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Incidence of Adverse Events Associated With the In-Hospital Transport of Critically III Patients

IMPORTANCE: Despite various reports on the incidence of adverse events related to the in-hospital transport of critically ill patients, there is little verification of the correlation between the occurrence of adverse events and the use of checklists. The risk factors for the occurrence of adverse events during transport based on the use of checklists have not been well studied. Understanding them can contribute to making patient transport safer.

OBJECTIVES: We aimed to investigate the frequency of adverse events and risk factors related to the in-hospital transport of critically ill patients in a hospital that uses a checklist for transporting patients.

DESIGN, SETTING, AND PARTICIPANTS: This single-center, prospective, observational study was conducted between February 1, 2020, and July 31, 2020, at Kobe City Medical Center General Hospital, Japan. Patients greater than or equal to 18 years old who were admitted to the ICU and were transported for examination or procedures were included.

MAIN OUTCOMES AND MEASURES: The transport member recorded patient information and any adverse events that occurred and filled out an information collection form. We then applied multivariate analysis to identify risk factors.

RESULTS: A total of 117 transports for 117 patients were evaluated in this study. Twenty-two adverse events occurred in 20 transports (17.1%). There were nine transports (7.7%) in which the patients required treatment, all of which were related to patient instability. Multivariate logistic regression analysis showed that the use of sedative drugs was related to adverse events (odds ratio, 2.9; 95% CI, 1.0-8.5; p=0.04). We were not able to show a relationship of either the severity of the illness or body mass index with the occurrence of adverse events.

CONCLUSIONS AND RELEVANCE: This study revealed that the frequency of adverse events related to the in-hospital transportation of critically ill patients based on the use of a checklist was 17.1% and that the use of sedatives was associated with adverse events.

KEY WORDS: adverse event; check list; in-hospital transport; patient safety; risk factor; sedative drug

ritically ill patients in the ICU are often transported within the hospital for examinations and procedures. In-hospital transport is associated with the occurrence of adverse events. According to previous reports, the incidence of adverse events related to the in-hospital transport of critically ill patients ranges from 37.4% to 79.9% (1–4). In addition, patient-related risk factors contributing to the occurrence of adverse events during in-hospital transport have been reported, including high illness severity scores (1, 2), ventilation with positive end-expiratory pressure (PEEP) greater than or equal to 6 (3), sedation before in-hospital transport (2, 3, 5), antihypertensive drugs (5), and body weight (2).

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In some countries, the formulation of guidelines or checklists for the in-hospital transport of critically ill patients is recommended (6–9), but there are few studies on the occurrence of adverse events based on the use of checklists (10, 11). There are few studies investigating the risk factors for the occurrence of adverse events using the checklists as well. Understanding the incidence of adverse events when using the checklists, and what precautions, in addition to the checklists, would make patient transport safer, would be useful to further improve patient safety.

The purpose of this study was to determine the occurrence of adverse events and to quantitatively validate the associated risk factors by using checklists for in-hospital transport of critically ill patients in the ICU.

METHODS

Study Setting

This single-center, prospective, observational study was conducted at Kobe City Medical Center General Hospital (KCMCGH), Japan, a 768-bed tertiary referral center with 22 ICU beds, divided into eight medical ICU, six cardiac care unit (CCU), and eight surgical ICU beds. Approximately 1,400 patients are admitted to the ICU annually. Intensivists consist of attending physicians, clinical fellows, and senior residents. Most ICU patients are managed by intensivists (closed ICU), while neurosurgery and cardiology patients are managed by the physicians in charge who are not working as intensivists (open ICU). There are two criteria for selecting transport members (Supplementary Table 1, http://links.lww.com/CCX/A944): 1) a doctor always accompanies the transport of mechanically ventilated patients and 2) nurses attend all patients' transports. These criteria are consistent in all ICUs. At our hospital, no specific training is provided for the members who accompany the transports. The transports are conducted by nurses and intensivists with several years of experience. Since April 2015, before initiating the transport of a mechanically ventilated patient, transport members conduct a briefing using a checklist. To improve safety, the following items are included in the checklist: check the remaining amount of oxygen in the oxygen cylinders before transport, share the respiratory management method during transport among transport members, check the patient monitoring device, bring along emergency drugs and check the route

