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Impact of Intensive Care Unit Physician on Care Processes of Patients with Severe Sepsis in Teaching Hospitals

Takeshi Umegaki, Miho Sekimoto and Yuichi Imanaka*

Department of Health care Economics and Quality Management, Kyoto University Graduate School of Medicine, Kyoto, Japan

Abstract

Objective: The purpose of the study was to investigate associations among intensive care unit (ICU) staffing and care processes in patients with severe sepsis.

Design: An observational multicenter cross-sectional study performed from October 2007 to March 2008.

Setting: Forty-nine teaching hospitals in Japan.

Participants: Patients (n=576) with severe sepsis identified using ICD-10 codes from administrative data.

Main outcome measures: Care processes including mechanical ventilation, dialysis, enteral feeding, parentetal nutrition, and antibiotic empirical therapy which were available in administrative data.

Results: ICUs were classified as high- or low-intensity based on policies regarding the responsibilities of intensivists. There were no differences in baseline patient characteristics between the ICU groups. In the high-intensity group, ICU stay for survivors was about two days shorter and hospital stay was significantly shorter by three days. Majority of patients had high rates of enteral feeding; however, the high-intensity group had significantly earlier initiation of enteral feeding and a significantly shorter duration of mechanical ventilation. A shorter duration of mechanical ventilation was significantly associated with the ICU structure.

Conclusions: The results showed an association between ICU physician and processes of intensive care, and high-intensity ICU was aggressive in mechanical ventilation in patients with severe sepsis.

Keywords: Intensive care unit; Sepsis; Structure; Care process; Multicenter study

Introduction

Patients in the intensive care unit (ICU) require complex care relating to a broad range of acute illnesses and pre-existing conditions. The innate complexity of the ICU makes organizational structuring of care an attractive quality measure and a target for performance improvement strategies. In other words, organizational features relating to medical and nursing leadership, communication and collaboration among providers, and approaches to problem-solving may capture the quality of ICU care more comprehensively than do practices related to specific processes of care.

Many authors have shown wide variations in mortality in ICU, which may have developed studies on the associations between ICU organizations and outcomes. There is many patterns in ICU organization, [3,42] and it seemed that differences in ICU organization associated with patient outcomes. For instance, ICU staffings focused on the role of intensivists in critical care units.

The relationship between the role of intensivists and outcomes has been examined since the 1980s. A number of studies have shown that staffing the ICU with intensivists has a beneficial impact on outcomes. [2-16] A recent multicenter retrospective study using a large database of critically ill patients, however, showed that hospital mortality was higher for patients managed by ICU physicians. [17] Intensivists may improve clinical outcomes, but these paradoxical results may be due to differences in patient characteristics and methodology among these studies.

Although indicators such as morbidity and mortality have been used as performance measures of intensive care, it is usually difficult to assess performance of ICUs by simply using of crude mortality, since clinical conditions of patients (i.e., as patient characteristics, diseases, and severity of illness) are quite different between them. Therefore, risk adjustment mortality has been used in ICU outcome study. Clear findings regarding associations between ICU staffings and outcomes, however, have not been gained yet, and it has been desirable to assess ICU structure and care processes to achieve further opinion about ICU performance. [14,11,13] Kahn et al. [26] demonstrated that evidence based approach was associated with the role of intensivists in the ICU. Intensivists may have important role for processes affecting to patient outcomes. We hypothesize that staffing ICUs with critical care physicians (intensivists) have significant association with care processes in intensive care units. In this study, we investigated the effect of ICU physicians on care processes, which were available in administrative data, in patients with severe sepsis. In this study, we used large administrative database of Japan, which is called “Diagnosis procedure combination (DPC)” data introduced in Japanese medical payment system since 2002 [43].

***Corresponding author:** Yuichi Imanaka, Department of Healthcare Economics and Quality Management, Kyoto University Graduate School of Medicine, Yoshida Konoe-cho, Sakyo-ku, Kyoto 606-8501, Japan, Tel: +81-75-753-4454; Fax: +81-75-753-4455; E-mail: imanaka-y@umin.net

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Materials and Methods

Setting

All data were extracted from the Quality Indicator / Improvement Project (QIP). The QIP collects Japan's administrative healthcare data (Diagnosis Procedure Combination data; DPC data) from hospitals and analyzes numerical indices of the healthcare process, patient outcomes, and management efficiency and provides feedback to participating establishments. Administrative data were comprised of clinical information and healthcare claim data. Clinical information included patient demographics, primary and secondary diagnoses, comorbidities at the time of and after admission, operative data, severity of illnesses, as well as any special treatments (i.e., radiation therapy, artificial respiration, chemotherapy). In contrast, healthcare claim data itemized the type, quantity, and fees for all tests, medications, procedures, use of intensive or specialized care, and nursing services.

