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An Evaluation Trial of The National Perfusion Registry

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Abstract: The International Consortium for Evidence-Based Perfusion (ICEBP) is a collaborative group whose mission is to improve, continuously, the delivery of care and outcomes for patients undergoing cardiac surgery. To achieve this end, the ICEBP supports the development of perfusion registries to evaluate clinical practices and has established evidence-based guidelines for perfusion. The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) developed a perfusion registry to examine variation in perfusion practice in Japan. A pilot study was designed to determine the rate and accuracy of data extraction from patients' medical records and perfusion practice records and the subsequent entry of data into the registry form. We designed an input matching test using medical records and perfusion records from a sample of patients. Five institutions participated in data extraction and entry from 10 randomly selected case records. Perfusionists entered data in the registry form in accordance with the instruction manual prepared by the JaSECT guideline committee. The time taken to input every case in the registry was measured. An interview-based survey was carried out across institutions after the completion of the pilot. The time required for data entry stabilized after approximately five cases to a rate that was 40% of the first case entry time. Data entered into the registry by perfusionists for multiple-choice items were accurate 65% of the time and accurate 25% of the time for numerical data. The interview-based survey identified a total of 38 opportunities for improvement in the input form and 58 recommended changes for the instruction manual. The accuracy of data may be improved by developing a method allowing the objective detection of deficient data when present in the perfusion case record by developing automatic data acquisition from the automatic perfusion recording system currently in use, and by changing as many numerical value input items as possible to multiple-choice items. **Keywords:** perfusion, database, extracorporeal circulation. *JECT. 2014;46:258–261*

In cardiovascular surgery, perfusion using an artificial heart–lung machine is performed as a basic life support control method. In recent years, the demand for evidence-based medicine has been increasing. The International Consortium for Evidence-Based Perfusion (ICEBP) is a partnership and collaboration among perfusion societies, medical societies, clinicians, and industry to improve continuously the delivery of care and outcomes for patients undergoing cardiac surgery. To achieve this end, the ICEBP supports the development of perfusion registries to evaluate clinical practices and has established evidence-based guidelines for perfusion (1,2) Scientific evidence is derived from randomized controlled trials, observational studies, meta-analysis, and expert opinion. Registries have an important role in identifying variation in practice or for pilot observational studies.

The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) designed a perfusion registry after reflecting on the results of analysis in a nationwide survey of the present status of perfusion in 2010 in the Perfusion Registry Parameters of the ICEBP (3) (Figure 1). Because the percentage of institutions using electronic perfusion recording is less than 50% in Japan, an input method using a keyboard and mouse was selected as the prototype of the registry database.

