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Rationale, Design, and Methodology of the MORCOR-TURK Trial: Predictors of In-hospital MORtality in CORonary Care Patients in Turkey

ORIGINAL INVESTIGATION

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ABSTRACT

Background: Coronary care units are sophisticated clinics established to reduce deaths due to acute cardiovascular events. Current data on coronary care unit mortality rates and predictors of mortality in Turkey are very limited. The MORtality predictors in CORonary care units in TURKey (MORCOR-TURK) trial was designed to provide information on the mortality rates and predictors in patients followed in coronary care units in Turkey.

Methods: The MORCOR-TURK trial will be a national, observational, multicenter, and noninterventional study conducted in Turkey. The study population will include coronary care unit patients from 50 centers selected from all regions in Turkey. All consecutive patients admitted to coronary care units with cardiovascular diagnoses between 1 and 30 September 2022 will be prospectively enrolled. All data will be collected at one point in time, and the current clinical practice will be evaluated (ClinicalTrials.gov number NCT05296694).

In the first step of the study, admission diagnoses, demographic characteristics, basic clinical and laboratory data, and in-hospital management will be assessed. At the end of the first step, the predictors and rates of in-hospital mortality will be documented. The second step will be in cohort design, and discharged patients will be followed up till 1 year. Predictors of short- and long-term mortality will be assessed. Moreover, a new coronary care unit mortality score will be generated with data acquired from this cohort.

Results: The short-term outcomes of the study are planned to be shared by early 2023.

Conclusion: The MORCOR-TURK trial will be the largest and most comprehensive study in Turkey evaluating the rates and predictors of in-hospital mortality of patients admitted to coronary care units.

Keywords: Cardiovascular mortality, coronary care unit, in-hospital mortality, mortality predictors, mortality scoring system

INTRODUCTION

Coronary care unit (CCU) was first established in the 1960s to reduce cardiovascular (CV) mortality which is the leading cause of death worldwide. After Killip and Kimball showed a 20% mortality reduction in acute myocardial infarction (MI) in CCU follow-up, this new precise intensive care concept was recognized and spread quickly worldwide.[1] Afterward, CCU has been widely used in the follow-up and treatment of patients with other CV emergencies like acute heart failure (HF), life-threatening arrhythmias, and hemodynamically unstable conditions due to other cardiac diseases. Besides, with the development of continuous monitoring systems, specialized nursing services, and advanced treatment modalities, CCUs have been upgraded to more functional facilities.

With the widespread use of dedicated CCUs, countries have shared their data regarding CCU patient characteristics and predictors and incidence of mortality. Reported mortality rates varied between 5% and 13% among countries.[2-4] These differences may arise from different factors, including demographic characteristics, diagnostic and therapeutic tools, and the socioeconomic level of the

countries. Thus, comparing mortality rates in CCUs between countries may not be rational due to distinctive opportunities and managing methods. However, it would be very favorable for each country to document the CCU experiences and mortality predictors in line with their circumstances and draw a management algorithm accordingly.

To date, only single-center and limited data on CCU mortality registries have been identified in Turkey, and these studies were designed retrospectively.[5,6] There is no current multicenter and prospective study examining the mortality rate and its predictors on a national basis in the literature. Therefore, an investigation of MORtality predictors in CORonary Care Units in TURKey (MORCOR-TURK) study was planned to provide up-to-date data on rates and predictors of short and long-term mortality in patients admitted to the CCU with various cardiac emergencies in Turkey.

Moreover, mortality scoring systems have been developed and used to predict in-hospital mortality in intensive care unit (ICU) patients for more than 20 years.[7,8] Afterward, they have been validated and customized in large sample of medical and surgical ICUs and provided a probability of hospital mortality using logistic regression (LR) models.[8-10] Coronary care patients were mostly excluded from analysis in these trials. Some recent studies have been published examining the previous and establishing new mortality scoring systems in CCU patients.[11-13] However, there are some limitations in these studies in terms of the number of the centers, including patient population and the study design. Therefore, with this prospective, national, and multicenter study, we planned to develop a new mortality scoring system using LR method in this group of patients.

METHODS

Study Design

The MORCOR-TURK (clinicaltrials.gov NCT05296694) is a multicenter, prospective, cross-sectional, and noninterventional study. It is implemented as a nationwide registry in 50 cardiology centers selected from 7 geographical areas according to their population sample weight, prioritizing the volume of hospitals in each region (Figure 1). It is also the largest registry in Turkey, which provides information on patient characteristics as well as short- and long-term outcomes during CCU follow-up. All consecutive patients admitted to the CCU will be recruited prospectively for 1 month. The names of the centers and researchers are listed in Supplementary File 1.

The first part of the study has a cross-sectional design in which baseline information such as risk factors, demographic data, and cohort characteristics will be assessed. Predictors and risk factors of CV events and in-hospital mortality will be assessed primarily. In the second part of the study, the patients safely discharged from CCU will be followed up by the participating centers for at least 12 months. It will provide information on the predictors of long-term mortality, rehospitalization, and CV events.