of drug administration, and check the fixation of internal insertions (**Supplementary Fig. 1**, http://links.lww.com/CCX/A944). The medical ICU, CCU, and CT scan are located on the first floor, while the surgical ICU and CT scan are located on the fourth floor. MRI is located on the first floor, away from each ICU. The angiography room is located on the first floor, near the medical ICU and CCU.

Study Protocol

This was a single-center, prospective, observational study. The research plan was prepared in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.

The Ethics Committee of the Institutional Review Board for KCMCGH approved the study design (approval number zn200120). The need for written informed consent from patients was waived due to the noninterventional nature of the study.

The observation period was from February 1, 2020, to July 31, 2020.

Patients greater than or equal to 18 years old who were admitted to any ICU or CCU during the study period were included. Patients who were transported for either an examination or a procedure, those who left the ICU and returned, and those who required monitoring during transport were included. All consecutive eligible patient transports were investigated. If a doctor was among the transport members, the doctor completed the information collection form (**Supplementary Fig. 2**, http://links.lww.com/CCX/A944) before the transport; otherwise, the nurse did so.

As soon as the patient left the ICU, the time required for transport was recorded (transport time). During transport, the occurrence of adverse events described in the information collection form was monitored. For patients undergoing examinations, transport time included the examination time. However, for patients undergoing procedures, the time spent during the procedure was not included. After returning to the ICU and preparing the patient's environment, the remaining portion of the information collection form, that is, events and vital signs, was completed. If an adverse event occurred and intervention was required unexpectedly, it was recorded on the sheet. The degree of influence of the events that occurred was classified in accordance with the classification of the National University Hospital Medical Safety Management

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Council (**Table 1**) [https://www.fmu.ac.jp/byoin/new/sosiki/25houkokukennsuu.pdf]. Under this classification, events greater than or equal to level 3a were considered serious adverse events. Occurred adverse events were categorized as follows: patient instability, intravascular device-related events, equipment-related events, and delays and communication errors. Details of the categories are provided in **Supplementary Table 2** (http://links.lww.com/CCX/A944).

The following patient data were obtained from the electronic medical records at a later date: height; body mass index (BMI); severity of patient's illness (Acute Physiology and Chronic Health Evaluation [APACHE] II score, Sequential Organ Failure Assessment score, and Simplified Acute Physiology Score II score); diagnosis; number of days since hospitalization; number of days since ICU admission; medications (vasopressor, sedatives, analgesics, and antihypertensive drugs); internal devices (peripheral venous line, central vein catheter, vascular access, arterial line, gastric tube, urinary catheter, and drainage tube); blood gas analysis report before transport (pH, Paco₂, bicarbonate, and lactate); and vital signs before and after transport (heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, and percutaneous oxygen saturation).

Statistical Analyses

Since this study was observational, we did not perform a statistical sample size calculation a priori, but attempted to collect data for 120 transports, according to previous methodology (1–3). In addition, considering the frequency of transporting critically ill patients in our

hospital, we set the observation period to 6 months. For multiple transports of the same patient, we collected data for only the first transport. We considered that experience with previous transfers would have a moderating effect on the occurrence of adverse events in subsequent transfers. Nominal variables are expressed as values and percentages. Continuous variables are expressed as medians (interquartile ranges). The chi-square test (or Fisher exact test) for the nominal variables and the Mann-Whitney U test for continuous variables were used to assess the relationships between patient characteristics and the adverse event occurrence. Dunn test with Bonferroni correction was used for multiple comparisons of the severity of illness among groups categorized according to the composition of the transporting team. Subsequently, to assess the relationships between patient characteristics and the occurrence of adverse events, multiple logistic regression analysis was used for the predetermined variables, including sedatives, illness severity, and BMI. All p values were two-tailed. p values of less than 0.05 were considered statistically significant. All data were analyzed using JMP 16.0 (SAS Institute, Cary, NC).