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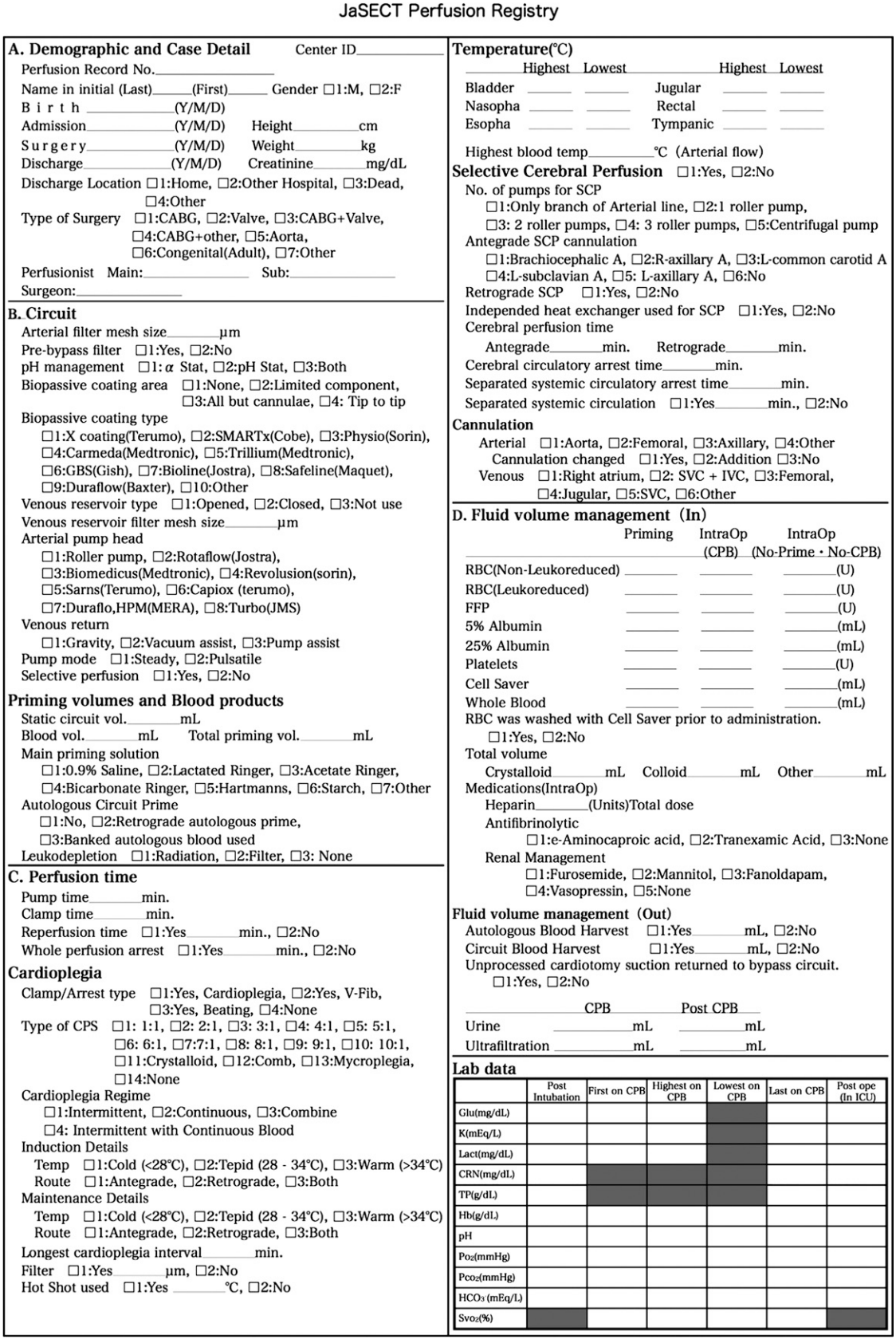

JaSECT Perfusion Registry

A. Demographic and Case Detail Center ID_____

Perfusion Record No._____

Name in initial (Last)_____(First)_____ Gender ☐1:M, ☐2:F

Birth _____(Y/M/D)

Admission_____(Y/M/D) Height_____cm

Surgery_____(Y/M/D) Weight_____kg

Discharge_____(Y/M/D) Creatinine_____mg/dL

Discharge Location ☐1:Home, ☐2:Other Hospital, ☐3:Dead, ☐4:Other

Type of Surgery ☐1:CABG, ☐2:Valve, ☐3:CABG+Valve, ☐4:CABG+other, ☐5:Aorta, ☐6:Congenital(Adult), ☐7:Other

Perfusionist Main:_____ Sub:_____

Surgeon:_____

B. Circuit

Arterial filter mesh size_____μm

Pre-bypass filter ☐1:Yes, ☐2:No

pH management ☐1:α Stat, ☐2:pH Stat, ☐3: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: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:Yes, ☐2:No

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:Starch, ☐7:Other

Autologous Circuit Prime

☐1:No, ☐2:Retrograde autologous prime, ☐3:Banked autologous blood used

Leukodepletion ☐1:Radiation, ☐2:Filter, ☐3: None

C. Perfusion time

Pump time_____min.

Clamp time_____min.

Reperfusion time ☐1:Yes_____min., ☐2:No

Whole perfusion arrest ☐1:Yes_____min., ☐2:No

Cardioplegia

Clamp/Arrest type ☐1:Yes, Cardioplegia, ☐2:Yes, V-Fib, ☐3:Yes, Beating, ☐4:None

Type of CPS ☐1: 1:1, ☐2: 2:1, ☐3: 3:1, ☐4: 4:1, ☐5: 5:1, ☐6: 6:1, ☐7:7:1, ☐8: 8:1, ☐9: 9:1, ☐10: 10:1, ☐11:Crystalloid, ☐12:Comb, ☐13:Mycroplegia, ☐14:None

Cardioplegia Regime

☐1:Intermittent, ☐2:Continuous, ☐3:Combine

☐4: 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:Yes_____μm, ☐2:No

Hot Shot used ☐1:Yes _____℃, ☐2:No

Temperature(℃)

	Highest	Lowest		Highest	Lowest
Bladder			Jugular		
Nasopha			Rectal		
Esopha			Tympanic		

Highest blood temp_____℃ (Arterial flow)

Selective Cerebral Perfusion ☐1:Yes, ☐2:No

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:Brachiocephalic A, ☐2:R-axillary A, ☐3:L-common carotid A ☐4:L-subclavian A, ☐5: L-axillary A, ☐6:No

Retrograde SCP ☐1:Yes, ☐2:No

Independed heat exchanger used for SCP ☐1:Yes, ☐2:No

Cerebral perfusion time

Antegrade_____min. Retrograde_____min.

