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Influence of adverse drug events on morbidity and mortality in intensive care units: the JADE study

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Abstract

Objective. To identify the influence of adverse drug events (ADEs) on morbidity and mortality in intensive care units (ICUs).

Design. A prospective cohort study.

Setting. ICU setting at three acute care hospitals in Japan.

Participants. All patients aged ≥15 years were admitted to all ICUs during a 6-month study period.

Intervention. No intervention.

Main Outcome Measures. Mortality in the ICUs and the length of the ICU stay. .

Results. We included 459 patients with a total of 3231 patient-days. Ninety-nine ADEs occurred in 70 patients (15%), so that the incidence of ADEs was 30.6 per 1000 patient-days and 21.6 ADEs per 100 admissions. Seventy-three patients (16%) died during their ICU stay. Excluding 38 deaths within 3 days after admission, 12 patients (17%) died among the 70 patients who had at least one ADE during their ICU stay and 23 (7%) died among 351 without an ADE ($P = 0.003$). The median ICU length of stay was 3 days. Excluding 73 patients who died during their ICU stay, the median ICU stay of patients with at least one ADE was 13 days, while it was only 2 days in the remainder ($P < 0.0001$). ADEs were associated with longer length of ICU stay but not with mortality even after adjusting for patients' severity of illness.

Conclusions. ADEs were common in ICUs and significantly associated with longer length of ICU stay but did not influence on mortality.

Keywords: adverse drug events, epidemiology, intensive care unit, mortality, length of ICU stay, and patient safety

Introduction

Adverse drug events (ADEs) are injuries due to medication use [1]. ADEs are especially important in intensive care units (ICUs) because ADEs are associated with substantial increases in morbidity and mortality and many drugs are used in ICUs [2–4]. The European Society of Intensive Care Medicine in 2009 declared that there is a clear need to build and evaluate strategies to prevent or ameliorate ADEs and medication errors and thereby improve the outcome of critically ill patients [5].

Several studies have reported that the incidence of ADEs in ICUs is higher than that in general wards [4, 6, 7]. Critical care is complex and commonly requires urgent high-risk decision-making, often with incomplete data and by physicians with varying levels of critical care training [8]. Furthermore, the nature of critical illness reduces both the patients' natural resilience and their ability to defend themselves. The number of high-risk drugs administered to such patients is likely also partly responsible for the high ADE rates. Cullen *et al.* [9] reported that ICU patients received significantly more drugs in the 24 h before an ADE than non-ICU patients (15 vs. 9, $P < 0.0001$). However, the reports that assess the impact of the higher incidence of ADEs in ICU on mortality and morbidity of ICU patients were limited [10, 11]. Furthermore, most reports have been from Western countries, and their results cannot be extrapolated to other parts of the world without

local data [12]. The lack of such basic data represents one of the barriers to implementing strategies to improve patient safety in ICUs, especially outside the West.

To address this knowledge gap, we evaluated the epidemiology of ADEs in the ICUs as well as their impact on morbidity and mortality. We analyzed the data of the Japan Adverse Drug Events (JADE) study, a multicenter cohort study [6], and we used the length of ICU stay as morbidity.

Methods

Study design and patient population

The JADE study was a prospective cohort study involving all adult patients aged ≥15 years who were admitted to three urban tertiary care hospitals in Japan from January through June 2004[6]. The present study was limited to the patients admitted to all ICUs in these hospitals. The total number of beds among the three ICUs was 32 including the medical and the surgical beds. Patients were followed until transfer, discharge or death. The institutional review boards of three participating hospitals approved the study. Informed consent was waived because all data were collected in the daily practice.

Data collection and classification

The data collection method was based on that described in previous reports [1, 6]. ADE was defined as any unintended injury due to a medication use regardless of existing errors [1, 13]. Investigators trained nurses and nursing students in a standard manner and placed them in the participating hospitals where they reviewed practice data such as charts, laboratories or prescription data. They collected demographic data for all patients on admission to the ICUs and identified ADEs.

