Comparative Validity Sequential Scoring System Organ Failure Assessment (SOFA) and Quick - Sequential Organ Failure Assessment (qSOFA) on Estimating Mortality for Patients Treated in the Intensive Care Unit of Sanglah General Hospital

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Abstract

**Objectives:** The purpose of this study was to assess that qSOFA validity is equal with SOFA as the predictor of mortality, both in sepsis and nonsepsis patients.

**Design:** Diagnostic test with a retrospective design.

**Setting:** Intensive Care Unit in Sanglah General Hospital, Bali, Indonesia.

**Subjects:** Patients admitted to the ICU Sanglah General Hospital, from July 2015 to December 2016 (n=192), that have complete data and able to be evaluated with SOFA score.

**Interventions:** None

**Measurement and Main Results:** With the total population sampling techniques, 192 patients have met the criteria as the samples. The descriptive statistical analysis were performed, and the area under the ROC curve (AuROC) were used. The cutoff points will also be determined and will conclude the sensitivity and specificity of each score. From the 192 patients, the cutoff point for the SOFA and qSOFA are 11 and 2. While the AuROC from SOFA and qSOFA are 0.9307 and 0.9241, with p=0.7037 (95% confidence interval).

**Conclusion:** In this study, we conclude that the validity of qSOFA is equal to SOFA, both in sepsis and nonsepsis. So, for the reasons of efficiency and effectiveness, qSOFA can be used to replace SOFA score in predicting mortality in ICU.

**Keywords:** Outcome; Morbidity; Organ failure; Critically ill; Intensive care; Respiratory failure; Renal failure; Hepatic failure; Coagulation abnormalities; Neurologic dysfunction; Circulatory shock; Circulatory failure

Introduction

In this modern era of medicine, medical science has grown fast. Various advanced life support can now be given in an intensive care facility that can improve life expectancy and reduce mortality in critically ill patients. But it is not equal with the availability of intensive care. Selection should be taken to determine priorities, based on the mortality rate in patients who require treatment in intensive care. Moreover, with the implementation of a variety of insurance-based payment system which has now been widely applied, which cost efficiency becomes a very important thing without neglecting the optimal treatment for the patient.

Some criteria’s have used to determine the priority of the patient to be treated in intensive care. SCCM (Society of Critical Care Medicine) has developed four priorities to assess indications of treatment in intensive care. Patients with priority 1, which has a poor condition and unstable that requires absolute care and monitoring in intensive care, until patients with priority 4, who have an excellent and stable condition, or in the contrary, are too ill to get much benefit from treatment in intensive care [1].

Scoring systems have been used to determine the mortality rate and life expectancy of patients who will be treated at ICU. Obviously, the scoring system used, ideally should be easy to use, can be implemented quickly by medical personnel, and do not cost much. The scoring system that commonly used is APACHE II (Acute Physiological and Chronic Health Evaluation II), APACHE III, APACHE IV, SAPS II (Simplified Acute Physiological Score II), Score SOFA (Sequential Organ Failure Assessment), MPM II (Mortality Probability Model II), and now also known qSOFA (Quick Sequential Organ Failure Assessment).

SOFA scoring system itself has been developed by the European Society of Critical Care Medicine (ESCCM) in 1994 and has been
wide used as a system to assess the status of patient mortality in the ICU. Essentially, the SOFA scoring system judges the six parameters of different organ systems separately [2]. OFA took 4 laboratory parameters (PaO₂, creatinine, bilirubin, and platelets) and 2 clinical parameters for the assessment (GCS and vasopressor requirement). But the SOFA score was also assessed to be less practical and there are still some parameters that are difficult to obtain (PaO₂, bilirubin, and creatinine) [3].

