Jpn J Extra-Corporeal Technology 52(1) : 12-23, 2025

Research and Reporting

Current status of safety management in circulatory support in Japan: Insights from the 2021 questionnaire survey on incidents, accidents, and safety measures — secondary publication (complete translation) —

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Abstract

Since 2010, the Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) has been conducting questionnaire surveys aimed at improving the quality and safety of extracorporeal circulation. In 2021, we conducted a follow-up survey titled "Questionnaire on Incidents, Accidents, and Safety Measures Related to Cardiopulmonary Bypass and Circulatory Support 2021." This survey targeted cases involving cardiopulmonary bypass and circulatory support performed in 2019 and 2020, achieving a response rate of 67.2%. We compared the collected data on circulatory support with results from previous surveys. Notably, during the COVID-19 pandemic, there was an increase in the total number of circulatory support procedures and the number of devices owned by facilities, trends not observed in earlier surveys. Understanding the details of reported incidents and accidents and actively sharing this information among multidisciplinary teams are crucial for ensuring medical safety. It is essential to continue similar surveys to gather comprehensive information and disseminate the findings globally, contributing to the establishment of safe circulatory support practices.

Key words : circulatory support, safety management, incidents, accidents, questionnaire survey, COVID-19

Ⅰ. Introduction

The Japanese Society of Extra-Corporeal Technology in Medicine (JaSECT) has been conducting biennial surveys since 2010 to enhance and promote safety in extracorporeal circulation management. In the latest survey, "Questionnaire on Incidents, Acci-

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[Accepted February 20, 2025]

footnote : This article is based on a study first reported in the "Iwamoto K, Motoyoshi N, Tomisada K, Kodama K, Takeshima T, Miyagawa S, Sonoda M : Questionnaire survey on the current status of safety management in mechanical circulatory support in Japan - Based on incident, accident, and safety questionnaire JaSECT 2021-. Jpn J Extra-Corporeal Technology, 51 (1) : 12-21, 2024"

dents, and Safety Related to Cardiopulmonary Bypass and Circulatory Support 2021," information was collected regarding incidents and accidents related to cardiopulmonary bypass and circulatory support that occurred during 2019 and 2020 [1]. Based on the aggregated results of this survey and previous ones, we examined and report on the current status and changes in safety management for circulatory support.

Ⅱ. Brief Description of the 2021 Questionnaire Survey on Circulatory Support

1. Subjects and Methods

The 2021 survey targeted 656 medical institutions where JaSECT members are affiliated, focusing on circulatory support procedures performed in 2019 and 2020. The survey was conducted by sending a cooperation request letter to the heads of the target facilities and JaSECT members designated as representatives at those facilities. Respondents were asked to submit their answers using a questionnaire form created on the JaSECT website via WordPress. Since the survey required hospital information to be disclosed, facilities were required to obtain internal approval before participation. Initially, the survey period was set from April 11 to May 16, 2022; however, to improve the response rate, the deadline was extended to June 15, 2022.

2. Levels of Impact on Patients

The classification of patient impact levels was based on the system utilized by the National Hospital Organization and similar institutions (**Table 1**) [2]. To ensure uniformity in responses, survey participants were briefed on this classification and requested to report the number of cases in the following three categories: Level 0; Levels 1-3a; and Levels 3b-5.

3. Earlier Survey Results for Comparison

To assess the trends and current status of safety management in circulatory support, we compared the results of the 2021 survey with those of the 2019 [3] and 2017 [4] surveys. 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

Among the 656 targeted facilities, 441 responded to the survey, yielding a response rate of 67.2%. Excluding 13 facilities that lacked internal approval to participate, the number of valid responses was 428.

2. Trends and Current Status of Circulatory Support Cases

Among the 428 facilities that provided valid responses, 412 reported performing extracorporeal membrane oxygenation (ECMO) procedures. In 2019, the total number of circulatory support cases was 5,949 (adults: 5,655; pediatrics: 294), and in 2020, it was 6,230 (adults: 5,958; pediatrics: 272). The distribution of cases from 2015 to 2020 is presented in **Table 2**. Approximately half of the facilities handled 10 or fewer cases annually (2019: 54.4%; 2020: 54.2%). However, compared to 2015 and 2016, there was a decrease in facilities managing five or fewer cases per year, while those handling more than 51 cases

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).

annually increased. Regarding the number of facilities by patient age group, those treating only adult cases accounted for about 80% of the total (2019: 79.7%; 2020: 82.2%). Facilities exclusively treating pediatric cases remained relatively unchanged since 2017, with 12 such facilities in 2020 (2.9%). Facilities managing both adult and pediatric cases decreased to 37 in 2020 (8.8%), compared to the 2019 survey (**Table 3**).

