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Research and Reporting

Current status and trends in the safety management of cardiopulmonary bypass in Japan: Insights from questionnaire surveys on incidents and accidents — secondary publication (complete translation) —

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Abstract

Over the past 46 years since its establishment in 1976, the Japanese Society of Extra Corporeal Technology in Medicine (JaSECT) has undertaken various initiatives to improve the quality of cardiopulmonary bypass (CPB) and circulatory support. As part of these efforts, a questionnaire survey on incidents, accidents, and safety measures related to CPB and circulatory support was conducted in 2021 to gather foundational data for developing appropriate safety standards and guidelines. The results were compared with a paper published in 2013 and earlier questionnaire findings. The 2021 survey targeted 656 medical institutions, with responses received from 441 (response rate: 67.2%) regarding CPB and circulatory support cases from 2019 and 2020. Analysis revealed an annual accident rate of at least 0.03% for CPB cases with patient impact levels of 3b or higher. In response to past serious accidents, significant advancements in safety measures have been implemented by the Japanese government and relevant societies. This report aims to present the current status and trends in safety management while contributing to the development of global evidence and guidelines for safer CPB practices.

Key words : Cardiopulmonary bypass (CPB), safety management, incidents, accidents, questionnaire survey

Ⅰ. Introduction

Over the 46 years since its establishment in 1976, the Japanese Society of Extra Corporeal Technology in Medicine (JaSECT) has implemented various initiatives to improve the quality of cardiopulmonary bypass (CPB) and circulatory support procedures. Among these efforts, JaSECT has been conducting questionnaire surveys on incidents, accidents, and

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safety in CPB and circulatory support since 2010. The 2013 report, titled "The Current Status of Safety Management in CPB: Based on Incident Reports from the 2013 JaSECT Questionnaire Survey" [1], highlighted the need for strengthened safety measures in CPB. In 2021, another questionnaire survey was conducted to collect data on CPB/circulatory support-related incidents and accidents that occurred in 2019 and 2020, with the results published in 2023 [2]. Based on these findings and earlier surveys, this paper reviews the evolution and current status of safety management in CPB.

Ⅱ. Brief Description of the 2021 Questionnaire Survey

1. Subjects and Methods

The 2021 survey targeted 656 medical institutions where JaSECT members are affiliated, focusing on CPB cases performed in 2019 and 2020. The survey method involved sending a cooperation request letter to the heads of the target facilities and the JaSECT members assigned as responsible persons at those facilities, inviting them to input their responses into the questionnaire form created on the JaSECT website. As the survey required disclosure of hospital information, each facility needed internal approval before participation. Initially, the survey was conducted from April 11 to May 16, 2022; however, the deadline was extended to June 15, 2022, to allow sufficient time for the approval process.

2. Levels of Impact on Patients

For the classification of patient impact levels, the system used by the National Hospital Organization and similar institutions was adopted as a reference (**Table 1**) [3]. To ensure consistency in responses, survey participants were informed about this classification and asked to report the number of cases in each of the following three categories: Level 0, Levels 1-3a, and Levels 3b-5.

3. Earlier Survey Results for Comparison

To evaluate the trends and current status of safety management in CPB, the results of the 2021 Questionnaire Survey were compared with those of the 2013 Questionnaire Survey, as well as the 2017 Questionnaire Survey [4] and the 2019 Questionnaire Survey [5]. The 2017 survey collected data on incidents, accidents, and safety related to CPB and circulatory support during 2015 and 2016, while the 2019 survey gathered similar data for 2017 and 2018.

Ⅲ. Results

1. Response Rate and Number of Valid Responses in the 2021 Questionnaire Survey

Out of the 656 targeted facilities, 441 responded to the survey, resulting in a response rate of 67.2%. After excluding 13 facilities that did not obtain approval to participate, the number of valid responses totaled 428 facilities.

2. Current Status and Trends of CPB

Among the 428 facilities that provided valid responses, 409 reported performing surgeries utilizing CPB. In 2019, these facilities conducted a total of 40,277 CPB procedures, comprising 35,687 adult cases and 4,590 pediatric cases. In 2020, the total number of CPB procedures was 38,120, with 33,818 adult cases and 4,302 pediatric cases. **Table 2** presents the distribution of case numbers from the 2013 Questionnaire Survey and annually from 2015 to 2020. Over this six-year period, approximately 60% of the facilities consistently performed fewer than 100 cases per

Table 1 Classification of Patient Impact Levels

Level	Description
0	Errors or failures were detected in pharmaceuticals or medical devices that were not used on the patient.
1	Errors or failures were detected in pharmaceuticals or medical devices used on the patient but had no impact.
2	Caused changes in the patient's vital signs and/or required medical evaluation.
3a	Required minor treatment or procedures (e.g., disinfection, cooling, administration of analgesics).
3b	Required major treatment or procedures (e.g., unplanned procedures, hospitalization, or extended hospital stay).
4	Resulted in permanent disability.
5	Resulted in death (excluding death due to the natural progression of the primary disease).

year, indicating no significant change in this proportion.

Details regarding the types of main pumps, extracorporeal circuits, and venous drainage methods are provided in **Table 3**. Comparisons among the 2021, 2019, 2017, and 2013 Questionnaire Surveys reveal minimal changes in the types of main pumps and circuits used. However, there was a notable shift in venous drainage methods, with a decrease in the exclusive use of gravity drainage and an increase in the combined use of gravity drainage and vacuum-assisted venous drainage (VAVD).

3. Incidents and Accidents in CPB

The numbers and rates of incidents and accidents in CPB are presented in **Table 4**. Similar to the findings from the 2013 survey and previous surveys, incidents and accidents of varying patient impact levels have occurred at a rate of 1.0% or more annually, with accidents at patient impact level 3b or higher occurring at a rate of 0.03% or more.

