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Pediatric Cardiac Surgical Patterns of Practice and Outcomes in Japan and Europe

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Abstract

Objectives: The Japan Cardiovascular Surgery Database–Congenital section (JCVSD-Congenital) and the European Congenital Heart Surgeons Association (ECHSA) Congenital Heart Surgery Database (CHSD) share the same nomenclature. We aimed at comparing congenital cardiac surgical patterns of practice and outcomes in Japan and Europe using the JCVSD-Congenital and ECHSA-CHSD. **Methods and Results:** We examined Japanese (120 units, 63,365 operations) and European (96 units, 90,098 operations) data in JCVSD-Congenital and ECHSA-CHSD from 2011 to 2017. Patients' age and weight, periprocedural times, mortality at hospital discharge, and postoperative length of stay were calculated for ten benchmark operations. There was a significantly higher proportion of ventricular septal defect closures and Glenn operations and a significantly lower proportion of coarctation repairs, tetralogy of Fallot repairs, atrioventricular septal defect repairs, arterial switch operations, truncus repairs, Norwood operations, and Fontan operations in JCVSD-Congenital compared to ECHSA-CHSD. Postoperative length of stay was significantly longer following all benchmark operations in JCVSD-Congenital compared to ECHSA-CHSD. Mean STAT mortality score (Society of Thoracic Surgeons European Association for Cardio-Thoracic Surgery mortality score) was significantly higher in JCVSD-Congenital (0.78) compared to ECHSA-CHSD (0.71). Mortality at hospital discharge was significantly lower in JCVSD-Congenital (4.2%) compared to ECHSA-CHSD (6.0%, $P < .001$). **Conclusions:** The distribution of the benchmark procedures and age at the time of surgery differ between Japan and Europe. Postoperative length of stay is longer, and the mean complexity is higher in Japan compared to European data. These comparisons of patterns of practice and outcomes demonstrate opportunities for continuing bidirectional transcontinental collaboration and quality improvement.

Keywords

cardiac surgery congenital, database, Europe, Japan, outcome

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Abbreviations and Acronyms

ASO	arterial switch operation
CHD	congenital heart disease
CHSD	Congenital Heart Surgery Database
CPB	cardiopulmonary bypass
CoA	coarctation of aorta
EACTS	European Association for Cardio-Thoracic Surgery
ECHSA	European Congenital Heart Surgeons Association
ECHSF	European Congenital Heart Surgeons Foundation
IPPV	intermittent positive pressure ventilation
JCVSD-Congenital	Japan Cardiovascular Surgery Database–Congenital section
PLOS	postoperative length of stay
STS	Society of Thoracic Surgeons
TGA	transposition of the great arteries
TOF	tetralogy of Fallot
VSD	ventricular septal defect

Introduction

Congenital heart disease (CHD) is one of the most common causes of congenital anomalies. The birth prevalence of CHD is 9.3 per 1,000 live births in Asia and 8.2 per 1,000 live births in Europe. Asia and Europe have the highest total birth prevalence compared to all other continents.[1] Most of the patients will require cardiac surgery once or more during lifetime.[2] From countries with reported complete annual numbers of operations for CHD, we can estimate that the annual number of operations equals approximately the annual number of live births with CHD. Based on the birth rate and CHD birth prevalence in Japan[3] and European countries,[4] this extrapolates to an estimated 9,000 operations per year for CHD in Japan and 36,000 operations in Europe.

Surgery for CHD is documented in the Japan Cardiovascular Surgery Database–Congenital section (JCVSD-Congenital) in Japan[5] and in the European Congenital Heart Surgeons Association (ECHSA) Congenital Heart Surgery Database (CHSD) in Europe.[6] Both databases use the International Paediatric Cardiac Code of the International Society for Nomenclature of Paediatric and Congenital Heart Disease (www.ipcc.net).[7] Based on the assumption that the annual number of operations equals approximately the annual number of live births with CHD, we report on almost all operations performed in Japan and on approximately one-third of the operations performed in Europe during the study period. The purpose of this analysis is to compare pediatric cardiac surgical patterns of practice and outcomes in Japan and Europe using the JCVSD-Congenital and ECHSA-CHSD participants.

Patients and Methods

The study was carried out according to the policies of JCVSD-Congenital and the ECHSA-CHSD (available at: jcvsd.umin.jp/about.html#kiyaku and www.echsacongenitaldb.org, paragraph 2, respectively). Because the individual patients were not identified, both database committees waived the need for parental consent. Parental or patient (>16 years of patients' age in some countries) consent is available for individual data submitting units if the respective institutional review board requires it for participating the databases.

