

The IndONEsia ICCU Registry: Protocol and Preliminary Analysis for a Multicenter Cohort of Intensive Cardiovascular Care Units Patients in Indonesia

Dafsah Arifa Juzar¹, Hendry Purnasidha Bagaswoto², Akhtar Fajar Muzakkir³, Faisal Habib⁴, Tri Astiawati⁵, Indra Prasetya⁶, Hendy Wirawan⁷, Yose Ramda Ilhami⁸, Dewi Utari Djafar⁹, Safir Sungkar¹⁰, Siska Suridanda Danny¹.

¹ Department of Cardiology & Vascular Medicine, Faculty of Medicine, University of Indonesia.

² Department of Cardiology & Vascular Medicine, Faculty of Medicine, Public Health, and Nursing, University of Gadjah Mada, Yogyakarta.

³ Department of Cardiology & Vascular Medicine, Faculty of Medicine, University of Hasanudin.

⁴ Department of Cardiology & Vascular Medicine, Faculty of Medicine, University of Sumatera Utara.

⁵ Department of Cardiology & Vascular Medicine, Faculty of Medicine, Universitas Brawijaya, East Java.

⁶ Department of Cardiology & Vascular Medicine, Faculty of Medicine, University of Brawijaya, Malang, East Java.

⁷ Department of Cardiology & Vascular Medicine, Faculty of Medicine, University of Udayana, Denpasar, Bali.

⁸ Department of Cardiology & Vascular Medicine, Faculty of Medicine, Universitas Andalas, West Sumatera.

⁹ Department of Cardiology and Vascular Medicine, Faculty of Medicine, University of Sam Ratulangi, North Sulawesi

¹⁰ Department of Cardiology & Vascular Medicine, Faculty of Medicine, University of Diponegoro, Semarang, Central Java.

Correspondence:

Dafsah Arifa Juzar,
Department of Cardiology & Vascular
Medicine, Faculty of Medicine, University of
Indonesia.
Email: djuzar@gmail.com.

Abstract

Introduction: Patients in the Intensive Cardiovascular Care Unit (ICCU) often present with cardiovascular disease (CVD) issues accompanied by various non-cardiovascular conditions. However, a widely applicable scoring system to predict patient outcomes in the ICCU is lacking. Therefore, developing and validating scores for predicting ICCU patient outcomes are warranted. The aims of the IndONEsia ICCU (One ICCU) registry include developing an epidemiological registry of ICCU patients and establishing a multicentre research network to analyse patient outcomes.

Methods and Results: This nationwide multicenter cohort protocol will capture data from patients receiving cardiovascular critical care treatment in 10 Indonesian hospitals with ICCU facilities. Recorded data will encompass demographic characteristics, physical examination findings at hospital and ICCU admission, diagnoses at ICCU admission, therapy, intervention, complications on days 3 and 5 of in-ICCU care, in-hospital outcomes, and 30-day outcomes.

Protocol Registration: Registered at clinicaltrials.gov (NCT06265714).

Conclusion: The One ICCU is a large, prospective registry describing the care process and advancing clinical knowledge in ICCU patients. It will serve as an investigational platform for predicting the mortality of ICCU patients.

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Keywords: *One ICCU Registry; Multicenter Cohort; Cardiovascular Critical Care; Patient Outcomes; Epidemiological Registry.*

Introduction

Cardiovascular diseases (CVD) have become the leading cause of death and disabilities all over the world. Intensive Cardiovascular Care Units (ICCU) have become inseparable in managing patients with CVD.¹ There have been remarkable shifts in the demographic characteristics of patients admitted to ICCU, with a reduction in the proportion of acute myocardial infarction and a higher proportion of patients with hemodynamic compromise associated with non-cardiovascular conditions. A higher proportion of patients with chronic cardiovascular disease presenting to ICCU with acute non-cardiovascular complications has also been observed, projecting that the need for critical care will increase markedly.²⁻⁴

As the fourth most populous country in the world, Indonesia is experiencing a swift epidemiological transition where the burden of non-communicable diseases is becoming a major public health issue.⁵ Almost a third of all deaths in Indonesia are associated with CVD.⁶ In light of such progression towards more complex conditions of patients with CVD admitted to ICCU, studies that objectively characterize the demographics, diagnoses, technologies, therapies, and outcomes in the current ICCU are needed to achieve quality improvement in the management of patients treated in ICCU.

Healthcare system organization is heterogeneous throughout Indonesia, with various hospital sizes, distribution and technical capabilities, standard operating procedures, and multidisciplinary interaction with other specialties. In 2021, the Indonesian Heart Association established an expert consensus document for the structure, organization, and operation of ICCUs in Indonesia, in which ICCUs are classified into three classes (Class I, Class II, and Class III) according to available resources and technical capabilities in each unit.⁷ Differences in the organization of ICCU across Indonesia may lead to gaps in the demographics and management of ICCU patients.