Table 2 Distribution of Annual CPB Cases per Facility

Year	Total Responding Facilities	0 Cases	1-50 Cases	51-100 Cases	101-150 Cases	151-200 Cases	201-250 Cases	251-300 Cases	>301 Cases
2011	394	4 (1.0%)	151 (38.3%)	112 (28.4%)	60 (15.2%)	21 (5.3%)	19 (4.8%)	11 (2.8%)	9 (2.3%)
2012	394	0 (0%)	139 (35.3%)	113 (26.7%)	73 (18.5%)	23 (5.8%)	17 (4.3%)	11 (2.8%)	11 (2.8%)
2015	445	13 (2.9%)	149 (33.5%)	138 (31.0%)	67 (15.1%)	31 (7.0%)	21 (4.7%)	13 (2.9%)	13 (2.9%)
2016	445	12 (2.7%)	143 (32.1%)	134 (30.1%)	70 (15.7%)	36 (8.1%)	22 (4.9%)	15 (3.4%)	13 (2.9%)
2017	416	12 (2.9%)	133 (32.0%)	126 (30.3%)	65 (15.6%)	41 (9.9%)	15 (3.6%)	11 (2.6%)	13 (3.1%)
2018	416	10 (2.4%)	137 (32.9%)	120 (28.8%)	72 (17.3%)	41 (9.9%)	14 (3.4%)	13 (3.1%)	9 (2.2%)
2019	409	10 (2.4%)	137 (33.5%)	115 (28.1%)	69 (16.9%)	36 (8.8%)	21 (5.1%)	11 (2.7%)	10 (2.4%)
2020	409	13 (3.2%)	141 (34.5%)	119 (29.1%)	69 (16.9%)	31 (7.6%)	18 (4.4%)	7 (1.7%)	11 (2.7%)

Table 3 Trends in Main Pump and Extracorporeal Circuit Types and Venous Drainage Methods

		2021 Survey	2019 Survey	2017 Survey	2013 Survey
Main Pump Type	Roller pump only	75 (18.5%)	60 (14.5%)	89 (20.0%)	101 (25.6%)
	Centrifugal pump only	238 (58.8%)	255 (61.9%)	245 (55.1%)	182 (46.2%)
	Used according to cases	90 (22.2%)	97 (23.3%)	110 (24.7%)	111 (28.2%)
	Others	2 (0.5%)	3 (0.7%)	1 (0.2%)	
Extracorporeal Circuit	Open circuit	338 (83.3%)	336 (81.0%)	373 (83.8%)	330 (83.7%)
	Closed circuit	8 (2.0%)	7 (1.7%)	4 (0.9%)	6 (1.5%)
	Used according to cases	32 (7.9%)	41 (9.9%)	36 (8.1%)	57 (14.5%)
	Both open and closed circuits used	28 (6.9%)	31 (7.5%)	32 (7.2%)	
Venous Drainage Method	Gravity drainage only	74 (18.6%)	93 (22.5%)	130 (29.5%)	172 (44.3%)
	Combined gravity and VAVD	248 (62.3%)	246 (59.6%)	242 (54.9%)	166 (42.8%)
	VAVD only	34 (8.5%)	31 (7.5%)	34 (7.7%)	38 (9.8%)
	Roller pump assisted	2 (0.5%)	5 (1.2%)	7 (1.6%)	6 (1.5%)
	Used according to cases	40 (10.1%)	38 (9.2%)	27 (6.1%)	
	Other	0 (0%)	0 (0%)	1 (0.2%)	5 (1.3%)

Note: The number of responding facilities for each survey is as follows: 2021 (409), 2019 (416), 2017 (445), and 2013 (394).

Table 4 Number and Rates of CPB-Related Incidents and Accidents

	2021 Survey		2019 Survey		2017 Survey		2013 Survey	
	2020	2019	2018	2017	2016	2015	2012	2011
Total CPB cases	38,120	40,277	40,669	40,786	44,180	42,303	37,000	35,015
Impact level (0)	284 (0.75%)	259 (0.64%)	393 (0.97%)	379 (0.93%)	440 (1.00%)	431 (1.02%)	411 (1.11%)	390 (1.11%)
Impact level (1-3a)	245 (0.64%)	192 (0.48%)	345 (0.85%)	340 (0.83%)	274 (0.62%)	265 (0.63%)	241 (0.65%)	232 (0.66%)
Impact level (3b-5)	12 (0.03%)	11 (0.03%)	22 (0.05%)	16 (0.04%)	26 (0.06%)	24 (0.06%)	27 (0.07%)	22 (0.06%)
Total	541 (1.42%)	462 (1.15%)	760 (1.87%)	735 (1.80%)	740 (1.67%)	720 (1.70%)	679 (1.84%)	644 (1.84%)

Table 5 presents the number of facilities that experienced incidents or accidents related to each item, along with the number of occurrences and incidence rates categorized by patient impact level. Additionally, Table 6 summarizes the types and details of troubles reported for each item in the 2021 Ques-

Table 5 Numbers of Facilities and Incidents by Impact Level Related to Different Items

Cardiopulmonary Device-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	114 (28.2%)	115 (28.5%)	132 (30.1%)
Impact level (0)	172 (0.22%)	199 (0.24%)	278 (0.32%)
Impact level (1-3a)	112 (0.14%)	117 (0.14%)	65 (0.08%)
Impact level (3b-5)	6 (0.01%)	6 (0.01%)	12 (0.01%)

Oxygenator-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	124 (30.9%)	116 (28.4%)	123 (28.0%)
Impact level (0)	119 (0.15%)	89 (0.11%)	96 (0.11%)
Impact level (1-3a)	106 (0.14%)	120 (0.15%)	132 (0.15%)
Impact level (3b-5)	4 (0.01%)	12 (0.01%)	13 (0.02%)

