

Data analysis of the perfusion registry in Japan Aggregate data between 2014 and 2016

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Abstract

The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) established the Japanese Perfusion Database and started its operation in 2013. This database collects pre-surgery physical findings of patients who have undergone perfusion during cardiovascular surgery, as well as perfusion conditions and outcomes. The purpose is to tabulate and analyze data on a nationwide scale. In this study, we analyzed 6,956 cases of adult (age 16 and up) cardiovascular surgery performed with perfusion. The data was collected over three years, from January 1, 2014 to December 31, 2016. In Japan, perfusion is most frequently performed with valve surgery, followed by aortic surgery and coronary artery bypass grafting (CABG). Differences according to type of surgery are discovered by analyzing the perfusion registry, which suggests that collecting this data is useful. It should be noted, however, that data analyzed for this study was obtained from only 30 institutions, so it did not represent the entire country. The results also show large variations for some data items. In the future, data accuracy is expected to increase as efforts are made to modify the input interface and more institutions participate in the registry to catalog more cases.

Key words : cardiopulmonary bypass, database, case registry, extra-corporeal circulation

I. Introduction

The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) established the Japanese Perfusion Database to collect pre-surgery physical findings of patients who undergo perfusion during cardiovascular surgery, as well as the perfusion conditions and outcomes. The purpose is to tabulate and analyze the data on a nationwide scale. As preparation for database development, the perfusion registry project began in 2009 by studying similar overseas activities and conducting national surveys of data input environments at institutions performing perfusion.

The database then went into operation in 2013.¹⁻⁴⁾

The registry entries are designed to improve the extra-corporeal technology from the standpoint of perfusionists, so they differ from the entries of the Japan Adult Cardiovascular Surgery Database run by the Japan Cardiovascular Surgery Database (JCVSD). There were originally 177 entry items in five categories: 1) Demographic and Case Detail, 2) Circuit and Priming, 3) Perfusion, 4) Fluid volume management, and 5) Lab data. Of the 177 items, 46 were multiple-choice and the remaining 131 required text answers. The entries increased to 251 with outcome-related

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items added in 2016. After the registry started in 2013, registrant institutions increased to 38, with registered cases 8,962 as of October 2017.

II. Objective

Medical institutions often create their own databases to catalog data on cardiovascular surgeries carried out with perfusion. However, to accurately monitor the state of the surgery in Japan, data must be properly gathered, maintained, and put to good use. Accordingly, the JaSECT Perfusion Database is updated every six months with data collected from each institution. In this study, to examine the current status of perfusion in Japan, we compiled data collected in the three years from 2014 to 2016 and analyzed patient information and basic perfusion parameters by type of surgery.

III. Objective and Methods

The Perfusion Database contains 6,956 cases of adult (age 16 and up) cardiovascular surgery performed with perfusion during the three years from January 1, 2014 to December 31, 2016. For patients who were non-consenting, we excluded their results from our analysis such as missing values and abnormal values.

Compiled Demographic and Case Detail data comprises gender, age, height, weight, body surface area, and BMI. BMI is divided into five levels: under 18.5, 18.5-under 25, 25-under 30, 30-under 35, and 35 and over to indicate the percentage of each in the different surgeries. "Circuit and Priming" data comprises arterial filter, pre-bypass filter, arterial pump, biopassive coating area, pH management, blood volume, total priming volume, and priming of non-blood transfusion. Data on pH management indicates its percentage in each type of surgery. Use rates are indicated for arterial and pre-bypass filters, as well as for arterial pumps that are represented by roller pumps. Perfusion data comprises pump time, clamp time, deep body temperature measurement sites, and highest blood temperature (arterial flow). As for the temperature measurement sites, percentages of each are shown by type of surgery. The highest blood temperature (arterial flow) is divided into four levels: under 37°C, 37-under 38°C, 38-under 39°C, and 39-under 40°C.

We used JMP® 12 (SAS Institute Inc.) to prepare and statistically analyze the above data. This research

has been approved by the Epidemiology and Clinical Research Ethical Review Committee of Fujita Health University (date of approval: July 18, 2017).

