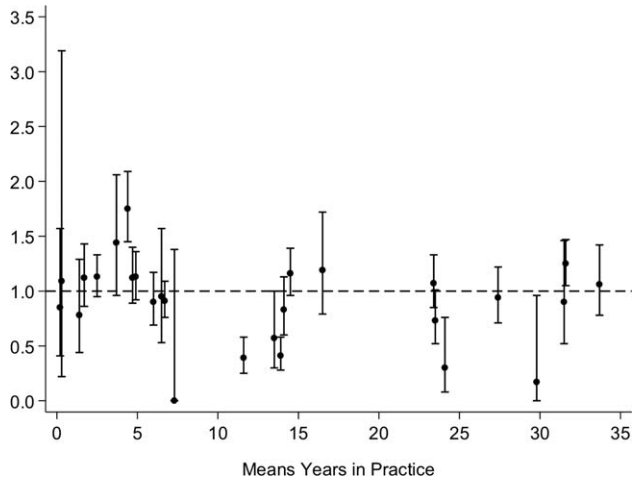

Fig. 2. Any level 3/4/5 adverse event: SAERs and 95% confidence intervals are shown for individual operators.

5<25 years in practice (Table IV), although the latter relationship does not achieve statistical significance. Operators with more than 25 years in practice did not have a significantly higher incidence of any or high-severity preventable AE when compared with operators with 5<25 years in practice. Preventable AE made up 15% of all adverse events for operators with less than 5 years in practice, but only 8% for those with 5<25 years in practice, and 9% for those with 25 or more years in practice ($P < 0.001$). For high severity AE, preventable AE made up 12% of all adverse events for operators with less than 5 years in practice, but only 8% for those with 5<25 years in practice, and 5% for those with 25 or more years in practice ($P < 0.001$).

When examining the type of AE, there was no significant difference between operators of different years in practice for the odds of a hemodynamic AE, a vascular enry site AE, or a sedation/anesthesia/airway-related AE. However, operators with less than 5 years in practice had significantly higher odds of vascular or cardiac trauma (OR 1.81, 95% CI 1.11–2.97, $P = 0.02$), or a technical AE (OR 1.98, 95% CI 1.31–2.99, $P = 0.001$) when compared with operators with 5<25 years in practice, while operators with 25 or more years in practice had significantly higher odds of vascular or cardiac trauma (OR 2.12, 95% CI 1.06–4.24, $P = 0.03$), arrhythmia (OR 1.45, 95% CI 1.11–1.90, $P = 0.007$), or reperfusion innjury / bleed via the endotracheal tube (OR 2.48, 95% CI 1.51–4.05, $P < 0.001$) when compared top operators with 5<25 years in practice (Fig. 3). However, when removing a single operator from the ≥25 years in practice group, the odds for vascular or cardiac trauma were not statistically significant from those in the 5<25 years group (OR 1.06, 95% CI 0.69–1.63, $P = 0.78$).

TABLE IV. Impact of Operator Years in Practice on Incidence of Preventable Adverse Events

	Incidence of preventable AE			Multivariable model (after risk adjustment[a])	
Risk factor	Total Cases n	Cases with prevent. AE n (%)	Univariate *P*-value	*P*-value	Odds ratio (95% CI)
Any preventable AE					
Operator years in practice					
< 5 years [10 operators]	2993	71 (2.4)	<0.001	0.004	2.61 (1.36, 5.02)
5 < 25 years [16 operators]	6285	56 (0.9)		–	1.00
≥25 years [5 operators]	1607	24 (1.5)		0.44	1.38 (0.61, 3.09)
Level 3–5 Preventable AE					
Operator years in practice					
<5 years [10 operators]	2993	21 (0.7)	0.05	0.14	1.95 (0.81, 4.72)
5 < 25 years [16 operators]	6285	21 (0.3)		–	1.00
≥25 years [5 operators]	1607	6 (0.4)		0.68	0.79 (0.26, 2.42)

[a]Risk adjustment was performed using CHARM, adjusting for procedure type risk group, hemodynamic vulnerability, and age.