Venous Reservoir-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	40 (10.6%)	62 (15.4%)	58 (13.3%)
Impact level (0)	30 (0.04%)	46 (0.06%)	52 (0.06%)
Impact level (1-3a)	21 (0.03%)	36 (0.04%)	28 (0.03%)
Impact level (3b-5)	0 (0%)	4 (<0.01%)	2 (<0.01%)

Arterial Filter-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	6 (1.6%)	8 (2.0%)	13 (3.0%)
Impact level (0)	5 (<0.01%)	6 (<0.01%)	17 (0.02%)
Impact level (1-3a)	1 (<0.01%)	3 (<0.01%)	3 (<0.01%)
Impact level (3b-5)	0 (0%)	0 (0%)	0 (0%)

Blood Supply Interruption Incidents & Rates due to Blood Pump Failure			
No. of facilities	2021 Survey	2019 Survey	2017 Survey
Impact level (0)	15 (3.7%)	16 (3.9%)	20 (4.6%)
Impact level (1-3a)	7 (<0.01%)	7 (<0.01%)	16 (0.02%)
Impact level (3b-5)	8 (0.01%)	7 (<0.01%)	8 (0.01%)
No. of facilities	0 (0%)	0 (0%)	0 (0%)

Blood Pump Mishandling Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	17 (4.3%)	25 (6.3%)	28 (6.5%)
Impact level (0)	14 (0.02%)	12 (0.01%)	23 (0.03%)
Impact level (1-3a)	9 (0.01%)	39 (0.05%)	15 (0.02%)
Impact level (3b-5)	0 (0%)	0 (0%)	1 (<0.01%)

Meter/Alarm-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	17 (4.3%)	72 (18.0%)	87 (20.7%)
Impact level (0)	120 (0.15%)	134 (0.16%)	167 (0.19%)
Impact level (1-3a)	25 (0.03%)	26 (0.03%)	28 (0.03%)
Impact level (3b-5)	0 (0%)	0 (0%)	0 (0%)

Heater-Cooler Device-Related Incidents & Rates	
	2021 Survey
No. of facilities	46 (11.4%)
Impact level (0)	68 (0.09%)
Impact level (1-3a)	17 (0.02%)
Impact level (3b-5)	0 (0%)

CPB Circuitry-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	114 (28.4%)	108 (26.7%)	119 (27.2%)
Impact level (0)	152 (0.19%)	145 (0.18%)	167 (0.20%)
Impact level (1-3a)	71 (0.09%)	110 (0.14%)	28 (0.09%)
Impact level (3b-5)	0 (0%)	2 (<0.01%)	6 (0.01%)

Cannula-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	67 (16.7%)	76 (18.6%)	66 (15.1%)
Impact level (0)	48 (0.06%)	41 (0.05%)	55 (0.06%)
Impact level (1-3a)	49 (0.06%)	92 (0.11%)	67 (0.08%)
Impact level (3b-5)	11 (0.01%)	16 (0.02%)	12 (0.01%)

Incidents & Rates of Forgetting to Supply Oxygen at the Start of CPB			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	46 (11.5%)	49 (12.0%)	71 (16.1%)
Impact level (0)	38 (0.05%)	44 (0.06%)	65 (0.08%)
Impact level (1-3a)	32 (0.06%)	34 (0.04%)	46 (0.05%)
Impact level (3b-5)	0 (0%)	0 (0%)	0 (0%)

Incidents & Rates of Inadvertent Air Entry			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	21 (5.5%)	17 (4.4%)	19 (4.5%)
Impact level (0)	− (−)	− (−)	− (−)
Impact level (1-3a)	28 (0.04%)	17 (0.02%)	16 (0.02%)
Impact level (3b-5)	3 (0.01%)	2 (0.01%)	5 (0.01%)

Incidents & Rates of Unexpected Blood Drainage After CPB			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	39 (9.7%)	56 (13.5%)	65 (14.8%)
Impact level (0)	− (−)	− (−)	− (−)
Impact level (1-3a)	42 (0.05%)	65 (0.08%)	74 (0.09%)
Impact level (3b-5)	2 (0.01%)	4 (0.01%)	2 (0.01%)

Incidents & Rates of Medication Errors			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	21 (5.3%)	23 (5.7%)	24 (5.5%)
Impact level (0)	1 (0.01%)	8 (0.01%)	17 (0.02%)
Impact level (1-3a)	19 (0.02%)	19 (0.02%)	10 (0.01%)
Impact level (3b-5)	0 (0%)	0 (0%)	3 (0.01%)

Incidents & Rates of Intraoperative Dissection			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	64 (16.0%)	67 (16.5%)	69 (15.9%)

Cardioplegia Device-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	26 (7.0%)	50 (12.5%)	39 (9.0%)
Impact level (0)	26 (0.03%)	33 (0.04%)	34 (0.04%)
Impact level (1-3a)	8 (0.01%)	6 (0.01%)	8 (0.01%)
Impact level (3b-5)	0 (0%)	0 (0%)	1 (0.01%)

Cardioplegia-Related Incidents & Rates			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	95 (23.8%)	123 (30.5%)	121 (27.5%)
Impact level (0)	95 (0.12%)	136 (0.17%)	128 (0.15%)
Impact level (1-3a)	87 (0.11%)	114 (0.14%)	80 (0.09%)
Impact level (3b-5)	2 (0.01%)	2 (0.01%)	1 (0.01%)

Incidents & Rates related to Power Interruption/Outage			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	11 (2.7%)	15 (3.6%)	22 (4.9%)
Impact level (0)	6 (0.01%)	11 (0.01%)	14 (0.01%)
Impact level (1-3a)	3 (0.01%)	5 (0.01%)	12 (0.01%)
Impact level (3b-5)	0 (0%)	0 (0%)	0 (0%)

Incidents & Rates related to Medical Gas Supply Interruption			
	2021 Survey	2019 Survey	2017 Survey
No. of facilities	1 (0.2%)	1 (0.2%)	3 (0.7%)
Impact level (0)	− (−)	− (−)	− (−)
Impact level (1-3a)	1 (0.01%)	1 (0.01%)	0 (0%)
Impact level (3b-5)	0 (0%)	0 (0%)	0 (0%)

Note 1: The number of facilities that reported incident/accident occurrence (s) in each survey is as follows: 2021 survey (409 facilities), 2019 survey (416), and 2017 survey (445).

