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BRIEF COMMUNICATION

Congenital Heart Disease After the Fukushima Nuclear Accident: The Japan Cardiovascular Surgery Database Study

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BACKGROUND: In March 2011, the Fukushima Daiichi nuclear power plant disaster inflicted radiation damage across the Tohoku region of Northern Japan. The consequent harm to pregnant mothers and newborns was a matter of concern. We performed a registry-based analysis of the incidence of congenital heart disease during 2010 to 2013 using the Japan Cardiovascular Surgery Database.

METHODS AND RESULTS: We selected patients who had complex congenital heart disease and who were born between January 1, 2010 and December 31, 2013 undergoing surgery, and assessed the trend in the number of first-time surgeries performed for patients aged 2 years and younger by birth year over time. The numbers of first-time surgeries for birth years 2010 to 2013 were 2978, 2924, 3077, and 2940, and no increasing trend was detected. Additionally, no increasing yearly trend was detected when the number of cases was divided by the total number of births in Japan in each birth month. The mortality of first-time surgeries performed for complex diseases, which often involves multiple subsequent surgeries, decreased from 4.7% in 2010 to 2.2% in 2013.

CONCLUSIONS: Our analyses showed no increase in the number of patients with congenital heart disease during 2010 to 2013. The yearly increase in the total number of surgeries following the Fukushima Daiichi nuclear disaster in a previous report can be explained by the decline in the mortality of first-time surgeries for complex cases. Such use of only the increase in the total yearly number of surgeries to claim the effects of a nuclear disaster on the incidence of congenital heart disease is a far too simplistic and dangerous proposition.

Key Words: congenital heart disease ■ database ■ Fukushima nuclear accident

The Great East Japan Earthquake occurred on March 11, 2011, and triggered a massive tsunami. This natural disaster precipitated the Fukushima Daiichi nuclear disaster, which inflicted radiation damage across a vast area centered around the Tohoku region of Northern Japan. In particular, the effects[1] of this damage on pregnant mothers[2] and newborns was a matter of concern to all.

Murase et al have reported a significant increase in the number of surgeries performed for complex cardiac abnormalities throughout Japan since 2011 using the results of a survey questionnaire by the Japanese Association for Thoracic Surgery, and argued that this increase appears to be causally linked to the Fukushima nuclear disaster.[3] Use of the survey questionnaire published by Japanese Association for Thoracic Surgery for such analyses has a few substantive problems. First, it only lists the number of surgeries performed, but not the number of patients. For complex cardiac abnormalities, multiple palliative

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procedures precede a final radical surgery, causing a significant discrepancy between the number of surgeries and the number of patients operated upon. Second, the survey counts the number of surgeries performed within the given date range, and not the number of patients with a given condition who were born in that date range. For instance, many of the procedures performed after the nuclear incident were for children who were born much earlier. Thus, the results of the survey cannot serve as an appropriate tool to directly evaluate the causal relationship between the nuclear disaster and the incidence of congenital cardiac abnormalities or diseases. Furthermore, the effect of the nuclear disaster would be evident only in fetuses that were exposed to radiation before the eighth week, the gestational age at which organogenesis is largely complete. In this regard, the number of surgeries performed on congenital cardiac abnormalities would start to increase only at 8 months after the occurrence of the disaster; that is, after November 2011. However, the Murase et al study makes no such considerations, but insists that the number of surgeries increased since 2011. Also, this study counts only the surgeries performed on infants ≤1 year of age. If indeed the nuclear disaster were to increase the incidence of congenital cardiac abnormalities, this effect should be delayed beyond 2011 and start around 2012. Thus, it is quite likely that the primary contention of this study—that the number of patients has increased since 2011—is incorrect. Finally, the Murase et al study does not perform regionalized analysis of the Tohoku area, including Fukushima, which weakens its methodological legitimacy.