Database

This study was designed as a retrospective cohort analysis. We obtained data from the JCVSD-Congenital (available at: www.ncd.or.jp) and the ECHSA-CHSD (available at: www.echsacongenitaldb.org). The JCVSD-Congenital collects procedure-related data on patients undergoing cardiac surgery for CHD since 2008. It is the translation of the Society of Thoracic Surgeons (STS) CHSD. The ECHSA-CHSD, established by the European Congenital Heart Surgeons Foundation (ECHSF) and the European Association for Cardio-Thoracic Surgery (EACTS) in 1999, is the result of transformation of the European Congenital Heart Defects Database created by ECHSF in 1992 (ECHSF is the former name of ECHSA). Like the JCVSD-Congenital, the ECHSA-CHSD shares the nomenclatures to a large extent with the STS CHSD to allow the comparison of data from all participating countries. Data collected in the JCVSD-Congenital and the ECHSA-CHSD include basic demographic information, anatomic diagnoses, intraoperative data, type of surgical procedure, and hospital mortality. The databases are entirely anonymous regarding identifiable information of the patient, hospital, or surgeon and preclude researchers from requesting units for additional information not contained within the database.

Patients

The study population consists of operations for CHD at a JCVSD-Congenital or ECHSA-CHSD participating unit between January 1, 2011, and December 31, 2017. Accordingly, data from 120 units in Japan and 96 units in Europe were eligible for analyses. For operations consisting of several concomitant procedures, the procedure with the highest STAT Mortality Score (STS-EACTS Mortality Score)[8] was used for analysis. In cases in which patients had more than one operation during the same admission, only the first major cardiac operation (index cardiac operation) was analyzed. If an operation without cardiopulmonary bypass (CPB) and an operation with CPB was performed during the same admission, the operation with CPB was defined as the index operation (note, the definition of index operation as used in this study differs from definitions used in other contexts and other registry databases, in which index operation is defined as the first cardiovascular surgical operation of a hospitalization regardless of whether or not CPB is used).

Data collected included patient's age, weight, diagnosis, type of operation, STAT mortality score, time on CPB, aortic cross-clamp time, circulatory arrest time, postoperative time on mechanical ventilation (intermittent positive pressure

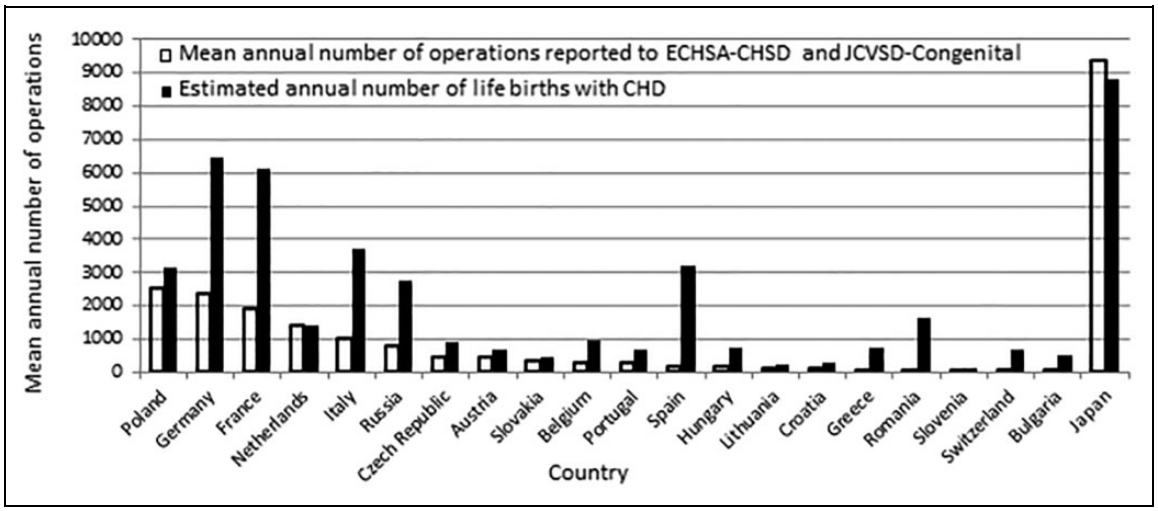

Figure 1. Mean annual number of operations submitted to JCVSD-Congenital or ECHSA-CHSD and mean annual number of live births with CHD by country. Estimated according to the number of live births in 2016 or 2017[3,4] and the CHD birth prevalence.[1] CHD indicates congenital heart disease; ECHSA, European Congenital Heart Surgeons Association; CHSD, Congenital Heart Surgery Database; JCVSD-Congenital, Japan Cardiovascular Surgery Database–Congenital section.