Next, two independent physician reviewers evaluated all events and classified collected ADEs as ADEs or exclusion. Then, physician reviewers classified ADEs into 10 categories according to the symptoms as well as rated the severity of ADEs using a four-point scale. The categories of symptoms were bleeding, central nervous, allergic reaction, liver disorder, cardiovascular, gastrointestinal, renal, respiratory, bone marrow suppression, and sepsis. For example, symptoms of bleeding included anemia and gastrointestinal bleeding due to warfarin, antiplatelet agents or NSAIDs; central nervous symptoms included delirium and muscle weakness due to sedative agents; gastrointestinal symptoms included diarrhea, constipation, nausea and vomiting due to antibiotics or opiates; respiratory symptoms included nosocomial infections which could be related to the use of antibiotics. We defined nosocomial infections as a patient who had negative culture on admission became to have positive culture after use of antibiotics. Categories of severity were fatal, life-threatening, serious, and significant. Fatal ADEs resulted in death; life-threatening ADEs caused such issues as anaphylactic shock or cardiopulmonary arrest; serious ADEs included gastrointestinal bleeding, altered mental status, excessive sedation, increased creatinine or a decrease in blood pressure; and significant ADEs included cases with rash, diarrhea or nausea, for example. When disagreements affected the classification of an ADE and its severity, the physician reviewers reached consensus through discussion.

To assess the severity of patients on admission to ICUs, we used the sepsis-related organ failure assessment (SOFA) score, later called the sequential organ failure score because it is not restricted to sepsis, to evaluate the presence of organ dysfunctions objectively [14]. The SOFA score consists of six components of organ systems such as respiratory, coagulation, liver, cardiovascular, central nervous system and renal. Each organ system is evaluated using a score from 0 (normal) to 4 (most abnormal) depending on its severity. To evaluate the presence of each organ dysfunction in this study, we used the SOFA score. The presence of each organ dysfunction was defined as follows: respiratory dysfunction; PaO_2/FiO_2 ≤400 mmHg, coagulopathy; platelets $\leq 150 \times 10^3/\mu l$, liver dysfunction; bilirubin ≥1.2 mg/dl, hypotension; mean arterial pressure <70 mmHg, unconsciousness; Glasgow Coma Scale ≤14, and renal dysfunction; creatinine ≥1.2 mg/dl.

Statistical analyses

The ADE incidence per 1000 patient-days and rates per 100 admissions were calculated. Continuous variables are presented as means with standard deviations (SDs) or medians with interquartile ranges, and categorical variables are shown as numbers and percentages. Relationships between patients' demographic data and ADEs were assessed using the Wilcoxon rank sum test when the data were continuous and the chi-square test when the demographic data were categorical. To assess associations between ADEs and mortality, we used the chi-square test. Because patients who died soon after admission had no chance to have an ADE, we did the same comparison eliminating patients who died within 3 days after admission to the ICUs. We used the *t*-test to compare the length of ICU stay between patients with ADEs and without ADEs during the ICU stay among those who were discharged from the ICU alive. We used a Cox proportional hazard model to estimate the hazard ratios (HRs) of ADEs for the risk of mortality along with 95% confidence intervals (CIs). We also used a linear regression model to assess the effects of the ADEs on the length of ICU stay. Both models were adjusted for age and the presence of organ dysfunctions such as respiratory, coagulopathy, liver, hypotension, unconsciousness and renal variables defined using the SOFA score. Patients with missing values for any selected variables were excluded from both analyses. We carried out all statistical analyses using the JMP 8.0 (SAS Institute Inc., Cary, NC). *P* values of <0.05 were considered to be statistically significant.

Results

We enrolled 459 admissions, accounting for a total of 3231 patient-days in the ICUs. Among the 459 patients, 290 (63%) were males and the mean age was 66 (SD 16) years; 60% were 65 years and older. The medical and the surgical ICUs admitted 263 (57%) and 196 (43%) patients, respectively. Of all admissions to the ICUs, 84% were emergent. The median

number of organ dysfunctions which patients suffered from on admission to the ICUs was 2 (inter-quartile range 1–3) and respiratory dysfunction was the most frequent (67%) followed by unconsciousness (46%) (Table 1).

Adverse drug events

We identified 99 ADEs in 70 patients (15%) for an incidence of 30.6 [95% CI 24.6–36.7] per 1000 patient-days and a rate per 100 admissions of 21.6 [95% CI 17.9–25.6]. The median day of the ADE onset after admission was 3 days.