IV. Results

Table 1 shows patient gender and age by type of surgery, based on data collected in the three years from 2014 to 2016. When classified by type, valve surgery had the highest number of cases at 3,020, followed by 1,711 for aortic surgery and 790 for CABG. The breakdown by age indicates 2,585 patients in their 70s, 1,871 in their 60s, and 1,127 in their 80s. When cross-tabulated by age and type of surgery, the largest group comprised patients in their 70s who had valve surgery, followed by patients in their 60s who had valve surgery, and then patients in their 70s who had aortic surgery.

Table 2 shows patient height, weight, body surface area, and BMI by type of surgery. The tallest patient height was 161.9 ± 8.8 cm for CABG and other surgery, but heights did not differ much by type of surgery. The heaviest weight was 62.5 ± 12.1 kg for CABG, and the lowest was 56.0 ± 12.0 kg for congenital surgery. The largest body surface area was 1.679 ± 0.185 m² for CABG, and the lowest was 1.572 ± 0.188 m² for CABG and valve surgery. As for BMI, the normal weight range of 18.5-25 had the highest percentage, followed by the obesity level-1 range (25-30), and the underweight range under 18.5, for all types of surgery. The only exception was congenital surgery, for which the second and third places were reversed.

Table 3 shows the current status of circuit configuration. The use rate of arterial filters was as high as 99.5% whereas that of pre-bypass filters was only 20.8%. Roller pumps accounted for 16.1% of arterial pumps in use. As for the biopassive coating area, "all but cannulae" accounted for 69.4%, the highest score for all kinds, followed by "limited component" 19.2%, "tip to tip" 11.3%, and "none" 0.1%.

Table 4 shows pH management and priming volume by type of surgery. As for pH management, alpha-stat was most frequently used in all types of surgery: 95.8% in CABG and 69.8% in aorta. Use of both alpha-stat and pH-stat was higher in aortic surgery than in other types. As for the blood volume, the largest volume was 487.5 ± 170.3 mL for CABG, followed by 427 ± 204.2 mL for aortic surgery and 384.6 ± 173.6 mL for CABG and valve surgery. The largest total

Table 1 Characteristic of patients by operation type (gender, age)

		type of surgery							total
		isolated CABG	isolated valve	CABG and valve	CABG and other	aorta	congenital	other	
gender n = 6,955	male	614	1,670	421	103	1,092	56	273	4,229
	female	176	1,350	263	22	619	74	221	2,725
	NA	0	0	1	0	0	0	0	1
	total	790	3,020	685	125	1,711	130	494	6,955
age n = 6,954	<20	0	14	0	0	4	7	0	25
	20-29	1	25	1	0	14	16	8	65
	30-39	7	54	3	2	29	12	15	122
	40-49	32	127	10	4	123	18	56	370
	50-59	104	307	36	9	197	24	77	754
	60-69	282	755	155	37	474	37	131	1,871
	70-80	284	1,185	303	56	610	14	133	2,585
	80-90	78	539	170	15	251	2	72	1,127
	>=90	1	14	7	2	9	2	2	35
total	789	3,020	685	125	1,711	130	494	6,954	

CABG : coronary artery bypass graft / NA : not available

Table 2 Characteristic among patients by operation type (hight, weight, BMI, body surface area)

