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ORIGINAL RESEARCH

PEDIATRIC CARDIOLOGY

Changes in Practice/Outcomes of Pediatric/Congenital Catheterization in Response to the First Wave of COVID



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ABSTRACT

BACKGROUND The COVID-19 pandemic has posed tremendous stress on the health care system. Its effects on pediatric/congenital catheterization program practice and performance have not been described.

OBJECTIVES The purpose of this study was to evaluate how case volumes, risk-profile, and outcomes of pediatric/congenital catheterization procedures changed in response to the first wave of COVID-19 and after that wave.

METHODS A multicenter retrospective observational study was performed using Congenital Cardiac Catheterization Project on Outcomes Registry (C3PO) data to study changes in volume, case mix, and outcomes (high-severity adverse events [HSAEs]) during the first wave of COVID (March 1, 2020, to May 31, 2020) in comparison to the period prior to (January 1, 2019, to February 28, 2020) and after (June 1, 2020, to December 31, 2020) the first wave. Multivariable analyses adjusting for case type, hemodynamic vulnerability, and age group were performed. Hospital responses to the first wave were captured with an electronic study instrument.

RESULTS During the study period, 12,557 cases were performed at 14 C3PO hospitals (with 8% performed during the first wave of COVID and 32% in the postperiod). Center case volumes decreased from a median 32.1 cases/month (IQR: 20.7-49.0 cases/month) before COVID to 22 cases/month (IQR: 13-31 cases/month) during the first wave ($P = 0.001$). The proportion of cases with risk factors for HSAE increased during the first wave, specifically proportions of infants and neonates ($P < 0.001$) and subjects with renal insufficiency ($P = 0.02$), recent cardiac surgery ($P < 0.001$), and a higher hemodynamic vulnerability score ($P = 0.02$). The observed HSAE risk did not change significantly ($P = 0.13$). In multivariable analyses, odds of HSAE during the first wave of COVID (odds ratio: 0.75) appeared to be lower than that before COVID, but the difference was not significant ($P = 0.09$).

CONCLUSIONS Despite increased case-mix complexity, C3PO programs maintained, if not improved, their performance in terms of HSAE. Exploratory analyses of practice changes may inform future harm-reduction efforts. (JACC Adv 2022;1:100143) © 2022 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

**ABBREVIATIONS
AND ACRONYMS****AE** = adverse events**C3PO** = Cardiac Catheterization
Project on Outcomes Registry**FTR** = failure to rescue**HSAB** = high-severity adverse
events**PCCL** = pediatric/congenital
catheterization laboratory

The COVID-19 pandemic has posed an unprecedented stress on all aspects of health care. Although the clinical burden of the first wave of COVID-19 infections was disproportionately felt in older adults and largely spared children,^{1,2} the pandemic still affected the delivery of medical care to children with chronic medical conditions in ways that had the potential to lead to harm. In the spring of 2020, rapidly rising infection rates and early outbreaks raised the concern that scarcity of medical resources (specifically ventilators and intensive care beds) would result in excess mortality. Preemptive delay or cancellation of elective medical procedures, which would both reduce unnecessary exposure to nosocomial infection and preserve finite medical resources, was proposed as a temporizing measure. This led to both voluntary and government-mandated delays and cancellations of elective medical and surgical procedures across the United States.

Pediatric and congenital cardiac programs faced unique challenges in this context. The incidence of congenital heart disease is a stable proportion of live births (of which a similarly stable proportion had critical congenital heart disease obligating neonatal intervention), as a result of which the demand for cardiac procedures is less elastic than in other areas of medicine.³⁻⁵ As a part of congenital heart programs, pediatric/congenital cardiac catheterization laboratories (PCCLs) confronted the complicated decision of choosing which procedures should be delayed and which should be performed, balancing the risk of delay for individual patients against the risk of

iatrogenic exposure for patients, families, and staff along with the societal risk of occupying potentially necessary hospital resources in a time of scarcity. These tensions were reflected in both multicenter surveys of the immediate response of queried centers to the first wave of COVID-19,⁶ and a report from Morgan Stanley Children's Hospital of New York (located in one of the hardest hit metropolitan areas in the U.S.) described their PCCL's response to the pandemic.⁷ To our knowledge, no multicenter study has, to date, described how PCCL programs changed their practice in response to the pandemic and whether these changes were accompanied by measurable changes in outcome.

In response to these pressures, we anticipated: 1) that case volumes would have decreased in this period; and 2) that the case-mix would be characterized by increased preprocedural risk of adverse events (AEs)—measurable increases in the proportion of patients with indicators of vulnerability (based on age, procedure-associated risk, other comorbidities, or hemodynamic condition). At the same time, we were curious if changes in practice in response could have allowed centers to maintain the quality of care provided in the face of these adverse conditions. If so, identifying practices that facilitated delivery of high-quality care during these trying times could provide meaningful benefit beyond this time period.