Table 1 Demographic data in study population

	Total ($n = 459$)
Age, ≥65 (years) (*n*, %)	276 (60)
Male (*n*, %)	290 (63)
Departments (*n*, %)	
Medicine	263 (57)
Surgery	196 (43)
Admission pathway (*n*, %)	
Scheduled admission	75 (16)
Emergency admission	384 (84)
Principal reason for admission to unit (*n*, %)	
Cardiac disorders	136 (30)
Vascular disorders	49 (11)
Respiratory disorders	59 (13)
Neurological disorders	50 (11)
Kidney disorders	29 (6)
Gastrointestinal disorders	19 (4)
Trauma	32 (7)
Intoxication	5 (1)
Metabolic disorders	5 (1)
Others	75 (16)
Organ dysfunction on admission (*n*, %)	
Respiratory disorders (PaO_2/FiO_2 ≤400 mmHg)	306 (67)
Coagulopathy (platelets ≤150 × $10^3/\mu l$)	88 (19)
Liver dysfunction (bilirubin ≥1.2 mg/dl)	73 (17)
Hypotension (mean arterial pressure <70 mmHg)	79 (17)
Unconsciousness (Glasgow Coma Scale ≤14)	211 (46)
Renal dysfunction (creatinine ≥1.2 mg/dl)	152 (33)
Temperature (centigrade degrees) (mean, SD)	36.6 (0.9)
History of allergy (*n*, %)	21 (5)
Past history and statement (*n*, %)	
Heart failure, NYHA = 4	253 (55)
Home oxygen therapy	17 (4)
Hemodialysis	64 (14)
The number of medications on admission (median, quartile)	5 (4–7)
Length of experienced years of a doctor in charge (median, quartile)	8 (4–16)

NYHA, New York Heart Association.

Among the 70 patients who had at least one ADE, 49 patients (70%) were 65 years and older and 21 patients (30%) were under 65, and 51 patients (73%) admitted urgently to the ICU and 19 patients (27%) did not. There was a trend for those 65 years and older to have a higher rate of ADEs compared with younger patients though this difference was not statistically significant ($P = 0.07$). Those admitted urgently to the ICU had a higher risk of ADEs ($P = 0.008$). The median age of the physician's experience among the doctors in charge who cared for patients with ADE was 6 years (inter-quartile range 3–13) while that without ADEs was 9 years (inter-quartile range 4–16). Thus, having a less experienced physician as the doctor in charge increased the ADE risk compared with having a senior physician ($P = 0.01$). Having organ dysfunction of any type at ICU admission was not associated with a higher risk of having an ADE (Figs 1 and 2). The number of medications on admission was also not significantly correlated with having an ADE [median 5 (inter-quartile range 3–7) vs. 5 (4–8); $P = 0.7$] though the median of the number of medications administered within the 24 h before an ADE was 11 (inter-quartile range 6–14).

Seven fatal or life-threatening ADEs occurred in 7 patients, which accounted for 7% of the 99 ADEs. Fatal or life-threatening ADEs included nosocomial infections caused by antibiotic use and shock associated with omitted vasopressor use. Serious ADEs and significant ADEs accounted for 34 and 59% of all ADEs, respectively.

Liver disorders and gastrointestinal disorders were the most frequent types of ADEs, accounting for 29% of all ADEs, respectively (Table 2).

Influence of ADEs on mortality and morbidity

Among the 459 patients admitted to the ICU, 73 patients (16%) died during their ICU stay. The mortalities of patients with ADE and without ADE were 17% (12/70) and 16% (61/389), respectively ($P = 0.8$). Among the 73 deaths, 38 died within 3 days of admission to the ICU. After excluding those 38 deaths, 12 deaths occurred among 70 patients (17%) who had at least one ADE during their ICU stay and 23 deaths (7%) occurred among 351 patients who had no ADEs during their ICU stay ($P = 0.003$). A Cox proportional hazard model showed that ADEs did not increase the mortality in the ICUs after adjusting for age and organ dysfunction status (HR: 0.7; 95% CI: 0.3–1.5) (Table 3).

Among the remaining 386 patients after excluding 73 patients who died during their ICU stay, the median ICU stay of those who had at least one ADE was 13 days (inter-quartile range: 6–20), while 2 days (inter-quartile range: 1–6) in those who had no ADEs ($P < 0.0001$). A linear regression model for the length of ICU stay showed that ADEs significantly increased the length of ICU stay, even after adjusting for age and organ dysfunction status (Table 3).

Discussion

We found that the presence of an ADE was associated with longer ICU stay consistent with previous studies [11, 15].