At the time of the study, one hundred and eight medical institutions voluntarily participated. Among these institutions, we selected 70 teaching hospitals with ICU, which accounted for approximately 10 % of all teaching hospitals in Japan. In November 2008, we sent questionnaires to the directors of these 70 hospitals, with a request for information on ICU management to be provided by the physician responsible for intensive care.

Organizational model

For consistency with previous studies, [2] if the ICU physicians had primary responsibility or mandatory critical care consultation (the intensivist is the patient's primary attending physician or the intensivist is not the patient's primary attending physician, but every patient admitted to the ICU receives a critical care consultation), the ICU was defined as a high-intensity ICU. In contrast, if the ICU physicians had elective critical care consultation or no critical care physician (the intensivist is involved in the care of the patient only when the attending physician requests a consultation or intensivists were unavailable), the ICU was defined as a low-intensity ICU. An intensivist was defined as a physician with a primary appointment in the ICU.

Patient characteristics

All patients who were treated for severe sepsis in ICUs in the studied hospitals between October 1, 2007, and March 31, 2008 were included in the study. Severe sepsis was defined based on the sepsis-related ICD-10 code and coding for single or multiple organ failure (Table 1). Organ failure was based on Martin's study, [18] and ICD9-clinical modification (CM) codes were converted to ICD-10 codes. We excluded ICUs with less than 5 patients of severe sepsis. Patients younger than 20 years of age and those hospitalized for more than 60 days were also excluded from the analysis, since patients with extremely long hospitalization might involve social problems such as the lack of an available nursing home.

Patient characteristics were identified from administrative data. The administrative data included clinical information such as patient demographics, diagnoses, comorbidities at the time of and after admission, operative data, and treatment (radiation therapy, mechanical ventilation, chemotherapy). Age, gender, and reasons for ICU entry were recorded for all patients. To evaluate severity, the expected mortality was calculated using the Critical care Outcome Prediction Equation (COPE). [19] The COPE model uses information from standard administrative data and is a robust, risk-adjusted hospital mortality prediction tool. And we showed that the COPE model had good performance for ICU patients in Japan [20].

Care processes evaluation

Measures for process of care were selected among quality indicators for intensive care that are associated with outcomes and available in administrative data. [21-24] for patients under mechanical ventilation, non-invasive positive pressure ventilation was excluded. Dialysis included continuous renal replacement therapy, intermittent renal replacement therapy, plasma absorption, and plasma exchange, but excluded peritoneal dialysis since this is rarely used for ICU patients. We also examined the initiation of antibiotic empirical therapy (defined as use of a carbapenem, a 3rd or 4th generation cephalosporin, or a combination of a β-lactam and an aminoglycoside [25]) during the ICU stay. Therefore, processes were evaluated based on the initiation of

Condition	Code	Organ failure	Code
Salmonella septicemia	A02.1	Respiratory	
Septicemic plague	A20.7	Acute respiratory failure	J96.0
Anthrax septicemia	A22.7	Adult respiratory distress syndrome	J80
Erysipelothrix septicemia	A26.7	Respiratory arrest	R09.2
Listerial septicemia	A32.7	Ventilator management	a
Streptococcal septicemia	A40	Cardiovascular	
Other septicemia	A41	Orthostatic hypotension	I95.1
Actinomycotic septicemia	A42.7	Cardiogenic shock	R57.0
Disseminated herpesviral disease	B00.7	Hypovolemic shock	R57.1
Candidal septicemia	B37.7	Septic shock	A41.9
Disseminated coccidioidomycosis	B38.7	Idiopathic hypotension	I95.0
Disseminated histoplasmosis capsulati	B39.3	Renal	
Disseminated blastomycosis	B40.7	Acute renal failure	N17
Disseminated paracoccidioidomycosis	B41.7	Acute nephritic syndrome	N00
Disseminated sporotrichosis	B42.7	Hemodialysis	a
Disseminated aspergillosis	B44.7	Hepatic	
Disseminated cryptococcosis	B45.7	Hepatic failure, not elsewhere classified	K72
Disseminated mucormycosis	B46.4	Hematologic	
Puerperal sepsis	O85	Disseminated intravascular coagulation	D65
		Purpura and other haemorrhagic conditions	D69
		Metabolic	
		Acidosis	E87.2
		Neurologic	
		Delirium, not induced by alcohol and other psychoactive substances	F05
		Anoxic brain damage, not elsewhere classified	G93.1
		Encephalopathy, unspecified	G93.4
		Coma, unspecified	R40.2

[a]Specific code for a universal fee schedule in Japan

Table 1: ICD-10 codes used for identification of septic patients and acute organ dysfunction.