There are 2 major obstacles to stringently studying these questions. First, a large sample from diverse centers is necessary to determine if changes in case mix and outcomes are legitimate. Second, willingness of centers to share how their practices changed is necessary to explore the changes in practice made in

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

response to the first wave of COVID. To accomplish this, we leveraged data from the Congenital Cardiac Catheterization Project on Outcomes Registry (C3PO) to perform a retrospective cohort study evaluating both changes in practice and outcomes in the face of the first wave of COVID in the U.S.

METHODS

DATA SOURCE. C3PO is a collaborative composed of 14 centers at the time of this study, focused on improving outcomes of pediatric/congenital cardiac catheterization through both quality improvement and facilitating clinical research. Centers contribute data from all cases to a multicenter registry that began collecting data in 2007. Each member center collects data and sends a deidentified data set using a standard electronic data-collection tool. Data management and analysis are managed by the C3PO data-coordinating center at the Boston Children's Hospital. Data quality and reliability are assured through regular auditing of submitted data. Data sharing is governed by a series of data use agreements between C3PO and member institutions. These prohibit sharing of subject-level data. Statistical methods will be shared upon request. Analysis of deidentified data does not constitute human subjects research in accordance with the Common Rule (45 CFR 46.102(f)).

STUDY DESIGN AND POPULATION. The overall goal of this study was to evaluate how practice and outcomes changed at contributing PCCL programs. This was accomplished in 3 parts. First, we sought to describe changes in number of cases and case mix in response to COVID at C3PO centers. Second, we sought to describe how outcomes changed at these same centers. Finally, as an exploratory aim, we distributed an online instrument to evaluate the specific changes that each C3PO center made in response to COVID. For the first 2 parts, we studied all cases performed at contributing centers from January 1, 2019, to December 31, 2020. These cases were divided into pre-first-wave (January 1, 2019, to February 28, 2020), first wave (March 1, 2020, to May 31, 2020), and post-first-wave (June 1, 2020, to December 31, 2020) periods. These periods were chosen to establish a stable pre-COVID baseline, against which the immediate changes in response to COVID were compared, and also to see if changes persisted beyond the first wave. There were no exclusion criteria. In the third part of the study, we evaluated the specific changes each C3PO hospital made in response to the first wave of COVID, through an electronically distributed study instrument. All

active C3PO sites were eligible and invited to participate in this section.

STUDY MEASURES. Data were directly extracted from the C3PO database. For each subject, demographics, cardiac diagnosis, and preprocedural risk factors were extracted. The primary exposure was on the day of the PCCL procedure, which were divided into 3 time periods as described above. Outcomes collected were AEs as well as unplanned admission and death at ≤ 72 hours of catheterization procedure. AEs are stratified in the current version of C3PO using Strata (Stratacorp) similar to those described for previous iterations,⁸⁻¹¹ specifically stratified into 5 levels of increasing severity. A change in the most recent iteration is division of level 3 events between 3a events and more severe 3bc events. For the purpose of this analysis, high-severity AEs (HSAEs) were defined as level 3bc, 4, and 5 events. Catastrophic AEs were defined as level 4 or 5 AE. Failure to rescue (FTR) was defined as a level 5 AE and/or death within 72 hours in cases in which another less-severe AE (levels 1-4) also occurred.¹²

Potential covariates were identified from previous studies in large registries and databases after adjusting for case-mix^{8,9,12-16} and extracted covariates were cardiothoracic surgery in the preceding 90 days, noncardiac medical conditions (coagulation disorder, renal insufficiency, and other), single ventricular vs biventricular circulation, indicators of hemodynamic vulnerability (elevated systemic ventricular end-diastolic pressure, low mixed venous saturation, low systemic arterial saturation, elevated pulmonary pressure, and elevated indexed pulmonary vascular resistance),⁸ preprocedural cardiac status (a novel ordinal marker of preprocedural risk developed at the Boston Children's Hospital), and Procedure Risk in Congenital Cardiac Catheterization (PREDIC³T) case types.⁹ This panel of covariates includes measures (eg, PREDIC³T case type and cardiac status) that have been identified since the previous C3PO risk adjustment models and are included in the hopes of providing the most accurate depiction of risk in this cohort. Age of patients was divided into neonates (≤ 30 days), infants (>30 days and <1 year), children (≥ 1 year and <18 years), and adults (≥ 18 years) as described previously.^{8,12-15}

COVID RESPONSE SURVEY. A novel study instrument was developed to formally evaluate how hospitals adjusted their practices in response to COVID. No formal focus group or field testing was performed during survey development. The instrument requested information about 5 domains: patient selection, scheduling, staffing, recovery/observation, and

changes outside the PCCL. The instrument combined discrete questions (eg, “Did you restrict cases based on their perceived urgency?”) with opportunities for narrative comments, which were used to clarify responses to discrete questions. The instrument was electronically distributed to each C3PO institution using Research Electronic Data Capture tools hosted by the Boston Children’s Hospital. Electronic mail reminders were sent to encourage participation. No other incentives (financial or otherwise) were applied. Responses to survey questions were automatically anonymized, but whether a specific individual responded was known. These data enabled calculation of the response rate and permitted a limited description of the respondents (eg, number of centers and geographic spread).