Reports published by the World Health Organization in the wake of history's greatest nuclear disaster, the Chernobyl disaster, estimate that the effects on the incidence of congenital abnormalities were quite small.[4] Certain aspects of the generational impact of the Chernobyl disaster on the surrounding population still remain unascertained. However, after the Fukushima disaster, thorough tests have determined that the incident's effect is far smaller than that of the Chernobyl disaster.[5] Survey reports across the Fukushima Prefecture reveal that the incidence of newborn congenital abnormalities in the area did not increase after the nuclear disaster.[6] In light of these facts, it is quite hard to imagine that the Fukushima nuclear disaster will cause any sort of increase in the incidence of congenital abnormalities or diseases in all of Japan.

We hypothesized that the incidence of congenital heart disease (CHD) did not increase after the disaster, contrary to what Murase et al reported. To assess this hypothesis, we used the data from the congenital section of the JCVSD-congenital (Japanese Cardiovascular Surgery Database), a repository of explicit information on individual patient cases. We calculated the number of children undergoing their first congenital cardiovascular surgery in the database by the month they were born during 2010 to 2013, and evaluated its trend over time.

We consider the following points to be critically important for improving the validity of the study analysis:

1. By sorting the patients according to birth date and not by the day of surgery, we accurately captured the number of monthly incidences of CHD both before and after the Great East Japan Earthquake.
2. By extracting data on first-time surgeries only, we eliminated an issue plaguing the analysis using the Japanese Association for Thoracic Surgery survey for disease incidence estimation: the listing of multiple surgeries for a single patient.
3. We counted the number of surgeries conducted in the Tohoku area and compared it with that conducted across Japan.
4. We estimated the mortality of the procedures for complex diseases by year of operation. If the death rate for complex diseases—which often requires multiple surgeries—decreased, it would explain the apparent increase in the total number of surgeries.

METHODS

Data Availability

Based on the data use policy of the JCVSD-congenital database, data access for the JCSVD-congenital is approved through assessment by the data utilization committee of the JCVSD. Those interested in using the data should contact the JCVSD executive office (jcvsd_adult_congenital@ncd-core.jp) and submit a proposal.

Data Source

We used data from the JCVSD-congenital database, which is a nationwide registry of congenital cardiovascular surgeries that started data collection in 2008. At present, nearly all facilities in Japan performing such surgeries register all their case data to the initiative[7]; however, data were only available from 59 facilities at the beginning of 2010. To eliminate the impact of the increasing number of facilities in the database over time, we conducted the study using the data from these 59 facilities only. The cases reported from these 59 facilities comprised 77.2% (6801/8815) of all registered cases as of 2015 in which all the institutions participated in the database. Of the 59 institutions, 6 institutions were in the Tohoku area, which comprises 75% (6/8) of institutions in Tohoku

area. Regarding the case numbers, these 6 institutions performed 94.1% (399/424) of all the cases in the Tohoku area in 2015.

Data in the registry are collected on more than 300 information fields, including demographics, preoperational risks, diagnoses, surgical methods, intraoperative information, postoperative complications, and survival information. The definitions used in the database are the same as those used by the STS National Database[8] of the Society of Thoracic Surgeons.

Patients and Surgery Counts

We selected patients who underwent all types of congenital cardiovascular surgeries between January 1, 2010 and December 31, 2015 at the 59 facilities mentioned above in the database. We extracted information on patients' birth date, surgery date, age in days at the time of surgery, principal diagnosis for the baseline disease leading to the surgery, and 30-day postoperative survival. We excluded children who were over the age of 2 years at the time of operation, to capture the fuller picture of patients' surgery requirements for each calendar month. We categorized CHD diagnoses into "simple," "complex," or "other" diseases based on the surgical procedures required for treatment, as presented in Table S1. We defined "simple" diseases as those diseases that consist of (1) simple defects such as atrial septal defect, ventricular septal defect, etc or (2) simple stenotic lesions such as coarctation of aorta (without intracardiac lesions), pulmonary stenosis, etc. "Complex" diseases are those with more complex lesions such as tetralogy of Fallot, transposition of the great arteries, single ventricle, hypoplastic left heart syndrome, etc. "Other" diseases are those diseases that consist of (1) the lesions in which the severity of the lesion is very variable and hard to determine whether the disease is simple or complex (for example, aortic stenosis, coronary artery anomaly), or (2) the lesions in which whether or not they are congenital is undeterminable (for example, mitral regurgitation, cardiomyopathy). The classifications of the diseases are almost identical to those in the Murase et al study. One major difference is that although Murase et al defined pulmonary atresia with intact ventricular septum as "simple," we defined this as "complex" because many of these patients are candidates for single ventricle repair and often have accompanying important coronary anomalies such as coronary fistulae and stenosis. Pulmonary atresia with intact ventricular septum comprised 1.25% of all the cases. We excluded those procedures that were not categorized as congenital cardiovascular disease or were undefined.

