An Analytical Study Of Demographic, Clinical And Etiological Profile Of Patients With Sepsis.

[1]Dr. Virendra C Patil*,[2]Dr. Pooja Bhaskaran

[1]Email: virendracpkimsu@reddiffmail.com
Professor, Department of General Medicine. Krishna institute of medical sciences, Krishna vishwa vidhyapeeth, Karad.
[2]Postgraduate student, Department of General Medicine.
Krishna institute of medical sciences, Krishna vishwa vidhyapeeth, Karad.

KEYWORDS

Sepsis, SOFA Score, Procalcitonin, Lactate Levels, ICU Management

ABSTRACT

Introduction:
Sepsis, a life-threatening condition caused by a systemic inflammatory response to infection, continues to have high mortality rates, especially in ICU settings. The SOFA score and its variants have become essential tools for assessing organ dysfunction and predicting outcomes in sepsis.

Methodology:
This prospective observational study included 148 sepsis patients admitted to the ICU at KVV Hospital from September 2022 to February 2024. Patients were assessed using SOFA scores, demographic data, comorbidities, and laboratory parameters, including serum procalcitonin and lactate levels. Statistical analyses were performed to explore correlations between SOFA scores, patient outcomes, and other clinical parameters.

Results:
The mean age of patients was 45.5 years, with males accounting for 58.78% of cases. A statistically significant higher SOFA score (mean 13.87 ± 7.25) was observed among non-survivors compared to survivors (8.41 ± 4.53, $p < 0.001$). SOFA scores were significantly correlated with lactate levels ($r = 0.214$), and patients with comorbidities had higher mean SOFA scores ($p = 0.023$). Culture reports identified *Pseudomonas aeruginosa* (14.19%) as the most common pathogen, though 20.27% of cultures showed no growth.

Conclusion:
SOFA scores, along with serum procalcitonin and lactate levels, serve as reliable indicators for assessing sepsis severity and guiding timely interventions. These findings underscore the importance of integrating these parameters into early management strategies to improve patient outcomes.

Introduction

Sepsis, a systemic inflammatory response to infection complicated by acute organ dysfunction in severe cases, remains a leading cause of morbidity and mortality in critically ill patients despite advances in understanding, monitoring, and resuscitation. [1] Proving infection remains a challenge in sepsis diagnosis, with cultures identifying pathogens in only about 30% of cases and clinical signs like fever, tachycardia, and leukocytosis being non-specific and overlapping with non-infectious SIRS. This diagnostic difficulty often delays treatment, contributing to high mortality rates, with sepsis being a leading cause of death in ICUs

worldwide. [2] The early diagnosis and decided management can lead to lower mortality rates and improved outcomes.[3]

In the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-experts recommend the use of quick sequential organ failure assessment (qSOFA) for the diagnosis of sepsis and screening of patients with severe sepsis who are at higher risk of mortality.[4] The criteria of the qSOFA to predict poor outcomes in adult patients with sepsis are a respiratory rate of ≥22 breaths per minute, systolic blood pressure of ≤100mmHg (1mmHg=0.133kPa), and altered mentation. The qSOFA is fast and straight forward, making it appropriate for emergency department use. [5,6]

However, recent studies have shown the poor performance of qSOFA in predicting sepsis mortality. To enhance its effectiveness, researchers have developed various revised versions of the qSOFA by including additional parameters, including the lactate-enhanced qSOFA (LqSOFA), the procalcitonin (PCT) enhanced qSOFA (PqSOFA), and the modified qSOFA (MqSOFA). LqSOFA assigned a lactate level of ≥2 mmol/L one point based on the qSOFA score assignment method. Similarly, the PqSOFA assigned an additional point if PCT was at a threshold of >0.5 ng/mL. Likewise, the MqSOFA assigned an additional point calculated from the ratio of peripheral oxygen saturation and fraction of inspired oxygen (SpO2/FiO2ratio); a score of 0 was assigned if the SpO2/FiO2 ratio was ≥315, 1point if 314–236 and 2 points if ≤235. [7-9]

The introduction of the Sepsis-3 definition is still relatively new to the critical care literature, but given the ease of SOFA calculation and high specificity of SOFA/qSOFA scores, it is likely to be adopted as a consensus definition for future clinical research. [10]

The Sequential Organ Failure Assessment or SOFA score was developed to assess the acute morbidity of critical illness at a population level and has been widely validated as a tool for this purpose. A change in the SOFA score of 2 or more is now a defining characteristic of the sepsis syndrome. SOFA score may traditionally be calculated on admission to ICU and at each 24-hour period that follows. This scoring system employs six criteria reflecting the function of organ systems (respiratory, cardiovascular, renal, neurological, hepatic and hematological) and allocates a score of 0–4 to each. [11,12]

The present study was conducted to study the demographic, clinical and etiological profile of patients with sepsis at tertiary care centre.

