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Impact of early Coronavirus Disease 2019 pandemic on pediatric cardiac surgery in China



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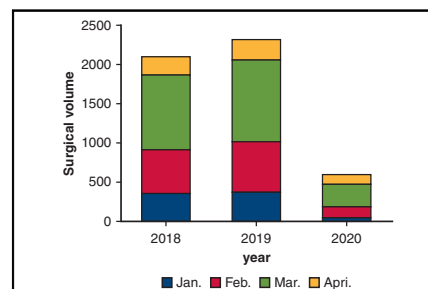
ABSTRACT

Objective: This study aimed to provide an insight into the impact of the early outbreak of the novel Coronavirus Disease 2019 on the care management for patients with congenital heart disease.

Methods: This study respectively enrolled a cohort of surgical patients who underwent surgery in 2018 (group I), 2019 (group II), and 2020 (group III) and a cohort of follow-up patients who had follow-up in 2017 (group A), 2018 (group B), and 2019 (group C) in 13 children hospitals.

Results: During the Coronavirus Disease 2019 era, there was a significant decrease in total surgical volume and a change in case mix in terms of an increase in the proportion of emergency operations. Decrease in migration scale index was correlated to the decrease in both surgical volume ($r = 0.64, P = .02$) and outpatient visit volume ($r = 0.61, P = .03$). There was a significantly higher proportion of patients who had follow-up through the internet or phone in group C (26.4% vs 9.6% in group B and 8.9% in group A; $P < .0001$). There was no statistical difference in death or rehospitalization among the 3 follow-up groups ($P = .49$). There was higher parents' anxiety score ($P < .0001$) and more use of telemedicine ($P = .004$) in group C compared with groups A and B.

Conclusions: The Coronavirus Disease 2019 pandemic has resulted in a considerable decrease in total surgical volume and a change of case mix, which seems to be related to the strict traffic ban. Follow-up through the online medical service appears to be an effective alternative to the conventional method. (J Thorac Cardiovasc Surg 2021;161:1605-14)



There was a substantial decrease in pediatric cardiac surgeries during the early outbreak of COVID-19 in children's hospitals in China.

CENTRAL MESSAGE

The COVID-19 pandemic has resulted in significant changes in congenital heart services, such as decrease in total surgical volumes, redistribution of the case mix, and change in follow-up strategies.

PERSPECTIVE

The public health responses to the COVID-19 pandemic have resulted in the deferral of surgery and limited access to structured follow-up in patients with CHD, potentially posing a big threat to this subgroup patients. Our results provide a platform for further study of better serving patients with CHD in terms of patient triage, tiered precautions, and optimizing allocation of resources during the COVID-19 era.

See Commentaries on pages 1615 and 1516.

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Abbreviations and Acronyms

CCHD	= complex congenital heart disease
CHD	= congenital heart disease
COVID-19	= Coronavirus Disease 2019
MSI	= migration scale index
IQR	= interquartile range

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The outbreak of the novel Coronavirus Disease 2019 (COVID-19) has enormously strained healthcare systems across the globe.^{1,2} Many hospitals, particularly those in epicenter areas, have curtailed or postponed surgical procedures in an effort to mitigate the disease transmission and preserve the resources to care for patients with COVID-19. In addition, patients' access to routine face-to-face visits is heavily restricted because of the aggressive actions taken by the local governments.

Congenital heart disease (CHD) remains a global public health concern.³ The majority of patients with CHD require surgical repair, and a considerable proportion of critically ill neonates require emergency operations.⁴ The ongoing worldwide pandemic has greatly affected the optimal treatments delivery to patients with CHD,^{5,6} potentially placing this population at increased risk for adverse outcomes. Of note, postoperative cardiovascular and noncardiovascular morbidity are common among this subgroup patients, particularly in those with complex CHD (CCHD), emphasizing the need for structured follow-up surveillance.⁷ Guidelines^{8,9} have stressed the importance of maximizing optimization of care for surgical patients during the COVID-19 era, including appropriate triage of cases as well as resource allocation, tiered precautions, use of telemedicine, and a detailed follow-up program. Because management care for CHD requires significant resources and an organized regional system,^{10,11} understanding how the current pandemic affects the congenital heart surgical program is paramount.

Chinese health authorities have taken strict, far-reaching antiepidemic actions in Wuhan since January 22, 2020.^{12,13} With the suppression of the outbreak of the new coronavirus disease, there has been a gradual recovery in healthcare provision in most areas since Wuhan instituted outbound travel restrictions on April 8, 2020. In the present study, we recruited 13 participating

pediatric cardiac surgery intuitions in China, representing the major children hospitals in the National Association of Pediatric Cardiology and Cardiac Surgery (the annualized case volume in each hospital in this association constitutes more than 60% of the CHD surgeries in the provinces/cities where these hospitals are located). Additionally, these 13 centers were located in the provinces where there was a reportedly considerable number of patients with a COVID-19 diagnosis. This study sought to evaluate the impact of early COVID-19 outbreak on the congenital heart surgery program and the outcomes of patients with repaired CCHD during this peak time when the COVID-19 forced significant changes in medical services in China.

MATERIALS AND METHODS**Study Design, Participants, and Definitions**

This multicenter observational cohort study included 13 pediatric tertiary cardiac centers (Figure E1) to survey the performance of CHD surgery and the follow-up program during the COVID-19 pandemic. The Ethics Committee approved this study, and informed consent was obtained. Data including the clinic and surgical information were retrospectively collected. Follow-up data including mortality and unplanned rehospitalization within 6 months after surgery were retrieved from the follow-up databases. Patients undergoing operations (surgical cohort) were classified into 3 groups. Groups I, II, and III refer to patients undergoing surgery between January 23 and April 8 in 2018, 2019, and 2020 (COVID-19 era), respectively. Patients who were discharged alive after surgical repair of CCHD and had follow-up (follow-up cohort) were also classified into 3 groups. Groups A and B refer to patients having follow-up between September 1 and December 31 in 2017 and 2018, respectively; group C refers to patients having follow-up between September 1, 2019, and January 23, 2020. Of note, there was a higher population in group C than groups A and B because additional data from January 1 to 23, 2020, were collected in group C, tending to better illustrate the impact of COVID-19. For patients discharged in 2017 and 2018, follow-up data including mortality and unplanned rehospitalization within 6 months after surgery were retrieved from the follow-up databases. Eleven patients (2.7%) were lost to follow-up in group A, and 13 patients (2.9%) were lost to follow-up in group B.

