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original article

A data analysis trial of the National Perfusion Registry in a pilot test

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Abstract

The Japanese Society of Extra-Corporeal Technology in Medicine has been conducting open tests based on a database of extracorporeal circulation cases since May 2013. The society collected data from the tests conducted by the end of December 2013 twice, and organized and analyzed the second collected data.

The number of data samples collected was 507. Roller-type and centrifugal pumps accounted for 19.5 and 80.5% of the total number of pumps used, respectively. Regarding venous drainage methods, gravity, vacuum-assisted, pump-assisted, and a combination of gravity and vacuum-assisted venous drainage accounted for 61.9, 11.4, 5.1, and 21.5%, respectively. The rate of using the pre-bypass filter was 32.5%. The error rates in data validation for multiple-choice and descriptive items were 0.8 and 18.9%, respectively. This suggests that the rate of cases excluded was 15.0%. However, when items were limited to those similar to the PERForm items adopted by the International Consortium for Evidence-Based Perfusion (ICEBP), the rate of excluded cases was 4.5%.

In the case of data from different institutions, items involving input errors and defects varied among institutions. In the case of data from the same institutions, input errors and defects were identified in the same items. However, we had asked the institutions to review input data, and there was a significant decrease in the number of systematic errors. This suggests that data input can be more accurate through the validation and assessment of data.

As data related to the same items are input according to the definitions in each institution and data from multiple institutions are analyzed, the results can be applied to assessment standards using actual data.

Key words : extracorporeal circulation, database, case registry, heart-lung machine

Ⅰ. Introduction

In recent years, there has been an increase in the demand for health care based on scientific evidence. The International Consortium for Evidence-Based Perfusion (ICEBP) aims to establish evidence-based care in extracorporeal circulation, develop its guidelines through international collaboration, and play a central role in the promotion of extracorporeal circulation using heart-lung machines - a basic life-sustaining/management method in the field of cardiovascular surgery, and its techniques.[1]

Emphasis has been placed on scientific evidence in randomized controlled trials (RCTs) and clinical studies including meta-analyses. On the other hand,

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clinical epidemiological studies, which are a similar observation-based clinical research method that uses common medical records, involve the creation of databases of medical records and other patient information and analyze significant amounts of data stored in these databases. With the aim of establishing a system of databases of extracorporeal circulation cases based on the latter analysis method, the ICEBP created a database in collaboration with a clinical case database developed by cardiac surgeons in the State of Michigan and initiated the collection of data.[2)]

The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) created a database of extracorporeal circulation cases, consisting of the items required to be input for their registration published by the ICEBP that reflect the analysis results of a 2010 national survey of the status of extracorporeal circulation.[3)] On the basis of this database, the JaSECT conducted input-matching tests in four institutions in Japan for four months since December 2012, using records of same cases that occurred in the institutions. The results of these tests suggest that: the input of data of one clinical case requires approximately 20 minutes, items related to defective data should be presented in an objective manner, and it is necessary for each institution to develop an instruction manual for accurate data input.[4)]

On the basis of the test results, we revised the database input form and manual, and conducted open tests for eleven months from May 2013 using the revised form and manual. We collected data input by the institutions by the end of December 2013. The present paper presents the results of tabulation and analyses conducted for each item.

Ⅱ. Methods

1. Open tests

The open tests, positioned as preliminary tests for the extracorporeal circulation case database project, were scheduled to be conducted based on the same procedures as those for the actual operation of the database project. The committee for the development of the guidelines, an organization in charge of the implementation of the project, provided an explanation of the project for the JaSECT representative assembly and projects of local communities.

Data stored in each institution are collected twice a year. Data between January and June are collected in August, and those between July and December are retrieved in February the following year. The tabulation and analysis results are published in data manager meetings held at education seminars (in spring) and academic conferences.

1) Institutions included in the study

As ethical consideration is required when institutions involved in extracorporeal circulation operate databases of extracorporeal circulation cases, the following ethical considerations were made: the project was implemented with the approval of the JaSECT ethics committee; methods for the implementation of the project and other information were published on the Internet to encourage the institutions to undergo ethics screening.