STATISTICAL ANALYSIS. Descriptive statistics were calculated. PCCL cases per month for each month of the study period were described across the entire collaborative and per center to provide complementary measures of procedural volume. Differences in monthly case volumes were compared between: 1) pre-COVID and first wave; and 2) between pre-COVID and post-first-wave periods using the Wilcoxon signed rank test.

Next, we sought to study changes in practice and outcomes in response to COVID. The primary exposure was time period. First, we evaluated whether case mix had changed over the study period. We did this by comparing the distribution of potential risk factors between the 3 preidentified time periods, using Kruskal-Wallis for continuous variables and Fisher’s exact tests for categorical variables. Second, we compared the risk of HSAE over the same time periods, expressed as likelihood with 95% CIs calculated using the exact binomial method. Finally, we evaluated whether the risk of HSAE changed after adjustment for measurable confounders, calculating multivariable logistic regression models for HSAE, with time period as the primary exposure and adjusted for prespecified covariates (PREDIC³T category, hemodynamic vulnerability score, and age category). The pre-first-wave period was the referent. As secondary analyses, we also evaluated for changes in the risk of catastrophic AE and FTR.

For the novel study instrument, response rate was calculated and reported. The results were tabulated and reported using standard descriptive statistics.

Missing data were limited with 2 exceptions. For PREDIC³T (>5%) and hemodynamic vulnerability scores (<1%), data were missing. Multiple imputation was not used to address missingness because there was no obvious way to predict the missing values based on other data. To avoid bias that might result

from case restriction, a category named “missing” was created as described previously.^{12,17,18}

RESULTS

PROCEDURAL VOLUME. During the study period, a total of 12,557 cases were performed at 14 hospitals. Of these, 60% (n = 7,536) were performed in the pre-first-wave period, 8% (n = 1,053) during the first wave of COVID, and 32% (n = 3,968) after the first wave (Table 1). Prior to the first wave of COVID, the median monthly total case volume at C3PO sites was 32.1 cases/month (IQR: 20.7-49.0 cases/month). During the first wave, case volumes decreased significantly to 22.2 cases/month (IQR: 13-31 cases/month, $P = 0.001$) (Central Illustration A), with the monthly procedural volume decreasing at 100% of centers. After June 2020, there was no significant difference in case volumes compared to the pre-COVID period (median: 34.8 cases/month; IQR: 22.3-52.3 cases/month; $P = 0.06$).

CHANGES IN CASE-MIX. During the first wave of COVID, increases in the proportion of procedures performed in neonates and older infants ($P < 0.001$), cardiothoracic surgery within 90 days ($P < 0.001$), renal insufficiency ($P = 0.02$), and higher hemodynamic vulnerability scores ($P = 0.02$) were observed. The proportion of cases with PREDIC³T scores for the anticipated procedure in the higher-risk categories (classes 3 and 4) increased from 17% and 14% to 21% and 18%, respectively ($P < 0.001$). The proportion of cases with the more-severe preprocedural cardiac status ($P < 0.001$) also increased. Unexpectedly, the proportion of procedures in which the performed procedure differed from the anticipated one decreased from 5% to 1% ($P < 0.001$). The proportion of cases in which the patient had a chronic lung disease, a genetic syndrome, single ventricle physiology, or abnormal coagulation did not change significantly (all $P > 0.05$). Interestingly, the reported proportion of cases with noncardiac conditions decreased in both the first wave of COVID and post-first-wave periods relative to the pre-COVID period ($P < 0.001$). Overall, these findings are consistent with a case-mix that is associated with a higher risk of HSAE and predicts greater numbers of observed HSAE.