RESULTS

Patient Characteristics

A total of 117 transports for 117 patients were evaluated in this study. In 109 cases (93.2%), the transports were for examinations, while for the remaining eight cases, the transports were for procedures. Patient characteristics are shown in **Table 2**. Median patient age was 69 years (58–79 yr) and 67 transports were performed

TABLE 1.Classification of Adverse Events

Level	Comments			
0	There was an error or defect in the drugs or equipment, but they did not affect the patient.			
1	The errors affected the patient, but there was no real harm. No observation or examination was required.			
2	Harm. Transient and mild. Examination and observation were required, but no treatment or intervention was needed.			
За	Harm. Transient and moderate. A simple procedure or treatment was required (e.g., wound washing, compression application, suturing of skin, or administration of painkillers).			
3b	Harm. Transient and severe. An advanced procedure or treatment was required (e.g., major changes in vital signs, fracture, mechanical ventilation, surgery, or extended hospital stay).			
4a	Harm. Persistent and mild to moderate. Permanent sequelae, but no significant functional impairment or cosmetic issues.			
4b	Harm. Persistent and moderate to severe. Permanent sequelae and significant functional impairment or cosmetic issues.			
5	Death.			

TABLE 2.Patient Characteristics

Patient Characteristics	Transport With Adverse Events (n = 20)	Transport Without Adverse Events (n = 97)	All Transport (<i>n</i> = 117)	p
Age, yr, median (IQR)	70.5 (57.8–78.0)	69.0 (57.5-80.0)	69 (58.0-79.0)	0.92
Sex, n (%), male	9 (45.0)	58 (59.8)	67 (57.3)	0.22
Body mass index, median (IQR)	23.0 (19.6-26.1)	22.7 (19.8-25.9)	22.8 (19.8-26.0)	0.72
Acute Physiology and Chronic Health Evaluation II, median (IQR)	19.0 (11.3–25.3)	22.0 (16.8–28.0)	21.0 (16.0–27.1)	0.07
Diagnosis, n (%)				0.52
Stroke	7 (35.0)	35 (36.0)	42 (35.9)	
Septic shock	1 (5.0)	16 (16.5)	17 (14.5)	
Acute respiratory failure	4 (20.0)	7 (7.2)	11 (9.4)	
Trauma	2 (10.0)	9 (9.3)	11 (9.4)	
Cardiopulmonary arrest	2 (10.0)	4 (4.1)	6 (5.1)	
Post-cardiovascular surgery	1 (5.0)	10 (10.3)	11 (9.4)	
Purpose of transportation				
Examination, n (%)	18 (90.0)	91 (93.8)	109 (93.2)	0.54
СТ	17	89	106	
MRI	1	4	5	
Others	0	1	1	
Procedure, n (%)	2 (10.0)	6 (6.2)	8 (6.8)	0.80
Endovascular treatment	1	1	2	
Others	1	5	6	
Transport member, n (%)				0.53
With an intensivist	12 (60.0)	55 (56.7)	67 (57.3)	
With a nonintensivist ^a	4 (20.0)	23 (24.7)	27 (23.1)	
Only nurses	4 (20.0)	19 (19.6)	23 (19.7)	
Transport time for examination (min), median (IQR)	14.5 (8.2–30.2)	12.1 (9.7–18.1)	12.4 (9.7–18.8)	0.39
Devices, n (%)				
Peripheral venous line	19 (95.0)	93 (95.9)	112 (95.7)	0.98
Central venous catheter	2 (10.0)	9 (9.3)	11 (9.4)	0.91
Vascular access	2 (10.0)	21 (21.6)	23 (19.7)	0.23
Arterial line	15 (75.0)	69 (71.1)	84 (71.8)	0.72
Gastric tube	14 (70.0)	68 (70.1)	82 (70.1)	0.99
Urethral catheter	17 (85.0)	76 (78.4)	93 (79.5)	0.50
Drainage tube	5 (25.0)	19 (19.6)	24 (20.5)	0.58
Mechanical ventilation in ICU ^b , n (%)	14 (70.0)	59 (60.8)	73 (62.4)	0.77
Manual ventilation during transport	13	56	69	0.67
Drugs, n (%)				
Vasopressor	7 (35.0)	26 (26.8)	33 (28.2)	0.46
Sedative	10 (50.0)	28 (28.9)	38 (32.5)	0.06
Analgesics	10 (50.0)	35 (36.1)	45 (38.5)	0.24
Antihypertensive	2 (10.0)	16 (16.5)	18 (15.4)	0.46

