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original article

Study profile of the perfusion registry in Japan

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Abstract

In response to activities of the International Consortium for Evidence-Based Perfusion, the Japanese Society of Extra-Corporeal Technology in Medicine started planning the preparation of scientific evidence-based guidelines for extracorporeal circulation in Japan in 2008, and after an about 6-year preparation period, registration of extracorporeal circulation cases was initiated in 2014. This project consists of cooperation between 'case registration' by participant institutions in which each case is input following the definitions of registration items without error and 'case database' in which registered cases are collected, managed, tabulated, and analyzed. The numbers of participant institutions and registered cases including those which participated in an open input test performed in 2013 reached 30 institutions and 7,443 cases by the end of 2016. Institutions participating in this project account for all Japan Adult Cardiovascular Surgery Database (JACVSD)-participant institutions. When registration of pediatric cases of extracorporeal circulation starts, a cohort study using the extracorporeal circulation case database will progress, and its achievement, scientific evidence, may lead to stability and improvement of clinical extracorporeal circulation techniques and development of the guidelines.

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

Ⅰ. Introduction

The American Society of Extra-Corporeal Technology (AmSECT) organized the International Consortium for Evidence-Based Perfusion (ICEBP) based on scientific evidence as a new committee organization in 2006. The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) participated in its management organization with several European, Oceanian, and Asian academic societies on extracorporeal circulation. The objective of ICEBP is to form several activity organizations, prepare scientific evidence-based guidelines for the extracorporeal circulation field, and provide these to clinical techniques. [1] Executive members of ICEBP published review articles based on the classification and evidence level in the American Heart Association and the American

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College of the Cardiology Task Force on Practice Guidelines in the same and following years.[2,3] These activities were great opportunities leading to seek for an academic basis of extracorporeal circulation in case registration epidemiological studies in Japan. To prepare scientific evidence-based guidelines for extracorporeal circulation in Japan in response to the ICEBP activities, JaSECT started planning in 2008. They visited America and Australia to investigate the state of activities,[4] and surveyed basic information concerning execution of extracorporeal circulation in institutions in 2011 aiming at constructing an extracorporeal circulation case database matched with the state of input items for registration of adult cases of extracorporeal circulation.[5] The results of this survey met the data collection items concerning operation of extracorporeal circulation recommended by ICEBP. Based on these results, we combined items concerning extracorporeal circulation during open heart surgery and related minimum required patient information items as draft case registration items.

In 2012, the database input form and input procedure were prepared using these draft case registration items, and then an input test and hearing survey on the input operation state were performed. Based on the hearing survey, specific descriptions in the input procedure were added and correction of input form failures were performed.[6]

In 2013, institutions participating in the registration of extracorporeal circulation cases were publically recruited and an input test was performed. The items with incorrect input and data missing were different among the institutions, and the same institutions repeated in the same item. Therefore, the input procedure was revised and called to attention. A meeting of data entry workers of the participant institutions was held and the situation was explained.[7]

After an about 6-year preparation period as described above, registration of extracorporeal circulation cases was initiated with JaSECT as the parent organization of the project in 2014. This project consists of cooperation between 'case registration' by participant institutions in which each case is input following the definitions of registration items without error, and 'case database' in which registered cases are collected, managed, tabulated, and analyzed, for which JaSECT performs diverse activities to register all cases of extracorporeal circulation nationwide, such as asking institutions for participation, setting a desk for inquiries related to the project for participant institutions and patients, procedures of participation in the case registration for institutions and data manager registration, management of the extracorporeal circulation case database, data manager meeting, tabulation and analysis of all registered case data and case data within participant institutions, feedback of the tabulation and analysis results to participant institutions, and re-examination of the case registration items and definitions.

