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original article

A survey of the present status of perfusion in institutions with members of the Japanese Society of Extra-Corporeal Technology in Medicine : Toward development of a perfusion database

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Abstract

To construct a perfusion database in Japan by modifying the input parameters of the adult perfusion registry of the International Consortium for Evidence-based Perfusion (ICEBP) to suit the present status of Japan, we surveyed basic information on perfusion using a questionnaire consisting of 108 questions (basic survey items and items regarding the practice of perfusion) in 557 institutions to which regular members of the Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) were affiliated.

The questionnaire recovery rate was 48%. Access to the Internet was possible in 87% of the responder institutions. As applications for data processing, 81% possessed MS-Excel, and 51% possessed FileMaker. Concerning circuits, handwriting was used for perfusion recording for 53% of circuits, and selective cerebral perfusion was used for 35%. A crystalloid priming solution was used for 87%.

The number of perfusion cases in these institutions accounted for 74% of that of registered cases during this year in the Japan Adult Cardiovascular Surgery Database (JACVSD). If all institutions where JaSECT members work participate in the perfusion case registration project, the number of registered cases will steadily increase, and a sufficient statistical power will be achieved early.

This survey suggested that the database parameters used by the ICEBP can be used commonly in Japan. In addition, based on the results of the open heart surgery cases in Japan, almost equal numbers of perfusion cases of coronary heart diseases, those of valve disease, and those of aortic diseases can be registered, which allows globally valuable characteristic epidemiological evaluation.

Key words : survey, questionnaire, cardiopulmonary bypass, database

Ⅰ. Introduction

In recent years, evidence-based medicine (EBM) has been established, and this term has been spreading to the general public. In the perfusion field, the term evidence-based perfusion (EBP) is globally spreading. Part of the evidence on perfusion and its technology has been provided by the evaluation of reviews of scientific studies and case reports according to the classification of recommendations and level of evidence[1] by the ACC/AHA[2,3].

Whether or not these evaluations are beneficial to patients can be determined through re-evaluation by clinical epidemiological studies performed after large-scale, long-term domestic or international perfu-

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sion case registration. In addition, new evidence is provided by perfusion case registration, and the re-evaluated and new evidence is published as guidelines providing common parameters.

In the perfusion technology field, such an attempt was started by the American Society of Extra-Corporeal Technology (AmSECT), who organized the International Consortium for Evidence-Based Perfusion (ICEBP), recognizing the importance of the development of guidelines and a case registry project [4]. The ICEBP announced the launch of a project to promote an international perfusion case registry, and initiated registration as a trial in Michigan in cooperation with the Michigan Society of Thoracic and Cardiovascular Surgeons [5].

The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) participated in the ICEBP in 2006, and initiated a project in 2008 to develop perfusion guidelines in Japan in the future. The purpose of this project is to realize the early provision of objective evidence to which clinical epidemiology is introduced, and contribute to improvement in treatment results by providing appropriate technical support.

The ICEBP and Perfusion Downunder in Australia, and the Belgian Society for Extra-Corporeal Circulation Technology (BelSECT) initiated the use (including trial use) of a perfusion database [6, 7]. To conduct perfusion registration in Japan, following these organizations, the JaSECT performed present status surveys in Japan, the U.S., and Australia [8].

Based on the results of these surveys, we paid attention to cases in which the use of the open heart surgery database by cardiovascular surgeons was successful. In Japan, the Japanese Association for Thoracic Surgery and Japanese Society for Cardiovascular Surgery jointly organized the Japan Adult Cardiovascular Surgery Database (JACVSD) System, and use the JACVSD. The input parameters for this database were initially the same as those of the database (STS National Database) used by the Society of Thoracic Surgeons (STS), but have been re-evaluated and gradually increased in number [9]. The ICEBP perfusion case registry aims at establishing internationally common parameters. To respond to this proposal, parameters reflecting the status in Japan should be established for the perfusion database constructed by JaSECT, and a design that can facilitate international statistical comparison is necessary.

To construct a perfusion database in which the input parameters of ICEBP's adult perfusion registry are adjusted to the present status in Japan, we performed a survey on basic information on perfusion practice in each institution.