Note 2: The number of incident cases reported in each survey is as follows: 2021 survey (78,397 cases), 2019 survey (81,455), and 2017 survey (86,483).

Table 6 Number of Incidents Related to Different Devices Reported in the 2021 Survey

Cardiopulmonary Device-Related Incidents, 114 facilities (28.2%)	
Roller pump	28
Centrifugal pump	16
Oxygen blender	34
Display panel	10
Occluder	17
Sensor or the likes	68
Stand unit	3
Power supply	11
Control/communication	15
Other	33

Oxygenator-Related Incidents, 124 facilities (30.9%)	
Inappropriate oxygenation	53
Insufficient CO2 removal	3
Blood or plasma leakage	29
Breakage	9
Increase in oxygenator inlet pressure	114
Clotting in oxygenator	16
Suction from oxygenator	6
Gas blender supply line dropout	4
Gas flow line disconnection	0
Other	14

Venous Reservoir-Related Incidents, 124 facilities (30.9%)	
Clotting in venous reservoir purge line	22
Clotting in cardiotomy filter	18
Breakage	3
Emptying of venous reservoir	2
Overflowing of venous reservoir	6
Positive pressure in venous reservoir	5
Other	3

Arterial Filter-Related Incidents, 6 facilities (1.6%)	
Clotting	1
Leakage	2
Breakage	2
Increase in inlet pressure	0
Air entry	0
Other	1

Blood Supply Interruption Incidents due to Blood Pump Failure, 15facilities (3.7%)	
Roller pump failure	1
Pump tubing breakage	0
Inappropriate occlusion	0
Drive motor (centrifugal pump) failure	5
Centrifugal pump head breakage/defect	3
Mis-installation of centrifugal pump	4
Malfunctioning of safety device	1
Other	2

Inappropriate Blood Pump Handling-Related Incidents, 17facilities (4.3%)	
Roller pump turned in the wrong direction	2
Wrong pump tube size	2
Inappropriate roller pump occlusion	5
Accidental backflow when using (starting) CP	14
Other	3

Measurement and alarm device-related incidents, 63 facilities (15.8%)	
Flowmeter failure	16
Bubble detector failure	15
Level sensor failure	52
Venous oxygen saturation meter failure	4
Abnormalities in extracorporeal blood gas analyzer	22
Pressure monitor failure	9
Mis-installation of meter/alarm device	11
Forgot to install meter/alarm device	22
Forgot to use meter/alarm device	3
Other	3

Cardiopulmonary bypass circuit-related incidents. 114 facilities (28.4%)	
Uncleanliness	26
Misconnection	22
Bending or twisting	33
Wrong rotational direction	21
Tube breakage	13
Misplaced or forgot to apply/remove clamp	35
Contamination with foreign substance	11
Detachment or loosening of connector	42
Forgot to install a component	0
Forgot to release roller pump occlusion	7
Forgot to open and close shunt line	12
Hollow fiber membrane leakage and breakage	5
Other	29

Cannula-Related Incidents, 67 facilities (16.7%)	
Initial failure of cannula	10
Arterial cannula disconnection	13
Venous cannula disconnection	13
Wrong cannula size (arterial)	8
Wong cannula size (venous)	10
Cannula breakage	5
Wrong cannula direction (arterial)	6
Dissection	12
Increase in circuit pressure due to bending or breakage at the end	14
Other	24

Accidental Air Entry-Related Incidents, 21 facilities (5.5%)	
Reservoir became empty while CPB device was left unmonitored	0
Reservoir became empty when CE took his/her eyes off the device	6
Suction from oxygenator (when using cerebral/cardioplegia line)	6
Suction into levocardia due to excessive drainage on vent insertion	1
Vent pump misplacement (reverse rotation)	0
Excessive negative pressure due to vent circuit (w/o check valve)	0
Mis-assembly of cardioplegia circuit	0
Cardioplegia reservoir become empty	3
Suction from MUF line	1
Suction from hemoconcentrator line	0
Air embolism in venous line	6
Initial failure of circuitry components	0
Loosening of 3-way stopcock, etc.	0
Other	8

Unexpected Drainage Through Arterial or Venous Cannulas, 39 facilities (9.7%)	
Accidental unclamping due to external force	1
Removed arterial clamp by mistake	15
Removed venous clamp or venous occluder	7
Applied tube clamp in the wrong place	4
Backflow due to low rpm of centrifugal pump	3
Reversed the flow with roller pump	2
Backflow to reservoir due to failure to close purge line, sampling port,	10
Other	3

Time of Occurrence of Intraoperative Dissection, 64 facilities (16.0%)	
Before CPB (during cannulation)	16
At the start of CPB	6
Shortly after starting CPB (50% to full flow)	7
Just after aortic cross-clamping	8
After switching to total CPB	3
During cardioplegia	2
Just after releasing aortic cross-clamping	12
Just before ending CPB	10
After ending CPB	4
Other	4

Cardioplegia Device-Related Incidents, 26 facilities (7.0%)	
Power supply systems	17
Control systems	13
Communication systems	3
Other	8