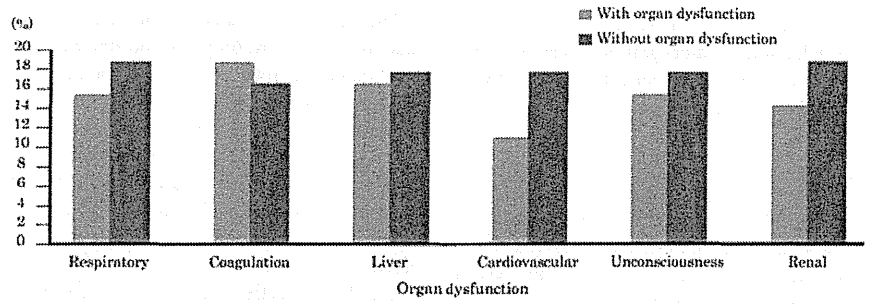

Figure 1 Comparison of the ratio of patients who had at least one ADE during their ICU stay between those who had any organ dysfunction and those without organ dysfunction.

After adjusting for the severity of illness and age, ADEs were still associated with a 10-day longer ICU stay. One interpretation of this result could be that patients with a longer ICU stay were more likely to experience an ADE. However, the median day of onset of ADEs after admission was 3 and the median length of ICU stay among those who had no ADEs was 2. This result suggests that ADEs increased the length of ICU stay rather than that longer ICU stays cause more ADEs, although both could play a role.

ADEs were not associated with increased mortality, although we had limited power to identify such an association. There were three deaths judged to be due to an ADE in this study, all of which were nosocomial infections associated with antibiotic use. Determination of cause is complex in such cases, but many such deaths have been reported previously; for example one study found that nosocomial infections in ICUs contributed to two fatal adverse events [8] and another study reported that nosocomial infections accounted for 24% of the adverse events identified in ICUs [16]. These results suggest that nosocomial infections are especially hazardous in critically ill patients.

We found that ADEs were common in ICUs in Japan, and the incidence of ADEs in ICUs was twice the rate of 16.2 per 1000 patient-days in the general wards [6]. These results were generally similar to previous studies from other countries. For example, Rothschild *et al.* [8] reported in a US study that the incidence of ADEs was 37.6 per 1000 patient-days, and Cullen *et al.* reported in another study from the USA that patients in ICUs experienced a higher rate of ADEs than non-ICU patients [9]. These results suggested that critically ill patients in ICUs are vulnerable to ADEs.

Among the factors contributing to this risk in ICU patients are likely organ dysfunction of a variety of types, the complexity of underlying disease in these patients, and the high number of medications and high-risk interventions they receive [8, 11]. Seynaeve *et al.* [17] reported that the severity of patients in ICUs was strongly associated with ADEs: the mean SOFA score was significantly higher on days when ADEs occurred than on days without ADEs (10 vs. 8). In our study, organ dysfunctions defined using the SOFA score were not related to

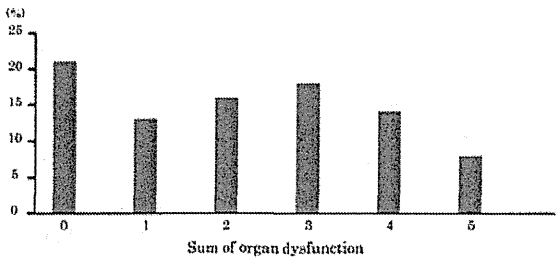

Figure 2 The percentage of patients who had at least one ADE according to the total number of organs dysfunctioning.

Table 2 Types of ADEs

Symptoms	ADEs (%)
Bleeding	5 (5)
Central nervous system	2 (2)
Allergic reaction	20 (20)
Liver disorder	29 (29)
Cardiovascular	7 (7)
Gastrointestinal	29 (29)
Kidney injury	2 (2)
Respiratory	2 (2)
Marrow depression	2 (2)
Sepsis	1 (1)

ADEs, adverse drug events.

ADEs. This could be because our assessment of the patients' severity was not sensitive enough to detect the relationship with ADEs. Because this study was based on the JADE study, which was done in both ICUs and non-ICUs, we did not perform a detailed severity assessment beyond the SOFA. Other studies have reported that a higher number of medications administered is associated with a higher ADE rate; one