	High-intensity group (n=234)	Low-intensity group (n=342)	P-value
Number of hospitals	19	30	
Number of patients	234	342	
Hospital background			
Number of beds in hospital	637.8±333.4	467.2±153.2	0.15
Number of ICU beds	12.7±9.9	5.8±4.6	0.01*
Number of intensivists per bed	0.4±0.3	0.3±0.4	0.62
Number of nurses per bed per day	1.8±0.9	1.7±1.1	0.72
Patient background			
Age	71.6±12.7	71.4±13.8	0.86
Gender (male %)	60.2	58.7	0.74
(female %)	79.8	41.3	
Admission course (%)			
Scheduled	12.3	12.9	0.85
Emergency	87.7	87.1	
Reason for ICU entry (%)			
Internal medical disease	57.4	44.6	
Post-emergency surgery	21.8	31.3	0.11
Post-scheduled surgery	20.8	24.1	
Processes of care			
Initiation of antibiotic empirical therapy during ICU stay (%)	86.3	85.4	0.89
(Carbapenem) (%)	52.1	52.6	0.51
(3rd or 4th generation cephalosporin) (%)	24.8	26.1	0.59
(Combination of a β-lactam and an aminoglycoside) (%)	9.4	6.7	0.48
Enteral feeding (%)	90.2	88.6	0.45
Timing of initiation of enteral feeding (days)	6.0±8.4	9.0±10.1	<0.01**
(Gastrointestinall diseases)	7.8±6.9 (n=68)	9.8±7.6 (n=129)	0.32
(Other diseases)	5.4±5.4 (n=166)	7.9±7.8 (n=213)	0.04*
Parenteral nutrition (%)	71.7	74.2	0.45
Timing of initiation of parenteral nutrition (days)	2.9±5.0	2.6±3.8	0.54
Mechanical ventilation (%)	67.2	65.6	0.69
Duration of mechanical ventilation (days)	7.5±7.3	11.5±10	<0.01**
Dialysis (%)	6.6	8.9	0.35
Times of dialysis	4.6±4.2	4.4±6.3	0.85
Outcomes			
Duration of hospital stay for survivors (days)	29.5±14.2 (n=111)	33.1±14.9 (n=162)	0.04*
Duration of hospital stay for non-survivors (days)	20.5±16.4 (n=123)	22.2±15.5 (n=180)	0.36
ICU duration of stay for survivors (days)	8.8±5.6 (n=172)	10.5±9.7 (n=267)	0.15
ICU duration of stay for non-survivors (days)	6.5±7.4 (n=62)	7.6±9.5 (n=75)	0.52
Expected mortality (%)	21.7±19.8	20.6±18.7	0.54
ICU mortality (%)	26.5	21.9	0.21
28-day mortality (%)	39.2	44.4	0.53
Hospital mortality (%)	47.4	45.9	0.73

[a]Continuous variable: mean ± SD; Categorical variable: percentage; *: $p < 0.05$, **: $p < 0.01$

Table 2: Hospital and patient backgrounds, processes and outcomes in ICU organizational structures[a].

empirical therapy, frequency and timing of enteral feeding, frequency and timing of parenteral nutrition, use of mechanical ventilation, duration of mechanical ventilation (days), dialysis, and times of dialysis. Monitoring of medical care on an hourly basis is not possible using administrative data, but data based on a calendar day were available. Thus, initiation of enteral feeding and parenteral nutrition therapy were defined with a baseline of the day of ICU entry. The duration of ICU stay and ICU mortality were determined as outcomes.

Statistical analysis

Continuous variables are presented as means ± standard deviations, and categorical variables as percentages. Analyses were performed using a Student t-test or one way analysis of variance for continuous variables and a χ-square test for categorical variables, with $P<0.05$ regarded as significant. To evaluate differences in process of intensive care between high- and low-intensity groups, Cox proportional hazards analysis or multiple logistic regression analysis were performed. Cox proportional hazards analysis used for continuous variables as independent variables. Multiple logistic regression analysis used for nominal variables. All analyses were performed using SPSS 11.0J (SPSS Inc., Chicago, IL). The Institutional Review Board of the Faculty of Medicine at the Graduate School of Medicine of Kyoto University approved the study.