We asked the institutions to participate in the project according to the following procedures since their understanding is essential:

①Consent provided by the clinical engineering section and clinical departments of cardiac surgery of the institutions
②Request for screening submitted to the ethics committees of the institutions and their or their directors' approval
③Notification of the implementation of the study sent to the users of the institutions continuously instead of obtaining informed consent
④Recruitment of data managers
⑤Registration of participation in the project submitted to the committee on the development of the guidelines
⑥Purchase of the software FileMaker Pro® and learning the method for its use
⑦Downloading the manual for the handling of the extracorporeal circulation case database and its understanding
⑧Preparation of the manual to quote data from medical and extracorporeal circulation records

2) Extracorporeal circulation case database

The extracorporeal circulation case database was created using FileMaker Pro® because the software operates on both Windows® and Mac OSX® - two common operating systems, independent of the user's PC environment. It also has high affinity with spreadsheet and statistical software, which is an advantage for individuals in charge of data collection.

The database involves the following five fields: basic patient information, circuits and priming fluids, fluid

volume management (In/Out), and inspection data management. It consists of a total of 177 input items: 46 multiple-choice and 131 descriptive (requiring numerical values) items. A function of the database automatically inputs data into the required items (if any) according to the procedure for the implementation of extracorporeal circulation, established by the institution. Therefore, the number of items to be entered manually using a keyboard was expected to be reduced by half.

The database has indicators on the input screen to allow the user to identify missing data (if any) in each field and item visually.

3) Data collection

The data stored in each institution were output to data collection files created using FileMaker Pro®, and collected through the Internet.

The exclusive web mail system for JaSECT members was used for data collection. This system allows terminal-to-terminal transmission using the SSL cipher communication system, and ensures security to prevent unauthorized online data acquisition.

The data managers of the institutions logged into the system and sent an email with necessary accompanying files to a designated address. The individuals in charge of data collection downloaded the attached files from the system, and stored them on a PC whose security had been established.

4) Disclosure of analysis data

The collected data were analyzed using JMP® (SUS), and the analysis results were published in a data manager conference. In this conference, the data managers reported the total analysis results and those obtained from each institution based on all data, using paper or electronic media.

2. Subjects and methods

Fifteen institutions that had been eligible for the care registry as of December 2013 were selected for the present study according to the above-mentioned procedures. Data registered by the end of December 2013 were collected and analyzed in February 2014, and published in a data manager conference held in June 2014. As defects in data and input errors were identified in the process of tabulation, we instructed the data managers who had participated in the conference to review the registered data by the time of the next data collection. In August 2014, the registered data in the same period were collected and analyzed again.

All files collected by the institutions were linked to each other, and the institution numbers and initials of patients were deleted. Following this, data were analyzed using JMP®.

The registry data were output in Excel® format. The data were visually examined, and the summarized data for each institution were examined using JMP®, followed by the aggregation of input data that included possible defects and errors. Data that did not follow the definition of data input including the following ones were regarded as error data: the maximum measurement input into an item field being lower than the minimum measurement, and the minimum measurement input into an item field being lower than the maximum measurement. (Data involving one of these two types of error were counted as an error incident.)

Ⅲ. Results

Fifteen institutions participated in the data collection test. The number of collected data samples was 507. As the number of participants increased, the number of registered cases increased (**Fig.1**). There were 305 males (60.2%) and 202 females (39.8%). The mean age of the patients at the time of surgery was 69.5±12.1 years old (68.4±11.9 for males and 71.3±12.1 for females). Regarding the types of surgery, the CABG, CABG+Valve, CABG+other surgical procedures, Valve, aortic surgery, and other surgical methods accounted for 9.1, 11.0, 1.6, 44.6, 26.8, and 5.5% of the total, respectively. The rate of patients with congenital disorders was 1.4%. A total of 83.0% of the patients were discharged to their homes, and 10.7% were transferred to other hospitals. The rate of patients who died in the institutions was 6.3% (n=506). **Table 1** presents the male-female ratio, acid-base balance management, time of extracorporeal circulation, and interrupting time according to the type of surgery.