In early 2016, the new criteria have been discovered to facilitate in determining mortality in septic patients, began to be widely used. The scoring criteria called quick-SOFA (qSOFA) has been used widely in line with the international consensus to define sepsis and septic shock. qSOFA scores expected to provide facilities associated with the complexity of the system. By minimizing the scoring system and use only the parameters that do not depend on the results of laboratory tests, the expected results of the assessment can be done more easily, quickly and interventions can be done early, so it can reduce the mortality rate in general [4]. This is supported by the results of studies that have been done before, that increased subvariable coagulation, renal, and hepatic did not provide significant correlation on mortality. On multivariate analysis with logistic regression obtained an influence on each sub-variable component of SOFA which were obtained by neurological, respiratory and cardiovascular provide meaningful relationship to mortality. Each increase of 1 point in the sub-variables of respiration will increase the mortality rate of up to 1.79 times. Each increase of 1 point in the sub cardiovascular variables will increase the mortality rate of up to 2.05 times and every increase of one point in the sub-variables of neurology will increase the mortality rate of up to 3.57 times [5].

The purpose of this study is to show that qSOFA validity is equal with SOFA, in which it has more practical measurement parameters and requires a simple examination that is routinely checked at Sanglah General Hospital.

Material and Methods

This study is a diagnostic test study with retrospective design. The data used is past data, taken with the results seen in the present. The data collection of research conducted through secondary data in the medical record of ICU in July 2015 - December 2016.

Samples that meet the inclusion and exclusion criteria, were taken with a total population sampling. Patients aged 18 to 65 years old who had complete data, both physical examination and laboratory, will be listed as a sample. This study uses the formula of a diagnostic test in a population. P is the prevalence of outcomes obtained from earlier studies, which found from the prevalence of mortality from non-surgical patients in ICU Sanglah General Hospital was 63.5% [5]. Moreover, in a previous study by the ROC curve obtained a sensitivity of 92% for SOFA. Standard deviation was set at 1.96 for the error type I. While the study determined a precision of 0.05 to minimize the difference between the results of the study population to obtain a larger number of samples. From this calculation obtained the total sample of 178 patients. But in this study, will be taken across the sample of ICU patients who meet the criteria (total population sample) during the period July 2015 until December 2016 with the total sample of at least 178 patients. From the selected sample, then will be classified into 4 groups based on the diagnosis, namely the "surgical-sepsis", "non-surgical-sepsis", "non-surgical-non-sepsis". Analysis of the ROC curve will also be performed on each group to determine the performance of each score on a sample group with different diagnoses. The wider area under the ROC (AuROC), the better the scoring system. Value is created for the cutoff point that will determine the value of sensitivity and specificity. Hypothesis test is assessed using the 95% CI and p value. The analysis of the data will be performed by software STATA SE 12.1.

Results

A total 192 patients were enrolled for this study. The characteristics of eligible subjects are presented in Table 1. Based on gender, 98 (51.04%) were male, and the rest 94 (48.96%) were female. The distribution of the sample in the group "Surgical-Sepsis" can be as many as 41 patients (21.35%), "Non-Surgical-Sepsis" is obtained in 69 patients (35.94%), "Non-Surgical-Sepsis" as many as 40 patients (20.83%), and "Non-Surgical Non-Sepsis" as many as 42 patients (21.88%).

| Variable       | n=192          |
|----------------|----------------|
| Age (y), mean ± SD | 44.5 ± 16.1 |
| Gender         |                |
| Male           | 98 (51.04%)    |
| Female         | 94 (48.96%)    |
| Diagnose       |                |
| Surgical-Sepsis| 41 (21.35%)    |
| Surgical-Non-sepsis | 69 (35.94%) |
| Non-Surgical-Sepsis  | 40 (20.83%)  |
| Non-Surgical Non-sepsis | 42 (21.88%) |
| Length of stay (day), median (IQR) | 4.5 (9.6) |

Table 1: Characteristics of subjects (n=192).

The Calculation of statistical values on the 192 patients who underwent assessment of SOFA score, the cutoff point on the SOFA score was ≥ 11 (87.50%). Details on the SOFA score cutoff point value will be described in Table 2. Based on the cutoff point value, 115 patients with SOFA score ≥ 10, is 95 survivors and 20 non-survivors. While the remaining 77 patients received the SOFA score >10 was 4 survivors and 73 non-survivors.