ventilation [IPPV]), postoperative length of stay (PLOS), and mortality at hospital discharge which was defined as death during the same hospitalization as the index cardiac operation regardless of timing or cause. Comparison of items was made for the following ten benchmark operations: off-pump repair of coarctation of aorta (CoA), closure of ventricular septal defect (VSD), repair of tetralogy of Fallot (TOF), repair of complete atrioventricular septal defect (AVSD), arterial switch operation (ASO) for transposition of the great arteries (TGA) with intact ventricular septum, ASO and VSD closure for TGA with VSD, Glenn or Hemi Fontan operation, any type of Fontan operation, truncus arteriosus repair, and Norwood operation.

Outcomes

Outcomes included the following: hospital mortality, IPPV time, and PLOS. Hospital mortality is defined as death during the same hospitalization as the index cardiac operation regardless of timing or cause. Outcomes were analyzed and stratified by European and Japanese data and in subgroups according to patients' age at the time of surgery and according to the ten benchmark procedures. Operations were assigned in age groups as follows: neonates: <30 days, infants: ≥30 days and <1 year, children: ≥1 year and <18 years, and adults: ≥18 years.

Statistics

Statistical analysis was performed using R (R Foundation for Statistical Computing, https://www.R-project.org/) or SPSS 20.0.0 (SPSS Inc). Frequencies are given as absolute numbers and percentages. Continuous data are expressed as means with SD or medians with range. Two-sided tests were performed for all analyses. Potential differences in frequencies between groups were analyzed using the χ^2 test. Potential differences in mean values between groups were analyzed using Welch *t* test or Mann-Whitney *U* test if data were not normally distributed. Normal distribution was tested using Shapiro-Wilk test.

Results

We identified 63,365 operations from 120 units in the JCVSD-Congenital and 90,098 operations from 96 units in the ECHSA-CHSD. Figure 1 depicts the mean annual number of operations reported to ECHSA-CHSD and JCVSD-Congenital and the estimated annual number of live births with CHD by country. Accordingly, we can estimate that Poland, the Netherlands, and Japan reported the majority of operations, whereas the number of reported operations for the remaining countries is incomplete. There was a difference in mean annual reported caseload by country. There was a significant difference in mean caseload by unit between JCVSD-Congenital and ECHSA-CHSD ($P < .001$, Mann-Whitney *U* test). There was a difference in mean annual caseload by unit between JCVSD-Congenital and ECHSA-CHSD: 42% and 9% of the Japanese units reached an annual case load of more than 100 and 250 operations, respectively, while 63% and 31% of the European units reached an annual caseload of more than 100 and 250 operations, respectively (Figure 2, units with a mean number of operations below ten per year are excluded). In JCVSD-Congenital, 62.3% of the units performed operations in STAT Mortality Category 4 or 5 (STAT score >1.2). The mean proportion of operations in STAT Mortality Category 4 or 5 in those units was 21.9% ± 8.5% (2.0%-39.3%). In ECHSA-CHSD, 70.8% of the units performed operations in STAT Mortality Category 4 or 5. The mean proportion of operations in STAT Mortality Category 4 or 5 in those units was 18.5% ± 5.8% (1.7%-31.3%). The relation between unit volume, survival, and STAT mortality score is depicted in Figure 3 (units with a mean number of operations below ten per year are excluded). In ECHSA-CHSD, there is a larger variation in