Regarding the number of circulatory support devices owned, in the 2021 survey, the most common response was two devices per facility (30.5%), followed by three devices (26.9%) and one device (11.5%), collectively accounting for over half of the responses. Compared to the 2019 and 2017 surveys, there was an increase in the number of facilities possessing three or more devices per facility (**Fig.1**).

3. Incidents and Accidents in Circulatory Support

The number and rates of incidents/accidents in circulatory support are presented in **Table 4**. In the 2021 survey, a total of 384 events were reported, resulting in an incidence rate of 3.2%. Similarly, the

Table 2 Distribution of Cases from 2015 to 2020

Year	0 cases	1-5 cases	6-10 cases	11-15 cases	16-20 cases	21-25 cases	26-30 cases	31-35 cases	36-40 cases	41-45 cases	46-50 cases	>51 cases
2015	44 (9.4)	166 (35.6)	83 (17.8)	59 (12.7)	42 (9.0)	24 (5.2)	16 (3.4)	11 (2.4)	10 (2.1)	5 (1.1)	5 (1.1)	1 (0.2)
2016	25 (5.4)	163 (35.0)	87 (18.7)	70 (15.0)	40 (8.6)	16 (3.4)	22 (4.7)	11 (2.4)	17 (3.6)	4 (0.9)	5 (1.1)	6 (1.3)
2017	38 (8.8)	114 (26.5)	99 (23.0)	57 (13.2)	30 (7.0)	23 (5.3)	14 (3.2)	14 (3.2)	18 (4.2)	8 (1.9)	7 (1.6)	9 (2.1)
2018	45 (10.7)	113 (26.8)	72 (17.1)	55 (13.0)	37 (8.8)	25 (5.9)	25 (5.9)	7 (1.7)	13 (3.1)	11 (2.6)	7 (1.7)	12 (2.8)
2019	35 (8.3)	122 (29.0)	72 (17.1)	53 (12.6)	37 (8.8)	24 (5.7)	19 (4.5)	24 (5.7)	10 (2.4)	5 (1.2)	5 (1.2)	15 (3.6)
2020	26 (6.2)	117 (27.8)	85 (20.2)	51 (12.1)	36 (8.6)	21 (5.0)	23 (5.5)	17 (4.0)	12 (2.9)	11 (2.6)	4 (1.0)	18 (4.3)

No of facilities (%)

Table 3 Number of Facilities Handling Adult and Pediatric Cases

Year	Adult only	Adult + Pediatric	Pediatric only	Not handling	Total no. of facilities
2017	379 (81.3)	64 (13.7)	11 (2.4)	12 (2.6)	466
2018	347 (80.5)	47 (10.9)	12 (2.8)	25 (5.8)	431
2019	333 (79.7)	44 (10.5)	9 (2.1)	35 (8.3)	421
2020	346 (82.2)	37 (8.8)	12 (2.9)	26 (6.2)	421