CHANGES IN OUTCOME. The observed proportion of cases with HSAE was 4.8% (95% CI: 4.3%-5.3%) in the pre-COVID period. In the first-wave period, it was 3.9% (95% CI: 2.8%-5.3%), and in the post-first-wave period, it was 4.0% (95% CI: 3.4%-4.7%). Although suggestive, this difference in the observed HSAE risk was not significant ($P = 0.13$). The risk of secondary outcomes (all AE, catastrophic AE, and FTR) was not

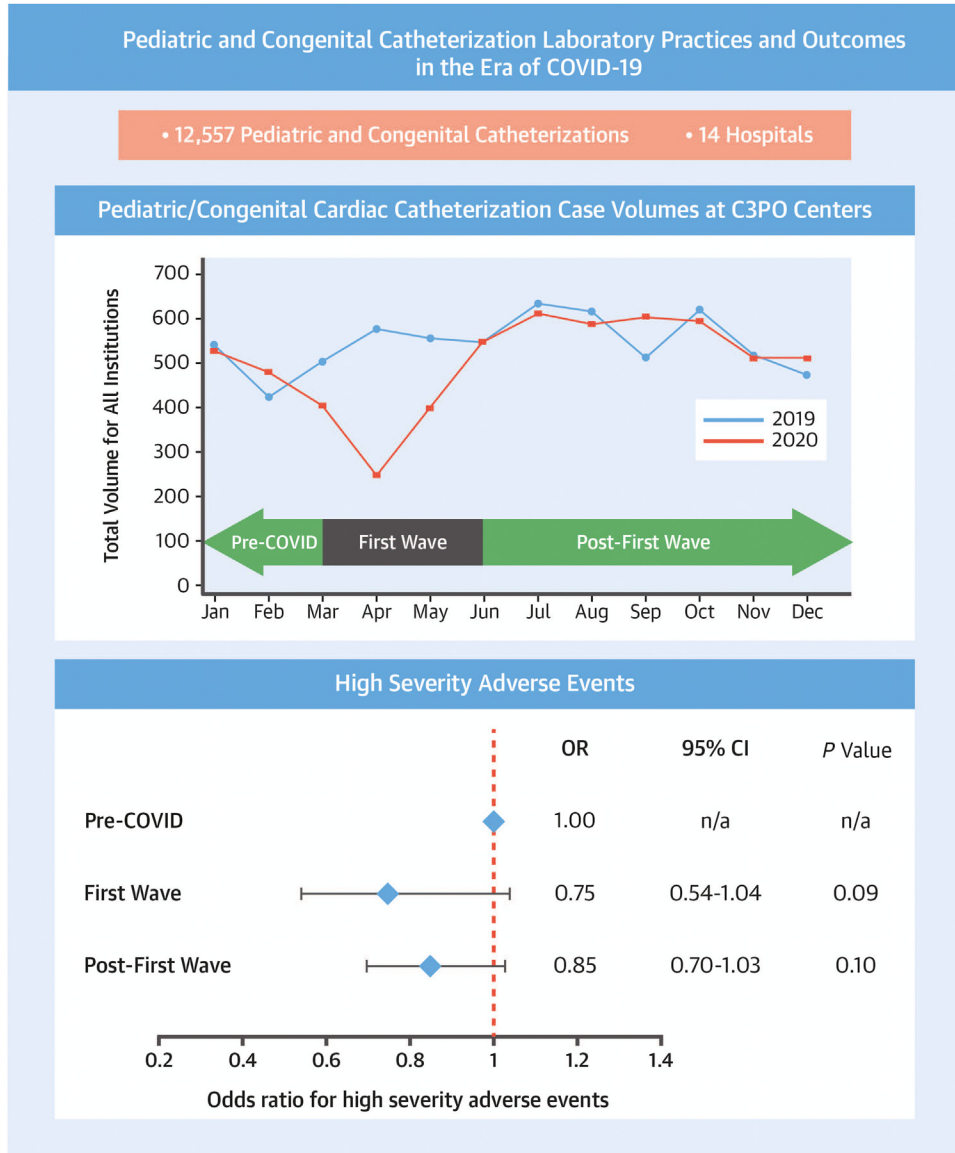
TABLE 1 Study Population

	1/2019-2/2020 (n = 7,536)	3/2020-5/2020 (n = 1,053)	6/2020-12/2020 (n = 3,968)	P Value
Male	54% (4,051)	55% (577)	54% (2,146)	0.80
Age at procedure (y)	3.0 (0.4-11)	1.0 (0.2-6)	3.0 (0.4-12)	<0.001
Age group				<0.001
≤30 d	10% (753)	17% (181)	9% (347)	
31 d-1 y	25% (1,881)	32% (336)	24% (952)	
1-17 y	53% (3,968)	44% (459)	54% (2,133)	
≥18 y	934 (12%)	77 (7%)	536 (14%)	
Height (cm) (n = 7,533; n = 1,053; n = 3,968)	92 (61-142)	73 (53-112)	96 (62-148)	<0.001
Weight (kg)	14.0 (6.0-39)	9.0 (4.0-19)	14.5 (6.2-42)	<0.001
Any noncardiac problem	23% (1,734)	21% (218)	18% (719)	<0.001
Chronic lung disease	6% (424)	7% (72)	5% (212)	0.18
Renal insufficiency	1% (58)	2% (17)	1% (44)	0.02
Coagulation disorder	1% (35)	0.2% (3)	1% (21)	0.65
Cardiothoracic surgery within 90 d	12% (876)	16% (173)	13% (496)	<0.001
Cardiac catheterization within 90 d	12% (909)	14% (152)	12% (479)	0.09
Genetic syndrome	16% (1,207)	15% (161)	16% (619)	0.76
Single ventricle (n = 7,504; n = 1,050; n = 3,954)	29% (2,173)	30% (312)	28% (1,107)	0.42
Hemodynamic vulnerability score (n = 7,504; n = 1,050; n = 3,954)				0.02
0	50% (3,756)	49% (513)	53% (2,082)	
1	20% (1,481)	18% (184)	19% (748)	
2	15% (1,145)	17% (176)	15% (577)	
≥3	15% (1,122)	17% (177)	14% (547)	
Indicators of hemodynamic vulnerability (n = 7,504; n = 1,050; n = 3,954)				
Elevated systemic ventricular end-diastolic pressure	5% (345)	4% (43)	5% (181)	0.79
Low mixed venous saturation	13% (974)	15% (154)	11% (422)	<0.001
Low systemic arterial saturation	31% (2,313)	31% (325)	28% (1,104)	0.004
Elevated pulmonary artery pressure	18% (1,362)	21% (225)	19% (736)	0.04
Elevated ratio of pulmonary to systemic blood flow	11% (790)	10% (104)	10% (396)	0.64
Elevated indexed pulmonary vascular resistance	14% (1,072)	14% (146)	14% (539)	0.63
PREDIC ³ T category (performed procedure)				<0.001
1	26% (1,955)	21% (225)	26% (1,032)	