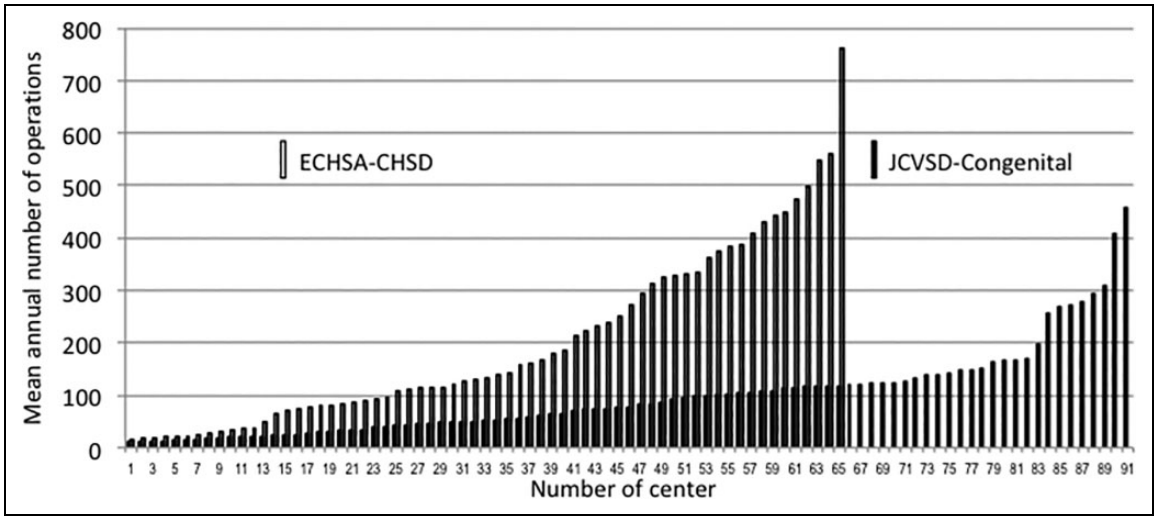

Figure 2. Mean annual number of operations performed in individual centers submitted to JCVSD-Congenital or ECHSA-CHSD. Units with a mean number of operations below ten per year are excluded. ECHSA indicates European Congenital Heart Surgeons Association; CHSD, Congenital Heart Surgery Database; JCVSD-Congenital, Japan Cardiovascular Surgery Database–Congenital section.

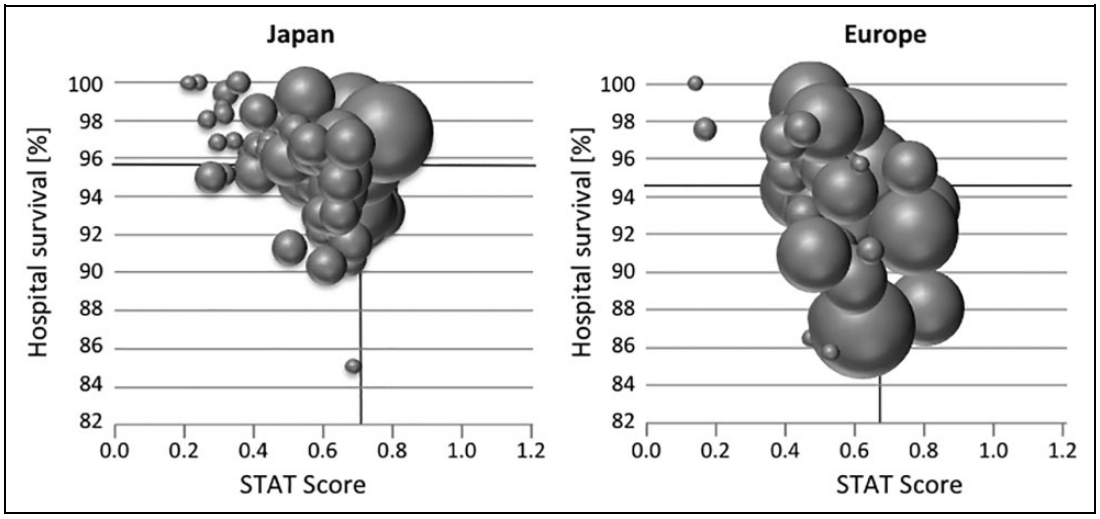

Figure 3. Plot of data submitted to JCVSD-Congenital or ECHSA-CHSD. Mean programmatic STAT mortality score on the x-axis and hospital survival on the y-axis, with the size of the bubble corresponding to programmatic volume of each unit. Horizontal and vertical lines indicate mean survival and mean STAT score, respectively. Units with a mean number of operations below ten per year are excluded.