Currently, available risk scores for the Intensive Care Unit (ICU), such as Acute Physiology and Chronic Health Evaluation (APACHE) and Sequential Organ Failure Assessment (SOFA), are widely utilized for assessing mortality risk stratification and disease severity in critically ill patient populations. However, existing

ICU risk scores have limitations, requiring the collection of all data within the first 24 hours of ICU admission to achieve optimal predictive results compared to using only admission data.^{8,9}

To date, no specific risk score for predicting mortality risk has been developed for patients in the ICCU. Additionally, there is a lack of modalities utilizing admission data to identify and assist in triaging low-risk patients. Consequently, there is a need for a large-scale research effort to collect clinical data from ICCU patients, serving as a foundation for developing a risk assessment system applicable to ICCU patients. Therefore, the development and validation of scores for predicting ICCU patient outcomes are warranted.

IndONEsia ICCU Registry (One ICCU Registry) is Indonesia's first multicenter observational cohort protocol. Previous protocols, such as the Critical Care Cardiology Trials Network (CCTN), also investigate the epidemiology of cardiac critical illness and establish a multicenter research network to conduct randomized clinical trials (RCTs) in patients with cardiac critical illness in the United States and Canada.¹⁰

We established a multicentre network protocol focused on cardiac critical care to determine the demographics, diagnoses, and outcomes of patients treated in the ICCU. The aims of the One ICCU Registry protocol include the development of an epidemiological registry of ICCU patients and the establishment of a multi-centred research network to analyze patient outcomes.

Methods and Results

Study Design

This prospective cohort registry study protocol comprised all consecutive primary medical ICCU admissions across one speciality hospital and nine general hospitals in Indonesia. The participating hospitals include the specialized National Cardiovascular Center Harapan Kita in Jakarta and nine general hospitals: Dr. Sardjito General Hospital in Yogyakarta, Dr. Wahidin Sudirohusodo General Hospital in Makassar, H. Adam Malik General Hospital in Medan, Dr. Saiful Anwar General Hospital in Malang, Dr. M. Djamil General Hospital in Padang, Dr. Iskak General Hospital in

Tulungagung, Prof. Ngoerah General Hospital in Denpasar, Prof. Dr. R. D. Kandou General Hospital Manado, and Dr. Kariadi General Hospital Semarang. Each participating hospital will contribute data for all consecutive medical ICCU admissions for a period of 2 years, from August 2021 to August 2023. The participating hospitals were carefully selected to represent all regions of Indonesia.

All of the participating hospitals were identified as having an ICCU class III, except for Dr. Saiful Anwar General Hospital in Malang and Dr. Iskak General Hospital in Tulungagung, which has an ICCU class II. Scientific oversight of the One ICCU Registry is conducted by its principal investigator and local investigators in each center. This study is coordinated by the Acute and Critical Cardiovascular Care Working Group of the Indonesian Heart Association (**Figure 1**).

ICCU level I service is an intensive care unit provided by cardiovascular specialists. ICCU level II has service capabilities in line with ICCU level I, enhanced with additional services such as pericardiocentesis, installation and monitoring of temporary cardiac pacemakers, and intensive hemodynamic monitoring. Meanwhile, ICCU level III possesses comprehensive hemodynamic support capabilities with advanced equipment. Care in ICCU Level III is primarily directed towards patients with acute and complex cardiovascular diseases involving multi-organ dysfunction.⁷

Study Population

The inclusion criteria of this study include patients aged ≥ 18 years old who consent to participate in the study. We exclude admissions solely for postoperative management following cardiac surgery. Patients willing to participate in this study are followed up on their day three and five of in-ICCU care, their hospital discharge time, and day 30 following the day of their hospital discharge.

Patients who were admitted to the ICCU and meet the inclusion criteria will be informed regarding the details of this study. In cases where patients cannot express their consent to participate in this study (e.g., those with loss of consciousness), informed consent may be obtained from the patients' guardians on their behalf. We estimate that each center admits a minimum of 500 patients to the ICCU per year. Therefore, over the course of one year, we anticipate collecting a total of 5000 subjects.

Data Collection

Data were collected using electronic Case Report Forms (eCRFs) filled by the person in charge in each hospital's medical records. The data recorded in this registry consist of demographic characteristics, physical examination findings upon hospital and ICCU admission, diagnoses upon ICCU admission, therapy, intervention, complications, in-hospital evaluation, and 30-day outcomes (**Table 1**).

