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Original Article

The Implementation of Sepsis Bundles on the Outcome of Patients with Severe Sepsis or Septic Shock in Intensive Care Units☆

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SUMMARY

Background: The goal of the study was to implement sepsis bundles and examine the effect on patients with severe sepsis or septic shock in intensive care units (ICUs).
Methods: All patients with severe sepsis or septic shock admitted to the 13-bed ICU were included. Sepsis bundles were implemented within 24 hours after admission. The implementation of sepsis bundles was categorized into preintervention (January to April 2010), education (July to October 2010), operational (November to December 2010), and postintervention (January to April 2011) phases. Comparison of bundle compliance and outcome between each phase were examined. We also found mortality predictors between preintervention and postintervention phases.
Results: There were 164 patients included in the study. Compared with the preintervention phase, the bundle compliance of each phase (education, operation, and postintervention separately) was higher (43.3%, 84.6%, and 79.2%, respectively, vs. 20.0%, $p < 0.05$), the hospital mortality was lower (10.0%, 23.1%, and 24.5%, respectively, vs. 43.6%, $p < 0.05$). Under multivariate analyses, the predictors for mortality between the preintervention and postintervention phases were: lactate at ICU (odds ratio [OR] 2.212), urinary tract infection (OR 0.026), and postintervention (OR 0.239).
Conclusion: Implementation of modified sepsis bundles was successful in changing sepsis treatment behavior and was associated with a substantial reduction in hospital mortality and trends of decreased hospital expenditure. Factors improved hospital mortality, as lower lactate levels at ICU, urinary tract infection, and postintervention. The proposed intervention is generally applicable to achieve similar improvements.
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1. Introduction

Severe sepsis, defined as sepsis with one or more episodes of acute organ dysfunction, may include persistent hypotension, hypoxemia, metabolic acidosis, oliguria, thrombocytopenia, and impaired liver function. In the United States, there are approximately 750,000 new cases of sepsis each year with a mortality rate consistently higher than 25% for severe sepsis and up to 70% for septic shock[1,2]. In Taiwan the age-standardized annual incidence rate of severe sepsis increased 1.6-fold (135 per 100,000 in 1997 to 217 per 100,000 in 2006). The proportion of patients with multiorgan (≥2) dysfunction increased (11.7% in 1997 to 27.6% in 2006), but there was little change in hospital mortality, averaging 30.8%[3].

Considering the recent advances of therapeutic strategies such as early appropriate antibiotic therapy[4,5], early goal-directed therapy (EGDT)[6], low-dose steroid therapy[7], tight glucose control[8], and lung-protective strategies[9] have all been shown to be associated with survival benefits. The Surviving Sepsis Campaign (SSC) guidelines, endorsed by many professional organizations throughout the world, were developed as a plan to reduce severe sepsis mortality by 25%[10]. The development and publication of guidelines often do not lead to changes in clinical behavior[11], and the most effective means for achieving knowledge transfer remains an unanswered question across all medical disciplines. National

☆ All contributing authors declare no conflicts of interest.

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efforts to promote the SSC guidelines are nonexistent in most of Asia, and are influenced by cost concerns that limit the implementation of potentially expensive bundles[12].

Bundle care has been demonstrated to improve survival using multifaceted strategies for changes in clinical behavior and quality improvement[13–15]. Although some of the recommendations are controversial, these studies suggested quality improvement efforts based on the SSC guidelines were associated with improved outcomes. Thus, an interdisciplinary team was needed to improve early recognition and process of care in patients with severe sepsis or septic shock based on SCC guidelines. The aim of the current study was to implement a modified sepsis bundle and to examine the effect of a continuous quality improvement (CQI) initiative on treated patients. It was hypothesized that improved guideline compliance would result in improved patient outcomes.

2. Materials and methods

2.1. Study design and patient selection

From January 1, 2010 to May 30, 2011, a prospective observational cohort study was conducted in a tertiary care medical center in southern Taiwan. All patients with severe sepsis or septic shock admitted to a 13-bed intensive care unit (ICU) via the emergency department were included in the study. The time of transferring such patients from the emergency department to the ICU was less than 6 hours. The ICU staff included intensivists, respiratory therapists, clinical nurse specialists, clinical dietitians, clinical pharmacists, and residents, who provided 24-hour coverage. The diagnostic criteria for severe sepsis or septic shock used in this study were adapted from the definition developed by the Consensus Panel of the American College of Chest Physicians and the Society of Critical Care Medicine (1992)[16]. Severe sepsis was defined as the presence of at least two of four criteria for systemic inflammatory response syndrome due to a proven or suspected site of infection, in association with at least one of the following sepsis-induced organ dysfunctions (Appendixes 1 and 2)[16].