Regarding the circuit configuration, roller- and centrifugal-type arterial blood pumps accounted for 19.5 and 80.5% of the total, respectively. Open-air- and closed-type reservoirs accounted for 98.2 and 0.8% of the total, respectively. The rate of patients who did not use a reservoir was 1.0%. Regarding the type of venous drainage, gravity, vacuum-assisted, pump-assisted, a combination of gravity and vacuum-assist-

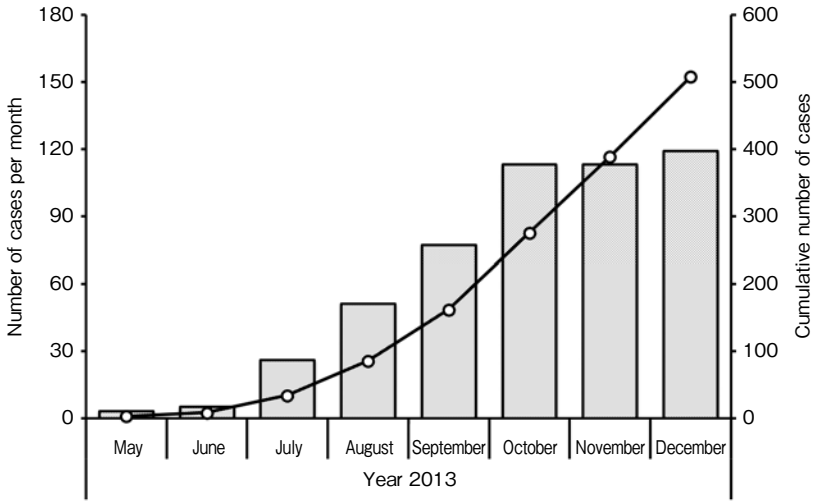


Fig.1 Monthly and cumulative numbers of registered cases

Table 1 Male-female ratio, acid-base balance management, time of extracorporeal circulation, and interrupting time (according to the type of surgery)

		CABG	CABG + Valve	CABG + Other	Valve	Aorta	Congenital (Adult)	Other
Cases	Number of cases	46	56	8	226	136	7	28
	Percentage of cases	9.1	11.1	1.6	44.6	26.8	1.4	5.5
	Male (%)	78.3	60.7	75.0	54.9	65.4	57.1	42.9
	Female (%)	21.7	39.3	25.0	45.1	34.6	42.9	57.1
pH management	α Stat (%)	97.8	58.9	37.5	62.8	79.4	71.4	50.0
	pH Stat (%)	0.0	21.4	25.0	19.5	8.1	28.6	42.9
	Both (%)	2.2	19.7	37.5	17.7	12.5	0.0	7.1
CPB Time (min)	Total (mean ± SD)	139 ± 50	235 ± 86	223 ± 114	166 ± 57	221 ± 85	55 ± 16	184 ± 93
	Clump (mean ± SD)	29 ± 45	145 ± 56	131 ± 73	113 ± 41	110 ± 71	27 ± 7	94 ± 55

Table 2 Number items that require data input and the error rate (specific to fields)

	Input method	Field					Total
		A	B	C	D	E	
Number of entry	Multiple-choice	7	13	20	6	0	46
	Numerical entry	7	4	31	34	55	131
Error ratio	Multiple-choice	0.0%	0.8%	0.0%	0.0%	0.0%	0.8%
	Numerical entry	0.6%	0.0%	3.2%	0.0%	15.2%	18.9%

ed, and a combination of gravity and pump-assisted venous drainage accounted for 61.9, 11.4, 5.1, 21.5 and 0.1% of the total, respectively. The rate of the use of a pre-bypass filter was 32.5%. In 18.7% of the cases, biocompatible coating was performed for all circuits including cannulas. The coating was implemented for all (excluding cannula) circuits limited components of circuits, and no circuits in 53.1, 27.8, and 0.4% of the cases, respectively.

In 97.6% of the cases, blood in the pericardium was returned from the sucker circuit directly to the reservoir. In 96.1% of the cases, blood in the pericardium was collected following the completion of extracorporeal circulation.