2	26% (1,966)	25% (264)	24% (959)	
3	18% (1,324)	21% (225)	17% (682)	
4	14% (1,085)	18% (188)	15% (593)	
5	9% (694)	7% (72)	9% (344)	
Not categorized	7% (512)	8% (79)	9% (358)	
PREDIC ³ T category for anticipated procedure				<0.001
0	0.1% (5)	0% (0)	0.02% (1)	
1	26% (1,973)	21% (225)	25% (1,000)	
2	26% (1,983)	25% (266)	25% (979)	
3	17% (1,277)	21% (224)	17% (661)	
4	14% (1,078)	18% (190)	15% (601)	
5	10% (728)	7% (72)	9% (368)	
Not categorized	7% (492)	7% (76)	9% (358)	
Performed procedure differs from anticipated procedure	5% (414)	1% (15)	3% (117)	<0.001
Preprocedural cardiac status				<0.001
1	39% (2,912)	35% (373)	43% (1,701)	
2	30% (2,264)	31% (329)	29% (1,159)	
3	16% (1,243)	16% (172)	13% (513)	
Not categorized	15% (1,117)	17% (179)	15% (595)	
Preprocedural cardiac status (n = 6,419; n = 874; n = 3,373)				<0.001
1	45% (2,912)	43% (373)	50% (1,701)	
2	35% (2,264)	38% (329)	34% (1,159)	
3	19% (1,243)	20% (172)	15% (513)	

Values are % (n) or median (IQR).

PREDIC³T = Procedure Risk in Congenital Cardiac Catheterization.

CENTRAL ILLUSTRATION Changes in Center Case Volume and Adjusted Risk of High Severity Adverse Events During the First Wave of COVID-19



Quinn B, et al. JACC Adv. 2022;1(5):100143.

(A) Comparison of catheterization procedure volumes between 2019 and 2020. Pediatric/congenital cardiac catheterization case volumes at C3PO centers are depicted in 2019 (blue) and 2020 (red) for the entire C3PO collaborative. Center case volumes decreased from the pre-COVID period (32.1 cases/month; IQR: 20.7-49.0 cases/month). It decreased significantly during the first wave of COVID (22.2 cases/month; IQR: 13-31 cases/month; $P = 0.001$). There was no significant difference between pre- and post-COVID case volumes (median: 34.8 cases/month; IQR: 22.3-52.3 cases/month; $P = 0.06$). (B) Multivariable model for high-severity adverse events. This forest plot depicts the main effects of multivariable model for the association between time period and odds of high severity adverse events adjusted for PREDIC³T procedure risk category, hemodynamic vulnerability score, and age category. The point estimate for odds ratio is depicted (blue diamond) along with 95% confidence intervals (brackets). Odds ratios to the left of unity (red hashed line) reflect reduced odds of high severity adverse events, while those to the right reflect higher odds.