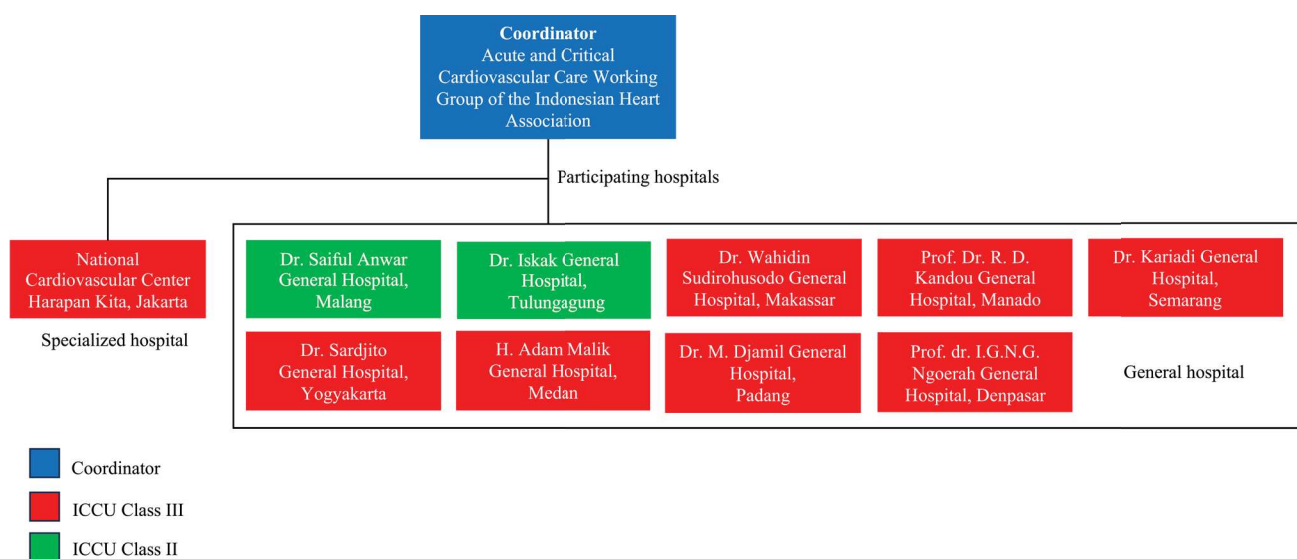


Figure 1. Organization structure of the One ICCU Registry.

Table 1. Morphology of the data collected by One ICCU.

No	Section	Collected data components
1	Patient Identity	Medical number, name, age, gender, height, weight, admission details
2	Pre-ICCU Examination	Vital signs, BP medications, signs of shock, EKG
3	ICCU Admission Examination	Vital signs, BP medications, signs of shock, EKG
4	ICCU Admission Diagnosis	Complete diagnosis, diagnosis classification
5	Comorbidities	Pneumonia, UTI, CKD, sepsis, SOFA score, lactate level, stroke
6	Acute Heart Failure	Incident time, oxygen management, ABG, dopamine, urine output
7	Shock	Incident time, ABG, ECG, examination results, shock type, supportive medications, VIS, urine output
8	Acute Coronary Syndrome	ACS type, Killip class, GRACE score, TIMI score, reperfusion type, reperfusion times, ACS-NSTE risk stratification, invasive strategy, PCI results, CAD severity
9	NIV Use	NIV mode, FiO ₂ , pressure support, PEEP, output
10	Invasive MV Use	MV mode, FiO ₂ , PEEP, tidal volume, RR, sedation, analgesia, muscle relaxants
11	Echocardiography Examination	Conducted, ejection fraction, TAPSE, PH, RMWA
12	Laboratory Examination	Conducted, blood tests, ABG results
13	Therapy	Medications
14	Other	Arterial line, central venous access, renal replacement therapy, TPM installation, circulation support devices, hypothermia therapy, urine output, bleeding
15	Day 3 Evaluation	Lab tests, comorbidities
16	Day 5 Evaluation	Lab tests, comorbidities
17	Mortality Score	M-CARS, APACHE II, SAPS II
18	Mortality	Cause, classification, location
19	Length of Stay (LOS)	ICCU LOS, in-hospital LOS
20	Outcome	30-day outcome, in-hospital mortality, ICCU mortality, 30-day mortality, and rehospitalization

* Abbreviations: ABG: arterial blood gas; ACS: acute coronary syndrome; BP: blood pressure; CAD: coronary artery disease; CKD: chronic kidney disease; ECG: echocardiography; EKG: electrocardiograph; FiO₂: fraction of inspired oxygen; GRACE: Global Registry of Acute Coronary Event; M-CARS: Mayo Cardiac Intensive Care Unit Admission Risk Score; MV: mechanical ventilation; NIV: Non-Invasive Ventilation; PCI: percutaneous coronary intervention; PEEP: positive end-expiratory pressure; PH: pulmonary hypertension; RR: respiratory rate; RMWA: regional wall motion abnormalities; TAPSE: tricuspid annular plane systolic excursion; TIMI: Thrombolysis in Myocardial Infarction; TPM: temporary pacemaker; UTI: urinary tract infection.