When data validation was conducted, data defects were identified in only one case: the examiner was unable to input the data and status of discharge of a patient because he was still hospitalized at the time of data collection. Data of cases in which the input definition was not followed were submitted by all institutions. The mean rate of data input not in accordance with the definition was 15.7±10.0%.

The error rates for multiple-choice and descriptive items were 0.8 and 18.9%, respectively (**Table 2**). This

suggests that the rate of cases excluded was 15.0%. However, when items were limited to those similar to the PERForm items adopted by the ICEBP, the rate of excluded cases was 4.5%.

Ⅳ. Discussion

In Japan, there are 570 institutions with a system for the implementation of extracorporeal circulation, and 529 of them conducted it for one or more patients during the year 2011.[5] In May 2013, an open test involving databases of extracorporeal circulation cases was initiated, and a total of 20 institutions initiated case registration (fifteen by the end of December 2013 and five by the end of December 2014). The percentage of institutions that implemented a system for databases of extracorporeal circulation cases was only 3.8%, although the comparison between two different periods may not be reliable. The results of the present study were obtained by collecting data of clinical cases that had occurred in a limited number of institutions during a specific period of time, and, therefore, they may not correctly represent the current status in Japan. However, since the clinical departments of the institutions that participated in the study are involved in the Japan Adult Cardiovascular Surgery Database (JACVSD) and the aggregation results are reported to each institution twice a year, the institutions can compare these results with their own aggregation results obtained from the database of extracorporeal circulation cases for the objective promotion of actions to improve extracorporeal circulation technology.

The rate of clinical cases excluded from the present study was 15.0%, and most of the excluded cases were related to items that required the input of numerical values. According to a study conducted by Paugh, et al., the rate of cases excluded from the aggregation due to defects in data and other causes was 2%, and the error rate for the same items as those of the STS database (six items: hospital identification, time of extracorporeal circulation, interrupting time, dates of birth, hospitalization, and discharge) was 8%.[2] However, when items were limited to those of the extracorporeal circulation case database in Japan that are similar to those of the PERForm adopted by Paugh, et al., the rate of excluded cases was 4.5%. Since the most common type of error is simple typing errors, as suggested by the results of the present study, the error rate can be decreased by setting the range of numerical values that can be input to the form or adopting multiple-choice systems so that irrelevant data cannot be input. Furthermore, since regular data collections and assessments based on the data, scheduled to be continued, are expected to reduce defects and errors in data as well as increase the accuracy, improvement to reduce the error rate can be accomplished from a logical point of view.

Regarding data collected in February 2013, in the case of data from different institutions, items involving input errors and defects varied among institutions. In the case of data from the same institutions, input errors and defects were identified in the same items. To address this problem, we had asked the institutions to review input data, and there was a significant improvement in the second collected data, including a decrease in the number of systematic errors. This suggests that earlier and more accurate data input can be implemented by asking institutions scheduled to participate in the case registration project to submit data obtained during the few months since their registration and examining/assessing the data.

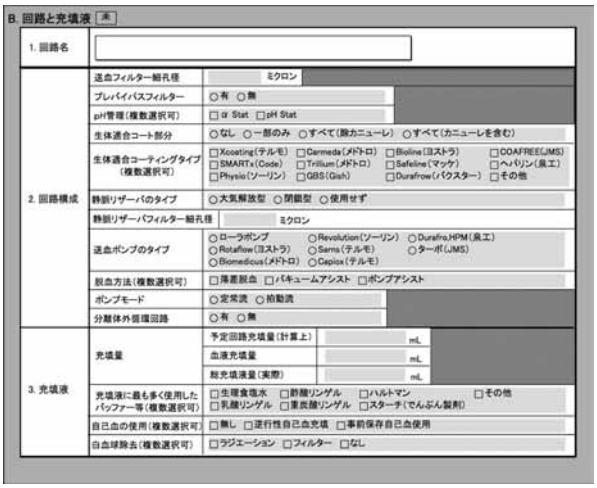
As data related to the same items are input according to the definitions in each institution and data from multiple institutions are organized, the results can be applied to assessment standards using actual data.