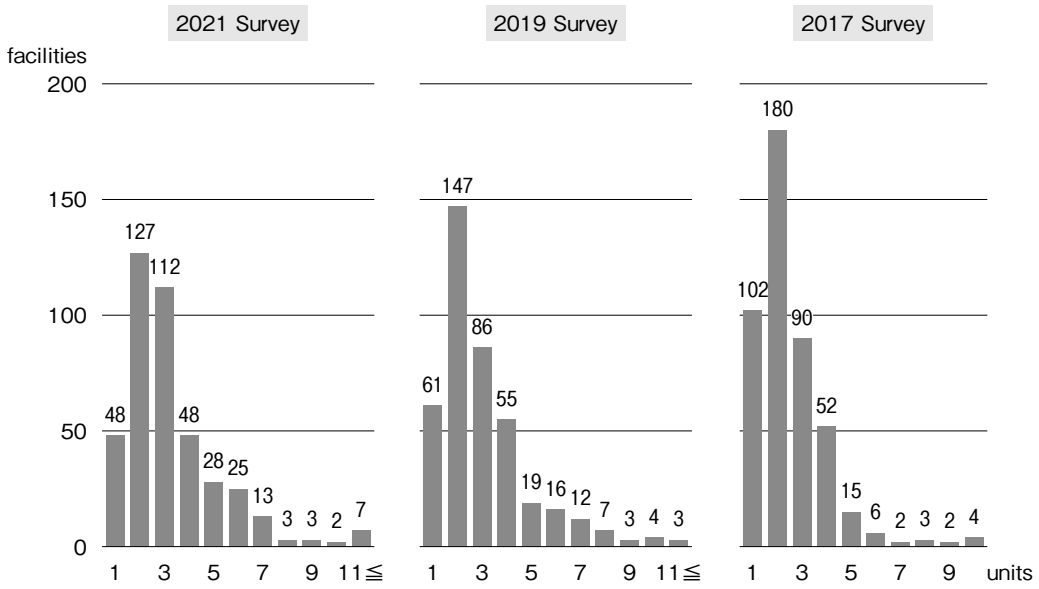

Fig.1 Number of ECMO Devices Owned

Table 4 Numbers and Rates of Circulatory Support-Related Incidents and Accidents

	2021 Survey		2019 Survey		2017 Survey	
	2020	2019	2018	2017	2016	2015
Total ECMO Cases	6,230	5,949	5,811	5,525	5,524	4,921
Impact Level (0)	55 (0.88)	59 (0.99)	58 (1.00)	57 (1.03)	45 (0.81)	51 (1.04)
Impact Level (1-3a)	119 (1.91)	105 (1.77)	161 (2.77)	128 (2.32)	123 (2.23)	92 (1.87)
Impact Level (3b-5)	24 (0.39)	22 (0.37)	27 (0.46)	23 (0.42)	25 (0.45)	12 (0.24)
Total No. of Events	198 (3.18)	186 (3.13)	246 (4.23)	208 (3.76)	193 (3.49)	155 (3.15)

No of facilities (%)

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

Incidents/Accidents Related to Sudden Pump Stops or Flow Reductions

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	75 (18)	59 (13.8)	62 (13.5)
Impact level(0)	0 (0)	0 (0)	0 (0)
Impact level(1-3a)	133 (1.09)	69 (0.61)	58 (0.56)
Impact level(3b-5)	16 (0.13)	8 (0.07)	3 (0.13)

Incidents/Accidents Related to Flow Sensors

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	51 (12.3)	49 (11.5)	43 (9.4)
Impact level(0)	65 (0.53)	53 (0.47)	52 (0.5)
Impact level(1-3a)	14 (0.12)	34 (0.30)	15 (0.14)
Impact level(3b-5)	1 (0.01)	1 (0.01)	1 (0.01)

Incidents/Accidents Related to Air Entrapment into the Circuit

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	48 (11.5)	46 (10.8)	47 (10.2)
Impact level(0)	0 (0)	0 (0)	0 (0)
Impact level(1-3a)	55 (0.45)	54 (0.48)	49 (0.47)
Impact level(3b-5)	11 (0.09)	7 (0.06)	9 (0.09)

Incidents/Accidents Related to Unintended Bleeding from the Circuit

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	53 (12.7)	46 (10.8)	46 (10)
Impact level(0)	0 (0)	0 (0)	0 (0)
Impact level(1-3a)	63 (0.52)	56 (0.49)	58 (0.56)
Impact level(3b-5)	6 (0.05)	2 (0.02)	4 (0.04)

Incidents/Accidents Related to Cannulation

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	78 (18.8)	79 (18.5)	71 (15.5)
Impact level(0)	11 (0.09)	16 (0.14)	13 (0.12)
Impact level(1-3a)	71 (0.58)	74 (0.65)	66 (0.63)
Impact level(3b-5)	51 (0.42)	40 (0.35)	31 (0.30)

Incidents/Accidents Related to Transport

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	51 (12.3)	54 (12.6)	49 (10.7)
Impact level(0)	0 (0)	0 (0)	0 (0)
Impact level(1-3a)	82 (0.67)	92 (0.81)	77 (0.74)
Impact level(3b-5)	4 (0.03)	5 (0.04)	3 (0.03)

Incidents/Accidents Related to Power Supply Interruptions

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	13 (3.1)	17 (4.0)	14 (3.0)
Impact level(0)	11 (0.09)	5 (0.04)	8 (0.08)
Impact level(1-3a)	3 (0.03)	9 (0.08)	9 (0.09)
Impact level(3b-5)	0 (0)	1 (0.01)	1 (0.01)

Other incidents/accidents related to ECMO including peripheral equipment

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	44 (10.5)	29 (6.73)	32 (6.87)
Impact level(0)	19 (0.16)	48 (0.42)	32 (0.31)
Impact level(1-3a)	45 (0.37)	68 (0.60)	31 (0.30)
Impact level(3b-5)	5 (0.04)	8 (0.07)	16 (0.15)

Incidents/Accidents Related to Medical Gas Supply Interruptions

	2021 Survey	2019 Survey	2017 Survey
No. of facilities	12 (2.9)	5 (1.2)	2 (0.4)
Impact level(0)	0 (0)	0 (0.99)	0 (0)
Impact level(1-3a)	11 (0.09)	5 (0.04)	2 (0.02)
Impact level(3b-5)	3 (0.03)	0 (0)	0 (0)

Note 1: The figures in the table at each impact level indicate the number of incident/accident occurrence (s) (%).
Note 2: The number of facilities that reported incident/accident occurrence (s) in each survey is as follows: 2021 survey (421 facilities), 2019 survey (431), and 2017 survey (466).
Note 3: The number of incident cases reported in each survey is as follows: 2021 survey (12,179 cases), 2019 survey (11,336), and 2017 survey (10,445).