Statistical Analysis

We report 3 types of numbers in this study:

1. We counted the number of first congenital cardiovascular surgeries by patients' birth year–month (January 2010, February 2010, …, December 2013) and by the type of surgery (simple, complex, or other) in all 59 of the facilities. We also repeated this for the facilities located in the Tohoku area only. We evaluated the trend in the number of patients undergoing surgery visually via a line graph. We also tested for a trend in the count of surgeries over time by estimating the Pearson's correlation coefficient between the birth year–month (recoding January 2010 as 1, February 2010 as 2, up to December 2013 as 48) and the number of patients undergoing first-time surgeries. For this trend to be a good proxy of that of the CHD incidence in Japan, we need to assume that the number of live births in areas in which the 59 facilities are located are fairly constant during 2010 to 2013.
2. We calculated the percentage of live births in Japan[9] that underwent their first congenital cardiovascular surgeries at these 59 facilities by patients' birth year–month. This does not capture the true incidence of congenital cardiovascular diseases among all live births in Japan, because the 59 facilities only captured ≈77% of the surgeries as explained above. However, if we assume that the proportion of patients among all those requiring congenital cardiovascular surgeries in Japan who are treated at these 59 facilities did not change over time, the trend of this percentage would be a good proxy for the trend of congenital cardiovascular disease incidence in Japan. We tested for the trend using Cochran-Armitage test for trends.
3. Last, we calculated the total number of operations for complex diseases (including second-time and all subsequent surgeries thereafter) performed on patients 1 year old and younger per operation year, regardless of when the patients were born. We performed this analysis to mimic the approach used by Murase et al and to show that the result coincides with the findings from their study. We also assessed the changes in the perioperative mortality over time for first congenital cardiovascular surgeries performed on such patients, and tested for the trend using the Cochran-Armitage test for trends. All analyses were carried out using SAS 9.4 (SAS Institute Inc., Cary, NC). All tests were 2-tailed, and $P<0.05$ was deemed to be statistically significant.

The study was approved by the data utilization committee of the JCVSD. We obtained study approval from the Institutional Review Board of Tokyo University

(2895-8). The board waived the requirement for informed consent because of the anonymous nature of the data.

RESULTS

We identified in the database 26 251 patients undergoing 44 818 congenital cardiovascular surgeries during 2010 to 2015. Among them, 11 919 were born between 2010 and 2013, and had undergone surgery at the age of 2 years or younger. The birth year–month of the patients born between January 2010 and December 2013 in the cohort are summarized in Table S2 for both all of Japan and in the Tohoku region.

Figure 1A shows the change in the number of first-time surgeries by patients' birth-year month for all and complex disease diagnoses. The yearly numbers of first-time surgeries during years 2010 to 2013 were 2978, 2924, 3077, and 2940. Visual inspection suggests no apparent monthly increase in the number of simple or complex cases over the observed time period. The Pearson's correlation coefficient for all procedures and in the complex group was −0.05 (95% CI, −0.24, 0.33) (*P* value: 0.75), and 0.08 (95% CI, −0.36, 0.21) (*P* value: 0.59), respectively. Figure 1B shows the same line graph, limited to the first-time surgeries performed at facilities in the Tohoku area. Again, we see no apparent monthly increase in the numbers of simple or complex cases under visual inspection. The Pearson's correlation coefficient was 0.12 (95% CI, −0.17, 0.39) (*P* value: 0.43) for all procedures, and −0.05 (95% CI, −0.33, 0.24) (*P* value: 0.76) among the complex procedures.