IQR = interquartile range.

^aNeurosurgeon or cardiologist.

^bAll of them used endotracheal tubes.

for men (57.3%). Median BMI was 22.8 (19.8–26.0). Median APACHE II score was 21 (16–27). There were no significant differences between those with or without adverse events in age, sex, BMI, or APACHE II score.

Stroke was the most frequent diagnosis (35.9%) at the time of ICU admission, followed by sepsis (14.5%), acute respiratory failure (9.4%), trauma (9.4%), postoperative cardiovascular surgery (9.4%), cardiopulmonary arrest (5.1%), and other diagnoses (16.3%). There were no significant differences in the diagnoses between the groups with and without adverse events. Vital signs before and after transportation and the results of the blood gas analysis are shown in **Supplementary Table 3** (http://links.lww.com/CCX/A944).

Transport and Internal Devices

Intensivists accompanied 67 transports, nonintensivists (neurosurgeons and cardiologists) accompanied 27 transports, and only nurses accompanied 23 transports. The median APACHE II score in the group of patients who were accompanied by an intensivist was 23.0 (17.0–29.5), which tended to be higher than those in the other two groups (18.0 [13.8–24.3], p = 0.05 in the nonintensivists group; 19.5 [16.3–23.8], p = 0.11 in the nurse-only group) (**Supplementary Fig. 3**, http://links.lww.com/CCX/A944).

There was no significant difference in the transport time for examination between the groups with and without adverse events (14.5 vs 12.1 min; p = 0.16) (Table 2). Almost all transports involved intravascular devices. The peripheral venous catheter was the most frequent intravascular device (95.7%), followed by the arterial line (71.8%), vascular access (19.7%), and central venous catheter (9.4%). Other internal devices included urinary catheters (79.5%) and gastric tubes (70.1%). There was no significant difference in the number of intravascular devices between the groups with and without adverse events (3.5 vs 3.0; p = 0.16) (Supplementary Table 3, http://links.lww.com/CCX/A944).

Treatment

A total of 73 patients (62.4%) were receiving mechanical ventilation with endotracheal intubation in the ICU. Of these, four were also receiving mechanical ventilation during transport, and the remaining 69 were receiving manual ventilation with a bag-valve mask (flow-inflating bag) during transport.

A total of 82 transports (70.1%) were performed for patients receiving continuous IV infusion; of these, 38.5% (45) were for analgesics, followed by 32.5% for sedatives, 28.2% for vasopressors, 15.4% for antihypertensive drugs, and 12.0% for other drugs. The use of sedatives tended to be higher in the group of patients with adverse events than in those without adverse events (50.0% vs 28.9%; p = 0.06) (Table 2).

Adverse Events

Among the 117 transports, 22 adverse events occurred in 20 transports (17.1%). Patient instability was the most frequent event (54.5%), followed by intravascular device-related events (18.2%), equipment-related events (13.6%), and delays and communication errors (4.5%) (**Fig. 1**). Of the 20 transports with adverse events, serious adverse events (\geq level 3a) occurred in nine transports (7.7%). There were no cases of cardiopulmonary arrest or death during transport (**Fig. 2**). All serious adverse events were attributed to patient instability, with hypoxemia as the most frequent event (**Fig. 3**).