Baidu migration¹⁴ is an open-source big data project characterizing population migration. Leveraging its location-based services system and Baidu Tianyan system, we obtained the daily migration scale index (MSI) from January 23 to April 8 in 2020 and 2019 of the cities where each recruited center is located. Haodaifu (Good-doctor) is one of the biggest online health services platform that provides online consultation services for patients.^{15,16} The number of network visits for each center from January 23 to April 8 in 2018, 2019, and 2020 was obtained from the customer service department as requested. Given the lack of nucleic acid testing outside the epicenter during this study period, each enrolled hospital followed a strict institutional protocol to control the spread of COVID-19, the principle of which included a 14-day quarantine duration before surgery (including patients and their parents) and negative pressure operation room plus personal protective equipment for emergency cases (Figure E2). During the 14-day quarantine duration, all patients and their parents were required to keep social distancing in a specific hotel near the hospitals and evaluation was done by specialized staff every day. During the hospital admission, clinical evaluation was made for patients and their parents. Examination including x-ray or computed tomography scan and serologic testing was also required. These principles were in line with the expert consensus guideline issued by the Chinese Medical Association for Pediatric Surgery^{17,18} and the policy of the local Health Bureau in 2020.

Because of the impact of COVID-19, follow-up data for children in group C were collected from the parents by phone call or social media app (WeChat). We first send questionnaires (Table E1) to parents or guardians and collect the feedback data. In case of no feedback, we recontact the parents via phone or WeChat to complete the follow-up. If we are unable to contact the parents or guardian by telephone and WeChat, and cannot obtain follow-up records, this case is considered to be lost to follow-up. We contact all of the survivors' parents or guardians, asking about the follow-up modes and the degree of family anxiety during the COVID-19 outbreak. The definition of CCHD and detailed types have been reported by our group.¹⁸

Outcomes

For the follow-up cohort, the composite end point was all-cause mortality and unplanned readmission events during follow-up. All-cause mortality was defined as death from any causes that occurred after discharge. Unplanned readmission was defined as admission to a healthcare facility for any unexpected reason during follow-up. Deaths and unplanned readmissions in groups A and B were confirmed in the hospital medical record and self-reported in group C.

Statistical Analysis

Data normality was tested for each continuous variable. Summary statistics were reported as median (interquartile range [IQR]) or number (%). Patient characteristics were compared through the Kruskal–Wallis test for continuous variables and chi-square test for categorical variables. Kaplan–Meier curve was performed to show the difference in the cumulative probability of death or unplanned readmission among the 3 follow-up groups. A linear regression was performed to show the correlation between MSI (partially reflecting the traffic ban) and decrease in surgical volume as well as outpatient visit volume. All reported *P* values are 2-sided. All analyses are performed using SPSS version 24.0 (SPSS Inc, Chicago, Ill) and R version 4.0.0.

RESULTS

Of the 13 hospitals, 5 were designated as hospitals to treat pediatric patients with COVID-19. A total of 47 nurses (7.5%) were assigned to support other departments in the

same hospital, such as the infectious department or fever clinic, whereas no pediatric cardiologist or surgeon was assigned to support other departments. Only 1 hospital's congenital heart surgery program subsidiary intensive care unit was requisitioned for the treatment of children with COVID-19. There was a scarcity of nucleic acid and serologic antibody testing during the study period, so the majority of the staff except those in Wuhan Children's Hospital were not screened with swabs or serologic testing.

The median surgical volume per center during the COVID-19 era was 25 cases (IQR, 12-63), which was significantly lower than the volume in 2018 (148 cases; IQR, 83-198) and in 2019 (158 cases; IQR, 81-225) ($P = .009$). During this pandemic, the decrease in the surgical volume or outpatient visit volume in each center was not correlated with the number of confirmed COVID-19 cases in the province or municipality where the center was located ($r = 0.374$, $P = .209$ and $r = 0.351$, $P = .436$, respectively), but was positively correlated with the decrease in the Baidu MSI in the city where the center was located ($r = 0.643$, $P = .018$ and $r = 0.614$, $P = .026$) (Figure 1). The total number of both emergency and elective surgeries during the pandemic was less than those in the last 2 years (Table 1, Figure 2). There was a change in case mix during the COVID-19 era (Figure 3, A). First, as a proportion of total surgical volume, there was a relative increase of emergency operations (6.3% in group III vs 3.1% in group I and 2.9% in group II). Second, elective operation for patients with asymptomatic CHDs (eg, isolated atrial septal defect, ventricular septal defect, patent atrial duct) was found to be curtailed in group III. No significant differences were found among the 3 surgical groups concerning the number