Modified sepsis bundles were implemented within 24 hours after ICU admission in order to improve patient outcomes[10] (Appendix 3). Sepsis bundles were divided into four phases: preintervention (January to April 2010), education (July to October 2010), operational (November to December 2010), and postintervention (January to April 2011). During the education phases, specific training, educational materials, and CQI initiative on physicians, nurses, and residency staff in the ICU were provided, including: (1) conference lectures, bedside tutorials on the definition of sepsis, and early recognition and treatment options including decision-making algorithms; (2) a Chinese translation of the SSC guidelines in poster and pocket format; (3) a checklist focused on the early recognition and treatment of sepsis with modified sepsis bundles; and (4) a computerized physician order entry set to aid the completion of bundles. The operational phase consisted of bundle delivery in the ICU setting. Physicians and nurses used a sepsis checklist and pocket cards as daily reminders of the processes involved in bundle delivery to the staffs in the ICU and emergency department. The postintervention phase was used as a long-term follow-up at the end of study. This study was approved by Institutional Review Board of Chi Mei Medical Center.

2.2. Measurements

The following data were collected: (1) demographic and clinical variables, including age, sex, body weight, height, and body mass index (measured as body weight per square height in meters), use of a ventilator, lactate levels in the emergency department and ICU, and mean blood glucose level within 24 hours of ICU admission; (2) severity of each patient's condition as determined by clinical nurse specialists upon ICU admission using the Acute Physiology and Chronic Health Evaluation (APACHE) II score, the Therapeutic Intervention Scoring System (TISS) scores, Glasgow Coma Scale, and the presence of acute organ dysfunction (as described in Appendix 2); (3) primary infection sites; (4) outcomes, including length of ICU and overall hospital stay, ICU and hospital mortality rate and total hospital costs; and (5) bundle compliance measurements, including individual bundles and all bundles. The primary endpoint was comparison of bundle compliance, hospital mortality, and hospital expenditure between each phase. Secondary outcome measures included predictors for hospital mortality between the preintervention and postintervention phases to avoid the possible Hawthorne effect due to intervention.

2.3. Statistical analyses

Median values, interquartile ranges, and group size were used to summarize the results for continuous variables. The differences among groups, and survival and nonsurvival groups at hospital discharge were examined by univariate analysis with a nonparametric test and a chi-square test. A p value <0.05 was considered statistically significant. Predetermined variables (as all sepsis bundles), or those significantly associated with hospital mortality in univariate analysis ($p < 0.05$), were tested for interaction with multiple logistic regression analysis. Odds ratios (OR) and 95% confidence intervals (CI) were also calculated. Statistical analysis of the data was done using SPSS 13.0 for Windows (SPSS, Inc., Chicago, IL, USA).

3. Results

There were 164 patients included in the current analysis (55 in the preintervention phase, 30 in the education phase, 26 in the operational phase, and 53 in the postintervention phase), and 42.1% were female. The median age was 74 years with a median APACHE II score, TISS score, and coma scale of 23, 27, and 9, respectively, on the day of admission to the ICU. Median body weight was 58.0 kg, with a median height of 1.6 m, and a median body mass index of 22.0 kg/m^2. There were 41 patients (25.0%) with severe sepsis, and 123 patients (75.0%) had septic shock upon admission to the ICU. The median number of acute organ dysfunctions per patient was two, the most common of which were cardiovascular failure (80.5%) and respiratory failure (46.7%). There were 125 patients (76.2%) who required intubation with ventilator support. Additional results are shown in Table 1. The major sources of infection were pneumonia (63.4%), urinary tract infection (UTI; 28.7%) and intra-abdominal infection (IAI; 8.5%), as shown in Table 2. The overall ICU and hospital mortality rates were 25.0% and 28.0%, respectively. The median duration of ICU and hospital stays was 11 and 19 days, respectively. For all patients, median hospital cost was 8.5 $\times$ 1000 US dollars (USD) (Table 3). Each group had similar baseline data, except the preintervention group had a lower lactate level in the emergency department (2.7 mmol/L) and a higher blood glucose level within 24 hours (178 mg/dL) as compared with other groups. There were also some differences on multiorgan failures between each group (hematologic, hepatic, metabolic, and respiratory failure). The completion of sepsis bundles was gradually higher after the education and operational phases (43.3% and 84.6%), and maintained a higher level (79.2%) even 1 year later during the postintervention phase as compared with the preintervention phase (20.0%, $p < 0.05$ as compared to each group), especially in broad antibiotic agents, central venous oxygen saturation ($ScvO_2$) survey, blood sugar $\leq$ 150 mg/dL (all $p < 0.05$,

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