The estimated percentage of the live births that underwent congenital heart surgeries at the 59 facilities (the number of first-time surgeries divided by overall number of newborns in Japan by birth-year month) is summarized in Figure 2. No apparent increase in the proportion of all or complex cases were observed. The *P* values from Cochran Armitage trend test were not statistically significant for all estimated values: *P* values were 0.16 for all surgeries in all Japan, 0.80 for complex surgeries in all Japan, 0.18 for all surgeries in Tohoku area, and 0.89 for complex surgeries in Tohoku area.

The total number of operations performed for complex diseases under 1 year old in years 2010–2013 in the database were 2104, 2177, 2253, and 2216, respectively. As shown in Figure 3, the number of operations appeared to increase over time, as reported by Murase et al. The mortality of the initial operations for complex diseases, which often involves multiple subsequent operations, decreased over the observed time (*P*<0.01).

DISCUSSION

In this study, we were able to use the data from JCVSD-congenital to clarify the following points:

1. When counting the first-time surgeries and surgeries based on birth date as opposed to the

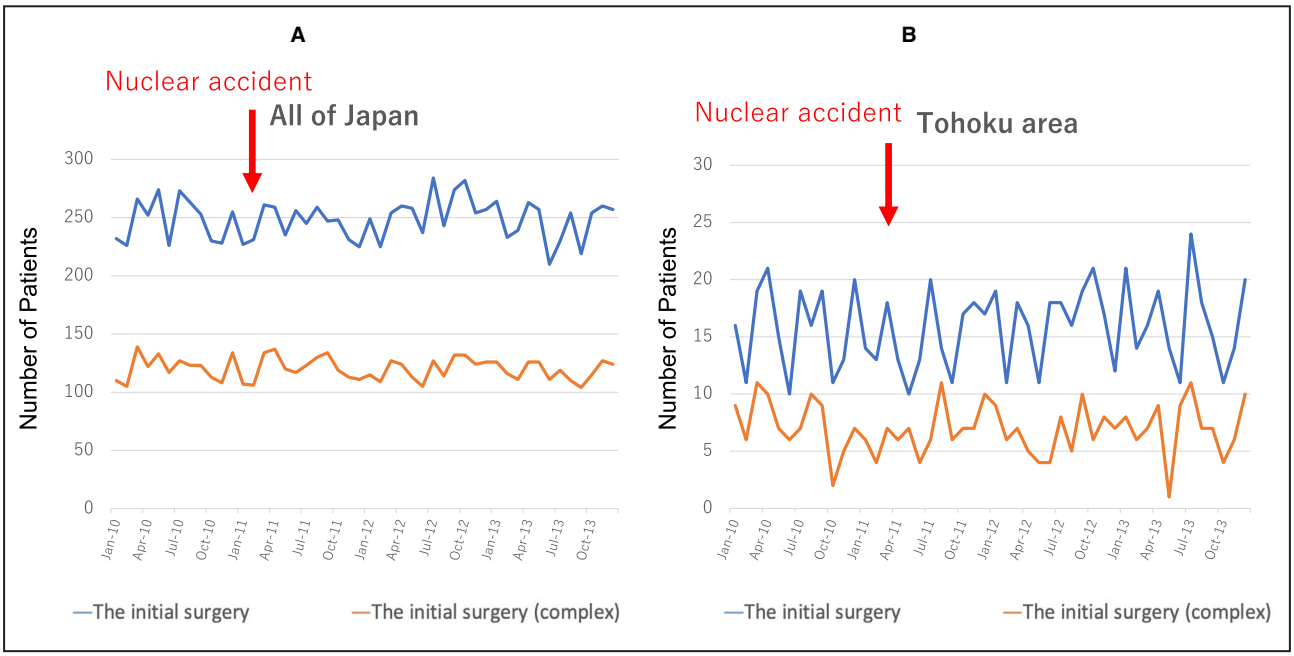


Figure 1. Number of initial operations between January 2010 and December 2013 for infants with all types and complex type congenital heart disease by year and month.
A, All of Japan. No apparent increasing trends were observed. **B**, Tohoku area. No apparent increasing trends were observed.