2017 and 2019 surveys indicated that approximately 3-4% of such events occurred annually, with accidents of patient impact level 3b or higher consistently accounting for at least 0.3% of cases. **Table 5** details the number of facilities reporting incidents and accidents related to circulatory support, categorized by patient impact level, while **Table 6** outlines the specific types of incidents and accidents reported in the 2021 survey.

Table 6　Number of Incidents Related to Different Items

Incidents Related Pump Stops or Flow Reductions, 75 facilities (18%)		
Drive motor (centrifugal pump) abnormalities	6 cases	(3.5%)
Roller pump abnormalities	0	(0%)
Pump head damage or defects	4 cases	(2.3%)
Improper pump head setup (e.g., dislodgement)	7 cases	(4%)
Coagulation (including within circuits and cannulas)	51 cases	(29.1%)
Cannula-related issues (e.g., kinking)	50 cases	(28.6%)
Unknown	2 cases	(1.1%)
Other	55 cases	(31.4%)

Incidents Related to Flow Sensors, 51 facilities (12.3%)		
Damaged flow sensor	19 cases	(23.5%)
Forgot to attach the flow sensor	6 cases	(7.4%)
Mishandling	21 cases	(25.9%)
Errors in flow display	14 cases	(17.3%)
Sensor detachment	2 cases	(2. 4 %)
Other (including unknown)	19 cases	(23.5%)

Incidents Related Air Entrapment into the Circuit, 48 facilities (11.5%)		
Air entrainment due to damage to the centrifugal pump or circuit	2 cases	(2.9%)
Air entrainment from the cannula	15 cases	(22.0%)
Air entrainment from the priming line	11 cases	(16.2%)
Air entrainment into the CRRT circuit due to operational errors involving the drainage line	3 cases	(4.4%)
Insufficient de-airing during priming or cannula connection	4 cases	(5.9%)
Circuit disconnection	1 case	(1.5%)
Issues related to three-way stopcocks in the venous drainage circuit	19 cases	(28.0%)
Other (including unknown)	13 cases	(19.1%)

Incidents Related to Unintended Bleeding from the Circuit, 51 facilities (12.3%)		
Bleeding from three-way stopcocks in the arterial line circuit	48 cases	(67.6%)
Damage to centrifugal pumps, circuits, oxygenators, etc.	7 cases	(9.9%)
Circuit disconnection	3 cases	(4.2%)
Accidental bleeding from the priming line	1 case	(1.4%)
Bleeding due to misconnection or mishandling of the CRRT circuit	3 cases	(4.2%)
Accidental removal of applied clamps	0	(0%)
Other	9 cases	(12.7%)

Incidents Associated with Cannulation, 78 facilities (18.8%)		
Arterial line cannula dislodgement	22 cases	(14.9%)
Venous line cannula dislodgement	6 cases	(4.1%)
Bleeding due to vascular injury	72 cases	(48.6%)
Arterial dissection	5 cases	(3.4%)
Unintended A-A or V-V cannulation	22 cases	(14.9%)
A-V shunting due to circuit misconnection	5 cases	(3.4%)
Other	16 cases	(10.7%)

Incidents during Transportation or at Destinations, 51 facilities (12.3%)		
Cannula dislodgement	6 cases	(6.7%)
Battery depletion during transport	4 cases	(4.5%)
Forgot to supply gas to the oxygenator during transport	4 cases	(4.5%)
Depletion of oxygen cylinders	4 cases	(4.5%)
Gas tube disconnected and not noticed	4 cases	(4.5%)
Forgot to administer (continuous) anticoagulant	1 case	(1.1%)
The rotational speed of the centrifugal pump has changed	6 cases	(6.7%)
Equipment tipped over	1 case	(1.1%)
Circuit got caught on something and disconnected	2 cases	(2.2%)
Decreased flow due to circuit kinking	46 cases	(51.7%)
Other	11 cases	(12.5%)

Incidents Related to Power Supply Interruptions, 13 facilities (3.1%)		
Unscheduled regional power outage	3 cases	(20%)
Planned regional power outage	0	(0%)
Unscheduled hospital-wide power outage	1 case	(6.7%)
Planned hospital-wide power outage	1 case	(6.7%)
Fire or earthquake	0	(0%)
Excessive equipment use in the operating room	4 cases	(26.6%)
Outlet short circuit	1 case	(6.7%)
Broken outlet or power cable	0	(0%)
Intentional or accidental plug disconnection	4 cases	(26.6%)
Other	1 case	(6.7%)

Incidents Related to Medical Gas Supply Interruptions, 12 facilities (2.9%)

1) Sudden Pump Stops or Flow Reductions

A total of 149 incidents (1.2%) were reported by 75 facilities (18.0%), with 16 cases (0.1%) classified as patient impact level 3b or higher. The primary causes identified included coagulation (including within circuits and cannulas) accounting for 51 cases (29.1%), and cannula-related issues (such as kinking) accounting for 50 cases (28.6%), together comprising over half of the incidents. Additionally, 57 cases (32.5%) were attributed to unknown or other causes. Other noted causes included improper pump head setup (e.g., dislodgement) in 7 cases (4.0%) and abnormalities in the drive motor (centrifugal pump) in 6 cases (3.5%). The main corrective actions taken during these incidents were straightening bent circuits or cannulas in 46 cases (24.7%), circuit replacement in 37 cases (19.9%), and oxygenator replacement in 20 cases (10.8%). Additionally, 40 cases (21.5%) were categorized as "Other" in the responses. The annual incidence rates of these incidents have increased over time, with 18% in the 2021 survey, compared to 13.8% in 2019 and 13.5% in 2017.