体外循環症例データベース
Japanese Perfusion Database

入力状況

A. 患者基本情報 未

1. 基本項目	体外循環記録No.	00005	施設ID	Test-001
	患者イニシャル	(姓)　(名)	入院年月日	
	性 別	○男性 ○女性	退院年月日	
	生年月日		退院時状況	○自宅 ○転院 ○死亡 ○不明
2. 手術情報	手術年月日		術者	
	人工心肺操作者	主操作者:	補助操作者:	
	手術タイプ	○CABG ○Valve ○CABG+Valve ○CABG+他 ○大動脈手術 ○先天性(成人) ○その他		
3. 身体所見	身長	cm	体重	kg　クレアチニン　mg/dL


B. 回路と充填液 未

1. 回路名		
2. 回路構成	送血フィルター細孔径	ミクロン
	プレバイパスフィルター	○有 ○無
	pH管理(複数選択可)	□α Stat □pH Stat
	生体適合コート部分	○なし ○一部のみ ○すべて(除カニューレ) ○すべて(カニューレを含む)
	生体適合コーティングタイプ(複数選択可)	□Xcoating(テルモ) □Carmeda(メドトロ) □Bioline(ヨストラ) □COAFREE(JMS) □SMART+(Code) □Trillium(メドトロ) □Safeline(マッケ) □ヘパリン(泉工) □Physio(ソーリン) □QBS(Gish) □Durafrow(バクスター) □その他
	静脈リザーバのタイプ	○大気解放型 ○閉鎖型 ○使用せず
	静脈リザーバフィルター細孔径	ミクロン
	送血ポンプのタイプ	○ローラポンプ ○Revolution(ソーリン) ○Durafro,HPM(泉工) ○Rotaflow(ヨストラ) ○Sarns(テルモ) ○ターボ(JMS) ○Biomedicus(メドトロ) ○Capiox(テルモ)
	脱血方法(複数選択可)	□陰圧脱血 □バキュームアシスト □ポンプアシスト
	ポンプモード	○定常流 ○拍動流
	分離体外循環回路	○有 ○無
3. 充填液	充填量	予定回路充填量(計算上) mL 血液充填量 mL 脱充填液量(実際) mL
	充填液に最も多く使用したバッファー等(複数選択可)	□生理食塩水 □酢酸リンゲル □ハルトマン □その他 □乳酸リンゲル □重炭酸リンゲル □スターチ(でんぷん製剤)
	自己血の使用(複数選択可)	□無し □逆行性自己血充填 □事前保存自己血使用
	白血球除去(複数選択可)	□ラジエーション □フィルター □なし


C. 体外循環 未

1. 体外循環時間	総体外循環時間	min	遮断時間	min		
	再体外循環	○有 ○無	再体外循環時間	min		
	完全循環停止	○有 ○無	完全循環停止時間(停止「有」の場合)	min		
2. 心停止/心筋保護法	遮断・心停止手段	○遮断、心筋保護液 ○遮断、心室細動 ○遮断、心拍動(血液) ○無し				
	心筋保護液(複数選択可)	□1:1 □3:1 □5:1 □7:1 □9:1 □晶質液のみ □K微量追加 □2:1 □4:1 □6:1 □8:1 □10:1 □併用 □無し				
	心筋保護手段	○間欠注入 ○持続注入 ○間欠注入+持続注入 ○間欠注入+血液灌流				
	導入(初回投与)の詳細	温度	○Cold(<28℃) ○Tepid(28~34℃) ○Warm(>34℃)			
		経路	○順行性 ○逆行性 ○併用			
	持続(2回目以降)の詳細	温度	○Cold(<28℃) ○Tepid(28~34℃) ○Warm(>34℃)			
		経路	○順行性 ○逆行性 ○併用			
	心筋保護液投与間隔の最長時間	min				
	ラインフィルター	○有 ○無	ラインフィルター細孔径(ラインフィルター「有」の場合)	ミクロン		
	Hot Shot	○有 ○無	Hot Shot温度(Hot Shot有の場合)	℃		
3. 深部体温所見	部位	最高温	最低温	部位	最高温	最低温
	膀胱	℃	℃	鼓静脈球	℃	℃
	鼻咽頭	℃	℃	直腸	℃	℃
	食道	℃	℃	鼓膜	℃	℃
	他:	℃	℃	他:	℃	℃
4. 送血温度所見	最高温(複温時):	℃				
5. 選択的脳灌流	○有 ○無					
	分岐用ポンプ	○分岐のみ ○ローラ-1基 ○ローラ-2基 ○ローラ-3基 ○遠心ポンプ				
	順行性脳灌流枝(複数選択可)	□腕頭A □右腋下A □左鎖骨A □左鎖骨下A □左腋下A □無し				
	逆行性脳灌流	○有 ○無				
	脳灌流専用熱交換器	○有 ○無				
	順行性脳灌流時間	min				
	逆行性脳灌流時間	min				
	脳循環停止時間	min				
	体循環停止時間	min				
	体灌流(下半身灌流)	○有 ○無				
		時間(体灌流「有」の場合): min				
6. 送血カニューレ挿入部	□大動脈 □大腿動脈 □腋窩 □その他	カニュレーション部位の変更	○有 ○追加 ○無			
7. 脱血カニューレ挿入部	○右房 ○上大静脈+下大静脈 ○大腿静脈 ○鼓静脈 ○上大静脈 ○その他					