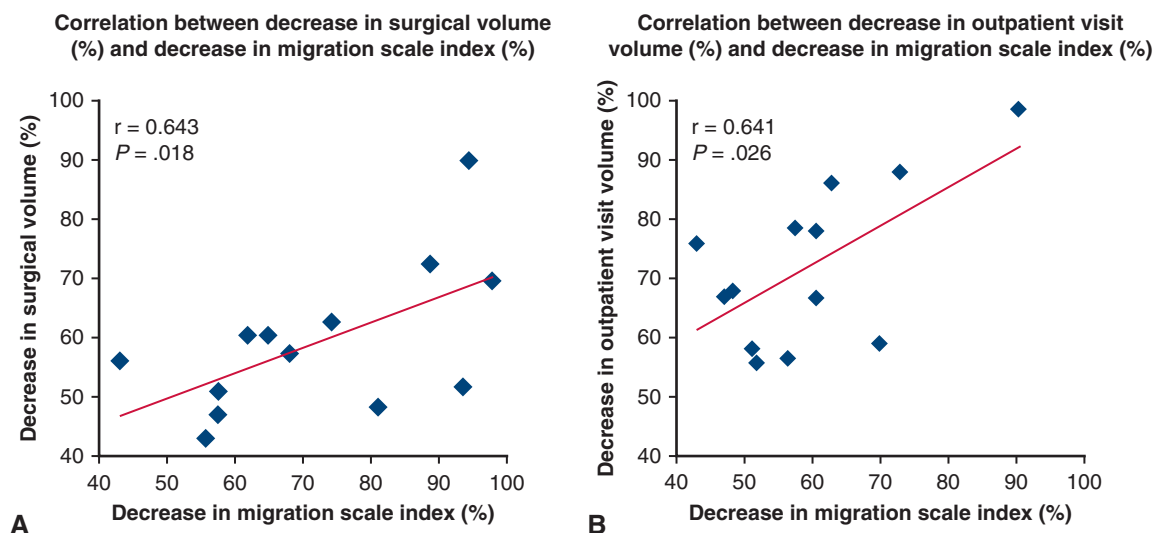


FIGURE 1. The scatter plot shows a correlation between decrease in MSI and decrease in surgical volume/outpatient visit volume. A, A positive correlation was found between decrease in surgical volume and decrease in MSI in the municipality where the center is located ($r = 0.643$, $P = .018$). B, A positive correlation was found between the decrease in outpatient visit volume and decrease in MSI ($r = 0.614$, $P = .026$).

TABLE 1. Survey for pediatric cardiovascular surgery program from January 23 to April 8 in 2018, 2019, and 2020

	Group I (2018)	Group II (2019)	Group III (2020)	P value
Outpatient cases (median, IQR)	19,398	19,620	4740	/
Internet access times (THS, IQR)	26 (6-41)	24 (7-51)	55 (17-67)	.004
Total operation cases	2076	2292	569	/
Emergency surgery (%)	65 (3.1%)	66 (2.9%)	36 (6.3%)	.000
Total anomalous pulmonary vein connection	14 (0.68%)	17 (0.74%)	5 (0.88%)	.876
Pulmonary atresia	14 (0.68%)	10 (0.44%)	6 (1.05%)	.207
Interrupted aortic arch	3 (0.14%)	5 (0.22%)	2 (0.35%)	.608
Transposition of great arteries	12 (0.58%)	6 (0.26%)	5 (0.88%)	.095
Coarctation	11 (0.53%)	14 (0.61%)	9 (1.58%)	.022
Tetralogy of Fallot	11 (0.53%)	14 (0.61%)	9 (1.58%)	.022
Selective surgery (%)	2009 (96.9%)	2226 (97.1%)	533 (93.7%)	.000
ECMO cases of surgery (%)	16 (0.8%)	11 (0.5%)	4 (0.7%)	.463
Mortality (%)	1 (1.5%)	2 (3.0%)	0 (0%)	.535
Emergency	1 (1.5%)	2 (3.0%)	0 (0%)	.535
Elective	32 (1.6%)	37 (1.7%)	8 (1.5%)	.960
No. of transfers (median, IQR)	N/A	2 (1~6)	0 (0~1)	.004
Baidu Migration Index (median, IQR)	N/A	319 (156-554)	138 (54-216)	.004
Blood product volume in hospital (packets, median, IQR)	794 (458-1365)	923 (602-1555)	595 (389-1127)	.032

Values are n (%) or median (IQR). IQR, Interquartile range; THS, thousand; ECMO, extracorporeal membrane oxygenation; N/A, not available.

of patients requiring the support of extracorporeal membrane oxygenation and the mortality of patients undergoing emergency surgery.

During the COVID-19 pandemic, there was a substantial reduction in the total number of outpatient visits (Table 1). The median number of transshipments received by the centers from other hospitals was 0 to 1, significantly lower than in 2019 ($P = .004$) (Table 1). Furthermore, the Baidu MSI of 13 hospital cities was 138 (IQR, 54-216), significantly lower than the same period in 2019 (319 [IQR, 156-554],

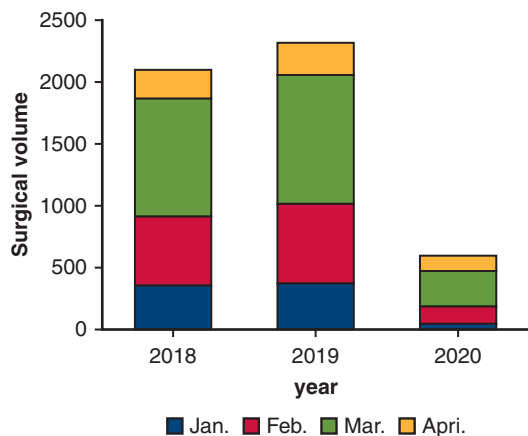


FIGURE 2. The change of surgical volume in 2018, 2019, and 2020. The stacked bar chart shows the respective total surgical volume of 13 participating hospitals between January 23 and April 8 in 2018 (N = 2076), 2019 (N = 2292), and 2020 (N = 569), which indicates a substantial decrease in total volume during the COVID-19 era compared with the same period in 2018 and 2019.

$P = .004$). The median number of blood products received by 13 hospitals from the city central blood station was 595 packets (IQR, 389-1127), significantly lower than in the same period in 2018 and 2019 ($P = .032$). Data from the Good-doctor website showed a median of 55,000 (IQR, 17,000-67,000) online access times during the COVID-19 pandemic, which was significantly higher than in the same periods in 2018 and 2019 ($P = .004$).

Of the 1475 patients in follow-up group, 44 (3%) were lost to follow-up, including 11 cases in group A, 13 cases in group B, and 20 cases in group C. There was no significant difference in age, weight, and primary diagnosis among the 3 groups (Table 2). Patients in group C had a higher proportion of palliative operations than patients in groups A and B ($P = .019$). The median duration of follow-up time in group C was 155 days (IQR, 110-180). There was a higher proportion of online or telephone follow-up in group C than in groups A and B. There was no difference in cumulative probability of death or unplanned readmission during the first 180 days among the 3 groups ($P = .52$) (Figure 3, B). The scores of anxiety index of the patients' parents in group C were 3.5 times higher than in groups A and B. The patients' parents from group C had the highest frequency to use phone or internet for follow-up (Table 3).