Methodology:

This prospective observational study was conducted at KVV Hospital after obtaining approval from the institutional ethical committee. The study included 148 cases of sepsis admitted to the Medicine ICU of KVV Hospital from September 2022 to February 2024. The primary objective was to monitor and analyze various clinical and laboratory parameters in patients diagnosed with sepsis according to the Sepsis-3 guidelines. Upon admission, patients over the age of 18 were screened for sepsis, and their vital parameters, including Glasgow Coma Score (GCS), heart rate (HR), blood pressure (BP), respiratory rate (RR), oxygen saturation (SpO2), and temperature, were recorded. Baseline investigations, such as arterial blood gas (ABG) analysis, complete blood count (CBC), kidney function test (KFT), liver function test (LFT), electrocardiogram (ECG), and chest radiograms, were performed. Septic profiles, including blood, urine, and endotracheal tube tip cultures, were sent for analysis.

Patients were followed throughout their ICU stay until discharge or death, with demographic information, co-existing diseases, and the source of infection also being documented.

The study employed a sample size calculation based on data from a previous study by **Daga et al**.[13], which reported a mean SOFA score of 8.84 ± 4.49 on day one. Using this information, a sample size of 104 was calculated, although 148 patients were ultimately enrolled in the study. The inclusion criteria targeted critically ill patients aged 18 years and older who met two Systemic Inflammatory Response Syndrome (SIRS) criteria and had a SOFA score of ≥2 upon ICU admission. Patients were required to have a minimum ICU stay of 24 hours and a diagnosis of sepsis according to Sepsis-3 criteria. Exclusion criteria included patients with insufficient information to calculate scores, those lacking outcome information, patients intubated upon arrival at the Emergency Department, and pregnant women. Written informed consent was obtained from all participants in both the local language and English.

The SOFA score was central to assessing organ dysfunction in these patients, incorporating six different scores across respiratory (PaO2/FiO2), cardiovascular (mean arterial pressure), hepatic (serum total bilirubin), coagulation (platelet counts), renal (serum creatinine), and neurological (Glasgow Coma Scale score) systems. Each system was scored from 0 to 4, with higher scores indicating worsening organ dysfunction. The study also involved comprehensive statistical analysis using SPSS version 21, with qualitative data represented in frequencies and percentages, while quantitative data were expressed as means and standard deviations. Chi-square tests were utilized to assess associations, unpaired t-tests compared quantitative variables between two groups, and Pearson correlation coefficients determined correlations between data sets. Statistical significance was defined as $p < 0.05$.

Observations and Results:

A total of 148 subjects were enrolled in this cross-sectional study, fulfilling the inclusion criteria of the study of which majority of patients were males 87 (58.78%) and 61 (41.22%) were females. The mean age of patients was 45.5 (SD ±14.43) years, with most common age group of greater than 70 years with 48 (32.43%) subjects, followed by 27 (18.24%) subjects were in the age group 61-70 years and 22 (14.87%) subjects were in the age group 51-60 years.

Of the total 148 subjects with diagnosis of sepsis, 57 (38.51%) patients had diabetes mellitus, 65 (43.92%) patients had hypertension, 67 (45.27%) patients had chronic kidney disease, 43 (29.05%) patients had coronary artery disease, 19 (12.84%) patients had liver disease, 41 (27.07%) patients had chronic obstructive pulmonary disease, 18 (12.16%) patients had malignancy. It was observed that few patients had more than one comorbidity.

It was observed that 64 (43.24%) patients had fever, 52 (31.15%) patients had altered sensorium / disorientation, 41 (27.70%) patients had difficulty in breathing, 37 (25%) patients had palpitations, 33 (22.30%) patients had vomitting, 29 (19.59%) patients had abdominal pain, 21 (14.18%) patients had hyperthermia, 19 (12.84%) patients had hypothermia, 11 (07.43%) patients had decreased micturition.