Cardioplegia-Related Incidents, 95 facilities (23.8%)	
Wrong composition of cardioplegic solution	16
Forgot to inject cardioplegic solution	4
Wrong injection rate	11
Wrong dosage	11
Wrong temperature	12
Wrong injection pressure	4
Breakage of circuitry or heat-exchanger	12
Wrong direction (antegrade or retrograde)	2
Inadvertent air entry	8
Disconnection of circuitry	11
Clamp (misplaced, forgot to apply/release)	30
Forgot to attach sensors	9
Forgot to measure circuit pressure	3
Forgetting to open and close the shunt line	15
Other	43

Heater-Cooler Device-Related Incidents, 46 facilities (11.4%)	
Turned off (Blown fuse)	8
Circulating water abnormalities	13
Temperature setting abnormal	30
Forgetting to set up	13
Disconnection	10
Other	17

Power Outage-Related Incidents, 11 facilities (2.7%)	
Unplanned regional blackout	5
Planned regional blackout	0
Unplanned outage of the whole building	1
Planned outage of the whole building	0
Fire or earthquake	0
Overload (circuit-breaker trip)	2
Short-circuiting of outlet	0
Breakage of outlet or cable	0
Unplugging (accidental or intentional)	0
Other	2

tionnaire Survey.

The occurrence rate of cardiopulmonary device-related incidents/accidents at patient impact levels 3b-5 was 0.01%. Sensor-related trouble occurred most frequently, with 68 cases reported.

The number of oxygenator-related incidents/accidents at patient impact levels 1-3a and 3b-5 decreased from the 2017 survey to the 2021 survey. Incidents involving excessive pressure rise inside the oxygenator also decreased compared to the 2013 survey.

The numbers of incidents/accidents related to venous reservoirs and cardiotomy reservoirs did not show significant changes from the 2017 survey to the 2021 survey, with occurrence rates not exceeding 0.06% at any patient impact level. Among these, two incidents involved emptying of venous reservoirs.

There were no incidents/accidents caused by blood pump failure at patient impact levels 3b or higher between the 2017 Survey and the 2021 Survey. At patient impact levels 0-3a, the occurrence rate was 0.02% or less.

The rate of incidents/accidents caused by misoperation of blood pumps at patient impact levels 1-3a decreased in the 2021 survey compared to the 2017 and 2019 surveys.

Incidents/accidents related to measuring and alarm devices showed no significant change from the 2017 survey to the 2021 survey. Among these, abnormalities in level sensors were the most frequently reported issue, with 52 cases.

From the 2017 survey to the 2021 survey, accidents involving cannulas at patient impact levels 3b or higher occurred at a rate of 0.01% or more. There were 13 cases reported involving dislodgement of arterial or venous cannulas.

The occurrence rate of air embolism incidents in blood circuits at patient impact levels 3b or higher was 0.01% from the 2017 survey to the 2021 survey. Incidents involving air entering the circuit from the oxygenator (during separation or myocardial protection circuit use) were reported eight times in the 2013 survey and six times in the 2021 survey.

Aortic dissection incidents during surgery were categorized as follows: 16 cases before the start of CPB (during cannulation), 12 cases immediately after releasing the aortic cross-clamp, and 10 cases near the end of CPB.

Regarding incidents and accidents related to myocardial protection, the 2019 and 2021 surveys reported no occurrences at patient impact levels 3b and above, and an incidence rate of 0.01% at levels 1 to 3a. Among these, there were 16 reports of errors in the composition of cardioplegic solutions. **Table 7** details the personnel responsible for preparing the cardioplegic solution and the verification methods employed post-preparation. Notably, in the 2021, 2019, and 2017 surveys, perfusionists were responsible for preparing the cardioplegia solution in approximately 80.8%, 78.5%, and 76.5% of all cases, respectively.

Table 7: Personnel Responsible for Cardioplegic Solution Preparation and Post-Preparation Verification Methods

Regarding incidents and accidents due to power supply interruptions, from the 2017 to the 2021 surveys, there were no occurrences at patient impact levels 3b and above, and the incidence rate at levels 0 to 3a was below 0.01%.

Regarding incidents and accidents due to medical gas supply interruptions, from the 2017 survey to the 2021 survey, there were no occurrences at patient impact levels 3b and above, and the incidence rate at levels 0 to 3a was below 0.01%.

Details concerning emergency kits are presented in **Table 8**. The proportion of facilities equipped with emergency kits has shown an increasing trend, with 78.1% in the 2017 survey, 79.2% in 2019, and 83.9% in 2021.

Table 9 presents the number of safety measures implemented during the use of Vacuum-Assisted Venous Drainage (VAVD). The number of facilities employing VAVD has been increasing annually, with 342 facilities in the 2021 survey, 335 in 2019, 313 in 2017, and 238 in the 2013 survey.

Regarding safety measures during VAVD, both the 2013 and 2021 surveys indicate that the

Table 7 Personnel Responsible for Cardioplegic Solution Preparation and Post-Preparation Verification Methods

Personnel responsible for cardioplegic solution preparation			
	2021 Survey	2019 Survey	2017 Survey
Perfusionist in all cases	324 facilities (80.8%)	321 facilities (78.5%)	332 facilities (76.5%)
Nurse in all cases	24 facilities (3.5%)	15 facilities (3.7%)	22 facilities (5.1%)
Pharmacy in all cases	24 facilities (6.0%)	29 facilities (7.1%)	32 facilities (7.4%)
Pharmacy in routine cases, perfusionist in emergency cases	17 facilities (4.2%)	23 facilities (5.6%)	20 facilities (4.6%)
Other	21 facilities (5.5%)	21 facilities (5.1%)	28 facilities (6.5%)

Post-preparation verification method. 409 facilities (98.0%)	
Biochemistry tests (electrolytes, etc.) are performed in the laboratory	19
Perfusionist checks with blood gas analyzer, etc.	75
Checked using a chuck list.	240
Double-checking	260
Not specifically done.	50
Other	12