DISCUSSION

To our best knowledge, this is the first nationwide multi-center study to investigate the impact of COVID-19 on pediatric congenital heart programs (Figure 4). Our main findings include that (1) COVID-19 has greatly affected

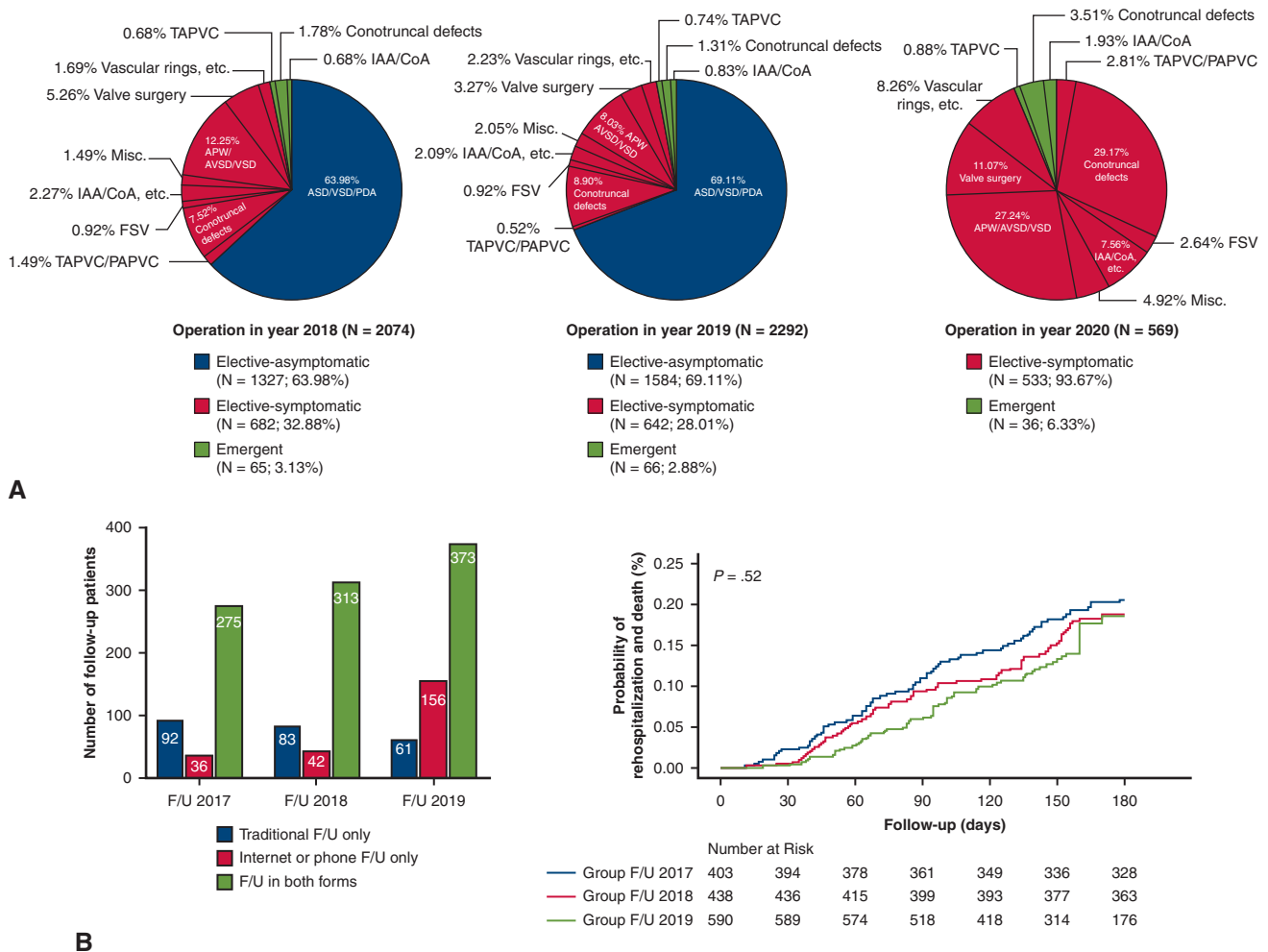


FIGURE 3. A, The redistribution of case mix in 2018, 2019, and 2020. The diagnosis of surgical cases between January 23 and April 8 in 2018, 2019, and 2020. Areas in green, red, and blue indicate the emergency cases, symptomatic elective cases for which surgery should be performed as early as possible, and asymptomatic elective cases for which surgery can be postponed, respectively. During the COVID-19 pandemic, all of the recruited centers have postponed asymptomatic elective cases. In 2020, emergency cases accounts for 6.3% of the total cases, which is statistically greater than 2.9% in 2019 and 3.1% in 2018 ($P < .0001$). B, The CHD follow-up program in 2017 (group A), 2018 (group B), and 2019 (group C). The bar chart shows the total number of follow-up in patients with CCHD in 2017, 2018, and 2019 in 3 follow-up forms (traditional follow-up only, internet or phone follow-up only, and follow-up in both forms). There was a significantly higher proportion of patients who only followed up through the internet or phone in group C (26.4% in group C vs 9.6% in group B and 8.9% in group A; $P < .0001$). The Kaplan–Meier curve showed that there was no significant difference in the cumulative probability of death or unplanned readmission among the 3 groups ($P = .52$). TAPVC, Total anomalous pulmonary venous connection; IAA, interrupted aortic arch; CoA, aortic coarctation; APW, aortopulmonary window; VSD, ventricular septal defect; AVSD, atrioventricular septal defect; Misc., miscellaneous; ASD, atrial septal defect; PDA, patent ductus arteriosus; FSV, functional single ventricle; PAPVC, partial anomalous pulmonary venous; F/U, follow-up.

the perioperative care for patients with CHD, including a substantial number of case delays and limited access to routine follow-up hospital visits; and (2) tele- and network follow-up might be an effective alternative to the conventional hospital visit in terms of potentially mitigating the risk of postrepair adverse outcomes.