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Operator Volume and Adverse Events

The relationship of operator volume with incidence of AE is listed in Table V. There were 6 operators with a case load of <75 cases/year, 4 operators with 75–149 cases/year, 4 operators with 150–199 cases/year, 7 operators with 200–249 cases/year, and 6 operators with ≥250 cases/year. There was no consistent trend for unadjusted adverse event rates, but operators with a volume of less than 75 cases per year appeared to have a lower incidence of any as well as high severity adverse events when compared to the other volume groups (Table V). In risk-adjusted analyses, there was no significant difference in the odds of any AE for operators with different case volumes (Figs. 4 and 5), which also applied when just considering interventional cases (excluding biopsies and hemodynamic cases). While operators with a yearly case volume of 200–249 cases appeared to have slightly higher odds of a high severity AE than operators with > 250 cases per year (OR 1.34, 95% CI 1.05–1.71, $P = 0.02$), the SAER documented a high degree of irregularity between operators with different case loads (Figs. 4 and 5). Furthermore, when looking at operator volume as a continuous variable, there was no significant relationship

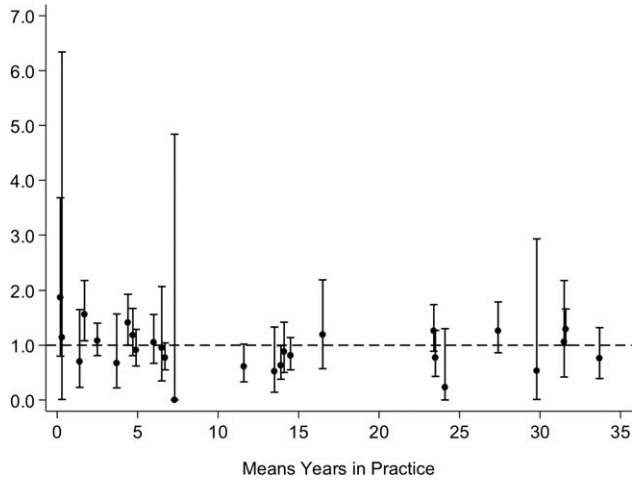

Fig. 3. Risk-adjusted odds ratios for different types of adverse events by operator years in practice. Solid circle: Vascular/Cardiac Trauma; Hollow square: Technical/Equipment AE; Solid triangle: Arrhythmias; Hollow diamond: Hemodynamic AE; Solid square: Vascular entry site AE; Hollow triangle: Sedation/Anesthesia/Airway AE; Solid diamond: Reperfusion injury/ET bleed.

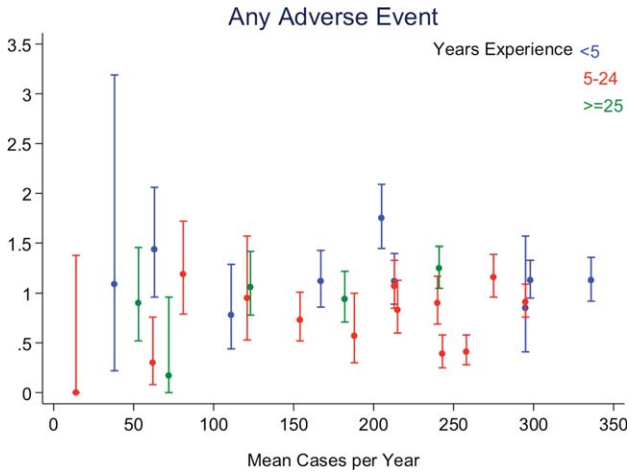

Fig. 4. Relationship between mean cases per year and SAER for any adverse events, for individual operators with different years in practice. Solid circle: <5 years in practice; solid square: 5–24 years in practice; solid triangle: ≥25 years in practice.

TABLE V. Relation Between Operator Volume on Incidence of Adverse Events

	Incidence of AE			Multivariable model (after risk adjustment[a])	
Risk factor	Total cases *n*	Cases with AE *n* (%)	Univariate *P*-value	*P*-value	Odds ratio (95% CI)
Any adverse events					
Operator Volume (cases/year)					
< 75 [6 operators]	637	53 (8.3)	0.004	0.64	0.86 (0.44, 1.65)
75 to 149 [4 operators]	837	103 (12.3)		0.69	1.06 (0.79, 1.43)
150 to 199 [4 operators]	1393	171 (12.3)		0.58	0.91 (0.64, 1.28)
200 to 249 [7 operators]	4005	551 (13.8)		0.51	1.14 (0.77, 1.68)
≥250 [6 operators]	4013	527 (13.1)		–	1.00
Level 3–5 adverse events					
Operator volume (cases/year)					
< 75 [6 operators]	637	15 (2.4)	0.001	0.30	0.78 (0.48, 1.25)
75 to 149 [4 operators]	837	33 (3.9)		0.97	1.01 (0.76, 1.34)
150 to 199 [4 operators]	1393	84 (6.0)		0.13	1.34 (0.91, 1.96)
200 to 249 [7 operators]	4005	224 (5.6)		0.02	1.34 (1.05, 1.71)
≥250 [6 operators]	4013	187 (4.7)		–	1.00

[a]Risk adjustment was performed using CHARM, adjusting for procedure type risk group, hemodynamic vulnerability, and age.