survival between units compared to JCVSD-Congenital. There was a significant difference in mortality at hospital discharge between both cohorts, 4.2% in JCVSD-Congenital compared to 6.0% in ECHSA-CHSD ($P < .001$, Mann-Whitney U test). Mortality in JCVSD-Congenital was significantly lower in neonates, infants, and children compared to ECHSA-CHSD (Table 1). STAT mortality score in JCVSD-Congenital was significantly lower in neonates and significantly higher in infants compared to ECHSA-CHSD (Supplementary Table 1). There was a minimal but significant difference in mean STAT mortality scores between both databases ($P = .009$, Mann-Whitney U test). The age at the time of surgery was different for some benchmark procedures between JCVSD-Congenital and ECHSA-CHSD. In JCVSD-Congenital, only 30.2% of the Norwood operations are performed in neonates, while in ECHSA-CHSD, 86.7% of the Norwood operations are performed in neonates (Supplementary Table 2). We observed a similar strategy of timing for ASO + VSD (64.0% vs 74.9% neonatal repair) and truncus (28.7% vs 45.0% neonatal repair, JCVSD-Congenital vs ECHSA-CHSD, respectively). In JCVSD-Congenital, operations were performed more frequently in infants than in other age categories, while in ECHSA-CHSD, operations were performed more frequently in children than in other age categories (Table 1).

With regard to the whole study populations, the mean time for CPB, aortic cross-clamp, IPPV, and PLOS was significantly longer in JCVSD-Congenital compared to ECHSA-CHSD. Mean weight, mean age, and mortality at hospital discharge were

Table 1. Number of Operations, Mortality at Hospital Discharge, and Mean Postoperative Length of Stay by Age Groups of Operations Submitted to JCVSD-Congenital or ECHSA-CHSD.

	Japan				Europe						Statistical tests				
	Number of operations		Discharge mortality	Postoperative length of stay (days)	Number of operations		Discharge mortality		Postoperative length of stay (days)		Number of operations[a]		Discharge mortality[a]	Postoperative length of stay[b]	
	n	%	%	Mean	SD	n	n	%	(%)	Mean	SD	n	*P*	*P*	*P*
Neonates	11,099	17.6	9.6	53.9	55.2	10,100	16,638	18.5	13.0	22.8	31.8	16,638	<.001	<.001	<.001
Infants	23,558	37.4	4.3	31.0	39.0	22,357	29,481	32.7	6.4	18.0	30.3	29,481		<.001	<.001
Children	24,336	38.6	1.9	20.2	24.6	23,714	35,218	39.1	3.2	13.3	27.1	35,218		<.001	<.001
Adults	4,026	6.4	2.4	21.8	23.7	3,916	8,752	9.7	2.9	11.5	14.4	8,752		.077	<.001

Abbreviations: ECHSA, European Congenital Heart Surgeons Association; CHSD, Congenital Heart Surgery Database; JCVSD-Congenital, Japan Cardiovascular Surgery Database–Congenital section.
[a]χ^2 test.
[b]Welch *t* test.

Table 2. Number of Operations, Mortality at Hospital Discharge, Mean STS Mortality Score, and Mean Postoperative Length of Stay by Era of Operations Submitted to JCVSD-Congenital or ECHSA-CHSD.

	Japan			Europe		
	2011-2013	2014-2017	Statistical tests	2011-2013	2014-2017	Statistical tests
Number of operations, n (%)	26,645	36,481	.837[a]	45,275 (50.3)	44,814 (49.7)	
Discharge mortality, n (%)	1,105 (4.1)	1,525 (4.2)	.006[b]	2,626 (5.8)	2,820 (6.3)	.002[a]
Score, mean (SD)	0.77 (0.76)	0.79 (0.77)	.017[b]	0.70 (0.73)	0.74 (0.77)	<.001[b]
Postoperative length of stay, days	29.6 (38.9)	30.3 (38.5)	.837[a]	15.8 (26.0)	17.0 (30.7)	<.001[b]

Abbreviations: ECHSA, European Congenital Heart Surgeons Association; CHSD, Congenital Heart Surgery Database; JCVSD-Congenital, Japan Cardiovascular Surgery Database–Congenital section; STS, Society of Thoracic Surgeons.
[a]χ^2 test.
[b]Welch *t* test.

significantly lower in JCVSD-Congenital compared to ECHSA-CHSD. The mean STAT mortality score and mean PLOS increased minimally but significantly in JCVSD-Congenital and ECHSA-CHSD from a first era including operations between 2011 and 2013 to a second era including operations between 2014 and 2017 (Table 2). Mortality did not change significantly in JCVSD-Congenital, whereas it increased by 0.5% in ECHSA-CHSD. There was a different distribution of frequencies in benchmark procedures (Table 3). The JCVSD-Congenital included significantly higher proportion of VSD closures and Glenn operations and significantly lower proportion of CoA repairs, TOF repairs, AVSD repairs, ASO, ASO + VSD closures, truncus repairs, Norwood operations, and Fontan operations compared to ECHSA-CHSD. Mortality at hospital discharge was significantly lower in the JCVSD-Congenital for VSD closure, Glenn operation, and Norwood operation. There was no significant difference in mortality following CoA repair, AVSD repair, ASO, ASO + VSD closure, Fontan operation, TOF repair, and truncus repair.

