ARTICLE IN PRESS

Journal of Critical Care xxx (2014) xxx-xxx



Contents lists available at ScienceDirect

Journal of Critical Care

journal homepage: www.jccjournal.org



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ARTICLE INFO

Keywords: Sepsis Severe sepsis Septic shock Cost-effectiveness analysis Outcome Protocol

ABSTRACT

Purpose: Severe sepsis is a time-dependent disease, and implementation of early treatment has been associated with mortality rate reduction. However, the literature is controversial regarding cost-effectiveness analysis of this intervention. The aim was to assess the cost-effectiveness of a managed protocol for the treatment of severe sepsis.

Materials and methods: This is a prospective cohort study involving a historical comparison (before and after the implementation of the protocol) of patients who had been hospitalized with severe sepsis and septic shock. The group of patients who were treated before the assistance routine was implemented was considered to be the control. The case-managed nurse involved with assistance protocol performed the data collection. This nurse received special training to ensure the quality of the data and to measure the intervention throughout the implementation process.

Results: A total of 414 patients were analyzed. The mortality rates were 57% in the control group and 38% in the protocol group (P=.002). After the implementation of the protocol, the absolute risk reduction was 18%; and the relative risk reduction was 31.8%. There was a tendency for a reduction in the cost of the full hospitalization, but this trend did not reach statistical significance. Nevertheless, the cost of hospitalization in the intensive care unit was reduced significantly from US \$138,237 \pm \$202,418 in the control group to US \$85,484 \pm \$127,471 in the protocol group (P=.003). The managed protocol for sepsis resulted in an average gain of 3.2 life-years after being discharged from the hospital (8.8 \pm 13.3 years in the control group and 12.0 \pm 14.0 years in the protocol group, P=.01).

Conclusions: Given that the incremental cost was lower than or equal to zero, the effectiveness of the protocol was justified by the significant increase in the life-years saved and the reduced mortality.

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1. Introduction

Sepsis is a common disease that is associated with high morbidity and mortality rates, especially in developing countries. In Brazil, there are an estimated 500,000 new cases of severe sepsis every year; and the sepsis mortality rate, ranging between 40% and 60%, is one of the highest in the world [1,2]. The direct costs associated with sepsis treatment have reached approximately 17 billion dollars per year [3].

Abbreviations: ICU, intensive care unit; SSC, Surviving Sepsis Campaign.

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In Brazil, Sogayar et al conducted an elegant study that found that the median total cost of sepsis treatment in the intensive care unit (ICU) was US \$9632 per patient, which corresponds to a daily cost of US \$934. Furthermore, nonsurvivors exhibited significantly higher costs than survivors [2].

Delays in recognition and treatment onset increase mortality risk of severe sepsis patients. A recent study showed that physicians' ability to recognize severe sepsis is unsatisfactory, which may impact the clinical outcome [4]. In addition, several studies have showed an association with lower mortality rate and implementation of the 6- and 24-hour bundles recommended by the *Surviving Sepsis Campaign* (SSC) [3,5–8]. Nevertheless, the expenses that are associated with these bundles and the direct costs that are related to the treatments have been only partially assessed [9–12]. Therefore, an assessment of the incremental costs and benefits of the SSC implementation is crucial, especially in developing countries such as Brazil.

The primary aim of the present study was to assess the costeffectiveness ratio of a managed protocol for severe sepsis that was

http://dx.doi.org/10.1016/j.jcrc.2014.03.008 0883-9441/© 2014 Elsevier Inc. All rights reserved.

[↑] Competing interests: The authors declare that they have no competing interests. ↑ Nonfinancial competing interests: Murillo Santucci Cesar Assuncao is a member of the Latin American Institute of Sepsis; Eliezer Silva is a member of the Steering Committee of the Global Sepsis Alliance, member of the Board of Sepsis Surviving Campaign, and former President of the Latin American Sepsis Institute.

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implemented at a private institution in Brazil. The secondary aims included assessments of morbidity before and after the implementation of the severe sepsis and septic shock treatment routine and the impact of the SSC's 6- and 24-hour bundles on the mortality of patients with severe sepsis and septic shock.

2. Materials and methods

2.1. Design and setting

The present study was a prospective cohort study involving a historical comparison (before and after the implementation of the protocol). The study included all patients with severe sepsis and septic shock who had been admitted to the ICU at the Hospital Israelita Albert Einstein, São Paulo, Brazil, between July 2005 and December 2008. The hospital is a 600-bed private institution that annually assists approximately 100,000 patients in the emergency department and 3000 patients in the ICU.

A managed protocol that was based on the SSC recommendations was implemented in April 2006 [13]. The protocol included lectures, *e-learning modules* for the multidisciplinary team, and the distribution of explanatory brochures about sepsis. The regular clinical staff and all of the physicians in the emergency department and ICU were included in the campaign. The group of patients who were treated before the assistance routine was implemented was considered to be the control. The data collection was performed by the nurse who managed the assistance protocol. This nurse received special training to ensure the quality of the data and to measure the intervention throughout the implementation process.

The diagnosis of sepsis was established according to the 1992 criteria of the American College of Chest Physicians/Society of Critical Care Medicine [14]. In the present study, the initial presentation of the patients was assessed as a function of the departments in which the diagnoses were performed, including the emergency department, wards, ICU, step-down unit, and operating room.

The approach for treating patients with severe sepsis and septic shock was assessed according to the SSC guidelines for 6-hour

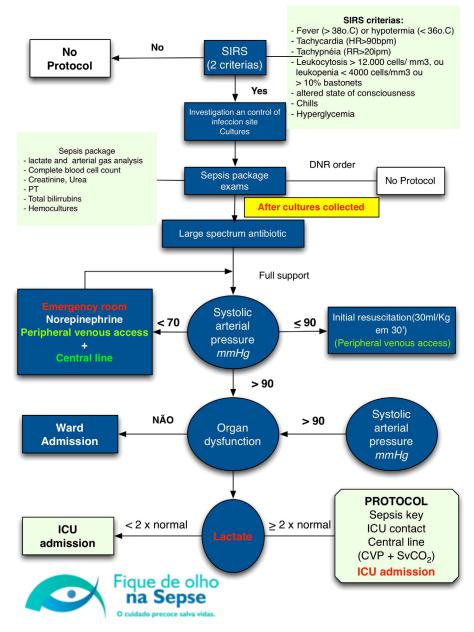


Fig. 1. Algorithm of the assistance routine in the treatment of patients with severe sepsis and septic shock.

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