2) Issues Related to Flow Sensors

A total of 80 incidents (0.7%) were reported by 51 facilities (12.3%), with one case (0.01%) classified as patient impact level 3b or higher. The primary causes were human factors, such as forgetting to attach the flow sensor, incorrect attachment, and errors in flow display, accounting for half of the incidents (50.6%). Additionally, 19 cases (23.5%) involved flow sensor damage. The main corrective actions taken included reattaching the sensor in 43 cases (51.8%) and replacing the flow sensor in 14 cases (16.9%). The annual incidence rates of these incidents have been increasing, with rates of 12.3% in the 2021 survey, 11.5% in 2019, and 9.4% in 2017.

3) Air Entrapment into the Circuit

A total of 66 incidents (0.5%) were reported by 48 facilities (11.5%), with 11 cases (0.09%) classified as patient impact level 3b or higher. The primary causes identified were related to three-way stopcocks in the venous drainage circuit (19 cases, 28.0%), cannulas (15 cases, 22.1%), and priming lines (11 cases, 16.2%). The main corrective actions taken during these incidents included air removal from cannulas and circuits (33 cases, 44.6%) and complete circuit replacement (17 cases, 23.0%). The annual incidence rates of these incidents remained relatively stable, with rates of 11.5% in the 2021 survey, 10.8% in 2019, and 10.2% in 2017.

4) Unintended Bleeding from the Circuit

A total of 69 incidents (0.6%) were reported by 53 facilities (12.7%), with 6 cases (0.1%) classified as patient impact level 3b or higher. The most common cause was bleeding from the three-way stopcock in the arterial circuit, accounting for 48 cases (67.6%). Additionally, 3 cases (4.2%) involved bleeding due to connection or operational errors with continuous renal replacement therapy (CRRT) circuits. The primary corrective action taken was correcting operational errors, which accounted for 45 cases (64.3%). The annual incidence rates of these incidents have shown a slight increase, with rates of 12.7% in the 2021 survey, 10.8% in 2019, and 10.0% in 2017.

5) Cannulation-Related Complications

A total of 78 facilities (18.8%) reported incidents, with vascular injury leading to bleeding being the most common, accounting for 72 cases (48.6%). Other notable issues included cannula dislodgement in 28 cases (18.9%), unintended arterial-venous (A-V) or venous-venous (V-V) cannulation in 22 cases (14.9%), circuit misconnection causing A-V shunting in 5 cases (3.4%), and dissection in 5 cases (3.4%). In response to these complications, re-cannulation or reconnection of circuits and cannulas was performed in 80 cases (63.0%), while in 17 cases (13.4%), circulatory support was discontinued. The incidence rates of these complications across the 2021, 2019, and 2017 surveys were 18.8%, 18.5%, and 15.5%, respectively, showing little variation. The distribution of incidents by patient impact level remained consistent over the years, with levels 1-3a being the most frequent, followed by levels 3b-5, and level 0.

6) Issues During ECMO Device Transport or at Transport Destinations

A total of 51 facilities (12.3%) reported experiencing issues during patient transport, such as for CT scans. The most common problem was decreased flow due to circuit kinking, accounting for 46 cases (51.7%). Other reported issues included cannula dislodgement (6 cases, 6.7%), battery depletion during transport (4 cases, 4.5%), depletion of oxygen cylinders (4 cases, 4.5%), forgetting to supply gas to the oxygenator (4 cases, 4.5%), and gas tube disconnection (4 cases, 4.5%). The incidence rates of these incidents were 12.3% in the 2021 survey, 12.6% in 2019, and 10.7% in 2017, indicating no significant decrease over time.

7) Power Supply Interruptions

A total of 13 facilities (3.1%) reported experiencing power supply interruptions, such as power outages. The primary causes included exceeding the rated capacity of overcurrent protection devices due to the total current usage of equipment in operating rooms (4 cases, 26.6%), accidental or intentional disconnection of power plugs (4 cases, 26.6%), and unexpected regional power outages (3 cases, 20.0%). In 8 cases, the devices continued to operate on internal

batteries without stopping. The incidence rates of these events were 3.1% in the 2021 survey, 4.0% in 2019, and 3.0% in 2017, showing no significant change over time.