Discussion

The present report analyzes data over an equivalent seven years' time period representing almost all operations for CHD in Japan and an estimated one-third of all operations for CHD in European countries contributing to ECHSA-CHSD. We show distinct differences with regard to distribution of benchmark operations, programmatic volumes, and outcomes between Japan and participating European countries.

Mortality in patients with CHD has dramatically decreased over the last decades,[9] a finding that we could not confirm in the present study due to the short and recent study period from 2011 to 2017. It is of note that complexity increased minimally but significantly when comparing these two short surgical eras. The main reasons for this include early CHD diagnosis and introduction and subsequent improvement of surgical and catheter interventions as well as perioperative care. At the same time, a universal nomenclature including diagnosis and procedures for CHD has been established as a prerequisite for comparison of case mix and outcomes.[7] For several years now, quality control in treatment of CHD is obligatory in Japan and many European countries. In Japan, all data are submitted to JCVSD-Congenital to monitor this metric. In contrast, many European countries have established national quality control standards, which may be exclusively by means of the ECHSA-CHSD, by using a database different from the ECHSA-CHSD, or by using a different database in addition

Table 3. Number of Operations, Mortality at Hospital Discharge, and Mean Postoperative Length of Stay for Ten Benchmark Operations Submitted to JCVSD-Congenital or ECHSA-CHSD.[a]

	Japan						Europe						Statistical tests		
	Number of operations		Discharge mortality	PLOS days			Number of operations		Discharge mortality	PLOS days			Number of operations[b]	Operative mortality[b]	PLOS[c]
	n	%	%	Mean	SD	n	n	%	%	Mean	SD	n	*P*	*P*	*P*
ASO	757	1.2	4.4	30.1	25.6	747	2,319	2.6	4.6	15.8	14.5	2,319	<.001	.770	<.001
ASO + VSD	397	0.6	6.5	34.2	35.8	379	867	1.0	8.0	17.6	18.5	867		.378	<.001
AVSD	1,227	2.0	3.0	27.8	26.7	1,182	2,894	3.2	3.3	15.2	17.3	2,894		.656	<.001
CoA	441	0.7	0.9	35.7	38.4	426	3,564	4.0	1.3	10.1	13.3	3,564		.442	<.001
Fontan	848	1.4	2.5	29.7	22.8	839	2,421	2.7	3.7	21.3	17.8	2,421		.086	<.001
Glenn	2,607	4.2	2.5	28.5	30.7	2,506	2,645	2.9	5.2	17.1	20.5	2,645		<.001	<.001
Norwood	625	1.0	19.5	73.8	66.5	551	1,502	1.7	23.6	39.0	43.8	1,502		.038	<.001
TOF	2,445	3.9	1.3	21.5	20.9	2,407	4,245	4.7	1.8	12.8	13.7	4,245		.076	<.001
Truncus	94	0.2	8.5	47.2	52.0	88	409	0.5	14.4	22.9	27.1	409		.128	<.001
VSD	11,232	18.0	0.3	15.2	15.5	11,084	9,124	10.1	1.0	10.4	12.6	9,124		<.001	<.001

Abbreviations: ASO, arterial switch operation; AVSD, atrioventricular septal defect; ECHSA, European Congenital Heart Surgeons Association; CHSD, Congenital Heart Surgery Database; CoA, coarctation of aorta; JCVSD-Congenital, Japan Cardiovascular Surgery Database–Congenital section; PLOS, postoperative length of stay; TOF, tetralogy of Fallot; VSD, ventricular septal defect.

[a]Units with a mean number of operations below ten per year are excluded.

[b]χ^2 test.