Results

Fifty-two hospitals (74.3%) with ICUs responded to the questionnaire. Between October 1, 2007, and March 31, 2008, a total of 665,442 patients were discharged from these 52 hospitals, and among these patients, 609 (0.1%) patients with severe sepsis were identified. An initial analysis of 665,442 patients discharged from these 52 hospitals identified 609 (0.1%) patients of severe sepsis in ICU patients. Three of the 52 hospitals (5.8%) and 33 of the 609 patients (5.4%) met the exclusion criteria, leaving 576 (94.6%) patients in 49 hospitals for analysis. 52 hospitals in this analysis were general hospitals and had more than 300 beds.

Characteristics of organizations and patients

In 19 of the 49 hospitals (38.8%), the ICU physicians had primary responsibility or mandatory critical care consultation. In another 30 hospitals (61.2%), the ICU physicians had elective critical care consultation. All ICUs in the study had intensivists on staff.

The patients included 234 patients in 19 ICUs in the high-intensity group, and 342 patients in 30 ICUs in the low-intensity group. Patients were identified with an ICD-10 code: the most frequent code was A41 (other septicemia, 94.1 %), followed by A40 (streptococcal septicemia, 3.0%), and B37.7 (candidal septicemia, 2.3%). There were no significant differences in the hospital backgrounds except for the number of ICU beds (Table 2). The mean age of patients (about 71 years old), the percentage of male patients (approximately 60%), and the reasons for ICU entry did not differ significantly between the ICU groups. However, internal medical disease was significantly more frequent in the high-intensity group (57.4% vs. 44.6%).

Variable	Adjusted Relative Risk Measure (95 % CI)		
	Hazards Ratio or Odds Ratio	95 % CI	P-value
Duration of mechanical ventilation[a]	1.36	1.01-1.81	0.04*
Initiation of enteral feeding on ICU day 0[b]	0.87	0.54-1.41	0.57
Initiation of enteral feeding by ICU day 1[b]	0.96	0.58-1.60	0.87
Initiation of enteral feeding by ICU day 2[b]	1.17	0.68-2.02	0.58
Initiation of enteral feeding by ICU day 3[b]	1.15	0.64-2.04	0.65
Duration of hospital stay for survivors[a]	1.14	0.91-1.43	0.27

[a]Hazards Ratio
[b]Odds Ratio
*: p < 0.05, **: p < 0.01
CI: Confidence Interval
A Hards Ratio > 1 indicates a shorter duration of mechanical ventilation or shorter duration of hospital stay for survivors in high-intensity ICU.
The Odds Ratio indicates the incidence of enteral feeding for the low-intensity ICU versus high-intensity ICU

Table 3: Results of Cox proportional hazards analysis and multiple logistic analysis.

Care process evaluation in different icu physician staffing models

Associations between ICU groups and processes of care are shown in (Table 2). The initiation of antibiotic empirical therapy during the ICU stay (86.3% vs. 85.4%) and the frequency of use of each antibiotic therapy did not differ significantly between the high- and low-intensity groups. Most patients received enteral feeding and the frequency did not differ significantly between the two groups (90.2% vs. 88.6%, p=0.45). However, initiation of enteral feeding occurred significantly earlier in the high-intensity group (6.0 vs. 9.0 days, p < 0.01). Initiation of enteral feeding in patients with gastrointestinal diseases did not differ significantly between the two groups (7.8 vs. 9.8 days, p=0.32), but significantly earlier initiation of feeding in patients of non-gastrointestinal diseases occurred in the high-intensity group (5.4 vs. 7.9 days, p=0.04). The frequency (71.7% vs. 74.2%, p=0.45) and initiation time (2.9 vs. 2.6 days, p=0.54) of parenteral nutrition did not differ significantly between the two groups.

The frequency of mechanical ventilation in the high- and low-intensity groups did not differ significantly (67.2 vs. 65.6%, p=0.69), but the duration of mechanical ventilation was significantly shorter in the high-intensity group (7.5 vs. 11.5 days, p<0.01). The rate and times of dialysis did not differ significantly between the two groups. The mean duration of ICU stay was shorter by approximately 2 days for surviving patients in the high-intensity group (8.8 vs. 10.5 days, p=0.15; Table 2), whereas non-survivors had a similar ICU stay in the high- and low-intensity groups (6.5 vs. 7.6 days; p=0.52). The mean duration of hospital stay was significantly shorter for survivors in the high-intensity group (29.5 vs. 33.1 days, p=0.04), but did not differ significantly for non-survivors (20.5 vs. 22.2 days; p=0.36). There were no significant differences in ICU (26.5% vs. 21.9%, p=0.21), 28-day (39.2% vs. 44.4%, p=0.53), and hospital (47.4% vs. 45.9%, p=0.73) mortality between the high- and low-intensity groups.