Ⅱ. Methods

We performed a survey of 557 institutions to which regular JaSECT members are affiliated. In each institution, 1 member was randomly selected, and a request for the survey was sent to this member by mail. An MS-Excel (Microsoft, WA, USA) file as a questionnaire was voluntarily downloaded by this member using the Internet from the server installed in Fujita Health University. Answers to questions were inputted, and the file was attached to an e-mail, and collected. The collection of the questionnaire was regarded as consent to the survey.

The questionnaire items included the environment for the use of the database and the number of perfusion cases as basic items, the constitution of generally used circuits, drug and examination parameters as parameters related to the practice of perfusion, and the composition of the priming solution. There were 108 questionnaire items, which consisted of 59 single-answer questions, 3 multiple-answer questions, 15 free-answer questions, and 31 numeric-answer questions.

The survey period was from January 11 to March 31, 2011. This survey was performed with the support of the Japanese Association for Thoracic Surgery and Japanese Society for Cardiovascular Surgery and with the approval of the Ethics Committee for Clinical Research of Fujita Health University (notification No. 10-173).

Ⅲ. Results

The questionnaire recovery rate was 48% (n=266).

1. Basic survey items

Institutions participating in the JACVSD project accounted for 57%. In 82% of the 57%, JaSECT members provided perfusion data necessary for JACVSD. In 93%, there was an information terminal that can be used for tabulation or database application. In 87% of the 93%, access to the Internet was possible. The data processing application possession rate (multiple-

Table 1 Total number of perfusion procedures (1 Jan. - 31 Dec., 2010)

Procedure	n
CABG	4,563
Conversion OPCAB to CABG	240
CABG + Valve (s)	1,849
CABG + Other	918
Valve (s)	7,677
Aorta	4,961
Congenital (Adult)	707
Other	2,769
Total	23,684

(n=244)

Table 2 Temperature monitoring locations in CPB

	Location	Percentage
In body	Bladder	77.1
	Nasopharnygeal	33.3
	Esophageal	28.1
	Jugular bulb	2.0
	Rectal	78.7
	Tympanic	28.6
	Dorsum pedis	18.0
	Dorsum manus	11.6
In line	Arterial blood line	96.7
	Venous blood line	91.9
	Outlet of heat exchanger	45.7

(n=249)

Table 3 Synchronous number of temperature monitoring locations

Number of locations	In body (%)	In line (%)
0	0.0	3.2
1	5.2	4.4
2	40.2	47.0
3	36.9	45.4
4	13.3	−
5	3.2	−
6	1.2	−

(n=249)

answer question) was 81% for MS-Excel, 51% for FileMaker (FileMaker, CA, USA), and 33% for MS-Access (Microsoft, WA, USA). Concerning the will to participate in the perfusion case registration project, 95% answered that participation is "possible".

The total number of perfusion cases during the 1-year period from January 1, 2011 was 23,684 (n=244), which consisted of 32% cases of coronary heart diseases, 32% cases of valve diseases, and 21% cases of aortic diseases (**Table 1**).

2. Perfusion survey items

1) Institution survey

The perfusion recording method was only handwriting in 53%, only automatic recording in 31%, separate use of handwriting and automatic recording due to use of multiple pumps in 3%, and double recording (both handwriting and automatic recording) in 13%.

The temperature monitoring location in the body was the rectum in 79%, and the bladder in 77%, and that in the lines was the arterial blood line in 97% and venous blood line in 92% (**Table 2**). Temperature monitoring was most frequently performed at 2 locations each in the body and lines (**Table 3**).

Myocardial protection using blood cardioplegia was performed in 70%, and leukocyte removal was performed in 2% of the 70%.

Among biological monitoring parameters, glucose, electrolytes, hemoglobin, hematocrit, blood gas, and hemodynamics were monitored in the operating room (from admission to the room) and in the postoperative intensive care unit in more than 90%. Renal function, liver function, and protein were monitored in the operating room in less than 20% of the all institutions (**Table 4**).

2) Circuit survey

There were 667 circuits in 248 institutions. The arterial filter installation rate was 94%, and the filter pore size was 30-40μm in 90% (**Table 5**).

Replacement by carbon dioxide was performed for the entire circuit in 16% of circuits, and only for the arterial filter in 19%.

Circuits washed with solution such as Ringer's solution accounted for 9%, and those with a pre-bypass filter accounted for 16%.

For pH management, the α-stat and pH-stat strategies were used in 85 and 14%, respectively.