[c]Welch *t* test.

to the ECHSA-CHSD. With the increasing awareness for the importance of quality control and utilizing a universal nomenclature, our analysis reports a transcontinental comparison of case mix and outcome.[10,11]

Based on the number of live births in Japan (946,065 in 2017[3]) and in participating European countries (Figure 1, 4,361,269 in 2016 or 2017[4]), the CHD birth prevalence,[1] and the assumption that the annual CHD birth prevalence equals the annual number of operations for CHD, we were able to analyze almost all operations performed in Japan and an estimated one-third of all operations performed in ECHSA-CHSD participating European countries. This observation is important since differences in patterns of practice between European countries may be important, and the ECHSA-CHSD may not be representative for all individual European countries or European units. The observed differences between the JCVSD-Congenital and the ECHSA-CHSD data may be less or more pronounced by comparing data from selected European countries with JCVSD-Congenital. This finding becomes obvious in the plot of mean programmatic STAT mortality score against hospital survival and programmatic volume in Figure 2. In ECHSA-CHSD, there are high-volume centers reporting high mean complexity and below-average survival. In JCVSD-Congenital, we could not identify centers with such attributes.

We observed differences in frequencies of benchmark procedures between JCVSD-Congenital and ECHSA-CHSD. The frequency of coarctation repair was six-fold higher, and the frequency of ASOs was twice as high in ECHSA-CHSD as compared to JCVSD-Congenital. The reason may be the higher birth prevalence of CoA and TGAs in Europe compared to Japan.[1] Van der Linde and colleagues also showed a higher birth prevalence of TOF in Asia compared to Europe.[1] In contrast, in our data, we observed slightly more TOF repairs in Europe than in Japan. Birth prevalence in different types of CHD may not be the only denominator for frequencies of related operations. Especially for highly complex CHD like hypoplastic left heart syndrome and other forms of univentricular hearts, different social attitudes regarding termination of pregnancy and compassionate care and different outcomes of operations for staged palliation may have an impact on the frequency of operations for staged reconstruction of functionally univentricular hearts.[12,13] The higher proportion of Glenn operations among the benchmark procedures in JCVSD-Congenital compared to ECHSA-CHSD may reflect the advanced experiences in Japan regarding functionally univentricular palliation.[14] Surprisingly, the proportion of Fontan completion is lower in JCVSD-Congenital compared to ECHSA-CHSD.

Mortality at hospital discharge was significantly lower for Norwood operations and Glenn operations in JCVSD-Congenital compared to ECHSA-CHSD. It is of note that PLOS was significantly longer for all benchmark operations in JCVSD-Congenital compared to ECHSA-CHSD, especially for Norwood operation (1.9 times), Glenn operation (1.6 times), and Fontan operation (1.4 times). The differences in mortality and PLOS may reflect differences in surgical strategy. In Japan, 68% of the Norwood operations are performed beyond the neonatal period, and in many instances, the Norwood procedure is preceded by placement of bilateral pulmonary artery bands, with the Norwood procedure (the index operation for purposes of the present study) being performed later during the same hospitalization.[14] In contrast, in ECHSA-CHSD, only

13% of the Norwood operations are performed beyond the neonatal period. A similar strategy of timing is also true for ASO + VSD and truncus repair. Postponing complex surgery beyond the neonatal period may result in selecting patients with lower risk profile because high-risk neonates may not reach the desired age for surgical intervention. Since the STAT mortality score is a procedure-dependent score and does not account for patient-specific preoperative risk factors and associated preoperative comorbidities, we could not verify this hypothesis. The differences in PLOS may also reflect the differences in health care systems. In Japan, the government covers all medical fee for the treatment of CHD. In Europe, this financial arrangement is not the case in all countries. Hence, shorter PLOS in ECHSA-CHSD may be a result of limited resources. Mean STAT mortality score is significantly lower for neonates in JCVSD-Congenital compared to ECHSA-CHSD and significantly higher in infants. The convention of postponing complex surgery beyond the neonatal period may also be attributed to the lower weight of neonates in JCVSD-Congenital compared to ECHSA-CHSD.[14,15] Furthermore, mean PLOS following the Norwood operation in Japan was 73 days, implying that infants often spend the interstage period in hospital. In ECHSA-CHSD, PLOS following the Norwood operation was 39 days. Hence, a larger portion of the patients is discharged after the Norwood operation and prior to the Glenn operation. It is of note that PLOS in neonates is three times longer in JCVSD-Congenital compared to ECHSA-CHSD.