Preliminary Data (Baseline)

Preliminary data were collected during the initial phase of the study to offer insights into the baseline characteristics of patients admitted to ICCUs across participating hospitals. This data includes demographic characteristics, past medical history, diagnosis, treatment, complications, outcome, and the follow up.

Current Status and Data Quality

A total of 13,694 respondents have been included in the cohort registry. Among those, 744 were readmitted and were therefore removed. Consequently, the number of patients reported in this study is 12,950. In addition to CVD, 4,474 respondents (34.4%) also have a non-CVD diagnosis admitted to ICCU. These respondents were collected from 10 hospitals across Indonesia

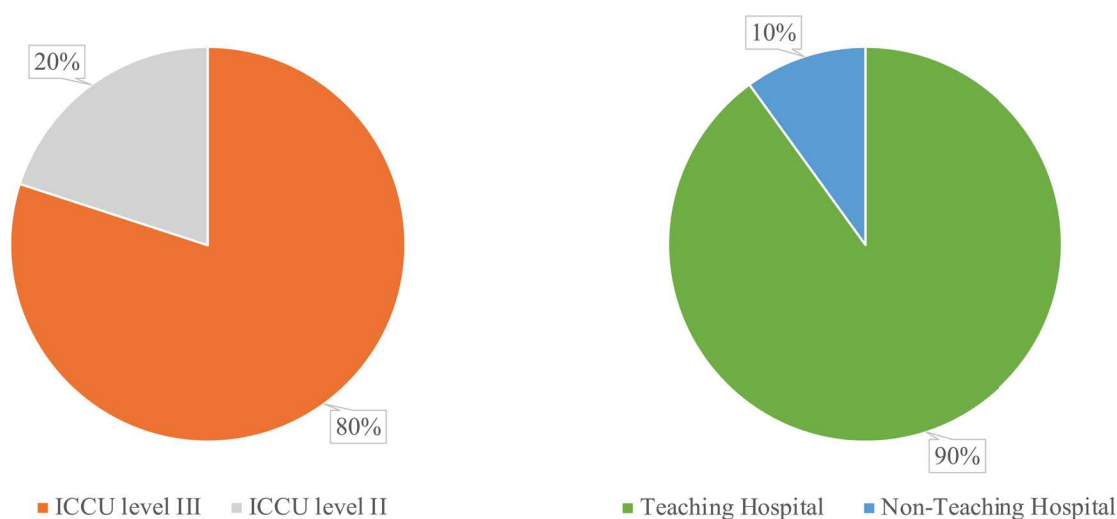


Figure 2. Characteristics of Participating Hospitals.

that participated in this registry. The hospitals were distributed across several islands in Indonesia (Java, Sumatra, Sulawesi, and Bali), comprising eight hospitals (80%) with ICCU class level III and two with ICCU class level II (20%). Most of the hospitals were teaching hospitals, totalling 9 hospitals (90%) (see **Figure 2**).

Discussion

Our study found that the median age of our ICCU patients were younger than previous studies abroad.⁴ Diagnosis of admission was predominated by acute coronary syndromes which accounted for approximately two-thirds of all admission. Non-cardiovascular complications were quite prevalent and some of them significantly predicted 30-day mortality.

Data Management and Evaluation

The One ICCU coordinator team holds the system information for all the data. Each hospital person in charge participates in a monthly meeting to discuss the progress of data input and address issues encountered during data collection and entry. Each hospital submits the collected eCRFs data in attributes in Microsoft Excel format (.xlsx). Data from each participating hospital in the One ICCU Registry consortium is collected and stored securely by the One ICCU coordination team.

Ethics and Dissemination

This study was approved by the National Institute of Health Research and Development, Ministry of Health Republic of Indonesia (Registry No. LB.02.01/2/KE.456/2021). Personal information about potential and enrolled participants will be collected, shared, and maintained to protect confidentiality before, during, and after the study.

The results from this study will be published in peer-reviewed journals and at suitable national and international meetings. The results will also be disseminated through the relevant quality registers.

Declaration of Interests

This study was funded by the Acute and Critical Cardiovascular Care Working Group of the Indonesian Heart Association.

Protocol Registration

This protocol study has been registered at clinicaltrials.gov (NCT06265714).

Conclusion

The One ICCU is a large, prospective registry

describing the care process and advancing clinical knowledge in ICCU patients. It will serve as an investigational platform for predicting the outcome of ICCU patients.

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