Ⅱ. Overview of extracorporeal circulation case registration

1. Objective

The objectives are progression of extracorporeal circulation techniques in Japan and contribution to promotion of national medical care and health through surveying the preoperative medical physical state of patients undergoing cardiovascular surgery or treatment under extracorporeal circulation, execution status, and results of extracorporeal circulation, preparation of database of these and nationwide summation, tabulation and analysis of large-scale samples using these data, and provision of the results of these. In addition, enabling risk assessment of extracorporeal circulation by international collaboration is aimed at.

2. Subjects

The target of collection is only adult patients aged 16 years or older, and each case of open heart surgery accompanied by extracorporeal circulation is regarded as one registration.

For institutions to participate in this case registration, approval by each institutional review board or director of the institution is required. In addition, the data manager managing case registration at each institution is required to be a full member of JaSECT.

3. Methods

For the registration of extracorporeal circulation cases, FileMaker Pro® (FileMaker Inc.) was used. This software can be used on the major OS, Windows and Mac OS, and inputters can use any personal computer. For the collector side, this software has high affinity to spreadsheet and statistical analysis software, being advantageous.

Data accumulated at each institution are output as a spreadsheet software file and collected through

the internet using the Web mail system exclusive for JaSECT members. In this system, inter-terminal communication is sent and received using the SSL encryption communication and security against data exploitation during communication is ensured.

Data accumulated at each institution is collected at Fujita Health University, compiled to a database, and tabulated and analyzed using JMP® (SAS Corp.). The tabulated results are published at data manager meetings (twice/year). In these meetings, aggregated results based on all data are reported, and data managers receive aggregated results of their own institution and overall aggregated results through electronic media (JaSECT ethical review approval 001, Fujita Health University ethical review approval HM17-088).

4. Contents of registration items

This case registration is comprised of 6 fields: basic patient information, circuit and filling fluid, extracorporeal circulation, in-and-out management, test data management, and outcome management, containing 84 multiple-choice input items and 159 descriptive items (inputting numerical values), 243 items in total. Of these, 46 multiple-choice input items and 131 descriptive items (inputting numerical values) are essential, 177 items in total (**Fig.1-1, 1-2**). The input items are mostly the same as those in the registration of extracorporeal circulation cases, PERForm, performed in State of Michigan, US, in collaboration with AmSECT. The items and definitions were translated into Japanese and matched.

5. State of registration

The numbers of participant institutions and registered cases including those in the open input test performed in 2013 are increasing yearly. Sixteen institutions participated in 2013, and several institutions participated yearly thereafter, reaching 30 institutions by the end of 2016. During this period, the number of cases registered from the participant institutions reached 7,443 (**Table 1**).

On summation by the main target disease of surgery, surgery for valvular disease alone (43.4%) is the most frequently performed, followed by aortic surgery (24.8%). The combined rate of surgery for coronary artery bypass alone (11.2%) and combined surgery with that for valvular disease was 22.9% (**Table 2**).

Table 1 Participated institutions and harvested cases between 2013 and 2016

calendar year	number of participating institutions	number of cases
2013	16	486
2014	19	1,587
2015	27	2,213
2016	30	3,157
total		7,443

Ⅲ. Discussion

In 2014, 540 institutions performed cardiovascular surgery in Japan, and the number of cases was 66,453 (including pediatric cases).[8] On the assumption that the same number of institutions performed surgery at the end of 2016, the rate of institutions participating in the registration of extracorporeal circulation is 5.6 %, and the rate of the registered cases is 4.8%. On the other hand, according to the Japan Cardiovascular Surgery Database Organization (JCVSDO) collecting adult cases, 63,168 cases were collected from 573 institutions in 2016,[9] and the rates of institutions participating in the registration of extracorporeal circulation and registered cases were 5.2 and 5.0%, respectively. The numbers were small in both databases, but it may be possible to report the state and outcome of extracorporeal circulation by analyzing the data registered in the extracorporeal circulation case databases. The mean number of case registrations