Multivariate logistic regression analysis with predetermined variables (sedative, illness severity, and BMI) was performed to identify factors associated with an increase in adverse events in critically ill patients during transport. However, due to missing data, only data from 109 of the 117 transports were included. Subsequently, only sedatives were found to be related to adverse events (odds ratio [OR], 2.9; 95% CI, 1.0-8.5; p = 0.04) (**Table 3**).

DISCUSSION

The frequency of adverse events related to in-hospital transport of critically ill patients in our hospital, which uses a transport checklist for mechanically ventilated patients, was 17.1%, and the use of sedatives was related to adverse events.

Rates for adverse events, which range from 37.4% to 79.9%, are higher than that reported in this study (1–4). Variation in the incidence in previous studies can be attributed to different criteria considered for adverse events. For example, Jia et al (2) considered delay in arrival at destination as an adverse event, while Parmentier-Decrucq et al (3) did not. In our study, the types of adverse events that were collected were determined according to previous methodology (1–4);

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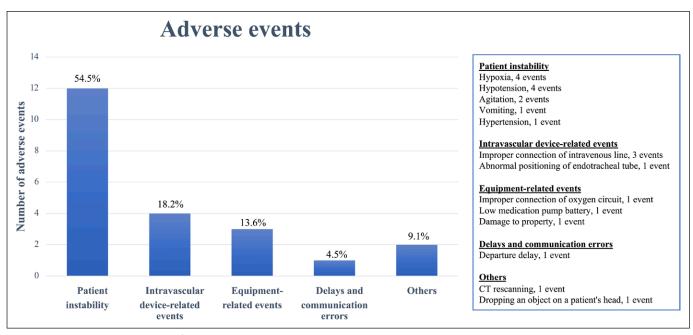


Figure 1. Adverse events. Details for each category in the right box.

therefore, it is unlikely that the number of adverse events was underestimated.

The method of collecting adverse events also differed among the studies. One study included a team specialized in collecting information in addition to the members who transported and treated the patients (1). Furthermore, Jia et al (2) reported that changes in vital signs during transport were automatically recorded every 5 minutes, which increased the number of adverse events collected. Thus, the method of collecting

adverse events (frequency and accuracy of monitoring and whether the information collectors were independent) also contributed to the variability in the reported incidence of adverse events. In our study, the transport members collected the information on the adverse events during their own transports. They were aware of being observed, which may have reduced the incidence of adverse events, due to the Hawthorne effect and reporting bias. However, changes in vital signs during transport were not automatically moni-

tored and may have been overlooked.

The severity of patient's illness and proportion of intubated patients in this study were comparable to those in previous studies (Supplementary Table 3, http://links.lww.com/CCX/A944). This may not mean that the lower severity of the patients' condition in our study resulted in a lower frequency of adverse events (1–4).

The incidence of adverse events preventable by the checklist in this study was less than that in

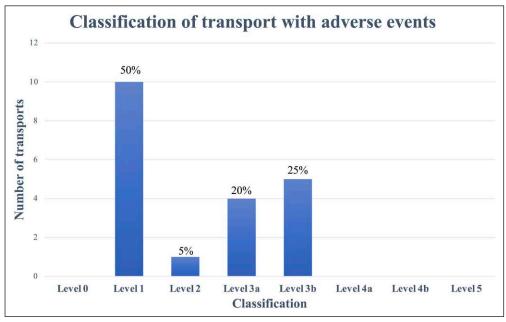


Figure 2. Classification of transport with adverse events.