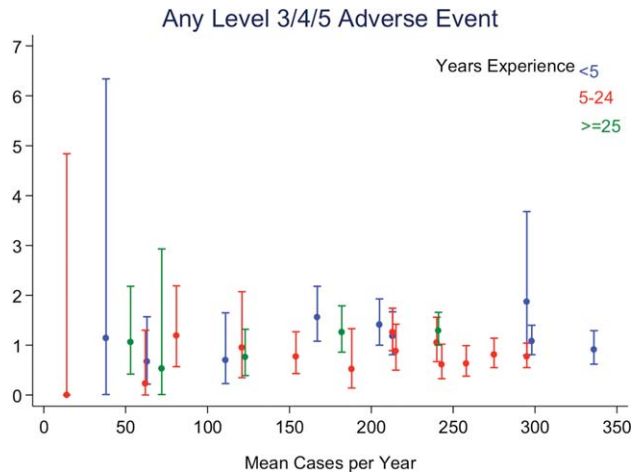

Fig. 5. Relationship between mean cases per year and SAER for any level 3/4/5 adverse events, for individual operators with different years in practice. Solid circle: <5 years in practice; solid square: 5–24 years in practice; solid triangle: ≥25 years in practice.

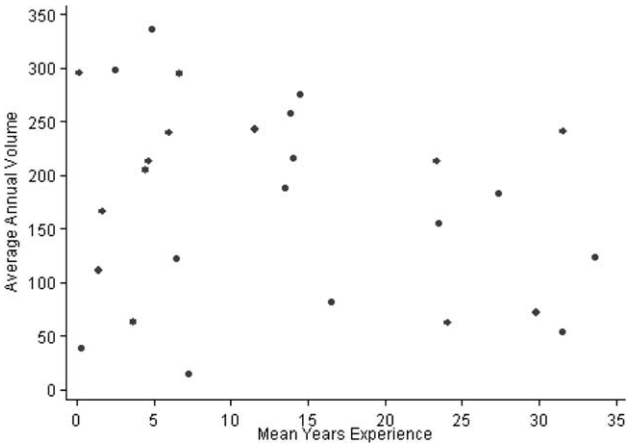

Fig. 6. Relationship between average annual operator volume and mean years in practice.

between operator volume and adverse events (and, level 3–5) in either univariate or multivariable analysis. Equally, at the operator level there was no correlation between average annual case volume and mean years in practice (Spearman's rank correlation coefficient = −0.18, $P = 0.38$, Fig. 6).

DISCUSSION

This study evaluated the incidence of procedure-related adverse events in a cohort of 10,855 cases performed at eight institutions. It identified operators with less than five years in practice to have higher odds of any AE (OR 1.42, 95% CI 1.14–1.77) or a high severity AE (OR 1.35, 95% CI 1.04–1.75), when compared with operators with 5<25 years in practice. In addition, the study showed that operators with 25 or more years in practice had higher odds of a high severity (but not any) AE (OR 1.39, 95% CI 1.08–1.80). In contrast, this study did not document any consistent relationship between operator volume and incidence of adverse events among this cohort of operators.

Improving procedural outcome has been the focus of many quality initiatives. However, to facilitate quality improvement, the availability of accurate, uniform, and comparable data on the quality of care that is being provided by different centers and operators is essential. Registries such as C3PO, CCISC, and IMPACT have been designed to aid in this data collection. While many studies and initiatives have focused on evaluating patient specific risk factors and improving patient care through process modifications such as standardized care pathways, very little data has been gathered on understanding the effect of operator and institutional characteristics on the incidence of adverse events associated with congenital cardiac catheterizations. In fact, the C3PO data on pulmonary artery rehabilitation has been the only study too date, that has evaluated the effect of operator years in practice and operator volume on procedure-related adverse events, reporting that operators with less than 10 years experience had 1.6 times higher odds of a high severity adverse events when compared to more experienced operators [7].

