

Study protocol synopsis and statistical plan for “Mortality of Sepsis in Swedish Intensive Care Units 2008 – 2016”

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Background

Accurate data on mortality in sepsis are important for several reasons, including allocation of resources, benchmarking, evaluation of interventions and for research purposes. Recent studies have indicated that the mortality of sepsis has decreased in the 21st century, although this view is not undisputed. Moreover, data on outcome beyond hospital discharge is limited. However, if mortality figures have improved, the cause of this is not entirely clear [1-3]. Preliminary data from Swedish intensive care units indicate that the mortality in sepsis may be relatively stable over the last decade in this setting. Therefore, we aim to study sepsis mortality from 2008 – 2016 in register data from Swedish intensive care units, and contrast this with mortality in other ICU patients. The specific research question is whether mortality has changed during this period. Primary outcomes are mortality at 30, 90 and 365 days after ICU admission. Secondary outcomes are hospital mortality and ICU and hospital length of stay.

Methods

Data are recovered from the Swedish Intensive Care Registry (SIR), a centrally administered nationwide collaboration where all general of intensive care units (ICU) in Sweden are members. We will include all adult (≥ 18 years) patients admitted to a general ICU between 1st of January 2008 and 18th of October 2016 (thoracic, neurosurgical, pediatric and burns ICUs are excluded). The cohort is divided in septic and non-septic patients. The former are identified by any of the International Classification of Diseases (ICD)-10 diagnoses R65.1, R57.2 and A41.9, which are used in the register to classify severe sepsis and septic shock. Data from SIR are linked with data from the national inpatient register of the Swedish Board of Health and Welfare (Socialstyrelsen), to recover chronic comorbidity data.

The septic and non-septic groups are characterized with regard to demographic factors; age, sex and type of treating hospital (regional, county, local), comorbidity; Charlson Comorbidity Index (CCI) and selected key diagnoses; diabetes, chronic heart or lung disease and malignancy, level of acute illness severity; Simplified Acute Physiology (SAPS)3 score, and selected interventions; invasive ventilation and renal replacement therapy. Also, ICU and hospital length of stay are described. These factors are described with appropriate statistics, i.e. mean and standard deviation (SD) or median and interquartile range (IQR) for parametric and nonparametric variables, or as proportions, and the beginning and end of the period are compared with t-test, u-test or χ^2 -test, respectively.

Proportional unadjusted mortality at hospital discharge, 30 days, 90 days and 365 days is also described in the whole population and in subgroups based on age, sex, type of treating hospital and severity of acute illness and chronic comorbidity.

The primary outcome measures; mortality at 30, 90 and 365 days after ICU admission, are further studied with logistic regression, adjusting for acute illness severity, comorbidity and demographic factors. Admission year is included as a regressor to assess the effect of time.

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