Table 2 Number of CPB cases categorized with type of procedures

calendar year	type of procedure							
	isolated CABG	isolated valve	CABG and valve	CABG and other	aorta	congenital	other	NA
2013	46	209	55	8	134	7	27	0
2014	161	743	155	21	370	19	118	0
2015	282	965	226	35	516	43	146	0
2016	347	1,312	304	69	825	68	230	2
Total	836	3,229	740	133	1,845	137	521	2

NA：not abailable

National Perfusion Registry

A. Demographic and Case Detail

Center ID_____ Located country_____
Perfusion Record No._____
Number of perfusion (Admission date was same)
☐1:1st, ☐2: 2nd, ☐3: 3rd, ☐4: 4th, ☐5: 5th or grater
First perfusion record No.(Admission date was same)_____
Gender ☐1:M, ☐2:F
Surgery date_____(Y/M)
Age at surgery___years___months
Admission to surgery____days, Hospital stay____days,
Surgery to discharge____days
Status ☐1:Elective,☐2:Urgent,☐3:Emargent,☐4:Salvage
Discharge Location ☐1:Home, ☐2:Other Hospital, ☐3:Dead, ☐4:Other (Unknown)

Surgical Information

Type of Surgery ☐1:CABG, ☐2:Valve, ☐3:CABG+Valve, ☐4:CABG+other, ☐5:Aorta, ☐6:Congenital(Adult), ☐7:Other
Number of CABG anastomosis sites ___
Aortic Valve Procedure ☐1:No, ☐2:Repair etc, ☐3:Replacement
Mitral Valve Procedure ☐1:No, ☐2:Repair etc, ☐3:Replacement
Tricuspid Valve Procedure ☐1:No, ☐2:Repair etc, ☐3:Replacement
Pulmonary Valve Procedure ☐1:No, ☐2:Repair etc, ☐3:Replacement
Aorta Procedure ☐1:No, ☐2:Repair etc, ☐3:Replacement
Others ☐1:No,☐2:LV procedure or LV rupture repair, ☐3:VSD, ☐4:ASD, ☐5:Arrhythmia correction surgery,☐6:Carotid endarterectomy, ☐7:Peripheral Vascular,☐8:Thoracic,☐7:Other

CV Surgical History

CV surgery history ☐1:1st ope, ☐2:re-ope(1st), ☐3:re-ope(2nd), ☐4:re-ope(3rd), ☐5:re-ope(4th or grater)
Previous CV surgery type ☐1:No, ☐2:CABG, ☐3:Valve, ☐4:Aorta, ☐5:Congenital, ☐6:Other cardiac

Pre-Operative Physical Information

MI history ☐1:No, ☐2:Less than 6hrs, ☐3: 6 to 24hrs, ☐4: 1 to 7days, ☐5: 8 to 21days, ☐6: Grater than 21days
LV Fraction ☐1:good, ☐2:medium, ☐3:bad
LVEF method ☐1:LV gram, ☐2:Echo, ☐3:Radio nucleotide, ☐4:Estimate, ☐5:Others
Cardiac Output(pre-induction)_____L/min.

Risk Factors

CHF ☐1:No, ☐2:Yes, ☐3:Unknown
Chronic Lung Disease ☐1:No, ☐2:Yes, ☐3:Unknown
Smoking ☐1:No, ☐2:Yes, ☐3:Unknown
Diabetes ☐1:No, ☐2:Yes, ☐3:Unknown
Arrhythmia ☐1:No, ☐2:Yes, ☐3:Unknown
Hypertension ☐1:No, ☐2:Yes, ☐3:Unknown
Hyperlipidemia ☐1:No, ☐2:Yes, ☐3:Unknown
Non cardiac vascular disease ☐1:No, ☐2:Yes, ☐3:Unknown
Cerebral vascular disease ☐1:No, ☐2:Yes, ☐3:Unknown
Renal Failure ☐1:No, ☐2:Yes, ☐3:Unknown
Dialysis ☐1:No, ☐2:Yes, ☐3:Unknown