According to the recent report from the National Health Commission, the numbers of diagnosis and treatment offered by the tertiary center in China were dramatically decreased by 51% during the COVID-19 era.¹⁹ Correspondingly, there was also a substantial decrease in

pediatric congenital heart surgery compared with the same period in 2018 and 2019. Further, as a proportion of total surgical volume, there was a relative increase in emergency operations. Such change in case mix may largely ascribe to the strict restriction placed on each enrolled hospital that elective operation for patients with asymptomatic simple CHDs was not allowed during the COVID-19 era. Further subdivided by the disease category, a significant difference can be found only in those with coarctation of aorta and tetralogy of Fallot. However, there was a trend for a higher percentage of patients in the other categories, and

TABLE 2. Baseline characteristics of follow-up cohort

	Group A (n = 403)	Group B (n = 438)	Group C (n = 590)	P value
Age (d) (median, IQR)	204 (69-541)	196 (90-649)	191 (67-557)	.203
Male (%)	28.7%	32.7%	38.6%	.061
Weight, kg (median, IQR)	7 (4.7-10)	7 (4.9-11)	6.8 (4.4-10)	.061
Primary diagnosis				
Tetralogy of Fallot	119 (29.5%)	136 (31.1%)	165 (28.0%)	.559
Total anomalous pulmonary vein drainage	53 (13.2%)	66 (15.1%)	59 (11.2%)	.184
Coarctation/VSD	54 (13.4%)	55 (12.6%)	100 (16.9%)	.103
Double outlet right ventricle	43 (10.7%)	38 (8.7%)	54 (9.2%)	.586
Pulmonary atresia	32 (7.9%)	33 (7.5%)	77 (13.1%)	.004
Transposition of great arteries	25 (6.2%)	27 (6.2%)	38 (6.4%)	.980
Single ventricle	18 (4.5%)	20 (4.6%)	26 (4.4%)	.993
Atrioventricular septal defect	35 (8.7%)	30 (6.8%)	31 (5.3%)	.104
Interrupted aortic arch	11 (2.7%)	9 (2.1%)	13 (2.2%)	.790
Miscellaneous	13 (3.2%)	24 (5.5%)	20 (3.4%)	.156
Operation type				
Biventricular repair	353 (87.6%)	385 (87.9%)	498 (84.4%)	.191
Palliative operation	34 (8.4%)	37 (8.8%)	77 (13.1%)	.019
Sing ventricle repair	16 (4.0%)	16 (3.3%)	15 (2.4%)	.405

Values are n (%) or median (IQR). IQR, Interquartile range; VSD, ventricular septal defect.

failure to find statistical differences may be partly due to the relatively low prevalence of these diseases. Notably, given the regionalization of congenital heart surgery services in China, where there is a growing CHD population with limited specialist resources, the majority of patients with CHD moved from other cities or rural areas to undergo surgical repair in a few tertiary centers.²⁰ During the COVID-19 era, such patient transfer was greatly restricted by the travel ban, explaining the decrease in surgeries, even in emergency cases. Additionally, parents' reluctance to seek care during this pandemic and the 14-day preadmission quarantine before surgery are other potential factors in such a decrease. Chinese government has implemented aggressive actions^{13,21} to control the spread of COVID-19, including strict control of entering or leaving from cities and rural areas, and reducing/shutting down the city public transportation and inter-city airline or high-speed railways. The decrease in emergency surgery raises substantial concerns. Critical CHDs (eg, duct-dependent CCHDs) usually constitute a large proportion of the emergency cases in which dramatic changes after birth may lead to rapid hemodynamic compromise and preoperative attrition. From the standpoint of clinical practice, there is only a narrow temporal window for these patients, and timely lifesaving surgical intervention is definitely required. Lack of surgical care in early life potentially poses a big threat to this patient population.

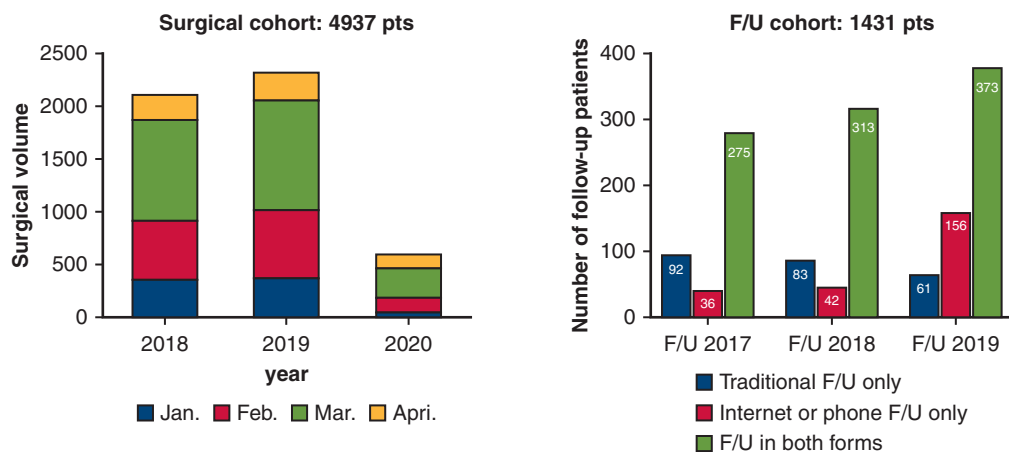
Guidelines related to adult patients undergoing cardiac surgery²² or heart transplant²³ in the context of the current pandemic have been published. These statements have recommended deferral of elective surgery during the COVID-19 era. Recent Taskforce and Society guidance

statements²⁴ have also stressed the necessity of deferring elective surgeries in efforts to control the spread of COVID-19 and preserve or redirect limited resources and personnel for the treatment of patients infected by COVID-19. Although there was an expected decrease in elective surgery in this cohort, some may still argue that maintaining elective surgery is not appropriate given that the potential harm in terms of COVID-19 transmission would seem extremely high and clearly unjustified when compared with the benign prognosis associated with deferring elective pediatric cardiac operations. First, we should clarify that surgery for patients with asymptomatic simple CHDs was heavily restricted. The elective cases in this study include some patients with tetralogy of Fallot or coarctation of aorta who presented with relatively stable clinical manifestations and infantile patients with large ventricular septal defects or complete atrioventricular septal defects who had signs of impaired heart function, a history of recurrent repertory infection, and failure to thrive. Postponing surgery in these patients might result in a cyanotic spell and severe heart failure during the waiting time, potentially increasing the perioperative mortality. The implications of deferred cardiac surgical operations remain unknown,²⁵ and comprehensive as well as careful risk-benefit evaluation should be made instead of making decisions solely on the basis of COVID-associated risks.²⁶ The policymakers should not prioritize needs to maximize the number of patients' care at the cost of disregarding care for vulnerable individuals.²⁷ On the other hand, we recognize that the significance of the potential damage of COVID-19 in patients undergoing cardiac surgery cannot be underestimated. Because of the lack of availability of

