



## Validity of SOFA Score as Predictor of Mortality in Critically-ill Burn Patients

**CLINICALTRIALS.GOV IDENTIFIER**  
NCT03930108

**RECRUITMENT STATUS**  
COMPLETED

**FIRST POSTED**  
APRIL 29, 2019

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### STUDY DESCRIPTION

#### Brief Summary

SOFA score is valid for mortality predictor for critically-ill patient in high care and intensive care burn unit

**Condition or Disease:** Mortality Prediction

**Intervention/treatment:** Other: SOFA score

**Phase:** N/A

#### DETAILED DESCRIPTION

N/A

### STUDY DESIGN

**Study Type:** Observational

**Estimated Enrollment :** 169 participants

**Intervention Model :** N/A

**Masking:** N/A

**Primary Purpose:** N/A

**Official Title:** Validity of Sequential Organ Failure Assessment (SOFA) Score as Predictor of Mortality in Critically-ill Burn Patients

**Actual Study Start Date:** September 2018

**Actual Primary Completion Date:** December 2018

**Actual Study Completion Date:** February 2019

### GROUPS AND COHORTS

Groups/Cohorts	Intervention/treatment
: Mortality outcome	Other: SOFA score Variables of sequential organ failure assessment score, including: P:F ratio; MAP or vasoactive treatment; creatinine or 24-h diuresis; platelet count; serum bilirubin; GCS.

### OUTCOME MEASURES

Primary Outcome Measures: 1. SOFA score Discrimination [ Time Frame: 30 days from admission ]  
SOFA score ability to discriminate outcomes based on variable scores: PaO<sub>2</sub>/FiO<sub>2</sub>; MAP/vasoactive treatment; serum creatinine or 24-h diuresis; platelet count; serum bilirubin; GCS

2. SOFA score Calibration [ Time Frame: 30 days from admission ]  
SOFA score cutoff to predict outcome based on variable scores: PaO<sub>2</sub>/FiO<sub>2</sub>; MAP/vasoactive treatment; serum creatinine or 24-h diuresis; platelet count; serum bilirubin; GCS

3. Correlation between SOFA score variables with outcome [ Time Frame: 30 days from admission ]  
Correlation between patient outcomes with each SOFA score variable: PaO<sub>2</sub>/FiO<sub>2</sub>; MAP/vasoactive treatment; serum creatinine or 24-h diuresis; platelet count; serum bilirubin; GCS

Secondary Outcome Measures: 1. Patient outcome [ Time Frame: 30 days from admission ]  
Patient outcome within 30 days of admission to burn units: deceased or survived

2. SOFA score: Partial Oxygen Pressure (PaO<sub>2</sub>)/ Fraction of Inspired Oxygen (FiO<sub>2</sub>) [ Time Frame: Day 1 ]  
The score for PaO<sub>2</sub>/FiO<sub>2</sub> variable cutoff: 0 point for >400 mmHg; point for <400 mmHg; points for <300 mmHg; points for <200 mmHg with respiratory support; points for <100 mmHg with respiratory support.

3. SOFA score: Mean Arterial Pressure (MAP) or vasoactive agent usage [ Time Frame: Day 1 ]  
The score for MAP or vasoactive agent usage variable cutoff: 0 point for MAP >=70 mmHg; point for MAP <70 mmHg; points for dopamine <= 5 mcg/kg/min OR dobutamine any dose; points for dopamine >5 mcg/kg/min OR norepinephrine or epinephrine <=0.1 mcg/kg/min; points for dopamine >15 mcg/kg/min OR norepinephrine or epinephrine >0.1 mcg/kg/min.

4. SOFA score: Serum creatinine or 24-hour diuresis [ Time Frame: Day 1 ]  
The score for serum creatinine or 24-hour diuresis variable cutoff: 0 point for creatinine <1.2 mg/dL; point for creatinine 1.2 - 1.9 mg/dL; points for creatinine 2.0 - 3.4 mg/dL; points for creatinine 3.5 - 4.9 mg/dL OR diuresis <500 mL/24h; points for creatinine >5.0 mg/dL OR diuresis <200 mL/24h.