Of the total 148 patients, 25 (16.89%) patients had central line associated blood stream infection, 18 (12.16%) patients have central nervous system associated infection, 6 (04.05%) patients had intraabdominal infection, 14 (09.45%) patients had pulmonary infection, 16 (10.81%) patients had skin and soft tissues related infections, 27 (18.24%) patients had uro-genital infection, 43 (29.05%) patients did not have a specific source of infection. [Table 1]

Table 1: Source of infection among patients

Source of infection	No of Patients (n=148)	Percent
CLABSI	25	16.89
Central nervous system	18	12.16
Intraabdominal	06	04.05
Pulmonary	14	09.45
Skin-soft tissue	16	10.81
Uro-genital	27	18.24
Unknown source	43	29.05

In the present study, it was observed that 21 (14.19%) patients culture showed growth of pseudomonas aeruginosa, 18 (12.16%) patients culture showed growth of staphylococcus epidermidis, 16 (10.81%) patients culture showed growth of escherichia coli, 15 (10.14%) patients culture showed growth of staphylococcus aureus (methicillin resistant), 13 (08.78%) patients culture showed growth of klebsiella pneumoniae, 12 (08.10%) patients culture showed growth of streptococcus pneumoniae, 7 (04.72%) patients culture showed growth of staphylococcus aureus (methicillin sensitive), 7 (04.72%) patients culture showed growth of enterococcus faecalis, 6 (04.05%) patients culture showed growth of candida albicans , 3 (02.02%) patients culture showed growth of proteus mirabilis and 30 (20.27%) patients culture patients culture showed no growth of any organism. [Table 2]

Table 2: Culture growth of micro-organisms among patients

Culture growth	No of Patients (n=148)	Percent
Pseudomonas aeruginosa	21	14.19
Staphylococcus epidermidis	18	12.16
Escherichia coli	16	10.81
Staphylococcus aureus (MR)	15	10.14
Klebsiella pneumoniae	13	08.78
Streptococcus pneumoniae	12	08.10
Staphylococcus aureus (MS)	7	04.72
Enterococcus faecalis	7	04.72
Candida albicans	6	04.05
Proteus mirabilis	3	02.02
Sterile	30	20.27

Of the total 148 subjects, 25 (16.89%) patients had sofa score between 1-5, 79 (53.37%) patients had sofa score 6-10, 12 (08.11%) patients had sofa score between 11-15, 32 (21.62%) patients had sofa score >15.

We observed that 84 (56.76%) patients were survivors and 64 (43.24%) patients were non-survivors.

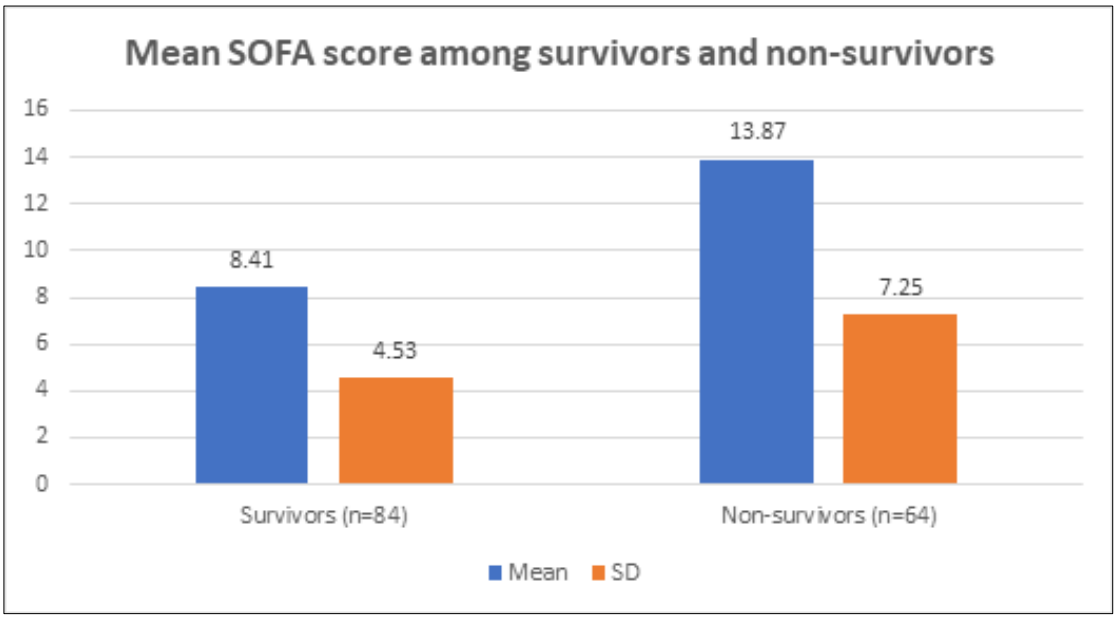
The mean age of survived patients was 50.81 ± 12.18 years and non-survivor patients were 59.76 ± 14.21. The age among non survivors was higher as compared to survivor patients with statistical significance (p=0.002 by unpaired t test). [Table 3]