Congenital Heart Surgery Program during Early COVID-19 in China (retrospective design, thirteen children's hospitals)

- The COVID-19 pandemic results in a substantial decrease in total surgical volume.
- The COVID-19 pandemic results in a redistribution of the case mix.
(decrease in asymptomatic elective surgery and increase in emergent case)
- Online F/U strategy appears to be effective during the COVID-19 pandemic.

F/U: follow-up
pts: patients
CHD: congenital heart disease



Implications:

Changes in management care for patients with CHD during COVID-19 era potentially pose a threat to this subgroup of patients.

Government should provide better service for patients with CHD regarding patient triage, tiered precautions and optimization of resource allocations.

FIGURE 4. This retrospective study includes 13 children's hospitals and aims to investigate the impact of the early COVID-19 outbreak on the CHD surgery program in China. The main findings of this study are that the COVID-19 pandemic has resulted in a substantial decrease in total surgical volume and that a redistribution of the case mix and online follow-up care strategy appears to be effective during the COVID-19 era. Our results provide a platform for further study of better serving patients with CHD in terms of patient triage, tiered precautions, and optimizing allocation of resources during the COVID-19 era.

nucleic acid testing during the early COVID-19 outbreak, every elective case and their parents must be observed for 2 weeks before surgery given the rationale that incubation period of COVID-19 is generally within 14 days after exposure.

According to the results, resource scarcities and the phenomenon of medical system breakdown were less common. For instance, resources in cardiac intensive care unit and the extracorporeal membrane oxygenation facilities were not allocated to those infected cases in the majority of the recruited hospitals. Only a small number of doctors/nurses were assigned to assist in the care management of patients infected by COVID-19, which is in line with a recent report that a small fraction of pediatric cardiologists from 56 US centers are reassigned to provide clinical services outside their scope of practice.⁶ There may be several explanations. First, the study period can be considered as an early phase in which resources were relatively plentiful compared with the peak phase,²⁸ and the majority of the hospitals were not at the epicenter. Second, pediatric patients constitute a small portion of cases infected by COVID-19 compared with adult patients.²⁹ Thus, there was a lower burden of hospitalized patients with COVID-19 in children's hospitals.

However, these results should be interpreted with caution because as this pandemic continues to a peak time, postponing elective surgery after careful patient triage should undoubtedly be advocated in efforts to preserve scarce resources. Of note, although there was a substantial decrease in blood donation during the COVID-19 era, it did not appear to be a main reason for the decrease in surgical volume given the liberal use of priming without blood and blood salvage in congenital heart surgery.³⁰

Preoperative and postoperative nucleic acid testing are both important because a recent case report found that COVID-19 infection was confirmed on postoperative day 13 in a patient undergoing the Fontan operation. There was a lack of testing kits in the early period of COVID-19 outbreak, and it was not until April 24, 2020, that nucleic acid testing was uniformly performed in China.³¹ Thus, the majority of the patients in this cohort did not undergo regular preoperative and postoperative testing. Although we used strict methods to control the spread of COVID-19 in patients undergoing congenital heart surgery in this series, we cannot rule out the possibility that there may be asymptomatic carriers because preoperative nucleic acid testing for COVID-19 was not routinely performed in

TABLE 3. Outcomes of the follow-up population after complex congenital heart disease surgery among the 3 groups

	Group A (n = 403)	Group B (n = 438)	Group C (n = 590)	P value
Death	8 (2.0%)	7 (1.60%)	5 (0.8%)	.296
Unplanned readmission	67 (16.6%)	68 (15.5%)	74 (12.6%)	.163
GAD-7				.000
0-4	164 (41.6%)	168 (39.0%)	208 (35.6%)	
5-9 (mild)	171 (43.4%)	173 (40.1%)	210 (35.9%)	
10-14 (moderate anxiety)	37 (9.4%)	55 (12.8%)	113 (19.3%)	
15-21 (severe anxiety)	22 (5.6%)	35 (8.1%)	54 (9.2%)	
Follow-up forms				.000
Traditional follow-up only	92 (22.8%)	83 (18.9%)	61 (10.3%)	
Internet or phone follow-up only	36 (8.9%)	42 (9.6%)	156 (26.4%)	
Follow-up in both forms	275 (68.2%)	313 (71.5%)	373 (63.2%)	
Satisfactory of follow-up via internet or phone				.091
Unsatisfied	8 (2.6%)	19 (5.4%)	26 (4.9%)	
Satisfied	231 (74.3%)	234 (68.5%)	349 (66.0%)	
Very satisfied	72 (23.2%)	93 (26.2%)	154 (29.1%)	

Values are n (%) or median (IQR). The GAD-7 score is calculated by assigning scores of 0, 1, 2, and 3, to the response categories of not at all, several days, more than half the days, and nearly every day, respectively. Scores of 5, 10, and 15 represent cut points for mild, moderate, and severe anxiety, respectively. GAD-7, Generalized Anxiety Disorder-7.