8) Medical Gas Supply Interruptions

A total of 12 facilities (2.9%) reported experiencing medical gas supply interruptions. Incidents classified as patient impact levels 1-3a accounted for 11 cases (0.09%), while those classified as levels 3b-5 accounted for 3 cases (0.03%). The incidence rates of these events have shown a slight upward trend, with rates of 2.9% in the 2021 survey, 1.2% in 2019, and 0.4% in 2017.

4. Preparation of Hand Cranks and Spare Equipment During Circulatory Support Operation

Among the 428 responding facilities, 380 (92.5%) reported having hand cranks or manual handles readily available during circulatory support operations, while 31 facilities (7.5%) did not have such preparations. Additionally, 358 facilities (85.7%) had spare circuits or oxygenators prepared during operations, whereas 55 facilities (14.3%) did not. The readiness of spare equipment has not shown improvement over the years, with preparation rates of 85.7% in the 2021 survey, 88.9% in 2019, and 90.0% in 2017.

5. Integration of Blood Purification Circuits, Such as CRRT, into Circulatory Support Circuits

In the survey, 269 facilities (64.4%) reported not integrating blood purification circuits into their circulatory support systems, whereas 101 facilities (24.2%) indicated that they do so in emergency situations where vascular access cannot be secured. Additionally, 15 facilities (3.6%) reported integrating these circuits specifically for pediatric patients. Overall, 32 facilities (7.7%) routinely incorporate blood purification circuits into their circulatory support setups.

6. Regular Maintenance of Circulatory Support Devices

Regular maintenance was conducted in 409 facilities (97.8%), with the most common inspection interval being annually, reported by 289 facilities (70.7%). Maintenance performed by the manufacturer was the most prevalent, occurring in 292 facilities (71.4%), while 98 facilities (24.0%) conducted maintenance jointly between the responsible technician and the manufacturer.

7. Nighttime Management Systems for Circulatory Support Devices

Among the surveyed facilities, 237 (57.1%) reported implementing on-call or night shift systems for managing circulatory support devices during nighttime hours. This represents an increase from 54.1% in 2019 and 47.3% in 2017. The most common management approach involved staff remaining onsite to conduct regular monitoring. This was followed by systems where on-call or night shift personnel were responsible for management, and arrangements where staff remained on standby at home, ready to respond in case of abnormalities. Notably, these preferences remained consistent even for extended periods of device operation exceeding one week.

8. Other Issues Related to Circulatory Support, Including Peripheral Devices

Various issues were reported concerning oxygen delivery, such as forgetting to connect the oxygen supply tube, neglecting to set the automatic oxygen flush, and failing to revert settings after the oxygen flush. Additionally, there were instances of forgetting to start the heater-cooler unit or patient hypothermia due to heater-cooler unit malfunctions. Other reported problems included neglecting to set flow alarms during circulatory support, and instances where clamps on the arterial or venous lines were left partially closed.

Ⅳ. Discussion

1. Trends in ECMO/PCPS Utilization for Circulatory Support Cases

Extracorporeal membrane oxygenation (ECMO) and percutaneous cardiopulmonary support (PCPS) have been used in Japan since the late 1980s, combining centrifugal pumps, membrane oxygenators, and closed blood circuits for cases with difficulty weaning from CPB or as support during percutaneous transluminal coronary angioplasty

(PTCA). Over time, advancements such as durable centrifugal pumps, percutaneously insertable cannulas, biocompatible coatings, and pre-connected circuits have facilitated the emergence of PCPS for emergency circulatory support. This technology has become widely utilized, particularly in critical care settings, for patients with cardiogenic shock or cardiac arrest. The SAVE-J study demonstrated the efficacy of extracorporeal cardiopulmonary resuscitation (ECPR) [5], encouraging its active implementation in Japan.

Meanwhile, ECMO for respiratory failure gained traction following Bartlett et al.'s 1976 report on successful neonatal ECMO treatment. Although neonatal ECMO established itself as a standard therapy for severe respiratory failure [6], adult ECMO outcomes were initially suboptimal. During the 2009 H1N1 influenza pandemic, Japan faced challenges in expertise and institutional proficiency [7], leading to unsatisfactory survival rates compared to international benchmarks. Consequently, the ECMO Project was launched to improve treatment outcomes [8], leading to broader implementation for acute respiratory failure.

Given these developments, ECMO cases in Japan have steadily increased. During the 2019-2020 survey period, coinciding with the COVID-19 pandemic, the number of cases exceeded those in 2015 by over 1,000 [9]. This upward trend is expected to continue. However, over half of the facilities perform 10 or fewer ECMO cases annually, and most own only 2-3 devices, highlighting a lack of case centralization into large-scale ECMO centers, as seen abroad [10]. In pediatric cases, the number of facilities exclusively treating pediatric patients has remained unchanged, while those treating both adult and pediatric cases have decreased, indicating a trend toward centralization.