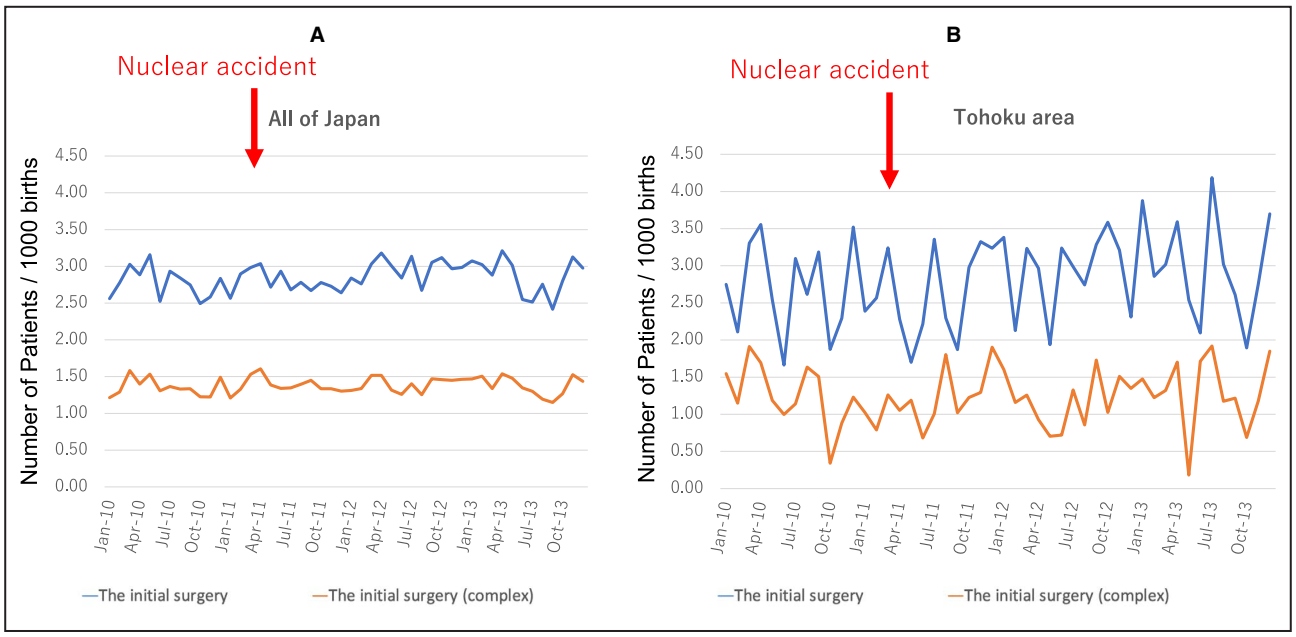
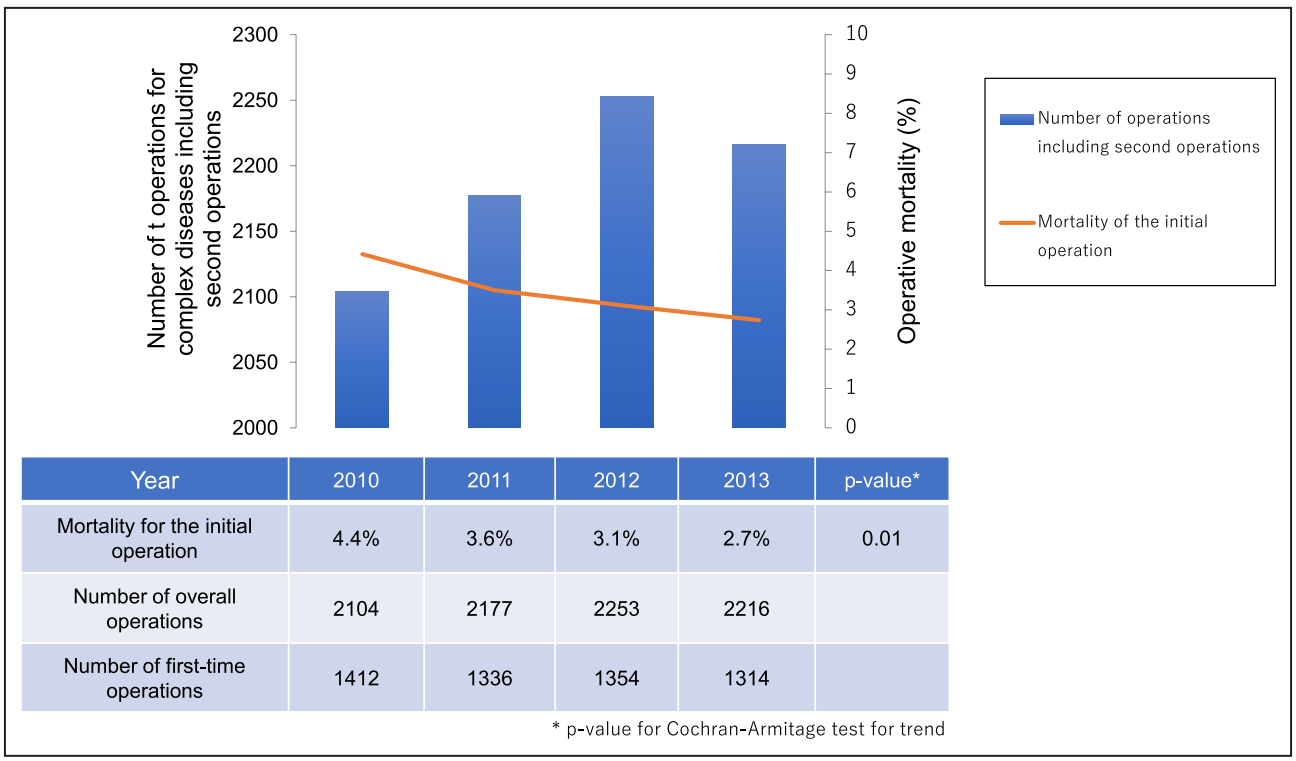