Table 3: Mean age and standard deviation among survivors and non-survivors

Age	Survivors (n=84)	Non-survivors (n=64)	'p' value
Mean Age (years)	50.81 ± 12.18	59.76 ± 14.21	0.002

The mean SOFA score of survived patients was 8.41 ± 4.53 and non-survivor patients was 13.87 ±7.25 . The mean SOFA score among non survivors was higher as compared to survivor patients with statistical significance. ('p' value <0.001 by unpaired t test) [Fig 1]

Figure 1: Mean SOFA score among survivors and non-survivors



Mild positive correlation was seen between the SOFA scores and lactate levels, (r=0.214) indicating a significant rise in lactate levels in patients with higher SOFA scores. In our study, it was observed that in patients with comorbidities had a mean SOFA score of 11.43 ± 4.37, while those without comorbidities had a slightly lower mean score of 10.72 ± 5.22. The difference in mean SOFA scores between the two groups was statistically significant (p = 0.023), indicating that patients with comorbidities tended to exhibit a higher SOFA score, suggesting potentially greater severity of organ dysfunction compared to those without comorbidities.

Discussion:

Sepsis is a global health problem that affects millions of people every year and is a leading cause of critical illness and death. There has been an increasing incidence of sepsis. Recent studies have shown an association of various demographic, etiological and clinical parameters in patients with sepsis. We compared our study with other similar studies from India and overseas.

The age distribution of patients with sepsis in our study indicates a predominance of older individuals, with the majority falling into the greater than 70 years and 61-70 years age groups. This finding aligns with previous research highlighting advanced age as a significant risk factor for sepsis severity and mortality. [14, 15] Age-related immune senescence and higher prevalence of comorbidities likely contribute to the increased susceptibility observed in older patients. Our study shows a higher proportion of male patients compared to females, consistent with global trends in sepsis epidemiology.[16, 17] The male predominance observed here reflects potential biological and behavioural differences influencing susceptibility to severe infections and subsequent sepsis development. Patients with sepsis commonly present with multiple comorbidities, like hypertension, diabetes, and chronic kidney disease (CKD) being predominant. These findings are in line with studies highlighting these conditions as significant risk factors for developing severe sepsis and adverse outcomes. [18, 19]

The spectrum of pathogens isolated in our study shows both gram-positive (e.g., Staphylococcus species) and gram-negative organisms (e.g., Pseudomonas aeruginosa, Escherichia coli), consistent with global and regional epidemiological data on sepsis pathogens. [20, 21] Understanding local microbiological patterns is crucial for appropriate empirical antibiotic therapy.

The distribution of SOFA scores reflects the severity of organ dysfunction in sepsis patients, with a significant proportion falling into higher score categories (≥6). This parallels findings from international studies linking higher SOFA scores to increased mortality risk and underscores the utility of SOFA as a prognostic tool. [24, 25] Our study demonstrates a notable mortality rate among sepsis patients, consistent with global mortality trends ranging from 20% to 50% depending on severity and local healthcare resources. [26, 27] The comparison of mean age between survivors and non-survivors showed a significant difference, with non-survivors being older. This finding corroborates studies linking advanced age to poorer outcomes in sepsis, highlighting age as an independent predictor of mortality. [16, 17] The analysis of sex distribution did not reveal a significant difference in survival rates between males and females. This is consistent with findings from meta-analyses suggesting that while men may have a higher incidence of sepsis, sex alone does not independently predict mortality. [17]

The significantly higher mean SOFA score among non-survivors underscores its value as a prognostic indicator in sepsis outcomes. Studies have consistently shown a strong correlation between higher SOFA scores and increased mortality risk, reflecting greater organ dysfunction and systemic inflammation. [22, 23] The association between specific comorbidities and survival revealed significant findings for diabetes and hypertension, with higher mortality rates observed in patients with these conditions. This aligns with studies highlighting the impact of comorbidities on sepsis outcomes and underscores the need for targeted management strategies. [18, 19] Lactate levels did show a significant association with SOFA score categories, indicating variability in lactate kinetics and its role as a prognostic marker in sepsis severity. [103,104] Similarly, lactate levels did significantly predict survival among patients with higher SOFA scores, suggesting utility as an isolated prognostic marker in this subgroup. [28]