5. SOFA score: Platelet count [ Time Frame: Day 1 ]  
The score for platelet count variable cutoff: 0 point for >=150 x10<sup>3</sup>/mm<sup>3</sup>; point for <150 x10<sup>3</sup>/mm<sup>3</sup>; points for <100 x10<sup>3</sup>/mm<sup>3</sup>; points for <50 x10<sup>3</sup>/mm<sup>3</sup>; points for <20 x10<sup>3</sup>/mm<sup>3</sup>.

6. SOFA score: Serum Bilirubin [ Time Frame: Day 1 ]  
The score for serum bilirubin variable cutoff: 0 point for <1.2 mg/dL; point for 1.2 - 1.9 mg/dL; points for 2.0 - 5.9 mg/dL; points for 6.0 - 11.9 mg/dL; points for >12.0 mg/dL.

7. SOFA score: Glasgow Coma Scale (GCS) [ Time Frame: Day 1 ]  
The score for GCS variable cutoff: 0 point for 15; point for 13 - 14; points for 10 - 12; points for 6 - 9; points for <6L.

### ELIGIBILITY CRITERIA

**Ages Eligible for Study:** 18 Years and older (Adult, Older Adult)

**Sexes Eligible for Study:** All

**Accepts Healthy Volunteers:** No

#### Criteria

Inclusion Criteria:

- adult patients (age 18 and above) who admitted to burn unit during sampling period

Exclusion Criteria:

- patients discharged or deceased less than 24 hours of admission

- patients referred to other hospital within 30 days admission

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#### CONTACTS AND LOCATIONS

##### Contacts

##### Locations

Indonesia, DKI Jakarta

Rumah Sakit Cipto Mangunkusumo

Jakarta Pusat

##### Sponsors and Collaborators

Indonesia University

##### Investigator

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#### MORE INFORMATION

##### Other Publications

Wardhana A, Basuki A, Prameswara ADH, Rizkita DN, Andarie AA, Canintika AF. The epidemiology of burns in Indonesia's national referral burn center from 2013 to 2015. *Burn Open*. 2017;1(2):67-73.

Queiroz LF, Anami EH, Zampar EF, Tanita MT, Cardoso LT, Grion CM. Epidemiology and outcome analysis of burn patients admitted to an Intensive Care Unit in a University Hospital. *Burns*. 2016 May;42(3):655-62. doi: 10.1016/j.burns.2015.08.002. Epub 2016 Jan 4.

Taofik S, Senapathi TGA, Wiryana M. Comparison Of Validity Apache II, SOFA And Customized Sequential Organ Failure Assessment (Csofa) For Predicting Non-Surgical Patient. *J Anestesiologi Indones*. 2015;7(2):102-13.

Sunaryo A, Redjeki IS, Bisri T. Perbandingan Validasi APACHE II dan SOFA Score untuk Memperkirakan Mortalitas Pasien yang Dirawat di Ruang Perawatan Intensif. *Majalah Kedokteran Terapi Intensif*. 2012;2(1):11-20.

Andrias A, Hanafie A, Wijaya DW. Comparison of APACHE II, SOFA, and CSOFA Scoring System Validity as Mortality Predictor in ICU Patients in H. Adam Malik General Hospital. *J Anestesi Perioper*. 2017;5(1):17-23j.

Bouch DC, Thompson JP. Severity scoring systems in the critically ill. *Contin Educ Anaesth Crit Care Pain*. 2008;8(5):181-5.

Vincent JL, de Mendonça A, Cantraine F, Moreno R, Takala J, Suter PM, Sprung CL, Colardyn F, Blecher S. Use of the SOFA score to assess the incidence of organ dysfunction/failure in intensive care units: results of a multicenter, prospective study. Working group on "sepsis-related problems" of the European Society of Intensive Care Medicine. *Crit Care Med*. 1998 Nov;26(11):1793-800.

Snell JA, Loh NH, Mahambrey T, Shokrollahi K. Clinical review: the critical care management of the burn patient. *Crit Care*. 2013 Oct 7;17(5):241. doi: 10.1186/cc12706. Review.

Jain A, Palta S, Saroa R, Palta A, Sama S, Gombar S. Sequential organ failure assessment scoring and prediction of patient's outcome in Intensive Care Unit of a tertiary care hospital. *J Anaesthesiol Clin Pharmacol*. 2016 Jul-Sep;32(3):364-8. doi: 10.4103/0970-9185.168165.