Height_____cm, Weight_____kg, Creatinine_____mg/dL
BMI_____ BSA_____m^2
Perfusionist Main:_____ Sub:_____
Surgeon:_____

Note
Name in initial (Last)_____(First)_____
Birth _____(Y/M/D)
Admission_____(Y/M/D)
Surgery_____(Y/M/D)
Discharge_____(Y/M/D)

B. Circuit

Arterial filter mesh size_____μm
Pre-bypass filter ☐1:No, ☐2:Yes
pH management ☐1:No, ☐2:α Stat, ☐3:pH Stat, ☐4:Both
Biopassive coating area ☐1:None, ☐2:Limited component, ☐3:All but cannulae, ☐4: Tip to tip
Biopassive coating type
☐1:X coating(Terumo), ☐2:SMARTx(Cobe), ☐3:Physio(Sorin), ☐4:Carmeda(Medtronic), ☐5:Trillium(Medtronic), ☐6:GBS(Gish), ☐7:Bioline(Jostra), ☐8:Safeline(Maquet), ☐9:Duraflow(Baxter), ☐10:COAFREE(JMS), ☐11:Heparin(MERA), ☐12:Other
Venous reservoir type ☐1:Opened, ☐2:Closed, ☐3:Not use
Venous reservoir filter mesh size_____μm
Arterial pump head
☐1:Roller pump, ☐2:Rotaflow(Jostra), ☐3:Biomedicus(Medtronic), ☐4:Revolusion(sorin), ☐5:Sarns(Terumo), ☐6:Capiox (terumo), ☐7:Duraflo,HPM(MERA), ☐8:Turbo(JMS)
Venous return
☐1:Gravity, ☐2:Vacuum assist, ☐3:Pump assist
Pump mode ☐1:Steady, ☐2:Pulsatile
Selective perfusion ☐1:No, ☐2:Yes

Priming volumes and Blood products

Static circuit vol._____mL
Blood vol._____mL Total priming vol._____mL
Main priming solution
☐1:0.9% Saline, ☐2:Lactated Ringer, ☐3:Acetate Ringer, ☐4:Bicarbonate Ringer, ☐5:Hartmanns, ☐6:Normosol, ☐7:Starch or dextran, ☐8:Other(Crystalloid only)
Autologous Circuit Prime
☐1:No, ☐2:Retrograde autologous prime, ☐3:Banked autologous blood used
Leukodepletion ☐1: No, ☐2:Radiation, ☐3:Filter

C. Perfusion time

Pump time_____min.
Clamp time_____min.
Re-perfusion time ☐1:No, ☐2:Yes_____min.
☐1:Hemodynamic instability, ☐2:Pulmonary failure, ☐3:Re-grafting, ☐4:Bleeding, ☐5: Valve function failure,☐6:Other
Whole perfusion arrest ☐1:No, ☐2:Yes_____min.

Cardioplegia

Clamp ☐1:No, ☐2:Yes, 3:Balloon Occlusion
Arrest type ☐1:No, ☐2:Cardioplegia, ☐3:V-Fib, ☐4:Beating
Type of CPS ☐1:None, ☐2: 1:1, ☐3: 2:1, ☐4: 3:1, ☐5: 4:1, ☐6: 5:1, ☐7: 6:1, ☐8:7:1, ☐9: 8:1, ☐10: 9:1, ☐11: 10:1, ☐12:Crystalloid, ☐13:Comb, ☐14:Mycroplegia
Cardioplegia Regime
☐1:First infusion only, ☐2:Intermittent, ☐3:Continuous ☐4:Combine, ☐5: Intermittent with Continuous Blood
Induction Details
Temp ☐1:Cold (<28℃), ☐2:Tepid (28 - 34℃), ☐3:Warm (>34℃)
Route ☐1:Antegrade, ☐2:Retrograde, ☐3:Both
Maintenance Details
Temp ☐1:Cold (<28℃), ☐2:Tepid (28 - 34℃), ☐3:Warm (>34℃)
Route ☐1:Antegrade, ☐2:Retrograde, ☐3:Both
Longest cardioplegia interval_____min.
Filter ☐1:No, ☐2:Yes_____μm
Hot Shot used ☐1:No, ☐2:Yes _____℃
Sum of cardioplegia solution_____mL (Exclude blood)