Cox proportional hazards analysis or multiple logistic regression analysis

Cox proportional hazards analysis was used to examine the impact between both ICU groups on duration of mechanical ventilation, and on duration of ICU stay for survivors after adjusted for variables of severity of illness (expected mortality calculated from COPE model), age, sex, and the number of ICU beds. In duration of mechanical ventilation, patients were censored for death (n = 113) or long-term ventilator facility (n = 8). The high-intensity group was associated with a shorter duration of mechanical ventilation after adjusted to covariates (Hazards Ratio [HR] 1.36; 95 % CI 1.01 to 1.81; Table 3), but this study showed that duration of hospital stay for survivors had no significant impact on ICU structure (HR 1.14; 95 % CI 0.91 to 1.43; Table 3).

Multiple logistic regression analysis was used for the examination of the impact of ICU structure on initiation of enteral feeding after controlling for the variables by similar approach. The dependent variable in multiple logistic regression analysis was defined as initiation of enteral feeding on ICU day 0, day 1, day 2, and day 3, respectively, because the definition of timing of enteral feeding was controversial, which should be initiated as early as possible. ICU day 0 was defined as the day of entry into ICU. ICU structure was not related to the initiation of enteral feeding by ICU day 3 (Table 3).

Discussion

A systematic review of physician staffing patterns and outcomes in critically ill patients showed that high-intensity ICU physician staffing reduces hospital and ICU mortalities and the durations of hospital and ICU stays compared with low-intensity ICU physician staffing. [2] In comparisons of the duration of ICU stay between staffing models, Pronovost et al. [3] and Rosenfeld et al.[5] found a shortened ICU stay in high-intensity models, whereas Dimick et al. [6] found no significant difference in ICU stay between high- and low-intensity models. Mortality from acute lung injury is lower in a closed-model ICU than in an open-model ICU, [7] and lower mortality has been reported in trauma patients in an intensive model compared to an open ICU. [8] Improved outcomes after a structural change from an open to closed ICU model have also been found, indicating that the staffing model has an important relationship with the outcome. Contrary to reports showing improvement of outcomes by ICU staffing, Levy et al. [17] recently suggested that patients managed by intensivists for the entire ICU stay had a higher risk of death compared to management by non-critical care physicians. Mortality and duration of stay had high impact of ICU studies. However, the effects of ICU staffing for outcomes, such as mortality and duration of stay, were controversial. In this study, there were no significant differences in outcomes in high- and low-intensity groups, except for duration of hospital stay for survivors.

In trend to discussing mortality and duration of stay as outcome indicators on ICU structural studies, Kahn et al. [26] examined some processes in different staffing models, and demonstrated that evidence based approach (e.g. the sedation interruption) was more likely to be taken in high-intensity ICUs, compared to low-intensity ICUs. The sedation interruption contributed to progressive weaning from mechanical ventilation and shorter duration of mechanical ventilation. [27] Singer et al. [28] examined duration of mechanical ventilation (care process) as main outcome on ICU staffing model, showed that a high-intensity ICU was associated with approximately 40 hours lower duration of mechanical ventilation, and that duration of mechanical ventilation was useful indicator for ICU structural study. In this study, we evaluated processes of ICU quality indicators to assess the impact of ICU organization. Addition to mechanical ventilation, indicators related to renal, nutritional, and antibiotic management were also selected as process measures, since these are important indicators at intensive care unit [21-24] and nutrition and anti-infective support in ICUs are essential for critically ill patients. [29,30] Our study also showed that high intensity ICU model was associated with 4 days shorter duration of mechanical ventilation, which supported the findings in previous studies on ICU staffing models, although mortality was not associated with ICU structure in this study. The difference in duration of mechanical ventilation in previous study may cause by the difference in patient settings whether various diseases or only septic patients in the study object.