Table 8 Matters Related to Emergency Kit

Do you have an emergency kit in place?			
	2021 Survey	2019 Survey	2017 Survey
Yes	339 facilities (83.9%)	323 facilities (79.2%)	342 facilities (78.1%)
No	65 facilities (16.1%)	85 facilities (20.8%)	96 facilities (21.9%)

Where is the emergency kit stored?			
	2021 Survey	2019 Survey	2017 Survey
In the operating room	203 facilities (62.5%)	203 facilities (62.5%)	211 facilities (62.4%)
Warehouse in operating room	71 facilities (21.8%)	71 facilities (21.8%)	78 facilities (23.1%)
Warehouse outside the operating room	28 facilities (8.6%)	28 facilities (8.6%)	25 facilities (7.4%)
Operating room corridor	22 facilities (6.77%)	22 facilities (6.77%)	23 facilities (3.8%)
Other	1 facilities (0.3%)	1 facilities (0.3%)	1 facilities (0.3%)

Contents of the emergency kit. 339 facilities (83.9%)	
Spare oxygenator	495
Spare venous reservoir	405
Spare cardiotomy reservoir	309
Spare arterial line filter	118
Spare cardiopulmonary bypass circuitry	700
Spare roller pump	243
Spare centrifugal pump	239
Spare hand crank or handle	498
Spare oxygen cylinder	361

Table 9 Matters Related to Vacuum-Assisted Venous Drainage

Are safety measures implemented for VAVD?			
	2021 Survey	2019 Survey	2017 Survey
Yes	342 facilities (84.9%)	335 facilities (81.5%)	313 facilities (70.8%)
No	2 facilities (0.5%)	2 facilities (0.5%)	12 facilities (2.7%)
Not using VAVD	59 facilities (14.6%)	74 facilities (18.2%)	117 facilities (26.5%)

Specific safety measures for VAVD, 342 facilities (84.9%)	
Reservoir pressure monitoring*	304
Positive pressure release valve*	333
Moisture trap*	331
Prohibition of use of filters*	317
Prohibition of reuse of single-use products*	309
Checklist	205
Optimization of venous reservoir height	270
Backup VAVD device	83
Other	10

*Recommended by 3 academic societies

Table 10 Regular Maintenance of CPB Devices and Related Peripheral Equipment

Are you conducting regular maintenance of CPB device and related peripheral equipment?			
	2021 Survey	2019 Survey	2017 Survey
Yes	401 facilities (98.5%)	401 facilities (98.5%)	436 facilities (98.2%)
No	6 facilities (1.5%)	5 facilities (1.2%)	8 facilities (1.8%)

Who is responsible for maintenance?			
	2021 Survey	2019 Survey	2017 Survey
Manufacturer's representative	321 facilities (80.3%)	311 facilities (76.6%)	336 facilities (77.4%)
Perfusionist	7 facilities (1.8%)	10 facilities (2.5%)	12 facilities (2.8%)
Manufacturer's representative and perfusionist	72 facilities (18.0%)	85 facilities (20.9%)	85 facilities (19.6%)

Inspection frequency 403 facilities (99.5%)	
Every 6 months	42 facilities
Every 12 months	321 facilities
Every 2 to 3 years	20 facilities
Irregular	8 facilities
Only in case of malfunction	1 facility
Other	9 facilities

number of facilities monitoring venous reservoir pressure was approximately 30 fewer compared to those implementing positive pressure relief valves or water traps in VAVD connection tubes.

Table 10 presents the number of facilities conducting regular maintenance on CPB devices and related peripheral equipment. The percentage of facilities performing regular maintenance remained consistent across the 2021, 2019, and 2017 surveys, at 98.5%, 98.5%, and 98.2%, respectively. However, it is noteworthy that a small number of facilities did not conduct regular maintenance during these periods.

Ⅳ. Discussion

1. Number of CPB Cases and Institutional Background

When comparing the 2021 survey to the 2013 survey, there was no significant change in the fact that over 60% of facilities in Japan handle fewer than 100 CPB cases annually. However, in 2020, the number of facilities performing 150 to 300 cases per year decreased compared to 2019. This decline is likely due to the impact of the COVID-19 pandemic, which led many institutions to limit surgical procedures starting in January 2020 [6].

Regarding CPB systems, there were no significant changes observed in the main pumps or circuits. However, in terms of venous drainage methods, the number of facilities using only gravity drainage decreased, while those combining gravity drainage with VAVD increased. This trend may be attributed to the 2018 revision of medical service fees, which introduced new surgical fees for thoracoscopic mitral valve plasty and thoracoscopic mitral valve replacement. Consequently, the insurance coverage for minimally invasive cardiac surgeries (MICS) became available in April 2018, leading to an increase in MICS procedures and a corresponding rise in the adoption of VAVD as a venous drainage method.

2. Device-Related Incidents and Accidents

Incidents involving critical components of CPB devices — such as roller pumps, centrifugal pumps, power supply units, and control communication parts — have been reported, including cases where surgeries were aborted due to device failures. As outlined in the "Guidelines for Training and Maintenance of Life Support Devices in Medical Institutions [7]," conducting preoperative inspections is essential to detect device malfunctions early.

Sensor-related incidents are also prevalent, with level sensor abnormalities being the most common among measurement and alarm device issues. There have been reports where the venous reservoir became empty when attention was momentarily diverted; proper functioning of the level sensor might have prevented such occurrences. However,

certain venous reservoir designs may not be compatible with sensors, and in pediatric cases, the small size of the reservoir can make sensor attachment challenging. Manufacturers are encouraged to address these design considerations.

The number of incidents involving air entrainment from the oxygenator into the circuit (during separation or cardioplegia circuit use) has not significantly decreased. JaSECT has issued Medical Device Safety Information No.17, "Preventive Measures Against Recurrence of Accidental Air Infusion from Cerebral Separation Circuits," to raise awareness. Cerebral separation circuits are often complex, necessitating caution. Implementing bubble detectors in these circuits, coupled with interlocking functions that halt the cerebral separation pump upon air detection, can enhance safety by preventing air entrainment.