The age distribution of patients at the time of surgery is different in JCVSD-Congenital compared to ECHSA-CHSD. The proportion of patients undergoing cardiac surgery during infancy is higher in JCVSD-Congenital compared to ECHSA-CHSD. This increased proportion of infants is at the expense of the number of neonates, children, and adults. As outlined above, it seems that in Japan, surgery is postponed beyond the neonatal period if possible.[15] Further studies should address this issue with detailed analyses stratified by diagnosis and procedures. The present data were not suitable for these further analyses. We can only speculate why in Japan, CHD is less frequently operated in adulthood. The reason may be a potentially higher proportion of "late presentation" in Europe[16,17] since surgery for CHD was not available to the same extent during the last decades in all European countries. In addition, adults with CHD may be underrepresented in congenital databases in Japan and Europe since these patients are also treated in departments of adult acquired heart disease.

Comparison of outcomes following surgery for CHD is challenging.[18] There are multiple different pediatric and congenital cardiac procedures (319 in the STS CHSD nomenclature) and multiple potential cofactors. Risk adjustment may be done by means of comparing homogenous groups of operations, like the benchmark operations, or by applying risk scores to the whole study population. Accordingly, mean STAT mortality score is marginally but significantly higher in JCVSD-Congenital compared to ECHSA-CHSD, and discharge mortality was lower in JCVSD-Congenital compared to ECHSA-CHSD. However, the utility of STAT mortality score in the present comparison may be limited due to the potential heterogeneity between JCVSD-Congenital and ECHSA-CHSD regarding individual patient-specific cofactors, which are not included in the STAT mortality score.[19] In addition to the challenges of risk adjustment, ECHSA-CHSD does not include data from all European countries (20/49) and includes only one-third of the data from ECHSA-CHSD participating European countries. The objectives of the present analyses were rather to identity differences in patterns of surgical practice that may have an impact on outcome and warrant further collaboration and analyses. Ideally, outcome of treatment of CHD should be reported starting at the time of prenatal diagnosis. The present databases are procedure based and not diagnosis based. Therefore, we can only report on outcomes following an operation. Hence, it would be ambitious to conclude that CHD is better treated in Japan compared to Europe because these databases do not include any data about patients who do not undergo surgery and these databases clearly do not include any data about patients who die awaiting surgery. Still, it is interesting to see that for example Norwood operations are documented in JCVSD-Congenital at an older age with lower mortality compared to ECHSA-CHSD. There may be important differences in surgical practice that may explain the differences in outcome. Bridging neonates with a need for a high risk for complex operation beyond the neonatal period by means of palliative procedures, hybrid procedures, or catheter interventions may be only one aspect.

Limitations

Limitations of our study include its retrospective nature. The ECHSA-CHSD data are derived from a large multicenter database. Because participation to the ECHSA-CHSD is voluntary, data from units within countries and data from patients within units are incomplete. Only a part of the data in both databases is verified by on-site audits (JCVSD-Congenital: 8.1% of units, ECHSA-CHSD: 14.2% of operations). No significant difference exists with regard to the selected items and outcomes between verified and nonverified data.[20,21] Outcome is assigned to one operation. In case of multiple operations, outcome is only assigned to one index operation. Therefore, some operations may not be included. This limitation is particularly important if a hospital admission covers the whole interstage period in functionally univentricular palliation. Only patients who survive long enough to have surgery for an index operation are eligible for inclusion in the analyses. If some patients expire without surgical intervention in the context of a prevailing strategy that favors postponement of surgery beyond the newborn period, then these mortalities are not included in comparisons of surgical outcomes. The strength of the study, its size, also implies a limitation: owing to the enormous power of the study, almost all *P* values become significant. Despite the large database size, it is possible that case mix, caseload, and outcomes in ECHSA-CHSD are not representative of all European units or countries. Furthermore, several individual procedures had relatively small sample sizes. It is therefore

important to differentiate between statistical significance and clinical relevance in the interpretation and conclusion of the results. Due to the limited data set of the databases, it was not possible to assess differences that might have an impact on outcome in preoperative risk factors, technical success, and postoperative management.

Conclusions

The first transcontinental comparison of case mix and outcomes following surgery for CHD in Europe and Japan reveals differences in the distribution of the benchmark procedures and age at the time of surgery. Operative times, PLOS, and complexity are higher in Japan compared to European data. Complex surgery is postponed beyond the neonatal period in Japan with potentially better results. These comparisons of patterns of practice and outcomes demonstrate opportunities for continuing bidirectional transcontinental collaboration and quality improvement.

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Supplemental Material

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