Figure 2. Number of initial operations between January 2010 and December 2013 for infants with congenital heart disease divided by the total number of births in Japan in each birth month.
A, All of Japan. No apparent increasing trends were observed; **B**,Tohoku area. No apparent increasing trends were observed.

total number of surgeries and date of operation, there was no increase in the number of patients with CHD during 2010 to 2013.

2. Even in the Tohoku region, there was no increase in the number of operations from 2010 to 2013 after sorting patients by first-time surgery and birth date.



Year	2010	2011	2012	2013	p-value*
Mortality for the initial operation	4.4%	3.6%	3.1%	2.7%	0.01
Number of overall operations	2104	2177	2253	2216	
Number of first-time operations	1412	1336	1354	1314	

* p-value for Cochran-Armitage test for trend

Figure 3. Total number of operations for complex diseases for the patients under 1 year old and operative mortality of the initial surgery by procedure year.

3. On the other hand, the number of total operations performed between 2010 and 2013 increased over time. A longitudinal decline in the death rate associated with first-time operations that occurred in the same period.

From the above findings, we can surmise that the increase in the number of total complex CHD surgeries derived from the results of the Japanese Association for Thoracic Surgery survey and discussed by Murase et al do not correspond to an increase in the number of patients with CHD; our results suggests that the decline in first-time operation mortality for complex CHD, which often involves multiple operations, indirectly led to an increase in the observed total number of operations performed over the given time period.

The Great East Japan Earthquake and the threat of radiation exposure caused by the destruction of the Fukushima Daiichi nuclear reactor forced many to evacuate their homes and stole the peaceful life of many more people. However, multiple subsequent surveys have clarified the real amount of radiation exposure caused by the incident. A report titled "Levels and effects of radiation exposure to the nuclear accident after the 2011 Great East Japan Earthquake and tsunami,"[5] published by the United Nations Scientific Committee on the Effects of Atomic Radiation in 2013, determined that in nearly all parts of Japan, the amount of radiation exposure that may have occurred both in the year of the accident itself and thereafter is smaller than the amount of background radiation exposure to the human body (in Japan, this equals 2.1 mSv). The report concludes that for people living several hundred kilometers from the Fukushima Daiichi nuclear reactor, radiation exposure is essentially not an issue.[4] The Fukushima Daiichi nuclear disaster did not alter the birth rate of low-birth-weight infants in Fukushima Prefecture.[1,10] A report published by Ishikawa[11] estimates that the real radiation exposure that occurred was most likely less than even that given in the 2013 United Nations Scientific Committee on the Effects of Atomic Radiation report. Both these objective reports and the data we have presented scientifically support that the Fukushima Daiichi nuclear disaster did not increase the number of infants born with CHD.