Cerebral circulatory arrest time_____min.

Separated systemic circulatory arrest time_____min.

Separated systemic circulation ☐1:Yes_____min., ☐2:No

Cannulation

Arterial ☐1:Aorta, ☐2:Femoral, ☐3:Axillary, ☐4:Other

Cannulation changed ☐1:Yes, ☐2:Addition ☐3:No

Venous ☐1:Right atrium, ☐2: SVC + IVC, ☐3:Femoral, ☐4:Jugular, ☐5:SVC, ☐6:Other

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)
Whole Blood				(mL)

RBC was washed with Cell Saver prior to administration.

☐1:Yes, ☐2:No

Total volume

Crystalloid_____mL Colloid_____mL Other_____mL

Medications(IntraOp)

Heparin_____(Units)Total dose

Antifibrinolytic

☐1:e-Aminocaproic acid, ☐2:Tranexamic Acid, ☐3:None

Renal Management

☐1:Furosemide, ☐2:Mannitol, ☐3:Fanoldapam, ☐4:Vasopressin, ☐5:None

Fluid volume management (Out)

Autologous Blood Harvest ☐1:Yes_____mL, ☐2:No

Circuit Blood Harvest ☐1:Yes_____mL, ☐2:No

Unprocessed cardiotomy suction returned to bypass circuit.

☐1:Yes, ☐2:No

	CPB	Post CPB
Urine	_____mL	_____mL
Ultrafiltration	_____mL	_____mL

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(%)						

Figure 1. The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) perfusion registry data form.

Accurate data entry into the registry is important. Although the use of a single data entry person is generally favored, it is not practical in many institutions. We wanted to determine whether multiple perfusionists could accurately extract data from a patient's medical records and perfusion practice records and input these data into a registry. We performed an input matching test using medical records and perfusion practice records from a sample of patients.

DESCRIPTION

The test period was 4 months between December 2012 and March 2013. Five institutions participated in the study. The subjects consisted of 10 patients randomly selected among those who underwent perfusion. A case registration form was developed using File maker Pro Version 11 (Filemaker®) by the JaSECT guideline committee. We created a manual containing the method to use this form, the input method, and an explanation of each data field. Using this manual, multiple perfusionists in each institution inputted cases into the case registration form. The data on each patient provided to each perfusionist were only the patient's ID and name, and necessary records were selected by each perfusionist. In addition, the time required for input per case was recorded. After the completion of the test, the input data matching and input time shortening rates in each institution were calculated. In addition, we visited each institution and performed an interview-based survey on points to be improved regarding the case registration form and the manual and the practice status.

All data values are reported as mean or mean ± standard deviation. Statistical significance was tested using Wilcoxon signed-rank test (JMP Version 10; SAS Institute Inc., Cary, NC). A p value < .01 was considered significant.

The total number of extracted patients was 50, who consisted of 28% with diseases requiring coronary artery bypass grafting and associated diseases, 23% with valve diseases, 45% with aortic diseases, 3% with congenital diseases (adults), and 3% with others.

When the input time for the first case was regarded as 1.00, that for the 10th case was .40 (mean). The input time gradually decreased from the first to the fifth case but the decrease became milder thereafter (Figure 2). In addition, one of the cooperation institutions has tried input data of 10 subsequent cases. The mean data entry time of these was even further decreased (Figure 3).

The mean data matching rate was 65% for multiple-choice items and 25% for numerical value input items, being significantly lower for the latter ($p < .0001$).

Among the multiple-choice items, the matching rate did not significantly differ between the single and multiple answer items.