Operator Years in Practice and Adverse Events

This study has documented that operators with less than five years in practice have about 1.4 times higher odds of procedural adverse event, when compared with operators with 5<25 years in practice, with a higher percentage of preventable AE. While these data are important, the higher risk of adverse events with lesser experience is not unique to pediatric cardiac catheterization. In fact, adverse events are not just an occurrence confined to procedures in medicine, but have an equally important effect on other safety-critical areas, such as for example the aviation industry. A report by Broach and colleagues from the FAA summarized air-traffic accidents by age using the results of four different studies, all of which documented higher accident rates for younger pilots [9]. Even though it is important to identify potential risk factors for adverse events, the ultimate goal has to be achieving a reduction in adverse events without adversely affecting the procedural efficacy. Quality improvement tools such as PDSA cycles (Plan, Do, Study, Act) may be very helpful in improving the necessary mentorship and guidance for less senior operators. Most centers participating in this study were larger centers with several operators, which allowed more senior operators to

provide support and mentorship for colleagues with fewer years in practice. This study did not include centers with a single operator and therefore conclusions cannot be made on the effect of years in practice on adverse events for operators practicing alone.

While higher odds of adverse events for junior operators are somewhat easier to understand and conceive this study also identified higher odds of very senior operators with 25 or more years in practice encountering a high-severity adverse event. Even though procedure type risk categories were established through a rigorous process consisting of consensus assignment of risk categories, and subsequent empirical reassignment [10], it is clear that these risk groups do not perfectly account the relative risk for each and every single case. For example, balloon dilation of eight pulmonary arterial branches in a compromised 2-year-old patient with tetralogy of Fallot and pulmonary atresia, with poor vascular anatomy and missing pulmonary vascular segments, is assigned to the same risk category as a patient with isolated placement of a stent in the mid portion of the right pulmonary artery. These are completely different patients for whom one would anticipate very different catheterization courses and potentially a different incidence of adverse events. While risk adjustment is important, available methodologies are not perfect, as they can lead to loss of some detailed case specific patient information that still can affect risk. This unaccounted variability in patient and case characteristics can become important, and may explain the higher odds of adverse events in operators with more than 25 years in practice. Whether additionally a more complex referral pattern may impact the slightly higher incidence of adverse events in more senior operators is unclear at this point. In this study, senior operators trended to have higher case and significantly higher fluoroscopy times, which could (among other factors) be a reflection of increased case complexity. On the other hand, more senior operators may be less fellowship trained and less familiar with new devices and technologies, which could explain the higher odds of adverse events. However, the data collected in this study in insufficient to decisively answer this question. Residual confounding factors such as differences in case mix could have influenced both, the higher odds of adverse events in operators with less than 5 years in practice, as well as the higher odds of operators with more than 25 years in practice.

Operator Volume and Adverse Events

In this study, operator volume did not appear to have any significant (and consistent) relationship to the incidence of procedure-related adverse events when adjusted for procedure type risk, hemodynamic vulnerability, and age. However, there exists considerable data documenting a relationship between operator as well as institutional volume and procedural outcome, in a wide variety of medical fields, including percutaneous coronary interventions as well as vascular procedures, which have suggested that higher volume operators have better outcomes [6,11–13]. The inability of these data to identify a consistent relationship of operator volume may be related to the relative homogeneity seen in the centers that participated within this study. All centers were tertiary referral centers that included several operators with a wide range of years in practice. It is likely that less senior or low volume operators benefited from the presence of more senior colleagues that were readily available to provide advice if and when needed to discuss case-specific problems. The effect of operator volume may therefore require more diverse cohorts such as IMPACT, to explore and detect these differences.

Adverse Events and Procedural Outcome

While this study has analyzed the incidence of adverse events, it is important to emphasize that adverse events are insufficient as a sole marker of procedural outcome. In fact, many if not most of the adverse events that comprise the composite outcomes in this series (i.e., any AE, level 3–5 AE), may often be "justified" in practice by the therapeutic outcome that is achieved and explicitly considered in the risk-benefit ratio related to a procedure. While adverse events remain undesirable, they cannot be looked at in isolation, independent of the whole of the procedural outcome. C3PO did not collect comprehensive data on procedural efficacy. In fact, there are very few, if any, universally acknowledged criteria on procedural efficacy available for therapeutic interventions performed in patients with congenital heart disease. This is further complicated by the lack of long-term outcome data, which is more important than the immediate procedural outcome. Therefore in the absence of therapeutic outcome data, the relative "adversity" of the adverse events cannot be determined.