Meanwhile, qSOFA scoring in 192 patients obtained cutoff point value on the score ≥ 2 (89.06%). Details on the qSOFA score cutoff point value will be described in Table 3. Based on the cutoff point value, 95 patients with qSOFA score ≤ 1, 87 survivors and 9 non-survivors. While the remaining 96 patients received qSOFA score ≥ 2, 12 survivors and 84 non-survivors.
From the discrimination analysis by using ROC curve (Receiver Operating Characteristic) to assess the sensitivity and specificity of SOFA score were obtained AuROC 0.9307. While the sensitivity and specificity of the qSOFA score were 0.9241 AuROC, with p value=0.7037. The ratio of the area under the ROC curve SOFA score with qSOFA represented in Figure 1.

In this study, the authors also divided the 192 samples into 4 diagnostic based-group, namely the "Surgical-Sepsis", the "Surgical-non-Sepsis", "Non-Surgical-Sepsis", and the group "Non-Surgical-Non-Sepsis". Each group then was performed stratification analysis to compare the SOFA and qSOFA illustrated in Table 4.

**Table 2: Cutpoint of SOFA Score.**

| Cutpoint | Sensitivity | Specificity |
|----------|-------------|-------------|
| ≥ 0      | 100%        | 48.44%      |
| ≥ 1      | 98.92%      | 55.73%      |
| ≥ 2      | 98.92%      | 58.85%      |
| ≥ 3      | 98.92%      | 67.71%      |
| ≥ 4      | 98.92%      | 72.92%      |
| ≥ 5      | 96.77%      | 76.56%      |
| ≥ 6      | 89.25%      | 77.60%      |
| ≥ 7      | 87.10%      | 82.81%      |
| ≥ 8      | 83.87%      | 85.94%      |
| ≥ 9      | 82.80%      | 85.94%      |
| ≥ 10     | 79.57%      | 87.50%      |
| ≥ 11     | 78.49%      | 87.50%      |
| ≥ 12     | 72.04%      | 84.90%      |

**Table 3: Cutpoint of qSOFA Score.**

| Cutpoint | Sensitivity | Specificity |
|----------|-------------|-------------|
| ≥ 0      | 100%        | 0.0%        |
| ≥ 1      | 98.92%      | 40.40%      |
| ≥ 2      | 90.32%      | 87.88%      |
| ≥ 3      | 67.74%      | 94.95%      |

**Table 4: Comparison of analysis stratification of SOFA and qSOFA in predicting mortality of patients treated at ICU Sanglah General Hospital.**

| Group               | ROC SOFA | ROC qSOFA | P value |
|---------------------|----------|-----------|---------|
| Surgical Sepsis     | 0.8187   | 0.9052    | 0.1270  |
| Surgical Non-Sepsis | 0.8235   | 0.8497    | 0.5295  |
| Non-Surgical Sepsis | 0.8667   | 0.7833    | 0.2522  |
| Non-Surgical Non-Sepsis | 0.9506 | 0.9400    | 0.7932  |

**Discussion**

In this study, authors collected data on ICU patients, both in surgical and non-surgical patients, that met the inclusion. Data for the scoring is taken from the data on the medical record, which is examination result during the first 24 hours of stay in the ICU. If the data is serial, then the worst data will be used. Every each patient will
be performed both SOFA and qSOFA. Furthermore, the authors also noted the long of stay in ICU and also the outcome. Patients will still be included in the non-survivor group when the patient died less than 30 days after discharged from ICU. Because if the patient died less than 30 days after discharge from ICU, the cause of death was frequently associated with prior critical illness. From a Brazilian study, the most common cause of death in patients after the discharge from ICU is caused by septic shock [6]. However, if the patient died more than 30 days after discharged from ICU, the patient will be included into survivor group. From the data are then conducted a statistical analysis to determine whether the validity of a scoring system qSOFA is equal to the SOFA score. In this study, patient data will be grouped into four main groups based on the diagnosis. Separation into four main diagnosis-based groups is aiming to generalize to the population sample. Due to the use of the SOFA and qSOFA score which have generally only used primarily for patients with sepsis. So, through this research was expected to be able to show that the SOFA and qSOFA score can be used to assess the mortality rate in patients admitted to the ICU in general.