TABLE 2 Outcomes

	1/2019-2/2020 (n = 7,536)	3/2020-5/2020 (n = 1,053)	6/2020-12/2020 (n = 3,968)	P Value
Major adverse events	4.8% (358) 95% CI: 4.3%-5.3%	3.9% (n = 41) 95% CI: 2.8%-5.3%	4.0% (159) 95% CI: 3.4%-4.7%	0.13
Secondary outcomes				
Any adverse event	12.2% (917) 95% CI: 11.4%-12.9%	10.8% (114) 95% CI: 9.0%-12.9%	11.3% (447) 95% CI: 10.3%-12.3%	0.23
Catastrophic adverse events	1.8% (132) 95% CI: 1.5%-2.1%	1.5% (16) 95% CI: 0.9%-2.5%	1.5% (58) 95% CI: 1.1%-1.9%	0.50
Unplanned admission	3.7% (280) 95% CI: 3.3%-4.2%	1.6% (17) 95% CI: 0.9%-2.6%	1.8% (70) 95% CI: 1.4%-2.2%	<0.001
Failure to rescue	(n = 917) 2.3% (21) 95% CI: 1.4%-3.5%	(n = 114) 0% (0) 95% CI: 0.0%-3.2%	(n = 447) 2.2% (10) 95% CI: 1.1%-4.1%	0.30

significantly different during the first-wave period (Table 2). The risk of unplanned admission decreased from 3.7% in the pre-first-wave period to 1.6% during the first wave, and it remained low in the post-first-wave period (1.8%, $P < 0.001$).

In multivariable adjusted models, the point estimate of the odds of HSAE decreased in both first-wave COVID (OR: 0.75; 95% CI: 0.54-1.04; $P = 0.09$) and post-first-wave periods (OR: 0.85; 95% CI: 0.70-1.03; $P = 0.10$), but the difference was not statistically significant (Central Illustration B, Supplemental Table 1). A similar pattern was seen for catastrophic AE, with the point estimates suggesting an association between the first-wave and post-first-wave periods and lower odds of catastrophic AE, although it again was not statistically significant ($P = 0.29$) (Supplemental Table 2). Because of the low event rate of FTR during the first-wave period, multivariable models were not calculated.

STUDY INSTRUMENT. Responses were collected from 14 of 14 (100%) C3PO member institutions (Table 3). All centers (14/14) reported restricting cases based on urgency in response to COVID, with 7% ($n = 1$) closing their catheterization laboratory and referring all patients to an associated program. Of all C3PO programs, 57% ($n = 8$) restricted cases to emergent cases, and 36% ($n = 5$) limited cases to those that were deemed urgent. This was similar to changes in scheduling surgical cases (1 program closing completely and the remaining 13 performing only urgent cases). Changes were mandated outside of the cardiac center in 93% ($n = 13$) of centers; 79% (11/14) of programs received mandates from the hospital/health system leadership, 21% (3/14) from their city government, and 36% (5/14) from their state government.

Procedure scheduling changes were common. The number of case slots was reduced at 93% (13/14) of programs (1 program opened a new lab during this

period, and their available slots increased). Ninety-three percent (13/14) of programs added preprocedural COVID testing for cases. No program increased the use of preprocedural testing in other (ie, noncardiac) areas, and 21% (3/14) offered telemedicine visits for preprocedural assessments. Finally, 57% (8/14) of programs added an additional review of cases prior to scheduling them.

In terms of staffing, 42% (6/14) of programs experienced staff reassignments to cover COVID patients within their institution. Staffing was impacted across the board, with 64% (9/14) of programs reporting lower staffing for nurses and/or technologists, 36% (5/14) reporting reduced staffing for interventional cardiologists and anesthesiologists, and 57% (8/14) reporting reductions in trainee availability. A sizeable minority (42%, 6/14) of centers created team cohorts to reduce the risk of occupational transmission of COVID. In terms of recovery from procedures, 36% (5/14) of programs had reductions in their recovery unit staffing, and 36% (5/14) reported conversion of recovery unit beds to service COVID patients.

DISCUSSION

In this multicenter cohort study from the C3PO registry, we evaluated the response of 14 U.S. PCCL programs to the first wave of COVID. All programs reported canceling or delaying elective cases, and this has resulted in a reduction in the total number of cases attended, both across the collaborative and at individual centers. As expected, prioritizing urgent and emergent cases resulted in cases with a higher-severity case mix. At the same time, there were reductions in staffing at many centers as well as unmeasured external stressors. However, contrary to expectations, the risk of HSAE with catheterization was not significantly different in unadjusted analyses, implying that programs maintained their safety

TABLE 3 Changes in Hospital Practices (N = 14)