Temperature(℃)

	Highest	Lowest		Highest	Lowest
Bladder			Jugular		
Nasopha			Rectal		
Esopha			Tympanic		

Highest blood temp_____℃ (Arterial flow)

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Fig.1-1 Parameter of the Perfusion Registry (1)

National Perfusion Registry

Selective Cerebral Perfusion ☐1:No, ☐2:Yes
No. of pumps for SCP
☐1:Only branch of Arterial line, ☐2:1 roller pump, ☐3: 2 roller pumps, ☐4: 3 roller pumps, ☐5:Centrifugal pump
Antegrade SCP cannulation
☐1:No, ☐2:Brachiocephalic A, ☐3:R-axillary A, ☐4:L-common carotid A, ☐5:L-subclavian A, ☐6: L-axillary A
Retrograde SCP ☐1:No, ☐2:Yes
Independed heat exchanger used for SCP ☐1:No, ☐2:Yes
Cerebral perfusion time
Antegrade_____min. Retrograde_____min.
Cerebral circulatory arrest time_____min.
Separated systemic circulatory arrest time_____min.
Separated systemic circulation ☐1:No, ☐2:Yes_____min.

Cannulation
Arterial ☐1:Aorta, ☐2:Femoral, ☐3:Axillary, ☐4:Other
Cannulation changed ☐1:No, ☐2:Addition ☐3:Yes
Venous ☐1:Right atrium, ☐2: SVC + IVC, ☐3:Femoral, ☐4:Jugular, ☐5:SVC, ☐6:,IVC ☐7:Other

Anticoagulation
ACT ☐1:Post Intubation_____sec., ☐2:Post systemic heparinization_____sec., ☐3:Highest on CPB sec., ☐4:Lowest on CPB_____sec., ☐5:Post Protamine infusion_____sec.

Whole circuit replacement
☐1:No, ☐2:Addition or replace limited parts ☐3:Yes

D. Fluid volume management (In)

	Priming	IntraOp (CPB)	IntraOp (No-Prime・No-CPB)
RBC(Non-Leukoreduced)			(U)
RBC(Leukoreduced)			(U)
FFP			(U)
5% Albumin			(mL)
25% Albumin			(mL)
Platelets			(U)
Cell Saver			(mL)
Conc. Circuit Blood			(mL)
Harvested Circuit Blood			(mL)
Whole Blood			(mL)
Other Blood product			(mL)
20% Albumin			(mL)
Starch or dextran			(mL)

RBC was washed with Cell Saver prior to administration.
☐1:No, ☐2:Portion, ☐3:Yes

Total volume
Crystalloid_____mL Colloid_____mL
Maximum administered solution
☐1:0.9% Saline, ☐2:Lactated Ringer, ☐3:Acetate Ringer, ☐4:Bicarbonate Ringer, ☐5:Hartmanns, ☐6:Normosol, ☐7:Starch or dextran, ☐8:Other(Crystalloid only), ☐9:Unknown
Other total vol._____mL (medicine, cardioplegia, etc)
Medications(IntraOp)
Heparin_____(Units)Total dose
Antifibrinolytic
☐1:No, ☐2:e-Aminocaproic acid, ☐3:Tranexamic Acid
Renal Management
☐1:No, ☐2:Furosemide, ☐3:Mannitol, ☐4:Fanoldapam, ☐5:Vasopressin

Fluid volume management (Out)
Autologous Blood Harvest ☐1:No, ☐2:Yes_____mL
Circuit Blood Harvest ☐1:No ☐2:Yes_____mL,
Unprocessed cardiotomy suction returned to bypass circuit. ☐1:No, ☐2:Yes
Filtration ☐1: No, ☐2: MUF, ☐3: HF, ☐4: HD, ☐5: Other
Added solution volume for MUF_____mL