patients and their parents. We recognize the significance of the potential damage of COVID-19 in patients undergoing cardiac surgery; however, as mentioned, the balance between postponing or curtailing surgery and potentially putting the vulnerable individuals at risk of deterioration of some specific CHDs requires a second ethical consideration. There was still a high overall surgical volume performed during the COVID-19 era in this series. There are several potential rationales and reasons for our relatively aggressive attitude toward performing surgery for those who may have a high risk of mortality and morbidity during the waiting time. First, the Chinese government has taken strict, far-reaching antiepidemic actions, particularly in Wuhan, which was the first outbreak area in China, which may effectively help to control the transmission of the disease. Second, given the rationale that the incubation period of COVID-19 is generally within 14 days after exposure, we strictly required an observation for 2 weeks (including both patients and their parents) before surgery. As for some emergency cases, operations must be performed in COVID-19–designated operating rooms (eg, negative pressure operation room) plus personal protective equipment. Such strict institutional protocols may be helpful to control the spread of COVID-19. Third, the study has shown that pediatric patients constitute a relatively small portion of cases infected by COVID-19 and usually have less severe clinical manifestations. A recent study³² from a Boston group indicated that the differences in expression of angiotensin-converting enzyme 2 or transmembrane serine protease 2 between younger and adult patients may potentially result in less vulnerability to the COVID-19 infection in pediatric patients. Although preoperative testing for COVID-19 is currently mandatory in the majority of

countries, it should be acknowledged that the availability of testing and its implementation are still not uniform around the world. In this sense, our experience may be of potential value. Finally, we should clarify that since April 24, 2020, we have changed our protocol by performing nucleic acid tests, instead of 14-day quarantine, in all pediatric patients undergoing surgery and their parents.

Orchestrated follow-up mechanism is crucial to the patients undergoing complex congenital heart surgery.³³ In this study, the aforementioned traffic control, social distancing policy, and parents' anxiety about being infected by COVID-19 were associated with a dramatic decrease in postoperative clinic visits. However, there is no increase in mortality or unplanned rehospitalization during the follow-up period compared with the rate in the previous 2 years. Our data indicate an increasing interaction between parents and CHD specialists via tele- and network follow-up visits. During the outbreak of COVID-19, the government has promoted the establishment of virtual hospitals, advocating tertiary hospitals to provide medical services via network and advocate dispensing by express delivery.³⁴ Meanwhile, some private third-party network platforms (eg, Haodaifu network) have provided point-to-point healthcare services between doctors and patients. Such liberal use of the tele- and network follow-up visits is helpful to provide better postrepair care for patients with CHD and partially explain why there is no difference regarding mortality or rehospitalization during this pandemic. Our finding is also in line with the guideline statement²² that other types of follow-up visit are required to help reduce the undue risk for hospital-acquired transmission. However, conventional hospital visits are still required in a portion of patients with CHD because they may need computed tomography angiography

or invasive catheterization evaluation. The duration of the follow-up period in this study was relatively short. There is the possibility that the lack of hospital visits may be related to an increase in mortality and rehospitalization during the longer follow-up if the medical service cannot return to normal. Thus, innovative methods, including wearable monitor devices designed for children and telemedicine between specialized hospitals and local clinics may become a main follow-up strategy post-COVID-19 era.

Study Limitations

First, data regarding the number of neonates born with CHD during the study period cannot be obtained, so detailed information regarding neonatal patients who died because of a lack of health care was not available. It is possible that lack of access to timely surgical intervention in some neonates with critical CHDs may result in increased mortality. Second, we lack information about the patients who potentially require surgical interventions during the COVID-19 era so that the association between their parent's psychologic factors and the decrease in surgical volumes cannot be identified. Third, we only follow up the patients via telephone or social media apps during the COVID-19 era, so we cannot definitely verify the death or unplanned readmission in group C. Fourth, the Shanghai Children's Medical Center and Beijing Children's Hospital were both national children's medical centers, so there were more patients coming from other areas to seek treatments for CHD in these 2 hospitals. There may be variations in institutional management care (eg, surgical experiences, postrepair intensive care), which may bias the results. Fifth, further study is required to obtain more robust data (eg, travel distance, data directly reflecting the status of traffic restriction) to help confirm the hypothesis that travel restrictions are a main barrier to CHD care during the early outbreak of COVID-19 in China. Finally, except for Wuhan Children's Hospital, all of the patients and members of the healthcare provider team outside the epicenter in this cohort did not undertake nucleic acid testing during the early outbreak of COVID-19 pandemic, so we cannot rule out the possibility that there may be asymptomatic carriers.

CONCLUSIONS

Although resource scarcities and the phenomenon of medical system breakdown were less common in children's hospitals during the COVID-19 era, there was a substantial decrease in both elective and emergency operations. The unprecedented measures taken by the governments, including traffic restrictions, bring a challenge to the regionalization of congenital heart surgery service. The online follow-up surveillance appears to be effective during such a public health crisis. Our study provides some valuable information regarding the impact of the ongoing COVID-19 pandemic on crisis management for CHD, highlighting

the importance and challenge of serving this subgroup patient under a public health crisis.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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This study recruited the major children's hospitals in the National Association of Pediatric Cardiology and Cardiac Surgery in China, including Shanghai Children's Medical Center, Hunan Children's Hospital, Jiangxi Children's Hospital, Wuhan Children's Hospital, Shanxi Children's Hospital, Yuying Children's Hospital, The Second Hospital affiliated to Harbin Medical University, Hainan Women and Children Medical Center, Xi'an Children's Hospital, Yan'an Hospital, Guangzhou Woman and Children's Hospital, Beijing Children's Hospital, National Center for Children Health, Beijing, China, and Shenzhen Children's Hospital.

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Key Words: congenital heart disease, COVID-19, follow-up, surgery



FIGURE E1. The geographic location of the 13 participating centers in China.