3. Incidents and Accidents Related to CPB Materials

Incidents Related to Oxygenators

The number of incidents involving elevated inlet pressure in oxygenators was reported as 114 cases (0.15%) in the 2021 survey, 114 cases (0.14%) in the 2019 survey, and 136 cases (0.16%) in the 2017 survey. These rates are comparable to the 0.127% incidence rate reported in the "Report on Increased Pressure of Extra-Corporeal Membrane During Cardiovascular Surgery Using Cardiopulmonary Bypass," which covered the years 2010-2012 [8]. Despite the submission of this report, such incidents continue to occur at a consistent rate.

In the 2017 survey, most facilities indicated replacing the oxygenator when the inlet pressure exceeded 500 mmHg. However, in the 2021 survey, the number of facilities using this threshold decreased, while those using a lower threshold of 350 mmHg increased (**Table 11**). This shift may stem from recommendations in a 2016 report, which suggested replacing oxygenators if the inlet pressure exceeded 400 mmHg or if the pressure differential across the oxygenator doubled under normal conditions. The increased use of circuits that allow oxygenator replacement without circulatory arrest, as promoted by JaSECT [9,10], may also account for this trend. However, this lower threshold of 350 mmHg is below the standard set in the report and warrants further investigation.

Additionally, the variability in oxygenator replacement criteria across facilities, as revealed by the survey, underscores the need for unified guidelines to ensure consistency and safety.

Incidents Related to Cannulas

Incidents at patient impact levels 3b-5 involving cannulas occurred more than 10 times in the 2021, 2019, and 2017 surveys. These included events such as the dislodgment of arterial or venous cannulas and the development of aortic dissections during cannula insertion or blood delivery, both of which can have severe consequences.

Unintentional cannula dislodgment is unpredictable and must be addressed promptly to prevent further complications. Conducting simulations and establishing preventive measures within the surgical team is recommended.

Aortic dissections during surgery were reported with an incidence rate of 0.09% in the 2021 survey, compared to rates of 0.16-0.35% reported for open-heart surgery in a previous study [11]. While such events are anticipated during cannulation and after clamping or declamping of the aorta, they also frequently occur just before weaning from cardiopulmonary bypass, requiring heightened vigilance.

Aortic dissections may necessitate changes to the blood delivery site or surgical approach, emphasizing the importance of intra-team communication and collaborative problem-solving. Reducing the occurrence of such incidents requires a multidisciplinary team effort, as perfusionists alone cannot mitigate all risks. Coordinated strategies involving the entire surgical team are essential to enhance patient safety and minimize incident rates.

4. Measures Against Incidents and Accidents

Progress in Safety Measures for CPB in Japan

Japan's safety measures for CPB have significantly progressed following incidents such as those caused by VAVD in 2001 and cerebral separation extracorporeal systems in 2010. Initiatives include

the development of the "Guidelines on Standard Connection Methods for CPB Devices and Corresponding Safety Education [12]," commissioned by the Ministry of Health, Labour and Welfare in March 2007, and the 6th edition of JaSECT's "Recommendations on Installation Standards for Safety Devices in CPB" issued in February 2020.

Implementation of Manuals and Checklists

To address incidents and accidents, it is essential to introduce and utilize manuals, checklists, and well-established troubleshooting protocols [13]. According to Soma [14], effective checklists must be created collaboratively by users, prioritize critical items, and undergo regular re-evaluation. Checklists should serve as tools for organizational process improvement and be used proactively. JaSECT's CPB seminars also recommend preparing emergency kits to manage potential CPB troubles [15]. Survey results show an increase in the proportion of facilities preparing emergency kits from 70.8% in 2013 to 83.9% in 2021, indicating greater recognition of their necessity. However, staff training, simulation exercises, and standardized procedures are equally important to ensure prompt and effective responses during emergencies.

Safety Measures for VAVD

Safety measures for VAVD, including venous reservoir pressure monitoring, installation of positive pressure relief valves, and adherence to single-use policies, are increasingly implemented. According to the "Report by the Joint Committee on Vacuum-Assisted Venous Drainage in Extracorporeal Circulation [16]," these measures have reduced the number of facilities without VAVD safety protocols from 12 in 2017 to 2 in 2021. However, venous reservoir pressure monitoring remains underutilized, highlighting an area for future improvement.

Incident and Accident Rates in CPB

The 2021 survey recorded 78,397 CPB cases over two years, with 23 accidents (patient impact level 3b-5) at a rate of 0.03% (1 in 3,408 cases) and 437 incidents (patient impact level 1-3a) at a rate of 0.56% (1 in 179 cases). While these rates are comparable to a French study by Charrière et al. [17] reporting accident rates of 1 in 3,220 and incident rates of 1 in 198 cases, differences in survey methods and criteria prevent direct comparison.

Insights from "Near Miss" Reports

Data from the Japan Council for Quality Health Care's 2021 report [18] indicated 1,010,921 near-miss cases across 646 facilities, with 1.4% potentially resulting in death or severe outcomes, 6.8% requiring intensive treatment, and 91.7% classified as minor or inconsequential. Among the 543 near-miss cases (patient impact level 0) in the 2021 survey, some might have led to severe outcomes had they been executed improperly.

Disaster Preparedness and Power Outages

Given a 70-80% likelihood of an earthquake along the Nankai Trough within 30 years, as reported by Japan's Earthquake Research Committee, disaster preparedness is crucial [19]. Suzuki emphasized the need for business continuity plans (BCP) and disaster simulations [20]. While few facilities reported experiencing power outages during CPB operations, future measures should address potential disasters comprehensively.