	CPB	Post CPB
Urine	mL	mL
Ultrafiltration	mL	mL
Wasted Blood	mL	mL

E. Lab data Next Sheet—>

F. Outcomes
Complications
Af requiring treatment ☐1:No, ☐2:Yes
Dialysis required ☐1:No, ☐2:Yes
Stroke ☐1:No, ☐2:Yes
New MI ☐1:No, ☐2:Yes
Intubation for 24hrs or more ☐1:No, ☐2:Yes
Return to OR ☐1: No, ☐2: Bleeding, ☐3: valve function failure, ☐4: Graft occlusion, ☐5: Other CV(cardiovascular) disturbance, ☐6: Other

Mechanical circulatory Support devices
IABP ☐1: No,☐2: Preop,☐3: Intraop,☐4: Postop
ECMO(PCPS) ☐1: No,☐2: Preop,☐3: Intraop,☐4: Postop
VAS(VAD) ☐1: No,☐2: Preop,☐3: Intraop,☐4: Postop
Total Artificial Heart ☐1: No,☐2: Preop,☐3: Intraop,☐4: Postop
Indication
☐1: Hemodynamic instability, ☐2: Circulatory support on PTCA, ☐3: Unstable refractory angina, ☐4: CPB wean, ☐5: Prophylactic indication, ☐6: Other, ☐7: Unknown

E. Lab data

	Post Intubation	First on CPB	Highest on CPB	Lowest on CPB	Last on CPB	Post ope (In ICU)
Glu(mg/dL)						
K(mEq/L)						
Lact(mg/dL)						
CRN(mg/dL)						
TP(g/dL)						
Hb(g/dL)						
pH						
Po_2(mmHg)						
Pco_2(mmHg)						
HCO_3^-(mEq/L)						
Svo_2(%)						

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Fig.1-2 Parameter of the Perfusion Registry (2)

per institution was 110 in the 2016 JACVSD report [9] and this was mostly the same as the mean number (105) of extracorporeal circulation case registrations per institution in the same year, suggesting that a cohort study can be performed using the database in which several thousands of extracorporeal circulation cases are accumulated.

AmSECT was involved in preparation of the blood transfusion management guidelines established by the collaboration of 2 academic societies, [10] and the temperature management guidelines for extracorporeal circulation were prepared in 2015 by the collaboration of 3 academic societies. [11] In addition, the registration items of extracorporeal circulation cases were reflected in the standard extracorporeal circulation techniques published by AmSECT and guidelines, [12] showing that the summation and analysis by the registration of extracorporeal circulation cases are admitted as scientific evidence. Furthermore, after publication of the guidelines, it has been suggested that the guidelines can be verified using the items of the data registered in the extracorporeal circulation case database, [13] which also indicates that the registration of extracorporeal circulation cases in JaSECT may also contribute to preparation of cardiovascular surgery guidelines.

If all institutions participating in JACVSD participate in this project and registration of pediatric extracorporeal circulation cases is initiated, a cohort study using the extracorporeal circulation case database may progress and its achievement, scientific evidence, may lead to stability and improvement of clinical extracorporeal circulation techniques and development of guidelines.

In Japan, a risk model was prepared using the case data accumulated in the JACVSDO database and JapanSCORE capable of calculating the predicted mortality before surgery in each case was published, leading to improvement of the quality of cardiovascular surgery. Since fewer extracorporeal circulation-related items are included in JACVSD, the use of data accumulated in the extracorporeal circulation case database is expected to improve the quality of surgery and lead to safe and appropriate medical care for patients.

〈Acknowledgments〉

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〈Appendices〉

1. Member of the Guidelines Formulation Committee (Year 2009-2017)

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The authors declare that they have no COI.

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