		type of surgery						
		isolated CABG	isolated valve	CABG and valve	CABG and other	aorta	congenital	other
hight (cm) n = 6,953	mean	161.5	158.5	156.9	161.9	161.6	160.0	160.1
	SD	8.8	10.2	9.7	8.8	10.3	10.7	10.1
	N	790	3,020	685	125	1,709	130	494
weight (kg) n = 6,955	mean	62.5	56.6	56.2	61.0	62.0	56.0	58.4
	SD	12.1	12.0	11.2	12.2	13.3	12.0	11.9
	N	790	3,020	685	125	1,711	130	494
body surface area (m ²) n = 6,953	mean	1.679	1.588	1.572	1.661	1.672	1.589	1.620
	SD	0.185	0.198	0.188	0.189	0.211	0.204	0.195
	N	790	3,020	685	125	1,709	130	494
BMI n = 6,952	<18.5	36 (12.7%)	385 (12.7%)	77 (11.2%)	8 (6.4%)	124 (7.3%)	27 (20.8%)	51 (10.3%)
	18.5-25	485 (61.4%)	2,013 (66.7%)	448 (65.4%)	81 (64.8%)	1,054 (61.7%)	79 (60.8%)	332 (67.2%)
	25-30	218 (27.6%)	521 (17.3%)	141 (20.6%)	32 (25.6%)	428 (25.1%)	22 (16.9%)	93 (18.8%)
	30-35	44 (5.6%)	91 (3.0%)	16 (2.3%)	3 (2.4%)	88 (5.2%)	2 (1.5%)	15 (3.0%)
	35<	7 (0.9%)	10 (0.3%)	3 (0.4%)	1 (0.8%)	14 (0.8%)	0 (0.0%)	3 (0.6%)
	total	790	3,020	685	125	1,708	130	494

CABG : coronary artery bypass graft / BMI : body mass index / SD : standard deviation

priming volume was 1,361.3±261.0 mL for aortic surgery, followed by 1,192.8±270.8 mL for CABG and valve surgery, and 1,179.3±280.7 mL for CABG and other surgery. The highest priming of non-blood transfusion was 96.9% for congenital surgery, and the lowest (79.5%) for CABG and valve surgery.

Table 5 shows pump time, clamp time, and deep body temperature measurement sites by type of surgery. The longest pump time was 240.8±102.4 min for CABG and other surgery, followed by 232.6±109.4 min for aorta surgeries and 212.0±74.8 min for CABG and valve surgery. The longest clamp time was

129.9±52.2 min for CABG and valve surgery, followed by 125.2±64.2 min for CABG and other surgery and 119.2±68.3 min for aorta. In all types of surgeries, deep body temperature was most often measured at the bladder, followed by nasopharynx and rectal sites. For congenital surgery, however, the second and third places were reversed.

Table 6 shows the distribution of highest blood temperature (arterial flow). Temperatures under 37°C accounted for the highest percentage at 53.2%, followed by 37-under 38°C at 39.8%, 38-under 39°C at 5.8%, and 39°C and over at 0.5%.

V. Discussion

The Japanese Perfusion Database started its registry operation in 2013. Data items unique to Japan were added to those that are comparable with data in databases overseas.⁵⁻⁷⁾ Data is gathered continuously

from perfusion records and protocols. Accumulation of such data has made it possible to analyze the status of cardiovascular surgery performed with perfusion in Japan.

In Japan, perfusion is most frequently performed during valve surgery, followed by aortic surgery and then CABG. Differences by type of surgery have been discovered through the analysis of perfusion registry data, suggesting the usefulness of collecting it.

Data analyzed for this study was collected from 30 institutions that participated in the project from January 1, 2014 to December 31, 2016. They account for only 5% of about 580 Japanese institutions that are reported by JACVSD to be performing cardiovascular surgery with perfusion (as of October 2017). We must therefore note that the data does not represent the entire country. Since the research was conducted by multiple institutions, the analyzed data also had missing values and abnormal values. Although these values were excluded before data compilation, some entries had a large standard deviation (SD), which means large fluctuations in data. In the future, the accuracy of registered data is expected to increase as efforts are made to modify the input interface and more institutions participate in the registry to catalog more cases. We must continue to maintain and expand the database and promote its use.