D. イン・アウト管理 未

		充填液		術中(CPB中)		術中(充填液・CPB外)	
	製剤	容量(mL)	単位	容量(mL)	単位	容量(mL)	単位
1. 使用した血液製剤	赤血球(白血球除去なし)						
	赤血球(白血球除去済)						
	FFP						
	5%アルブミン						
	25%アルブミン						
	血小板						
	血球洗浄後血球						
	全血						
	患者投与前に赤血球洗浄を行ったか ○はい ○いいえ						
2. 投与総量	晶質液	mL					
	膠質液	mL	その他	mL			
3. 薬物投与	ヘパリン(術中)	総単位数	単位				
	抗線溶薬(術中)(複数選択可)	□εアミノカプロン酸 □トラネキサム酸 □無					
	腎機能保護薬(術中)(複数選択可)	□フロセミド □マニトール □フェルラドパム □パソプレシン □無					
4. 排出液	自己血回収	○有 ○無	自己血容量(自己血回収有の場合)	mL			
	回路血回収	○有 ○無	回路血容量(回路血回収有の場合)	mL			
	心臓内血液をサッカー回路から直接リザーバ(体外循環回路)に返血	○した ○無し					
		術中(CPB中)	術中(CPB後)				
	尿量	mL	mL				
	術中輸液総量	mL	mL				


E. 検査データ管理 未

	Ope室入室後	CPB開始直後	CPB中(最高値)	CPB中(最低値)	CPB離脱直前	術後ICU帰室時
1. Glu(mg/dL)						
2. K(mEq/L)						
3. 乳酸(mg/dL)						
4. CRN(mg/dL)						
5. TP(g/dL)						
6. Hb(g/dL)						
7. pH						
8. Pao(mmHg)						
9. Paco(mmHg)						
10. HCO_3(mEq/L)						
11. Svo(%)						

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- Mitsuru Sago, Medical Corporation Choshinkai Toyohashi Heart Center
- Masatoshi Kojima, Social Medical Corporation Daiyukai, Daiyukai General Hospital
- Katsuhiro Otsubo, Ichinomiya Municipal Hospital
- Saori Ishida, Fujita Health University Hospital
- Yasuko Enya, Regional Independent Administrative Corporation Gifu Prefectural General Medical Center
- Yoshifumi Yagi, University Hospital, Kyoto Prefectural

University of Medicine
- Yoshitomo Kubo, Japan Labour Health and Welfare Organization Osaka Rosai Hospital
- Atsushi Kaida, Yamaguchi-ken Saiseikai Shimonoseki General Hospital
- Masanobu Tsurumoto, Tokushima Prefectural Central Hospital
- Shinichiro Hara, National Hospital Organization Kyushu Medical Center

(In random order)

The authors declare that they have no COI.

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