The Importance of Multidisciplinary Teamwork

While eliminating all incidents and accidents in CPB is impossible, minimizing patient impact through robust safety management is imperative. Team training has shown positive effects on clinical processes and patient outcomes [14]. Collaborative and continuous implementation of safety measures across multidisciplinary teams is essential to enhance CPB safety.

Ⅴ. Conclusion

Building upon previous reports, we analyzed safety measures in cardiopulmonary bypass (CPB) using data from JaSECT's 2021, 2019, and 2017 surveys on CPB and circulatory support-related incidents, accidents, and safety. While it is impossible to eliminate all incidents and accidents in CPB, we hope this report will be utilized by various institutions to enhance future safety measures.

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The authors declare that they have no COI.

References

1) Takai K, Anno M, Yoshida K, et al. The current status of the safety management in practices of cardiopulmonary bypass: focus to the report of JaSECT safety survey 2013. *Jpn J Extra-Corporeal Technology*. 2015；42（4）：381-392.
2) Japanese Society of Extra-Corporeal Technology Safety Committee. Survey on incidents, accidents, and safety related to cardiopulmonary bypass and circulatory support 2021. *Jpn J Extra-Corporeal Technology*. 2022；49（4）：421-451.
3) National Hospital Organization Medical Safety Measures. Medical Safety Report: 2021 Edition [in Japanese]. March 27, 2020. Accessed September 21, 2023. https://nho.hosp.go.jp/files/000192341.pdf
4) Japanese Society of Extra-Corporeal Technology Safety Committee. Survey on incidents, accidents, and safety related to cardiopulmonary bypass and circulatory support 2017. *Jpn J Extra-Corporeal Technology*. 2018；45（4）：429-456.
5) Japanese Society of Extra-Corporeal Technology Safety Committee. Survey on incidents, accidents, and safety related to cardiopulmonary bypass and circulatory support 2019. *Jpn J Extra-Corporeal Technology*. 2022；49（1）：42-71.
6) Ike S, Hamano K, Yokoyama H, et al. Impact of COVID-19 on cardiovascular surgery practice and infection control in Japan: a nationwide survey. *Jpn J Cardiovasc Surg*. 2022；51（2）：89-95.
7) Ministry of Health, Labour and Welfare. Guidelines for training and maintenance of life support equipment in medical institutions [in Japanese]. March 2021. Accessed September 21, 2023. https://www.mhlw.go.jp/content/10800000/000898768.pdf
8) Japanese Society for Cardiovascular Surgery Working Group for Increased Pressure of Extra-Corporeal Membrane. Report on increased pressure of extra-corporeal membrane during cardiovascular surgery using cardiopulmonary bypass [in Japanese]. Accessed December 14, 2022. https://plaza.umin.ac.jp/~jscvs/wordpress/wp-content/themes/amnk/pdf/jinkouhaisaisyuuhoukoku161020.pdf
9) Nagashima K, Ishikawa K, Matsuyama S, et al. A case where elevated oxygenator inlet pressure was observed immediately after the start of cardiopulmonary bypass but oxygenator replacement was not required. *Jpn J Extra-Corporeal Technology*. 2021；48（4）：290-297.
10) Saimyo Y, Yagi K, Tokui T, et al. A case of oxygenator replacement due to poor oxygenation without increased oxygenator pressure. *Jpn J Extra-Corporeal Technology*. 2020；47（4）：340-344.
11) Ajmer S, Yatin M. Intraoperative aortic dissection. *Ann Card Anaesth*. 2015；18（4）：537-542.
12) Ministry of Health, Labour and Welfare Pharmaceutical and Food Safety Bureau Safety Division. Guidelines on standard connection methods of cardiopulmonary bypass devices and corresponding safety education [in Japanese]. March 2007. Accessed September 21, 2023. https://www.mhlw.go.jp/topics/2007/04/dl/tp0427-10.pdf
13) Kyo S. Human errors and system errors in the causes of cardiopulmonary bypass troubles [in Japanese]. *Clin Eng*. 2019；30（9）：817（*Shujunsha Publishing*）
14) Soma T. Research on the development and application of the Japanese version of the "Surgical Safety Simple Evaluation System" using the WHO checklist [in Japanese] Report on the Grant for Health and Labour Sciences Research（Regional Medical Infrastructure Development Promotion Research Project）. 2015：93-101.
15) Japanese Society of Extra-Corporeal Technology. Textbook for cardiopulmonary bypass practical seminar Ver.1.7 [in Japanese].
16) The Japanese Association for Thoracic Surgery, The Japanese Society for Cardiovascular Surgery, The Japanese Society for Artificial Organs. Report by the joint committee on vacuum-assisted venous drainage in extracorporeal circulation [in Japanese]. *J Artif Organs*. 2003；32：S1-S11.
17) Charrière JM, Pélissié J, Verd C, et al: Retrospective survey of monitoring/safety devices and incidents of cardiopulmonary bypass for cardiac surgery in France. *J Extra Corpor Technol*, 39（3）：142-157, 2007.
18) Japan Council for Quality Health Care, Division of Adverse Event Prevention: Project to collect and analyze medical adverse event information（2021 Annual Report）[in Japanese]. Available at: http://www.med-safe.jp/contents/report/html/nennzi/2021/TTL301_YNR-01.html. Accessed September 21, 2023.
19) Cabinet Office, Government of Japan, Earthquake Research Committee: Nankai Trough Earthquake Disaster Response Guidelines for Diverse Occurrence Patterns [First Edition, in Japanese]. Available at: https://www.bousai.go.jp/jishin/nankai/pdf/honbun_guideline2.pdf. Accessed September 21, 2023.
20) Suzuki I: Disaster Preparedness in Extracorporeal Circulation [in Japanese]. *Clinical Engineering*, 30（9）：838-844, 2019.