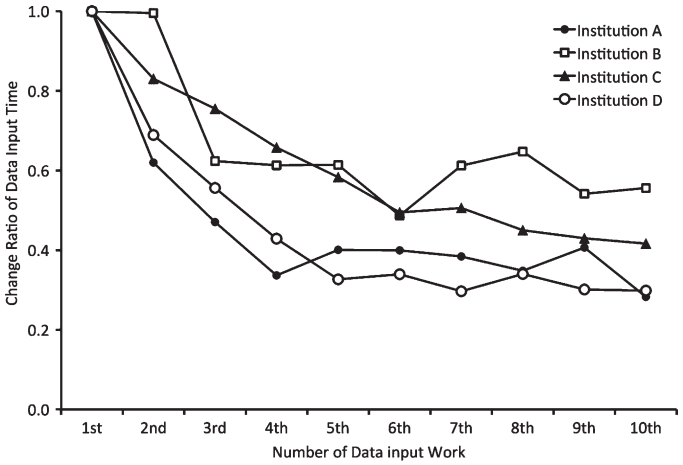

Figure 2. Change in input time from the first case to the tenth case. The input time for the first case was regarded as 1.00. Data are presented as mean. Time measurement was carried out with four institutions.

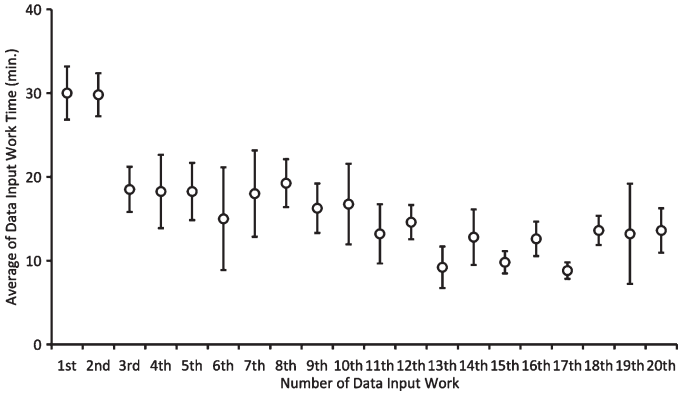

Figure 3. Data input time change over 20 sequential cases of institution B. Data are presented as mean ± standard deviation.

The interview-based survey identified a total of 38 opportunities for improvement for the input form and 58 improvement opportunities for the manual. When the items were classified into numerical value input and multiple-choice items, the total number of indications regarding points to be improved in the numerical value input and multiple-choice items were 19 and 19, respectively, for the input form and 43 and 15, respectively, for the manual.

DISCUSSION

The mean time required for registration per case decreased to approximately 15 minutes at the time of input of the tenth case and then became stable, suggesting that this perfusion registry can be performed by multiple perfusionists as a routine task without the need for a designated data entry person. In addition, the work becomes simple if data required for the registry are embedded within the perfusion records at each institution. Therefore, accurate

input in a short time may be possible by producing a simple manual using a correspondence table or illustration that shows correspondence between items of records used in each institution at present and those of the case registry form. The matching rate was low for both multiple-choice and numerical value input items. This may have been the result of the study design in which the test was performed by each perfusionist using the same manual based on data only on the ID and name of patients randomly extracted in each institution. In other words, which items of paper-based or electronic records stored in each institution are input was left to the discretion of the local center. In addition, the interview-based survey identified 96 indications regarding items causing difficulty in determining data for input. Because the total number points to be improved in the explanation contents for the numerical value input items was approximately three times that for the multiple-choice items, the person entering data may have had difficulty in determining input values. For example, when the time required for a certain process is explained as a conceptual description, differences among those entering the data tend to occur, and even if data can be collected from other institutions and analyzed, the results may be unreliable. Therefore, the initiation and discontinuation times should be definitely shown as "the time point when a certain action is undertaken that coincides with a specific event" to ensure the reliability of recorded data.

When designing a registry, it is important to be thoughtful with the process of data collection and determine how facile collection of data elements may be for participants. Moreover, the completeness and accuracy of the data should be assessed. Furthermore, data entry personnel should be surveyed to determine opportunities for improvements. It is possible that a data entry person's difficulty in making decisions leads to deficient data. In addition, because the perfusion database requires patient data before and after surgery, input omissions are more likely to occur for these specific data elements. Deficient data impair the analysis of collected data. It is possible that analysis cannot be performed because it is impossible to determine whether deficient data indicate input omissions (although data were present), the absence of data, or "zero" as the value of data (4). Since AmSECT revised the Standards and Guideline for Perfusion Practice, the data elements collected on perfusion records will likely become more consistent across centers and perhaps more consistently available (5). The accuracy of data may be improved by developing a method allowing the objective detection of missing data (6). Automatic data acquisition from the electronic perfusion recording system is increasingly being used. Furthermore, changing as many numerical value input items as possible to multiple-choice items will further improve data accuracy.

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