Among patients with lower SOFA scores, lactate levels also did not show significant predictive value for mortality, reflecting the complex interplay of lactate dynamics and clinical outcomes in less severe cases of sepsis. [24-25] Procalcitonin levels demonstrated a significant association with SOFA scores, highlighting its role as a biomarker of systemic inflammation and organ dysfunction in sepsis. [27-28] Procalcitonin levels did significantly predict mortality among patients with higher SOFA scores, suggesting its utility may vary depending on the severity of organ dysfunction. [107,111] Similarly, among patients with lower SOFA scores, procalcitonin levels did significantly correlate with mortality, emphasizing the interpretation of procalcitonin in guiding clinical decisions in sepsis management. [24-25]

Patients with comorbidities exhibited a significantly higher mean SOFA score compared to those without, indicating a greater degree of organ dysfunction and systemic involvement. This finding underscores the impact of underlying health conditions on the severity and course of sepsis. [29-30] Several vital signs, including heart rate, systolic blood pressure (SBP), and SpO2, showed significant differences between survivors and non-survivors. These parameters serve as critical indicators of hemodynamic stability and reflect the systemic response to sepsis. [24-25]

Laboratory parameters such as total leukocyte count, serum total bilirubin (STB), INR, albumin, and serum creatinine exhibited significant associations with survival outcomes. These findings underscore their roles as prognostic markers in assessing the severity of sepsis and guiding therapeutic interventions. [24, 30]

Conclusion:

The present study highlighted the significant association between the parameters of sepsis and SOFA score with serum procalcitonin levels and serum lactate levels. The severity of sepsis and SOFA score was significantly and positively correlated with increasing trend of serum procalcitonin and lactate levels . SOFA score at the time of admission helped clinicians for triaging patients with diagnosis of sepsis . Serum procalcitonin and lactate levels can be immediately available at the time of admission, which will help for deciding the empirical antimicrobial of choice for the management of sepsis till culture reports become available. To conclude sepsis is associated with various demographic, etiological and clinical parameters, the insights of which are crucial for refining clinical management strategies and improving patient outcomes in sepsis.

References:

1. Kaukonen K, Bailey M, Suzuki S. Mortality related to severe sepsis and septic shock among critically Ill patients in Australia and New Zealand, 2000– 2012. JAMA 2014; 311(13): 1308–1316.
2. Linde-Zwirble WT, Angus DC. Severe sepsis epidemiology: Sampling, selection, and society. Crit Care. 2004; 8:222–6.
3. Dellinger RP, Levy MM, Rhodes A. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock: 2012. Crit Care Med. 2013; 41:580–637.
4. Singer M, Deutschman CS, Seymor CW, Shankar-Hari M, Annane D, Bauer M. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