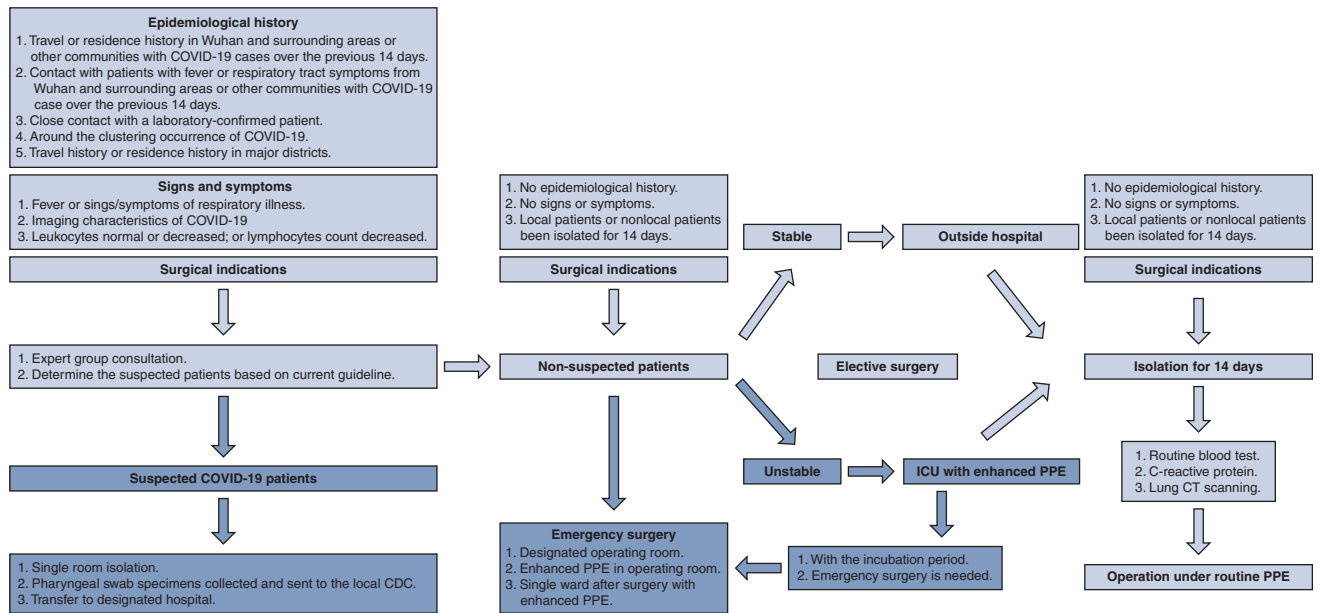


FIGURE E2. The protocol of surgical program of surgical repair for CHDs during January 23 to April 8 in the enrolled centers across China. *COVID-19*, Coronavirus Disease 2019; *CDC*, Centers for Disease Control and Prevention; *PPE*, personal protective equipment.

TABLE E1. Questionnaire for all the parents or guardian with children who survived after complex congenital heart surgery

1. Your child's name:
Your child's registered address:
Your child's year/month of birth: year month
2. Year/month of heart surgery is: year month
3. How is your child's physical condition after being discharged?
 - A. Not hospitalized again
 - B. Rehospitalization
 - C. Death
4. If death occurred unfortunately, the time of death is
Cause of death (hospital diagnosis)
(If this situation did not occur, please ignore this question. If death occurred, complete the questionnaire and ignore the rest of the survey.)
5. The number and time of your child's rehospitalization after being discharged from the hospital
 - A. none,
 - B. once. Time 1: year month
 - C. twice. Time 1: year month, Time 2: year month
 - D. 3 times or more. Time 1: year month,
Time 2: year month,
Time 3: year month.
6. If your child was hospitalized again after the operation, the reason for the hospitalization is (if you are not hospitalized again, please ignore this question)
 - A. Planned, prestage inspection
 - B. Planned, staged surgery
 - C. Unplanned, cause (with discharge diagnosis)
 - D. Other
7. Your child's follow-up (review) within 6 mo after the surgery: (multiple choices are allowed)
 - A. No follow-up. Reasons are
 - B. Follow-up at outpatient clinic of the hospital where the surgery was performed
 - C. Follow-up at local hospital, name of local hospital, follow-up times
 - D. Follow-up through phone or online social media. Number of follow-ups.
8. How many times your child was followed up within 6 mo after the operation (multiple choices)
 - A. 1 mo after surgery
 - B. 3 mo after surgery
 - C. 6 mo after surgery
 - D. Other
9. During the COVID-19 epidemic, what kind of follow-up method was used (multiple choices)
 - A. No follow-up, reason
 - B. Follow-up at outpatient clinic of the hospital where the surgery was performed
 - C. Follow-up at local hospital, name of local hospital, follow-up times
 - D. Follow-up through phone or online social media. Number of follow-ups
10. Are there any travel difficulties/restrictions during the 6-mo follow-up after surgery?
 - A. Yes
 - B. No
11. During the follow-up by phone or social media, your satisfaction with "Can you reach the doctor in time" is described as: (If you have not followed by phone or online social platform, please ignore this question)
 - A. Not satisfied
 - B. Satisfied
 - C. Very satisfied
12. During the follow-up by telephone or online social platform, your satisfaction with "Ease of communication between yourself and the doctor" is described as: (If you are not followed by telephone or social media, please ignore this question)
 - A. Not satisfied
 - B. Satisfied
 - C. Very satisfied
13. During the follow-up by phone or social media, your satisfaction with "Acceptance of this form of consultation and follow-up" is described as: (If you do not follow by phone or social media, please ignore this question)
 - A. Not satisfied
 - B. Satisfied
 - C. Very satisfied

(Continued)

TABLE E1. Continued

14. During the COVID-19 epidemic, are you willing to take your child to the hospital for follow-up:
 - A. Yes
 - B. No
 - C. No follow-up needed
15. Did you encounter travel difficulties during follow-up:
 - A. Yes
 - B. No
16. If you encountered travel difficulties during follow-up, is it related to the COVID-19 epidemic?
 - A. Yes
 - B. No
17. Did the child's main guardian "feel nervous, anxious, or on edge" during the COVID-19 epidemic?
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day
18. During the COVID-19 epidemic, did the child's primary guardian "unable to stop or control worrying":
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day
19. During the COVID-19 epidemic, did the child's primary guardian "worried too much about different things":
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day
20. During the COVID-19 epidemic, did the child's main guardian "trouble relaxing":
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day
21. During the COVID-19 epidemic, did the child's primary guardian feel "so restless that it's hard to sit still":
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day
22. Was the child's primary guardian "easily annoyed or irritable during the COVID-19 epidemic"
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day
23. During the COVID-19 epidemic, was the child's primary guardian "feel afraid as if something awful might happen"
 - A. Not at all
 - B. A few days a week
 - C. >1 wk
 - D. Almost every day