Cárdenas-Turanzas M, Ensor J, Wakefield C, Zhang K, Wallace SK, Price KJ, Nates JL. Cross-validation of a Sequential Organ Failure Assessment score-based model to predict mortality in patients with cancer admitted to the intensive care unit. *J Crit Care*. 2012 Dec;27(6):673-80. doi: 10.1016/j.jcrr.2012.04.018. Epub 2012 Jul 2.

de Brito MR, Barros AG, Valler L, Cardoso FB, Gasparotto AP, Tiziani L, et al. Evaluation of Sequential Organ Failure Assessment (SOFA) Performance in Neurocritical Care Patients Overtime: A Retrospective Cohort Study. *J Brain Disord*. 2017;1(1):38-43.

Nair R, Bhandary NM, D'Souza AD. Initial Sequential Organ Failure Assessment score versus Simplified Acute Physiology score to analyze multiple organ dysfunction in infectious diseases in Intensive Care Unit. *Indian J Crit Care Med*. 2016 Apr;20(4):210-5. doi: 10.4103/0972-5229.180041.

Cabré L, Mancebo J, Solsona JF, Saura P, Gich I, Blanch L, Carrasco G, Martín MC; Bioethics Working Group of the SEMICYUC. Multicenter study of the multiple organ dysfunction syndrome in intensive care units: the usefulness of Sequential Organ Failure Assessment scores in decision making. *Intensive Care Med*. 2005 Jul;31(7):927-33. Epub 2005 Apr 26.

Lorente JA, Vallejo A, Galeiras R, Tomicic V, Zamora J, Cerdá E, de la Cal MA, Esteban A. Organ dysfunction as estimated by the sequential organ failure assessment score is related to outcome in critically ill burn patients. *Shock*. 2009 Feb;31(2):125-31. doi: 10.1097/SHK.0b013e31817fc3ef.

Karlje J, Wardhana A. External Validation of Belgian Outcome of Burn Injury Score on Burned Patient In Burn Unit Cipto Mangunkusumo General Hospital. *New Ropanasuri J Surg*. 2017;2(1):90.

Emara SS, Alzaylai AA. Renal failure in burn patients: a review. *Ann Burns Fire Disasters*. 2013 Mar 31;26(1):12-5.

Ibrahim AE, Sarhane KA, Fagan SP, Goverman J. Renal dysfunction in burns: a review. *Ann Burns Fire Disasters*. 2013 Mar 31;26(1):16-25.

Carson J, Goverman J, Fagan S. Acute renal failure in association with thermal injury. In: Herndon D, editor. *Total Burn Care*. 5th ed. Elsevier; 2018. p. 318-27.

Nielson CB, Duethman NC, Howard JM, Moncure M, Wood JG. Burns: Pathophysiology of Systemic Complications and Current Management. *J Burn Care Res*. 2017 Jan/Feb;38(1):e469-e481. doi: 10.1097/BCR.0000000000000355. Review.

Enkhbaatar P, Sousse L, Cox R, Herndon D. The pathophysiology of inhalation injury. In: Herndon D, editor. *Total Burn Care*. 5th ed. Elsevier; 2018. p. 174-83.

Marck RE, Montagne HL, Tuinebreijer WE, Breederveld RS. Time course of thrombocytes in burn patients and its predictive value for outcome. *Burns*. 2013 Jun;39(4):714-22. doi: 10.1016/j.burns.2013.01.015. Epub 2013 Mar 13.

Guo F, Wang X, Huan J, Liang X, Chen B, Tang J, Gao C. Association of platelet counts decline and mortality in severely burnt patients. *J Crit Care*. 2012 Oct;27(5):529.e1-7. doi: 10.1016/j.jcrr.2011.12.006. Epub 2012 Feb 1.

##### Responsible Party :

Indonesia University

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IndonesiaUANes033

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**Studies a U.S. FDA-regulated Drug Product:** No

**Studies a U.S. FDA-regulated Device Product:** No

**Keywords provided by Indonesia University:** *Burn injury*  
*Mortality prediction SOFA score*  
*Organ failure*

**Additional relevant MeSH terms :** *Critical Illness*