The blood pump was the centrifugal pump in 69% and the roller pump in 31%. Pulsate flow extracorporeal circulation was used in 5%.

For drainage, gravity drainage, vacuum-assisted venous drainage, and kinetic assist were used in 69, 26, and 5%, respectively.

The reservoir was the open type in 94% and the closed type in 5%, and no reservoir was used in 1%.

Circuits that can be used for selective cerebral

Table 4　Biological monitoring parameters

Parameter		Percentage of responding centers			
		In theatre preCPB	In theatre CPB	In theatre postCPB	In recovery room
Biochemical test	Glucose	93.1	92.7	89.9	93.5
	Na	96.0	98.0	94.4	95.2
	K	95.6	97.6	94.0	94.8
	Cl	87.9	89.1	86.3	91.1
	Ca	92.7	93.1	90.7	91.9
	Creatinine	14.1	5.6	9.7	79.0
	BUN	17.7	10.5	13.7	79.0
	AST	12.1	3.2	6.9	78.2
	ALT	12.1	3.2	6.9	77.0
	LD	10.1	0.8	5.6	75.4
	Total protein	20.2	19.0	15.7	77.8
	Albumin	14.1	10.5	11.3	73.8
	Lactic acid	57.3	53.6	56.0	65.7
Blood count	WBC	45.2	37.5	43.1	85.9
	RBC	47.2	39.5	44.8	86.3
	Hb	94.8	95.2	92.7	94.4
	Ht	92.3	94.8	96.0	94.4
	Platelets	45.6	37.1	45.2	86.3
Blood gas	pH	96.0	98.0	94.4	94.8
	Pao_2	96.0	98.0	94.8	94.8
	$Paco_2$	96.0	98.0	94.8	94.8
	Spo_2	94.4	91.9	92.7	92.7
	Svo_2	73.8	90.3	68.5	75.4
Hemodynamics	AOP	95.6	96.4	94.0	93.5
	CVP	93.5	95.6	93.1	91.5
	PAP	87.5	88.3	88.3	87.1
	CI（or PI）	86.3	77.4	87.1	87.9

（n=248）

Table 5　Arterial filter installation

Installation	Percentage	Pore size（μm）	Percentage
Yes	93.7	～30	0.2
		30～40	90.2
		40～50	0.3
		50～100	2.7
		100～150	0.6
		150～200	2.9
		Unknown	3.0
No	6.3	–	–

（n=666）

perfusion accounted for 35%.

A survey of biocompatible coated circuits showed coating of the entire circuit including the cannula in 23%, that excluding the cannula in 57%, and coating of part of the circuit components in 20%. The coating material was heparin in 40%, PMEA in 42%, silicon in 1%, and their combination in 14% (**Fig. 1**).

The buffer solution used as the primer solution was Ringer's solution in 87%, and colloidal solution was added to 26% of the 87% (**Table 6**). Blood preparations with non-blood transfusion compositions were used in 87%. Leukocytes were removed (using filters and irradiation) from blood preparations used for the blood transfusion composition in 23%.

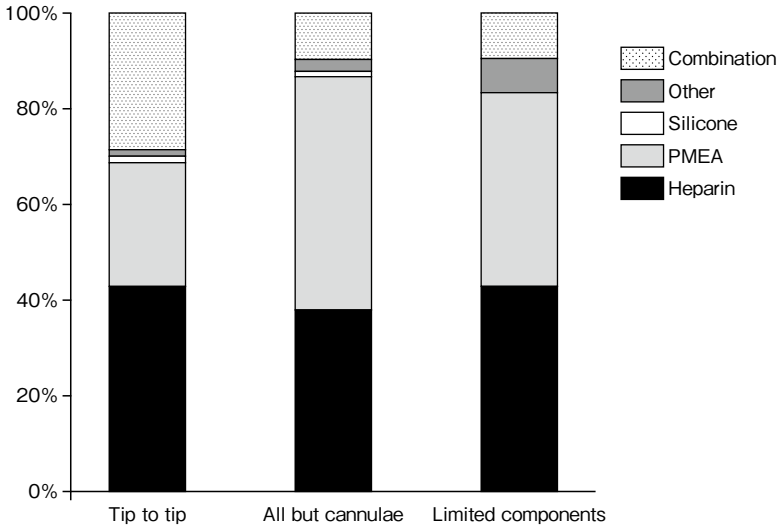

Figure 1 Biocompatible coating on circuit surface

Table 6 Priming solution for perfusion circuit

		Percentage
Crystalloid (n=659)	0.9% Saline	8.0
	Lactated Ringer	32.9
	Acetic Ringer	33.2
	Bicarbonate Ringer	20.8
	Hartmanns	5.0
Colloid (n=174)	Albumin (5%)	36.8
	Hetastarch	18.4
	Albumin (25%)	44.8