A notable trend compared to previous surveys is the increase in the number of devices per facility, likely driven by additional purchases to address COVID-19 demands. The rise in facilities performing over 51 cases annually also reflects the pandemic's impact, potentially contributing to a more robust circulatory support system in Japan in the future.

2. Issues with Blood Flow

The primary causes of sudden pump stoppage or decreased blood flow are often related to cannula issues, such as kinking, or coagulation. The ELSO guidelines [11] recommend measuring pressures at the inlet and outlet of the oxygenator, as well as within the drainage circuit, to detect early changes in circuit pressures and identify potential causes promptly. In response to decreased flow due to circuit coagulation, some facilities reported replacing the oxygenator or the entire circuit, while others continued using the same circuit. Thrombi can form at various points within the circuit, and there have been reports of substantial clots suddenly obstructing the pump or oxygenator, leading to abrupt pump stoppage [12]. Therefore, having spare circuits readily available is essential for rapid response. Circuit replacement requires multiple personnel, necessitating regular training for such procedures [13]. Issues like pump head detachment due to improper setup have also been reported. After attaching the drive unit of a centrifugal pump, it is advisable to perform visual checks not only from the front but also from multiple angles, such as the sides. If reattachment is needed while the centrifugal pump is operating, there is a risk of damaging the pump due to misalignment; hence, it is necessary to stop the drive unit before reattachment [14]. Regarding drive motor abnormalities, some cases were managed by rebooting the device, while others required device replacement, indicating the importance of having backup devices. However, 48 facilities reported possessing only one circulatory support device. Although these devices are expensive and not easily procured, it is crucial to consider this aspect from an equipment management perspective. Additionally, since flow sensor malfunctions have occurred, maintaining spare parts is also advisable.

3. Air Entrapment in the Circuit and Unintended Bleeding from the Circuit

To prevent air entrapment, it is advisable to verify the closure of three-way stopcocks on the drainage side, the closure of priming lines, and the

removal of air from the circuit during circulatory support initiation using checklists or similar tools. Regarding air entrapment caused by misconnection or operational errors in CRRT circuits, the Japan Association for Clinical Engineers has issued a recommendation on "Safety Standards for Continuous Blood Purification (CBP) Devices and Circuits," stating that "the percutaneous cardiopulmonary support (PCPS) drainage circuit in adult patients should not be used as vascular access for CBP." This recommendation prohibits connecting CRRT circuits to the drainage circuit of extracorporeal circulation systems [15]. As a general rule, a vascular access catheter should be placed in the patient, and this should be the first-choice access method. In cases where this is not feasible, such as in pediatric patients, there have been reports of incorporating blood purification circuits into bypass circuits of circulatory support systems [16]. However, it is essential to fully understand the associated risks and implement proper risk management.

As for corrective actions for air entrapment, if the amount of air entrapped is minimal, monitoring the patient and removing air from the cannula or circuit may suffice. However, if a large volume of air enters the circuit, an emergency circuit replacement may be necessary.

Operational errors involving three-way stopcocks can lead to significant complications — on the drainage side, they can cause massive air entrapment, whereas on the arterial side, they can result in unintended bleeding from the circuit. Therefore, extreme caution should be exercised when handling three-way stopcocks while ECMO is in operation, and checklists should be effectively utilized to ensure safe management.

4. Incidents Associated with Cannulation

Cannulation-related incidents are relatively frequent and have a high potential for severe consequences. In this survey, 71 cases (0.58%) were classified as patient impact levels 1-3a, while 51 cases (0.42%) fell under levels 3b-5, making this one of the highest-risk categories. Since cannulation is a critical step that largely determines the success of circulatory support, ensuring its safe execution is paramount. Among the reported complications, vascular injury leading to bleeding was the most common issue. According to Hadano et al., the most common adverse events in ECMO are malposition, dislodgement, and bleeding [16]. To prevent misplacement, it is recommended that cannulation be performed under ultrasound guidance or fluoroscopic imaging.

In terms of the distribution of ECMO cases across facilities, the most common range was 1-5 cases per facility, followed by 6-10 cases. The majority of facilities handled 10 or fewer cases per year, which is far from sufficient in terms of procedural proficiency. Therefore, ongoing cannulation training and team-based scenario simulations for troubleshooting should be actively conducted.

Additionally, accidental decannulation incidents have been reported. To prevent such occurrences, it is essential to:

- Regularly check the fixation of cannulas to the skin,
- Ensure appropriate sedation levels for patients, and
- Confirm cannula positioning and circuit arrangement during patient repositioning while communicating among team members.

Effective multidisciplinary collaboration is crucial in ensuring the safety of cannulation procedures.