Table 3 The influence of ADEs on mortality and morbidity

Variables	Mortality		Morbidity	
	Unadjusted HR (95% CI)	Adjusted HR (95% CI)	Unadjusted coefficient (95% CI)	Adjusted coefficient (95% CI)
ADE	0.7 (0.3 to 1.4)	0.7 (0.3 to 1.5)	10.6 (8.0 to 13.1)	10.2 (7.6 to 12.8)
Age (≥65)	0.9 (0.4 to 2.1)	1.0 (0.5 to 2.4)	2.5 (0.5 to 4.4)	1.9 (−0.02 to 3.9)
Respiratory disorders (PaO_2/FiO_2 ≤400 mmHg)	2.6 (1.2 to 6.6)	2.4 (1.0 to 6.1)	−1.3 (−3.3 to 0.7)	−1.4 (−3.4 to 0.7)
Coagulopathy (platelets ≤150 × 10^3/μl)	1.3 (0.6 to 2.7)	1.0 (0.4 to 2.3)	0.8 (−1.7 to 3.4)	0.8 (−1.8 to 3.4)
Liver dysfunction (bilirubin ≥1.2 mg/dl)	1.7 (0.7 to 3.5)	1.6 (0.7 to 3.6)	−0.7 (−3.5 to 2.2)	−0.4 (−3.2 to 2.4)
Hypotension (mean arterial pressure <70 mmHg)	1.7 (0.6 to 4.1)	1.2 (0.4 to 3.0)	0.2 (−3.3 to 3.8)	0.3 (−3.2 to 3.8)
Unconsciousness (Glasgow Coma Scale ≤14)	2.6 (1.3 to 5.6)	1.9 (0.9 to 4.3)	−0.2 (−1.8 to 2.1)	0.2 (−1.8 to 2.3)
Renal dysfunction (creatinine ≥1.2 mg/dl)	1.6 (0.8 to 3.0)	1.4 (0.7 to 2.9)	0.6 (−1.6 to 2.8)	1.0 (−1.2 to 3.1)

HR, hazard ratio; CI, confidence interval; ADE, adverse drug event.

showed the correlation using a database during a certain period where ADEs increased when more medications were used and another study showed that the number of medications used the month before admission was associated with ADEs [10, 18]. In our study, the number of medications administered on admission was not significantly correlated with having an ADE; however, the number of medications administered within the 24 h before an ADE was 11 and it was higher than 5, which was the number of medications administered on ICU admission. Even though the number of medications among those without ADEs was not assessed, this finding might address the issue that the more medications administered would be related to higher risk of an ADE. Though we assessed the relationship between patients' demographic data evaluated on admission to ICUs and ADEs, only several factors such as urgent admission and the length of experienced year of physicians in charge were associated with a higher ADE rate. Our results suggested that early prediction and prevention of ADEs simply by assessing the patients' demographic status evaluated on admission would likely not produce groups of sufficiently varying risk to be an effective approach.

This study has several limitations. First, some ADEs may not have been noted in the charts and may thus have not been detected, which would make our estimates a lower bound. However, more robust alternatives to measure ADEs have not yet been developed, so that the approach we used is the current standard one. Secondly, our data may not be sensitive enough to evaluate the characteristics or severity of critically ill patients because the JADE study did not focus on ICUs; thus, we evaluated the presence of organ dysfunction using the original SOFA score.

In conclusion, we found that ADEs were common and occurred to patients regardless of the presence of organ dysfunction in ICUs in Japan. ADEs were significantly associated with the length of stay though not related to mortality. Earlier detection of ADEs with close monitoring might improve the morbidity in ICUs.

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Conflict of interest

D.W.B. is on the clinical advisory board for Patient Safety Systems, which provides a set of approaches to help hospitals

improve safety. He also consults for Hearst, which develops knowledge resources, and serves on the clinical advisory board for SEA Medical Systems, which makes intravenous pump technology.

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医療安全・臨床研究
合同研修会

平成26年度第4回医療安全研修会

演題 島根県立中央病院の安全性を測定する
～多施設共同研究の成果から～

講師 兵庫医科大学　臨床疫学教授
森本　剛　氏

日時 平成27年3月24日（火）
18:00～19:30

場所 島根県立中央病院
大研修室

対象 全職員

※DVD研修は
予定しておりません。

●プロフィール●

平成7（1995）年京都大学医学部卒業。京都大学医学部附属病院総合診療部、市立舞鶴市民病院内科、国立京都病院総合内科、Brigham and Women's病院総合診療科を経て平成14（2002）年Harvard大学公衆衛生大学院公衆衛生修士課程修了。平成16（2004）年京都大学大学院医学研究科内科系専攻博士課程修了、京都大学医学部附属病院総合診療科助手。平成17（2005）年京都大学大学院医学研究科医学教育推進センター講師。平成20（2008）年慶應義塾大学大学院経営管理研究科科目履修生修了。平成23（2011）年近畿大学医学部救急総合診療センター教授。平成25（2013）年兵庫医科大学内科学総合診療科教授（本データはこの書籍が刊行された当時に掲載されていたものです）