Were catheterization laboratory cases restricted/halted? ^a	
Complete closure	7% (1)
Only emergency cases	57% (8)
Only urgent cases	36% (5)
If so, who mandated these changes	
Hospital	79% (11)
Local government	21% (3)
State government	36% (5)
Not mandated	7% (1)
Were changes made in the process of reviewing cases prior to scheduling them?	57% (8)
Were changes made to the precatheterization testing process?	
Addition of COVID testing	93% (13)
Conversion to telemedicine visit	21% (3)
As additional clinical review added prior to scheduling cases?	71% (10)
Were there changes in the number of case slots available?	
More	7% (1)
Same	0% (0)
Less	93% (13)
Were there changes in staffing of cases?	
Attending interventional cardiologist	
More	0% (0)
Same	64% (9)
Less	36% (5)
Nurses and/or technologists	
More	0% (0)
Same	36% (2)
Less	64% (9)
Anesthesiologists	
More	0% (0)
Same	64% (9)
Less	36% (5)
Trainees	
More	0% (0)
Same	43% (6)
Less	57% (8)
Were multidisciplinary teams cohorted to avoid exposure?	42% (6)
Were any team members reassigned to other duties because of COVID?	42% (6)
Were changes made to recovery location/practice?	14% (2) ^b
Did staffing of recovery unit change?	
More	0% (0)
Same	64% (9)
Less	36% (5)
Changes in surgical cases ^c	
Complete closure	7% (1)
Only urgent cases	93% (13)
Was cardiac bed space converted to care of COVID patients?	50% (7)
If yes, did these changes affect scheduling?	71% (5/7)
Values are % (n). ^a Of these, all reported that cases were restricted to those that were urgent or would otherwise suffer from a delay in scheduling. ^b General postanesthesia care unit cohort created. ^c 100% mandated.	

incidence of HSAE, these findings raise the possibility that performance was better than it was in the pre-first-wave period. This study is among the first in pediatric/congenital cardiology to utilize the unique circumstances in health care delivery introduced by COVID and an existing, audited, multicenter registry to 1) examine the impact of health care disruption on clinical outcomes, and 2) translate lessons from this unusual period to improve future care delivery.

Understanding the factors underlying these changes could have potential public health impact beyond the COVID pandemic. PCCL procedures represent episodes with increased risk of harm in vulnerable patients.^{13,19,20} Our study period serves as a potential natural experiment during which individual programs were able to maintain if not improve their performance despite challenging circumstances inside and outside of the hospital. Although quality-improvement efforts were in place prior to the COVID pandemic, these were disrupted during this period. Each center made a series of choices that governed how they would schedule cases and conduct procedures. It is possible that the observed trends in outcome are the result of dedicated care teams exerting themselves in the face of inclement conditions, which alone would be admirable. However, the observed improvements may also be the result of adoption of practices at individual centers in response to stresses resulting from COVID and associated restrictions. Identifying what changes were beneficial is challenging but would be advantageous to ongoing (non-COVID-related) harm-reduction and quality-improvement efforts in PCCLs.

We tried to determine what specific responses were employed using an electronically distributed novel instrument. Although the number of centers and variety of responses precluded quantitative evaluation of the relative contributions of each change, they do point to some practice changes that might warrant further investigation. First, as noted above, case volumes decreased. Over longer periods of time, studies have demonstrated that higher average case volumes at a center are associated with reduced likelihood of harm (specifically catastrophic AEs^{15,16,18} and FTR¹²). However, for a program with an established capacity (number of cases per year, historically), reducing the number of cases requested or performed might allow for better allocation of otherwise scarce resources (eg, staffing, equipment, and/or attention) and improved outcomes. The benefit from this acute drop in volume may be transient, as prolonged reductions in volume might result in erosion of the team experience and resources underlying associations between volume and performance. In a

performance in spite of a higher-risk case mix. Moreover, in analyses adjusted for measurable confounders, although the association is still insignificant, the point estimates for odds of HSAE were lower in both the first-wave and post-first-wave periods. In a study with a limited sample size relative to the

fee-for-service system, reducing catheterization case volumes below historical norms is unlikely to be popular. Moreover, the potential benefit may have arisen from other changes that can be implemented without affecting the PCCL capacity, and therefore, this is not sustainable.

During the study period, the majority of programs reported instituting a formalized case review process prior to scheduling cases. Although this procedure was likely intended to ensure that cases were performed according to their medical priority, case review processes also provide an opportunity for rational allocation of equipment, personnel, and time. It also provides an opportunity to ensure that all levels of the care team are aware of high-risk patients and an opportunity to discuss strategies to prevent AE and/or be better prepared to rescue them. The observation that the match between expected procedure and the procedure performed was better during the first wave and that the risk of unanticipated admission was reduced during the first wave both support the idea that increased preprocedural review was successful. We acknowledge that a possible alternative is that higher-priority cases may be more goal-directed than the usual case mix. Despite this limitation, we would contend that these findings support preprocedural review, risk assessment, and planning that are part of ongoing harm-reduction work within the C3PO collaborative and that the COVID period may have accelerated progress in this area.