Table 3 Current status of circuit configuration

		N	ratio
arterial filter		6,920	99.5%
pre-bypass filter		1,450	20.8%
arterial pump head	roller pump	1,118	16.1%
	none	8	0.1%
biopassive coating area	limited component	1,334	19.2%
	all but cannulae	4,829	69.4%
	tip to tip	785	11.3%

SD : standard deviation

N = 6,956

Table 4 pH management and priming volume by operation type

		type of surgery						
		isolated CABG	isolated valve	CABG and valve	CABG and other	aorta	congenital	other
pH management n = 6,954	alpha stat	757 (95.8%)	2,380 (78.8%)	546 (79.7%)	111 (88.8%)	1,195 (69.8%)	108 (83.1%)	439 (89.0%)
	pH stat	23 (2.9%)	369 (12.2%)	74 (10.8%)	7 (5.6%)	130 (7.6%)	16 (12.3%)	38 (7.7%)
	both	8 (1.0%)	270 (8.9%)	65 (9.5%)	7 (5.6%)	385 (22.5%)	6 (4.6%)	16 (3.2%)
	No	2 (0.3%)	1 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)	0 (0.0%)	0 (0.0%)
	total	790	3,020	685	125	1,711	130	493
blood vol (mL) n = 911	mean	487.5	379.7	384.6	323.3	427.0	280.0	366.0
	SD	170.3	171.4	173.6	106.4	204.2	0.0	184.1
	N	32	441	140	12	247	4	35
total priming vol (mL) n = 6,942	mean	1,085.7	1,160.8	1,192.8	1,179.3	1,361.3	1,051.9	1,093.7
	SD	263.7	254.3	270.8	280.7	261.0	254.0	330.1
	N	788	3,015	684	125	1,707	130	493
priming of non blood transfusion (%)		95.9	85.4	79.5	90.4	85.5	96.9	92.9

CABG : coronary artery bypass graft / SD : standard deviation

Table 5 Measurement region of CPB time and deep body temperature by operation type

		type of surgery						
		isolated CABG	isolated valve	CABG and valve	CABG and other	aorta	congenital	other
pump time (min) n = 6,953	mean	147.8	166.3	212.0	240.8	232.6	134.0	163.0
	SD	54.8	73.8	74.8	102.4	109.4	59.8	100.3
	N	789	3,020	685	125	1,711	130	493
clamp time (min) n = 6,570	mean	59.1	113.2	129.9	125.2	119.2	70.6	90.9
	SD	57.7	49.8	52.2	64.2	68.3	45.7	62.4
	N	602	3,006	684	119	1,598	127	434
cumulate number of temperature measurement site	bladder	607 (41.8%)	2,371 (43.7%)	489 (39.4%)	93 (41.2%)	1,321 (35.2%)	96 (42.9%)	376 (46.1%)
	jugular	0 (0.0%)	1 (0.0%)	1 (0.1%)	0 (0.0%)	14 (0.4%)	0 (0.0%)	0 (0.0%)
	nasopha	350 (24.1%)	1,383 (25.5%)	325 (26.2%)	57 (25.2%)	1,073 (28.6%)	53 (23.7%)	183 (22.5%)
	rectal	336 (23.1%)	931 (17.2%)	259 (20.9%)	46 (20.4%)	873 (23.3%)	60 (26.8%)	182 (22.3%)
	esophagus	87 (6.0%)	489 (9.0%)	90 (7.3%)	22 (9.7%)	175 (4.7%)	12 (5.4%)	45 (5.5%)
	tympanic	57 (3.9%)	181 (3.3%)	54 (4.4%)	5 (2.2%)	233 (6.2%)	3 (1.3%)	22 (2.7%)
	other	16 (1.1%)	72 (1.3%)	23 (1.9%)	3 (1.3%)	61 (1.6%)	0 (0.0%)	7 (0.9%)
	total	1,453	5,428	1,241	226	3,750	224	815

CABG : coronary artery bypass graft / SD : standard deviation

Table 6 Distribution of blood temperature (arteria flow)

blood temp.	No	ratio
<37	3,671	53.2%
37-38	2,750	39.8%
38-39	399	5.8%
39-40	32	0.5%
NA	52	0.8%
total	6,904	100.0%

NA : not available

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〈Appendices〉

Participate Institutions and Data-managers for the JaSECT Perfusion Registry

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(In random order)

The authors declare that they have no COI.

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