SOFA score requires investigation laboratory parameters such as bilirubin, creatinine, blood gas analysis and platelets frequently become an obstacle, and among the laboratory parameters, bilirubin result data is the most difficult to obtain. Therefore, from the total patients from July 2015 until December 2016, only 192 patients have bilirubin test data results and also the other laboratory data, so SOFA scoring can be done.

For the age factor, selected samples were patients aged 18 to 65 years. Statistical analysis of the results showed the mean ± SD was 44.5 ± 16.2 years. The results have a quite spacious standard deviation, which amounted to 16.2 due to the age range that qualifies to be sampled is quite spacious, which is between 18 to 65 years. The age range is selected according to the criteria of adult patients according to WHO criteria, which is expected to reduce the occurrence of bias in this study [7]. However, the sample population used in this study got a median of 46 years.

Length of stay patient in ICU was obtained by median (IQR) of 4.5 (9.6) days. This illustrates that the average patient treated at ICU was more or less for 4.5 days before being discharge with any outcome, both dead and alive. And of statistical analysis showed that the duration of treatment did not affect the outcome of each sample in this study. This suggests that the duration of treatment does not necessarily end up with bad outcomes, of course, the ability of human resources, in this case, intensivist, a variety of support equipment, and of course the condition of the severity of the patient’s condition is more decisive outcome of each sample in this study.

While based on the outcome, the sample was divided into two groups: survivor and non-survivor. The number of samples in the survivor group is as much of 99 patients (51.56%) and the non-survivor group has a total of 93 patients (48.44%).

For the calculation of the SOFA score, cutpoint value is ≥ 11. Which showed that patients receiving SOFA score of 11 or greater, have a high mortality rate, which had a sensitivity of 78.49% and a specificity of 95.96% with an accuracy of 87.5%.

For qSOFA score shows the cutpoint value is ≥ 2, which means that in patients taking qSOFA score of 2 or higher, have a high mortality rate, which had a sensitivity of 90.32% and a specificity of 87.88% with an accuracy of 89.06%.

Using the ROC curve (Receiver Operating Characteristic) to assess the sensitivity and specificity of the SOFA and qSOFA are determined with AuROC value, which is 0.9307% and 0.9241%, with p value=0.7037. The wider the area under the ROC curve (AuROC) the better the validity of the scoring system. With p value=0.7037 indicates that the differences are not significant. It can be concluded that the validity of qSOFA score is equal with SOFA score for predicting mortality in ICU. And in this study, researchers tried to do an analysis stratification on every diagnosis-based groups, with the aim to compare the strength of the SOFA and qSOFA against each the diagnosis. There were no significant differences in each group for both of the scoring system. It can be concluded that the validity of qSOFA is equal with SOFA, both in surgical and non-surgical patients. qSOFA score that uses a simple physical examination parameters for the calculation has made it more effective and efficient. SOFA score can predict mortality based on their multi-organ failure that occurred. The more organ failures the higher SOFA score obtained so that the higher the mortality rate. In the non-surgical patients, who often have a process that will involve more chronic organ function [8]. For the reason of efficiency and effectiveness, in our hospital, laboratory tests are usually done only if there is a clinical manifestation. This becomes the main concern because SOFA score will cost greater time, effort and money. While qSOFA score that using only simple clinical parameters that are routinely performed and easy to do, would be more effective and efficient. So, this study may indicate that validity of the qSOFA score is equal to the SOFA score in predicting mortality. Therefore, qSOFA score is good to be used for determining the priority of ICU admission.

Conclusion

In this study, we conclude that the validity of qSOFA is equal to SOFA, both in sepsis and non-sepsis patients. So, for the reasons of efficiency and effectiveness, qSOFA can be used to replace SOFA score in predicting mortality in ICU, in order to determine the priority of ICU admission.

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