5. Incidents During Transport

A wide variety of issues can occur during ECMO transport or at the transport destination. To prevent decreased flow due to circuit kinking or accidental cannula dislodgement, it is crucial to assign specific roles in advance, such as an ECMO console operator and a cannula/circuit monitor, and to conduct thorough simulations among staff before transport.

To mitigate risks such as gas supply interruption or gas tube disconnection during oxygen source switching, a checklist should be implemented before and after transport. This checklist should include verifying the color of the arterial blood and ensuring adequate oxygen cylinder levels to help prevent these errors.

Fig.2 Examples of Hand Cranks Permanently Installed on the ECMO Unit (indicated by arrows)

Furthermore, battery depletion during transport has been reported. To ensure safe transport, it is essential to confirm battery levels beforehand, secure backup power sources, and carry a hand crank as an emergency precaution (**Fig.2**).

6. Measures to Address Incidents and Accidents

In Japan, there had long been no standardized safety guidelines for circulatory support, and each institution implemented its own safety management measures. However, in October 2016, JaSECT issued a recommendation titled "Safety Management Standards for Circulatory Support [18]," providing a clear direction for ensuring safety. Additionally, in May 2022, the JaSECT Academic Committee published a proposal on ECMO documentation and checklists on its website for members, facilitating the shared awareness of risks related to incidents and accidents.

As with CPB, the implementation and use of manuals and checklists, as well as the development and strict adherence to troubleshooting protocols, are essential for addressing incidents and accidents in circulatory support [19].

Regarding the use of checklists, the WHO Guidelines for Safe Surgery 2009 [20] emphasize key principles for their effective implementation: verbalizing concise, practical steps during use, starting small within teams before expanding their application, and revising lists while tracking changes and improvements. These principles are applicable to all checklist-based workflows.

Globally, ECMO training primarily consists of hands-on programs at large ECMO centers and simulation-based courses in dedicated training facilities [21]. In Japan, following the launch of the ECMO Project in 2012, a nationwide, multidisciplinary, structured training course called the ECMO Simulation Lab was established [22], and currently, the NPO Japan ECMOnet hosts ECMO workshops. Understanding the importance of troubleshooting training and actively engaging in it is essential for all institutions.

Regarding the number and incidence rate of incidents and accidents, the 2021 survey identified 46 cases of accidents (patient impact level 3b-5) over two years among 12,179 cases (1 in 265 cases, 0.4%) and 224 cases of incidents (patient impact level 1-3a) (1 in 54 cases, 1.8%).

In comparison, the 2019 survey, which covered 11,336 cases, reported 50 accidents (1 in 220 cases, 0.4%) and 289 incidents (1 in 39 cases, 2.6%). The 2017 survey, which included 10,445 cases, recorded 37 accidents (1 in 282 cases, 0.4%) and 215 incidents (1 in 49 cases, 2.1%).

Internationally, a study by Kim et al. [23] reported a 4.0% incidence rate of mechanical complications over ten years in 549 ECMO cases, with accidental

cannula dislodgement being the most common issue (1.3%). Additionally, the ELSO registry reported that mechanical complications in the respiratory support group were primarily related to cannulas (17.0% in adults, 13.0% in pediatric patients) and oxygenator failures (18.4% in adults, 15.7% in pediatric patients) [24]. However, since these reports focus on mechanical complications specifically, direct comparison with Japanese data is challenging.

In the 2021 CPB survey [1], which covered 78,397 cases over two years, there were 23 accidents (patient impact level 3b-5), with an incidence rate of 1 in 3,408 cases (0.03%), and 437 incidents (patient impact level 1-3a), with an incidence rate of 1 in 179 cases (0.56%). Compared to CPB, circulatory support showed a higher rate of incidents and accidents. Although these figures cannot be simply compared, contributing factors may include limited institutional experience with cases, the prolonged duration of circulatory support in some cases, and differences in skill levels among different medical professions, affecting the ability to respond to problems.

New devices, techniques, and procedures are expected to emerge in the circulatory support field as new knowledge is acquired. If safety measures remain static, they may become inadequate. Therefore, it is crucial to continuously update information to ensure that safety standards do not become obsolete.

In recent years, the dissemination of knowledge and awareness regarding incidents and accidents in medical practice has been actively promoted by related academic societies, government agencies, and healthcare institutions. By ensuring that incidents are not ignored and are instead analyzed and shared across professions, healthcare providers can help prevent severe accidents that could significantly impact patients. This approach will ultimately enhance trust in the safety of circulatory support.

V. Conclusion

Using data from the 2021, 2019, and 2017 JaSECT Questionnaire Survey on Incidents, Accidents, and Safety in Cardiopulmonary Bypass and Circulatory Support, this study examined safety measures in circulatory support. By utilizing these findings as a resource for addressing incidents and accidents at individual institutions, this study aims to contribute to ensuring patient safety. Additionally, continuous surveys and further data collection will be necessary to enhance safety management in circulatory support.

The authors declare that they have no COI.

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