Furthermore, the adverse event severity criteria do not necessarily imply long-term adverse outcome as the vast majority of adverse events resolved or were self-limiting. For example, ventricular fibrillation requiring defibrillation is classified as a level 4 adverse event; yet, in many patients it does not leave any sequel. In contrast, jailing of a side branch of a vessel, often classified as level 2 adverse event, may not have any acute impact on flow to the adjacent vessel, but could theoretically lead to thrombus formation or

in-stent restenosis with vascular compromise of the jailed side branch at a later time. C3PO was not designed to capture long-term outcome and adverse events beyond the acute procedural episode, and as such adverse event data has to be regarded with caution. Finally, adverse events were captured irrespective of attributability, including adverse events that were a reflection of the underlying illness (such as the need for cardioversion of a patient with frequent supraventricular tachycardia who had experienced similar episodes on a regular basis prior to undergoing the catheter procedure).

Other Limitations

The study has a variety of additional limitations, most notably the small number of fairly homogenous participating centers, which may have impacted on the ability of this study, to identify any significant and consistent relationship between incidence of adverse events and operator volume. In addition, this registry only captures the primary operator, but not whether a more junior primary operator performed a procedure together with a more senior second operator, which may have an effect on procedural outcome.

More importantly, this study has documented considerable heterogeneity within the years-in-practice groups, thereby limiting the potential impact one can expect from operator years in practice as an independent contributor to adverse events. The effect, if present, is likely not strong and of considerable lesser importance when compared to procedure type risk group and hemodynamic vulnerability that have been established within the CHARM model.

Furthermore, operator years in practice was defined as years out from training, which is a crude measure of experience and does not take account of case volume, case varieties, and other clinical exposure of individual operators. While this study has demonstrated some differences in case characteristic between operators of varying years in practice, a lot of these factors are often specific to individual institutions, and as such conclusions that can be drawn from this data are limited.

Very little data is available on what comprises "experience," as it relates to years in practice. While many operators would use 5 years as a reasonable time in practice, this remains a subjective threshold. Furthermore, it was unclear, whether the odds of adverse events may follow a nonlinear fashion, increasing again in more senior operators due to the potential impact of higher case complexity or the lack of familiarity with new devices. To avoid using a priori (arbitrary) cut points and missing "true" cut point, a variety of cut-points were analyzed and eventually differentiated by three "experience" categories (<5 years, $5<25$ years, ≥ 25 years). It remains unclear though, whether a threshold of less than 5 years in practice has strong face validity. Furthermore, results may have been impacted by few operators, and while attempts were made to assess the impact of single operators by removing one operator at a time, this method is not necessarily robust, and for the larger "years in practice" groups (<5 years, $5<25$ years), 2 or 3 operators could have made a similar impact as removing a single operator from the >25 years group (which only included five operators). The data has also shown a fair amount of variability when looking at different operators with different years in practice (within the same "group"), and a discrete "threshold", as used in the analysis, may only incompletely describe the relationship between operator years in practice and risk-adjusted adverse events. The chosen cut-points in this study therefore will need to be validated in a separate data set. Similar applies to the relationship (or lack thereof) of operator case volume and risk-adjusted adverse events, where Figures 4 and 5 clearly show a wide variability in SAER for operators with different case volumes. While there may have been interactions between operator and institutional factors, this was not further explored in this study, due the limited number of participating institutions combined with a limited number of operators in each experience category.

In addition, while all AE were reviewed by interventional cardiologists not involved in the case, this was conducted in a non-blinded collaborative fashion, thereby having the potential for some degree of bias.

CONCLUSIONS

As a conclusion, this study has identified operator years in practice as an independent risk factor for procedure-related adverse events in patients undergoing cardiac catheterization for congenital heart disease. While an important consideration in guiding and mentoring operators with fewer years in practice, it is important to emphasize that reporting adverse events does not take into account procedural efficacy. Larger and more diverse cohorts, including procedural efficacy and long-term outcome data, are required to further evaluate the effect of operator volume on procedure-related adverse events.

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