Finally, almost all centers reported cohorting staff (specific combinations of interventionalist, anesthesiologist, nurses, and technologists) to maintain team function in the face of a communicable disease, but these efforts may have had unanticipated knock-on benefits. Formal team training programs to improve performance have been an area of active research in medicine and surgery following successes in other industries. Although not uniformly successful,²¹⁻²⁵ these programs aim to improve team-wide communication, create more accurate shared mental models, and reduce authority gradients in ways that will translate into improved outcomes. Although most research has focused on formalized training programs, there is evidence that familiarity either from long-standing working relationships²⁶ or from cohorting staff²⁷ is both associated with improved performance. The time course of team cohorting efforts in the first wave of COVID was short, but anecdotally, cohorting teams facilitated clear communication and improved efficiencies in cases. The connection between improved communication and outcomes may appear self-evident on face, but

efforts are necessary to evaluate both the implementation and durability of improvement outside of these extenuating circumstances.

Subsequent waves of infections due to the Delta and Omicron COVID variants invite a postscript to this analysis. In contrast to the first wave of infections described here, subsequent waves have been characterized by much more widespread cases including a higher proportion of children, which inflict a different set of stresses on PCCL programs. High community prevalence with large volumes of asymptomatic or mild infections extending into the pediatric population has resulted in an increase in late or last-minute cancellations of scheduled cases due to close contacts or documented COVID infections. These late substitutions complicate preprocedural review and communication. Moreover, widespread community infection also has had a greater direct impact on staffing with losses due to either personal infection of team members or their care responsibilities, losses that are superimposed on staffing shortages, and turnover that has been reported across medical fields. These losses can undermine the team dynamics that may have helped maintain high-quality care in the first wave, as well as adversely affecting morale. Finally, in contrast to the first wave, there have not been widespread restrictions. If anything, previous waves have left backlogs of untreated patients and pressure to increase or maximize capacity (including asking teams to work more shifts or longer days). Cumulatively, these conditions undermine all the potential factors that we posit might have resulted in preserving the high performance of centers during the first wave. It is beyond the scope of this study, but future analyses of the subsequent waves may (regrettably) provide further evidence to support the benefit of practices we identified during this study period.

STUDY LIMITATIONS. In addition to those mentioned previously, there are a number of limitations that should be recognized. First, we acknowledge that we cannot determine the cause of the observed trends seen. Although a number of centers contribute data, the combination of centers and practice changes observed does not result in a sufficient variety of combinations to differentiate which changes were more or less strongly associated with the observed changes in outcome. Moreover, as noted, the short period of the first wave also results in a small sample size and a high risk of type II error. A second important issue is that the impact of COVID's first wave on centers was extremely variable depending on their location, and it is impossible to account for this in our

analysis (with significant variation in infection rates in different regions). Although every attempt was made to adjust for measurable confounders, there remains the possibility of unmeasured confounding. We acknowledge that the potential improvements in outcome are not attributable solely to catheterization laboratory teams and that they are potentially the product of the efforts of the entire care teams at each center. Information about COVID infection is not available across the cohort, so could not be reported. Finally, centers contributing to C3PO represent a fraction of the pediatric/congenital catheterization procedures in the US. In addition, C3PO centers are all actively engaged in quality-improvement efforts. For both these reasons, the observations from this sample may not be universally applicable.

CONCLUSIONS

While acknowledging these limitations, we conclude that during the first wave of COVID, PCCL volume decreased while these cases were characterized by a higher-risk case mix. Paradoxically, in both observed and adjusted analyses, the likelihood of a major AE was at worst similar to that in the earlier period (with some indications that the odds were lower during this period). Substantial changes in practice made in response to COVID (eg, case scheduling, reducing volume below historical capacity, preprocedural team review of cases, and cohorting staff) were observed and may guide future efforts to develop targeted interventions to improve PCCL safety.

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PERSPECTIVES

COMPETENCY IN SYSTEMS-BASED PRACTICE:

Delaying or canceling elective procedures during the first wave of COVID decreased total PCCL case volumes and increased the risk profile of cases being performed. However, programs maintained their performance in terms of major adverse events (and may have improved it). A multi-institutional survey demonstrated that in addition to reducing case volumes, centers also implemented centralized preprocedural reviews and cohorted personnel (interventionalist cardiologists, anesthesiologists, nurses, and technologists).

TRANSLATIONAL OUTLOOK: For future quality-improvement and/or research efforts, the following changes: 1) reductions in case volume relative to the established capacity; 2) formal centralized preprocedural case review; and 3) cohorting staff into teams should be evaluated to determine if these changes are associated with improved outcomes outside of the pandemic setting.

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APPENDIX For supplemental tables, please see the online version of this paper.