Ⅳ. Discussion

1. Basic survey items

As equipment requirements for perfusion case registration, there are computers, Internet connection circuits, and software. The former two were mostly satisfactory in most institutions. As software, more than 90% of the institutions possessed MS-Excel or FileMaker. Therefore, the creation of interfaces for registration using these 2 types and a registration work test can be the first step. Perfusion Downunder constructed the Perfusion Downunder Collaborative Database (PDUCD), and compared collected data on open heart surgery with those in the Australasian Society of Cardiac and Thoracic Surgeons (ASCTS) database, and reported differences in data in the same parameters [6]. PDUCD data during the 1-year period after the initiation of registration (2007) were compared with those during the 2-year period from 2008, and a proposal to produce a high-quality database was reported [10]. This report showed that only 80% of the collected perfusion case data were reliable without missing values, and improvements such as data handling training to assure data quality and confirmation of whether data are effective were made. Takai et al. used a case registry interface produced using FileMaker for the unification of hospital data for JACVSD registration [11]. They solved problems in perfusion case registration by displaying the presence/absence of missing data and summary, and improving convenience. In addition, in the JACVSD, site visits to each institution to assure data quality are performed. Therefore, using these coping methods for perfusion case registration in the future, the database quality may be guaranteed.

The total number of registered JACVSD cases reached 100,000 in 2009, 8 years after the initiation of registration, and the Japan Score was open to the public. In October 2011, the number of cases exceeded 159,000 [12]. Perfusion cases in all institutions that responded to this survey accounted for 74% of all registered cases of the JACVSD in the same year (32,062 cases). If all institutions where JaSECT members work participate in the perfusion case registration project, and the number of registered cases steadily increase, not only the JACVSD but also a statistically reliable analysis function will be able to be provided early [12].

2. Perfusion survey items

1) Institution survey

For the registration of data without mistakes, inputting as straightforward as possible is desirable.

For this purpose, the automatic collection of perfusion data is necessary. Newland et al. constructed a system in which almost all data are transmitted from an electronic medical recording system and a data collection system installed in the cardiopulmonary bypass pump, and succeeded in improving the reliability of data and reducing the registration work time [6]. In this survey, the number of institutions using handwriting for perfusion recording was slightly higher than that of institutions using automatic recording. In each institution, since a certain time is necessary for registration work by transferring each case using a keyboard, measures to reduce labor may lead to the continuation of registration and assurance of data reliability.

Many biological parameters observed in this survey were not included in the ICEBP case registration parameters. Biological data necessary for perfusion are quantitative data and closely involved in perfusion practice. In a previous study, a preoperative scoring system was developed to evaluate the influences of perfusion on postoperative management [13]. If the usefulness of this system can be supported, or this system can be improved for common nationwide use, it will contribute to the preoperative prediction of outcomes. In this study, we also surveyed the presence or absence of measurement of parameters necessary for the calculation of the body fluid balance using quantitative blood analysis values, not depending on the fluid transfusion or urine volume. However, since measurement in the operating room is difficult, problems remain.

2) Circuit survey

The characteristics of the circuit composition in Japan are a low pre-bypass filter incorporation rate and a low circuit washing rate. As the blood pump, the percentage of circuits using a centrifugal pump was more than twice that of circuits using a roller pump. A survey performed in 2003 in Australia and New Zealand showed a pre-bypass filter incorporation rate of about 90% and a roller pump usage rate of 70% [14]. Although simple comparison is difficult because no results of overseas surveys have been reported since this survey, the results of this survey markedly differ from those of our present survey. An on-the-spot survey in 2009 confirmed that the pre-bypass filter and roller pump are routinely used in Australia [8], suggesting no marked changes in these differences.