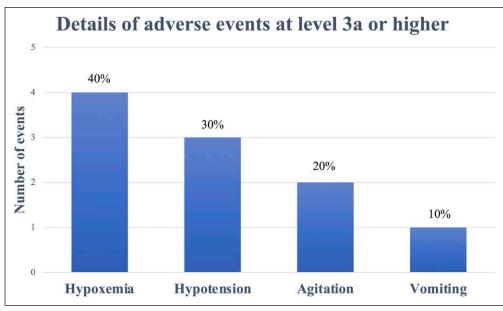


Figure 3. Details of adverse events at level 3a or higher.

previous studies: obstruction and inappropriate connection of the peripheral venous lines in three cases (2.7% [number of cases/total number of transports]), abnormal positioning of the endotracheal tube in one case (0.9%), inappropriate connection of the respiratory circuit in one case (0.9%), and insufficient battery level for the syringe pump in one case (0.9%) (1-3). Other preventable adverse events that were reported in previous studies, such as low oxygen cylinder levels, did not occur in this study (1-3). In our study, the use of a checklist may have suppressed the identification of the occurrence of adverse events and may be the reason for the lower overall frequency of adverse events. Previous studies have reported that checklists reduce adverse events. In the ICU, checklists and briefing reduced the incidence of adverse events from 1.08% to 0.17% (p = 0.01) (11). Furthermore, in the emergency department, checklists reduced the incidence of adverse events from 36.8% to 22.1% (p = 0.001) (12).

TABLE 3.Multivariate Logistic Regression Analysis

Variable	OR (95% CI)	p
Sedative	2.9 (1.0-8.5)	0.04
Body mass index	0.98 (0.87-1.09)	0.68
Acute Physiology and Chronic Health Evaluation II	0.94 (0.88–1.02)	0.11

OR = odds ratio.

Among the adverse events, patient instability is difficult to prevent because it is caused by the patient's general condition. Hypoxemia was most observed in this study (four cases, 3.4%). The proportion of patients with a diagnosis of acute respiratory failure tended to be higher in the group with adverse events (20% vs 7.2%; p = 0.07). Three of the four patients with hypoxemia were intubated, and manual ventilation was used during transport.

Unlike mechanical ventilation, appropriate PEEP management may not have been performed. In addition to the adverse effects of the acute respiratory failure on oxygenation and ventilation, hypoxemia may be attributed to the manual ventilation (inadequate PEEP management) provided for transport.

In this study, we investigated the risk factors for the occurrence of adverse events. The use of sedatives was associated with the occurrence of adverse events (OR, 2.9 [1.0–8.5]), similar to previous studies, but there are insufficient explanations on this association (2, 3, 5). In the study by Jia et al (2), agitation and anxiety were observed in 25% of transports, and pain, discomfort, and resistance to the ventilator were observed in 19% of transports. These were attributed to inappropriate sedation management (insufficient sedation) (2). In addition, sedatives have a circulatory depressant effect, and excessive sedation may also affect the hemodynamics of patients. We were not able to show that there was more agitation or hypotension in patients who received sedatives. Patients receiving continuous sedation are often mechanically ventilated. The endotracheal tube inhibits the closure of the glottis, preventing the patient from coughing effectively. These may result in tube obstruction by sputum and impaired ventilation during transport (13). In addition, sedatives can attenuate the cough reflex. In addition to the effects of sedative itself, the condition of patient requiring sedatives, such as mechanical ventilation, may also be associated with the occurrence

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of adverse events. Sedatives were administered to 38 patients, 37 of whom were receiving mechanical ventilation. However, there was no significant difference in the proportion of mechanically ventilated patients in the groups with and without adverse events. Although our results indicate that the use of sedatives could be a risk factor for adverse events, it was not possible to infer the reason from the data obtained. With a greater number of observations, we may be able to identify trends in patients using sedatives.

To prevent adverse events secondary to sedative use, we believe that it is important to practice appropriate sedation management without excessive or deficient sedation, have a good understanding of the condition of patients who require sedation management, and be well prepared for related changes in condition. For example, the depth of sedation should be checked, and if necessary, deepened, to prevent agitation. Deeper sedation is more likely to result in circulatory depression, thus vasopressors may be needed.