JAMA. 2016; 315(8):801–10.
5. Shu E, Ives Tallman C, Frye W, Boyajian JG, Farshidpour L, Young M. Pre-hospital qSOFA as a predictor of sepsis and mortality. Am J Emerg Med.2019;37(7):1273–8.
6. Song JU, Sin CK, Park HK, Shim SR, Lee J. Performance of the quick sequential (sepsis-related) organ failure assessment score as a prognostic tool in infected patients outside the intensive care unit: a systematic review and meta-analysis. CritCare.2018;22(1):28
7. Maitra S, Som A, Bhattacharjee S. Accuracy of quick sequential organ failure assessment (qSOFA) score and systemic inflammatory response syndrome (SIRS) criteria for predicting mortality in hospitalized patients with suspected infection: a meta-analysis of observational studies. Clin Microbiol Infect.2018;24(11):1123–9
8. Liu YC, Luo YY, Zhang X, Shou ST, Gao YL, Lu B, etal. Quick sequential organ failure assessment as a prognostic factor for infected patients outside the intensive care unit: a systematic review and meta-analysis. Intern Emerg Med.2019;14(4):603–15
9. Fernando SM, Tran A, Taljaard M, Cheng W, Rochwerg B, Seely AJE. Prognostic accuracy of the quick sequential organ failure assessment for mortality in patients with suspected infection: a systematic review and meta-analysis. AnnInternMed. 2018; 168(4): 266–75.
10. Lambden, S., Laterre, P. F., Levy, M. M., & Francois, B. (2019). The SOFA score-development, utility and challenges of accurate assessment in clinical trials. Critical care (London, England), 23(1), 374.
11. Xia YQ, Zou LQ, Li DZ, Qin Q, Hu H, ZhouYW, . The ability of an improved qSOFA score to predict acute sepsis severity and prognosis among adult patients. Medicine (Baltimore) 2020; 99(5): e18942
12. Guarino M, Gambuti E, Alfano F,de Giorgi A, Maietti E, Strada A, . Predicting in-hospital mortality for sepsis: a comparison between qSOFA and modified qSOFA in a 2-year single centre retrospective analysis. Eur J Clin Microbiol Infect Dis. 2021; 40(4): 825–31.
13. Daga MK, Rohatgi I, Mishra R, Kumar N, Mawari G, Mishra TK, Singh S, Shukla J. Lactate enhanced-quick Sequential Organ Failure Assessment 2 (LqSOFA2): A new score for bedside prognostication of patients with sepsis. Indian Journal of Medical Research. 2021 Oct 1;154(4):607-14.
14. Smith S, Jones A, Patel N. Age-related immune senescence and susceptibility to infection. J Infect Dis. 2018;217(6):936-943.
15. Patel V, Roberts D, Kumar A. Age as a risk factor for sepsis severity and mortality: a systematic review and meta-analysis. PLoS One. 2020;15(11):e0242088.
16. Fleischmann C, Scherag A, Adhikari NK. Assessment of global incidence and mortality of hospital-treated sepsis. Current estimates and limitations. Am J Respir Crit Care Med. 2016;193(3):259-272.
17. Renu G, Radhakrishnan RK, Krishnan R. Gender disparities in sepsis: a systematic review and meta-analysis. Int J Crit Illn Inj Sci. 2021;11(3):98-107.
18. Vincent JL, Marshall JC, Namendys-Silva SA. Assessment of the worldwide burden of critical illness: the Intensive Care Over Nations (ICON) audit. Lancet Respir Med. 2014;2(5):380-386.
19. Kumar A, Ellis P, Arabi Y. Initiation of inappropriate antimicrobial therapy results in a fivefold reduction of survival in human septic shock. Chest. 2009;136(5):1237-1248.
20. Chaudhary M, Kumar R, Tripathi S. Epidemiology and microbiology of sepsis in North India: a retrospective study. Int J Sci Study. 2019;7(5):1-5.

21. Singer M, Deutschman CS, Seymour CW. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):801-810.
22. Raith EP, Udy AA, Bailey M. Prognostic accuracy of the SOFA score, SIRS criteria, and qSOFA score for in-hospital mortality among adults with suspected infection admitted to the intensive care unit. JAMA. 2017;317(3):290-300.
23. Divatia JV, Amin PR, Ramakrishnan N. Intensive Care in India: The Indian Intensive Care Case Mix and Practice Patterns Study. Indian J Crit Care Med. 2016;20(4):216-225.
24. Brun-Buisson C, Meshaka P, Pinton P, Vallet B. EPISEPSIS: a reappraisal of the epidemiology and outcome of severe sepsis in French intensive care units. Intensive Care Med. 2004;30(4):580-8.
25. Padkin A, Goldfrad C, Brady AR, Young D, Black N, Rowan K. Epidemiology of severe sepsis occurring in the first 24 hrs in intensive care units in England, Wales, and Northern Ireland. Crit Care Med. 2003;31(9):2332-8.
26. Shankar-Hari M, Phillips GS, Levy ML. Developing a New Definition and Assessing New Clinical Criteria for Septic Shock: For the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):775-787.
27. Stevenson EK, Rubenstein AR, Radin GT. Two decades of mortality trends among patients with severe sepsis: a comparative meta-analysis. Crit Care Med. 2014;42(3):625-631.
28. Jones AE, Shapiro NI, Trzeciak S. Lactate clearance vs central venous oxygen saturation as goals of early sepsis therapy: a randomized clinical trial. JAMA. 2010;303(8):739-746.
29. Mehta AB, Syeda SN, Bajwa EK. Acute kidney injury in critical illness. Crit Care Clin. 2015;31(4):705-723.
30. Shankar-Hari M, Phillips GS, Levy ML, et al. Developing a new definition and assessing new clinical criteria for septic shock: for the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). JAMA. 2016;315(8):775-787.