Circuits used for selective cerebral perfusion accounted for about 30% of all circuits. This selective perfusion may have been used according to the surgical technique because operations for aortic diseases accounted for about 30% of all operations based on the annual number of patients for each disease category. The ICEBP parameters do not include parameters related to selective cerebral perfusion. However, analysis in this field is important for perfusion in Japan, and we should independently establish parameters.

This survey suggested that the choices for each parameter of ICEBP's perfusion registry can be mostly used. Many of the questions asked during this survey were concerned about the conversion method due to differences in the concentration units of drugs and the entry method due to differences between the trade and chemical names of drugs. This is because the trade names of commercially available drugs and perfusion circuit products are commonly used in clinical practice in Japan. In the case registration interface, it may be convenient to use trade names of routinely used products at the time of inputting. However, in the database, it is necessary to replace the drug concentrations and names by those used in the ICEBP database.

Ⅴ. Conclusion

This survey suggested that the ICEBP, PDUCD, and BelSECT database parameters can be also used as database parameters in Japan. In addition, as a result of the classification of open heart surgery cases, almost equal numbers of perfusion cases of coronary heart diseases, those of valve disease, and those of aortic diseases can be registered, suggesting an environment in Japan allowing globally valuable characteristic epidemiological evaluation.

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REFERENCES

1) American College of Cardiology Foundation and American Heart Association, Inc. : Methodology Manual and Policies From the ACCF/AHA Task Force on Practice Guidelines. http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm_319826. pdf, 2010.
2) Shann KG, Likosky DS, Willcox TW, et al. : An evidence-based review of the practice of cardiopulmonary bypass in adults : A focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response. J Thorac Cardiovasc Surg, 132 (2) ; 283-290, 2006.
3) Murphy GS, Hessel EA. II, Groom RC : Optimal perfusion during cardiopulmonary bypass : an evidence-based approach. Anesth Analg, 108 (5) ; 1394-1417, 2009.
4) Likosky DS : Integrating evidence-based perfusion into practices : the International Consortium for Evidence-Based Perfusion. J Extra Corpor Technol, 38 (4) ; 297-301, 2006.
5) ICEBP Executive Committee : ICEBP International Registry Concept, Vision, and Function. http://www.bestpracticeperfusion.org/documents/PDF/Intl_Registry_Wht_Paper_200907.pdf, 2009.
6) Newland R, Baker RA, Willcox TW, et al. : The Perfusion Downunder collaborative database project. J Extra Corpor Technol, 40 (3) ; 159-165, 2008.
7) Database Committee of Belgian Society of Extracorporeal Technology. BelSECT Perfusion Database. http://www.belsect.be/database/documents/Perfusion-database_2-0.pdf. 2010.
8) Hibiya M, Kamei T, Kenmoku K, et al. : The investigation of education and research of improving perfusion quality in Australia. - The report of inspection to Flinders Medical Centre and Alfred Hospital - . JJECT, 37 (4) ; 448-453, 2010.
9) Motomura N, Miyata H, Takamoto S, et al. : Risk model of thoracic aortic surgery in 4707 cases from a nationwide single-race population through a web-based data entry system - the first report of 30-day and 30-day operative outcome risk models for thoracic aortic surgery. Circulation, 118 (14 supple) ; S153-S159, 2008.
10) Tuble SC : Perfusion Downunder Collaboration Database - data quality assurance : towards a high quality clinical database. J Extra Corpor Technol, 43 (1) ; 44-51, 2011.
11) Takai K, Sawazaki M, Ogawa Y, et al. : Development of a new data entry system suitable for the Japan Adult Cardiovascular Surgery Database. Gen Thorac Cardiovasc Surg, 57 (4) ; 192-196, 2009.
12) A brochure of the Japan Adult Cardiovascular Surgery Database (JACVSD). http://www.jacvsd.umin.jp/file/JACVSD111001_1.pdf. 2011.
13) Jegger D, Revelly JP, Ruchat P : Establishing an association between a peri-operative perfusion score system(PerfSCORE) and post-operative patient morbidity/mortality during CPB cardiac surgery. Perfusion, 22 (5) ; 311-316, 2007.
14) Robert A. Baker, Timothy W. Willcox. : Australian and New Zealand Perfusion Survey : equipment and monitoring. J Extra Corpor Technol, 38 (3) ; 220-229, 2006.