Limitations

In 2010, not all facilities across Japan participated in JCVSD-congenital; and the number of cases listed therein for this time period is estimated to cover about 77% of the total cases performed in Japan. Theoretically, it is possible that the percentage of patients treated at JCVSD participating facilities have changed over time (with increased or decreased number of surgeries at nonparticipating facilities), leading to biased assessment on the trend of counts or of proportions over the birth-year month. However, newborn patients are usually sent to the same selective facilities depending on the their birth area in Japan, and thus we believe that the percentage should remain fairly consistent over the study period.

Of the various types of CHD, complex cardiac abnormalities nearly always require interventions within the first year of the patient's life; thus, it is likely that our data are nearly entirely reflective of new patients. However, the information was not available for the patients who did not receive surgery for one reason or another, and rates of abortions or spontaneous stillbirths were not available in Japan; this is another limitation of our study.

CONCLUSIONS

Various different surgical strategies exist for different types of CHD. Using only an increase in the total yearly number of surgeries to try to relate a nuclear disaster with the incidence of CHD is a far too simple and dangerous proposition. We believe that more accurate data and more precise interpretations are necessary for such conclusions. While the number of total surgeries increased over the period following the Fukushima Daiichi nuclear disaster because of a decline in the death rate of first-time surgeries for complex cases—which often require multiple surgeries—no increase in the number of patients with CHD occurred after the disaster.

ARTICLE INFORMATION

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Disclosures

None.

Supplementary Materials

Tables S1–S2

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Supplemental Material

Table S1. Categorization of congenital heart disease according to complexity.

Fundamental Diagnosis	class	patient numbers	%
Aortopulmonary window	**c**	40	0.15%
Aortic stenosis	**o**	302	1.15%
ASD	**s**	3762	14.33%
AVSD, Complete AVSD	**c**	959	3.65%
AVSD, Intermediate (transitional)	**c**	100	0.38%
AVSD, Partial	**c**	204	0.78%
Aortic arch hypoplasia	**c**	12	0.05%
Aortic insufficiency	**o**	67	0.26%
Aortic insufficiency and aortic stenosis	**o**	46	0.18%
Aortic valve atresia	**c**	12	0.05%
Cardiac tumor	**o**	41	0.16%
Cardiac, Other	**o**	107	0.41%
Cardiomyopathy	**o**	99	0.38%
CoA complex	**c**	362	1.38%
CoA	**s**	660	2.51%
Congenitally corrected TGA	**c**	195	0.74%
Cor triatriatum	**o**	67	0.26%
Coronary artery anomaly	**o**	133	0.51%
DCRV	**s**	208	0.79%
DOLV	**c**	9	0.03%
DORV	**c**	1045	3.98%
Ebstein's anomaly	**c**	224	0.85%
Hypoplastic LV	**c**	75	0.29%
Hypoplastic RV	**c**	33	0.13%
HLHS	**c**	524	2.00%
Interrupted aortic arch + VSD	**c**	360	1.37%
LV to aorta tunnel	**c**	5	0.02%
MAPCA(s) without Pulmonary atresia - VSD	**c**	16	0.06%
Mitral regurgitation	**o**	258	0.98%
Mitral regurgitation and mitral stenosis	**o**	7	0.03%
Mitral stenosis	**o**	41	0.16%