BMI and severity of illness were also investigated using multivariate analysis, to determine factors associated with the occurrence of adverse events. Only one study has examined physique in relation to body weight (2); it reported that transporting patients who weighed more than 65 kg involved a significantly increased risk of adverse events compared with transporting patients who weighed less than 65 kg (OR, 1.95 [1.30-2.94]). Physiologic changes such as decreased expiratory reserve and functional residual capacity make obese patients more prone to hypoxemia (14). Although body weight is directly related to transport difficulties, we examined BMI in this study because we believe that BMI influences changes in the physiologic status of patients more than body weight. However, we did not detect an association between BMI and the incidence of adverse events in this study. Most of our patients were normal weight or mildly obese, and it may be that we could not show an association in that patient group. For patients with greater obesity, the impact of physiologic changes may be greater, and there may be an association with the occurrence of adverse events.

Our results did not demonstrate an association between the severity of patient's illness and the occurrence of adverse events. Some studies have shown that the severity of patient's illness is associated with the occurrence of adverse events (1, 2). The risk of adverse events was significantly increased in patients with an APACHE

II score of 20 or higher than in those with an APACHE II score of 11 or lower (OR, 2.49 [1.23-5.03]) (2). In this study, the severity of illness tended to be higher in patients who were accompanied by intensivists (Supplementary Fig. 3, http://links.lww.com/CCX/ A944). Furthermore, it has been reported that the experience of the transporting physician is associated with decreased adverse events (emergency physicians [130 adverse events per 100 transports] vs junior residents [221] and senior residents [171]; p < 0.01) (4). Intensivists who accompanied the patient transports in this study were experienced enough to be able to respond to changes in the patient's condition and to anticipate and prepare for possible adverse events. Accompanying intensivists on the transport of more severely ill patients (higher-risk of adverse events) may experience reduced occurrence of adverse events. Therefore, association between the severity of patient's illness and occurrence of adverse events may not have been demonstrated.

There were several limitations to this study. First, results may have been influenced by a variety of information biases. As mentioned earlier, the Hawthorne effect and reporting bias may have led to an underestimation of the occurrence of adverse events. Although it may be difficult to blind the transporter, it may have been possible to reduce the reporting bias if the transporter and observer had been separated.

Second, the sample size was small, which may have prevented detection of differences between the groups. More accurate assessment of risk factors might be possible with an extended observation period and increased sample size.

Third, there is the issue of the study design. Based on the comparison with previous studies, we consider that the checklist reduced preventable adverse events; however, this was insufficient. A before-and-after comparative study is the appropriate study design.

Fourth, the study was conducted at a single institution. The circumstances surrounding patient transport, such as the location of hospital facilities, staffing (transport members), severity of the patients' illness, and patients' BMI in the community, vary among hospitals. Since the items on the checklists must be based on the occurrence of adverse events at the facility where it is used and the environment in which the transport is performed, it may be difficult to immediately use the same items at other facilities. It is important to create

checklists based on the circumstances of the facilities as described above and to educate healthcare professionals on the necessity of such checklists.

Finally, this study covered several adverse events, some of which were less harmful to the patients. In the future, studies that focus only on events that require intervention are warranted, and their findings may be easier to implement, clinically.

CONCLUSIONS

In this single-center, prospective, observational study, the frequency of adverse events related to in-hospital transport of critically ill patients was 17.1% in a hospital using a mechanical ventilation patient transport checklist. This result is lower than the incidence of adverse events in previous literature. We also found that the use of sedatives was associated with the occurrence of adverse events even when the checklist was used. However, it was impossible to suggest why sedatives are a risk factor. Investigating the occurrence of adverse events and risk factors based on the use of checklists will contribute to further improving patients' safety during transport. It is important that further research is conducted and the findings used to improve transportation safety.

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Drs. Nonami and Kawakami mainly participated in study conception, design, and execution. Drs. Nonami, Ito, Ouchi, Miyoshi, Tatebe, and Tsuchida were responsible for data collection. Dr. Nonami sorted the data, performed the statistical analyses, wrote the article, and produced the tables and figures. All the authors participated in data interpretation, revised the article for important intellectual content, and approved the final version of this article.

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