The association between the timing of initiation of enteral feeding and outcomes in patients with sepsis has been widely investigated. Several meta-analyses and systematic reviews [31-33] have indicated that early initiation of enteral feeding may reduce the incidence of infectious complications and shorten the duration of stay, but Ibrahim et al. [34] and Eyer et al. [35] found no significant effect of early enteral feeding on the incidence of infectious complications or duration of stay. Such mixed results on the effectiveness of nutritional therapy may be due to differences among study subjects and in the definition of early enteral feeding among studies. In this study, we showed earlier initiation of enteral feeding in high-intensity ICU, but the effect of ICU structure on enteral feeding was limited.

To assess antibiotic therapy, we investigated the initiation of antibiotic empirical therapy during the ICU stay. Based on a literature review of antimicrobial therapy for severe sepsis and septic shock using an evidence-based approach, Bochud et al. [25] found that a carbapenem, a 3rd or 4th generation cephalosporin, or a combination of a β-lactam and an aminoglycoside provided equally effective antibiotic empirical therapy. Therefore, we used these therapies as one variable in our study. Rapid initiation of appropriate antimicrobial therapy is a key to improving outcomes and reducing mortality in patients with sepsis and other infectious diseases. [25] In addition, daily reassessment of antibiotic use and discontinuation of antimicrobial therapy for non-infectious diseases are recommended in the 2008 Surviving Sepsis Campaign guidelines, and implementing these protocols may improve outcomes in patients with hospital-acquired pneumonia in critical care. [36]We could not evaluate these recommendations due to the limitations of our data.

In our study, duration of hospital stay was extremely longer than those reported by previous studies. There a specific reason for such long hospitalizations in Japan. Acute care hospitals in Japan have traditionally also provided sub-acute care and sometimes long-term care. [37] Recently shorter duration of hospital stay in the acute care hospitals has been promoted for pressure from Japanese Government. The duration of stay in Japan, however, has been much longer than in most Western nations, and a longer hospital stay may increase hospital mortality. Our results showed higher hospital mortality (45%) and longer hospital stays (20-30 days) in patients with severe sepsis, compared to 18-30% and 12-17 days reported in other countries. [18,38,39] Differences in the function of acute care, in which sub-acute care and nursing home care may or may not be included, in Japan and Western countries may account for these differences. However, ICU mortality (24.2%) and the duration of ICU stay (8.4 days) in our study were similar to the values of 10-35% and 7 days found by Vincent et al. [40] The ICU and hospital stays for survivors were both shorter by 2-3 days in the high-intensity group. This may suggest that the hospital stay is affected by differences in processes, especially duration of mechanical ventilation, in the ICU. Although Singer et al. [28] showed that the high-intensity ICU was associated with a reduced hospital mortality, it was difficult to evaluate the affect of ICU organization to hospital mortality in previous studies with regard to functional differences between Japan and other countries. As concerns ICU mortality, further examination should be performed using generalized severity coring system.

Our study has several limitations. First, risk adjustment and calculation of expected mortality of ICU patients are usually performed using the Acute Physiology and Chronic Health Evaluation (APACHE) versions I-IV, the Mortality Prediction Model (MPM) versions I-II, or the Simplified Acute Physiology Score (SAPS) versions I-III. However, administrative data in Japan does not include these scores. Thus, we evaluated illness severity using the COPE model, which require only administrative data. Second, we do not know the accuracy of the coding for sepsis, since the standard of coding and range of severity may differ among institutions. However, studies of septic patients using administrative data are accepted widely. [18,41] Therefore, we evaluated septic patients regardless of a coding bias among hospitals. In addition, the actual number of septic patients in our settings may be higher than 576 patients, because we selected patients for which both sepsis-related codes as the primary diagnosis and acute organ dysfunction were recorded. We believed that our inclusion criteria were small coding bias compared to the criteria including sepsis-related codes as the primary diagnosis and co-morbidities. In addition, university hospitals were not included in the QIP, which may have led to inclusion of only a small number of severe septic patients. Third, there may be a selection bias of ICU entry and intervention therapy. However, we believe that the effects of these biases were small since the ICUs in our study met the standards of the Ministry of Health, Labor, and Welfare. These standards specify ICU entry criteria and the processes we evaluated are widely performed in critical care settings. Finally, the study included only a small number of the acute-care hospitals in Japan, and the majority of hospitals in the study were large and/or educational hospitals. Therefore, further investigation is needed in smaller and/or non-educational hospitals and in a greater number of hospitals.

The current study is significant as the evaluation of care processes, which were available in administrative data, in ICU organization. The results showed a clear association between ICU organization and care processes. High-intensity ICU is associated with improved quality of care on mechanical ventilation.

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