Pulmonary atresia	**c**	37	0.14%
PAIVS	**c**	327	1.25%
Patent foramen ovalis	**s**	14	0.05%
Pulmonary insufficiency	**o**	6	0.02%
Pulmonary stenosis	**s**	129	0.49%
Pulmonary venous obstruction	**o**	16	0.06%
PAPVC	**s**	252	0.96%
PDA	**s**	2179	8.30%
Pulmonary artery origin from ascending aorta	**c**	22	0.08%
Pulmonary artery sling	**o**	33	0.13%
PAVSD	**c**	387	1.47%
PAVSD-MAPCA	**c**	199	0.76%
Pulmonary insufficiency and pulmonary stenosis	**o**	3	0.01%
Single ventricle	**c**	373	1.42%
Shone's complex	**o**	2	0.01%
Single Ventricle + TAPVC	**c**	67	0.26%
Single ventricle, DILV	**c**	83	0.32%
Single ventricle, DIRV	**c**	93	0.35%
Single ventricle, Heterotaxia syndrome	**c**	294	1.12%
Single ventricle, Mitral atresia	**c**	66	0.25%
Single ventricle, Tricuspid atresia	**c**	152	0.58%
Single ventricle, Unbalanced AV canal	**c**	59	0.22%
Sinus of Valsalva aneurysm	**o**	8	0.03%
TAPVC	**c**	767	2.92%
TGA	**c**	962	3.66%
TOF, AVSD	**c**	47	0.18%
TOF, Absent pulmonary valve	**c**	61	0.23%
TOF	**c**	1720	6.55%
Tricuspid regurgitation, non-Ebstein's related	**o**	31	0.12%
Tricuspid stenosis	**o**	12	0.05%
Truncus arteriosus	**c**	156	0.59%
Truncus arteriosus + Interrupted aortic arch	**c**	17	0.06%
VSD	**s**	7660	29.18%
Valsalva Aneurysm	**o**	3	0.01%
Vascular ring	**o**	87	0.33%

s: simple, c: complex, o: other cardiac abnormalities

ASD, atrial septal defect; AVSD, atrioventricular septal defect; CoA, coarctation of aorta; DCRV, double-chambered right ventricle; DORV, double-outlet right ventricle; HLHS, hypoplastic left heart syndrome; IAA, interrupted aortic arch; LV, left ventricle; MAPCA, major aortopulmonary collateral arteries;; PAIVS, pulmonary atresia with intact ventricular septum; PAPVC, partial anomalous pulmonary venous connection; PAVSD, pulmonary atresia with ventricular septal defect; PDA, patient ductus arteriosus; SV, single ventricle; TAPVC, total anomalous pulmonary venous connection; TGA, transposition of great arteries; TOF, tetralogy of Fallot; VSD, ventricular septal defect.

Table S2. The birth year-month of the patients born between January 2010 and December 2013 for both all of Japan and in Tohoku region.

Birth month for the first operation	Whole of Japan		Tohoku Area	
	All procedures	Complex procedures	All procedures	complex procedures
Jan-10	232	110	16	9
Feb-10	226	105	11	6
Mar-10	266	139	19	11
Apr-10	252	122	21	10
May-10	274	133	15	7
Jun-10	226	117	10	6
Jul-10	273	127	19	7
Aug-10	263	123	16	10
Sep-10	253	123	19	9
Oct-10	230	113	11	2
Nov-10	228	108	13	5
Dec-10	255	134	20	7
Jan-11	227	107	14	6
Feb-11	231	106	13	4
Mar-11	261	134	18	7
Apr-11	259	137	13	6
May-11	235	120	10	7
Jun-11	256	117	13	4
Jul-11	245	123	20	6
Aug-11	259	130	14	11
Sep-11	247	134	11	6
Oct-11	248	119	17	7
Nov-11	231	113	18	7
Dec-11	225	111	17	10

Jan-12	249	115	19	9
Feb-12	225	109	11	6
Mar-12	254	127	18	7
Apr-12	260	124	16	5
May-12	258	113	11	4
Jun-12	237	105	18	4
Jul-12	284	127	18	8
Aug-12	243	114	16	5
Sep-12	274	132	19	10
Oct-12	282	132	21	6
Nov-12	254	124	17	8
Dec-12	257	126	12	7
Jan-13	264	126	21	8
Feb-13	233	116	14	6
Mar-13	239	111	16	7
Apr-13	263	126	19	9
May-13	257	126	14	1
Jun-13	210	111	11	9
Jul-13	230	119	24	11
Aug-13	254	110	18	7
Sep-13	219	104	15	7
Oct-13	254	115	11	4
Nov-13	260	127	14	6
Dec-13	257	124	20	10