Study Population

All consecutive patients admitted to the CCUs in participating centers between 1 and 30 September 2022 will be included in the study. Both genders aged 18 years and older with various cardiac emergencies (acute coronary syndrome (ACS), acute HF, tachyarrhythmias, bradyarrhythmias, myopericarditis, and cardiogenic shock) and those who have signed an informed consent form will be enrolled. Patients meeting the following criteria will be excluded from the study: (1) who do not desire to participate in the study and are

HIGHLIGHTS

- Current data on mortality rates and predictors in coronary care unit (CCU) are limited.
- Knowing the main predictors of short- and long-term mortality may improve the clinicians' management of CCU patients.
- New mortality scoring system may help to categorize CCU patients and allow us to distinguish critically ill patients.
- MORCOR-TURK study is expected to contribute to the management of the CCU patients.

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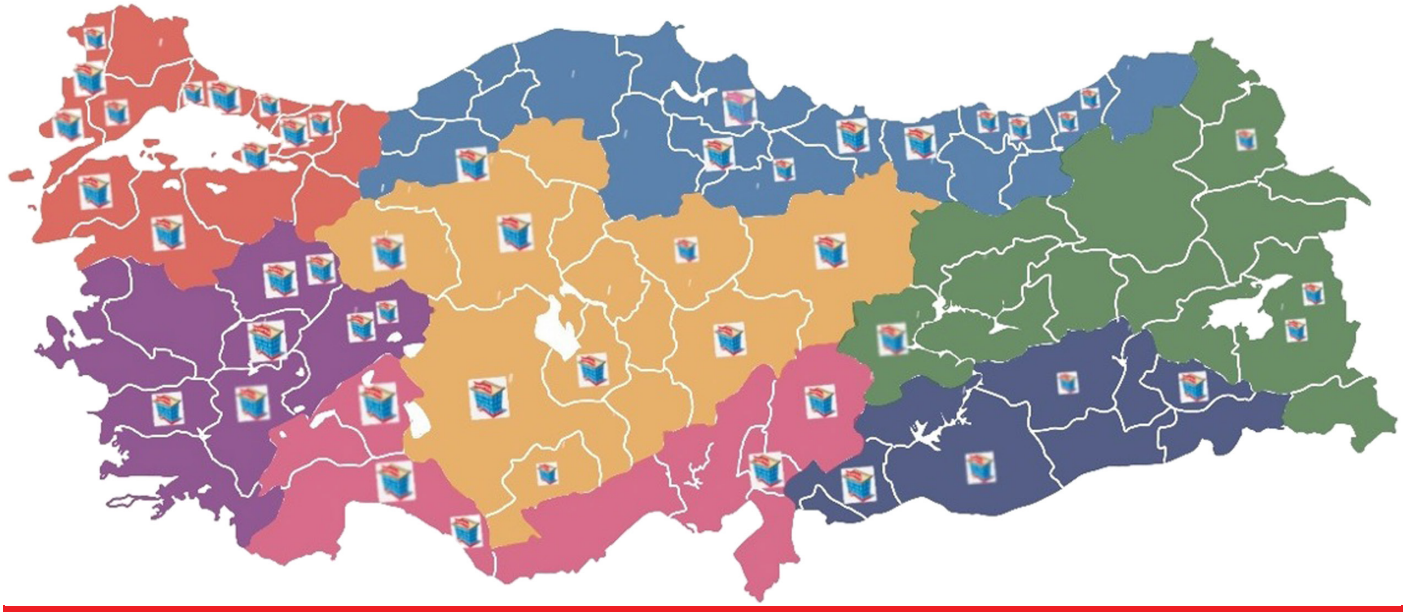

Figure 1. Geographic distribution of the MORCOR-TURK study centers in Turkey. MORCOR-TURK, MORtality predictors in CORonary care units in TURKey.

unwilling to sign informed consent, (2) patients admitted to CCU with noncardiac diseases by other disciplines, (3) discharged from CCU within 4 hours due to patient request, (4) those who followed in CCU after elective interventional procedures (percutaneous coronary and peripheral interventions, transcatheter valve interventions, and other cardiac interventions), and (5) patients who arrived at CCU under cardiopulmonary resuscitation (CPR) and did not respond to CPR will also be excluded.

Demographic and clinical characteristics, hemodynamic status and laboratory findings, primary admission diagnoses, in-hospital adverse events, and discharge status will be recorded. All patients will be followed in CCU under the care of cardiologists and will receive standard care of medical and interventional treatment in accordance with current clinical practice guidelines. All medications used during the follow-up and patients' vital signs will be recorded. Adverse events such as arrhythmias (atrial fibrillation [AF], ventricular tachycardia/fibrillation, atrioventricular blocks, etc.], ischemic or hemorrhagic stroke, acute renal failure, minor-major bleeding, and death during in-hospital follow-up will also be recorded. Patients enrolled in the study will not receive any additional medical or interventional treatment due to their participation. The study flow chart is shown in Figure 2.

Center Selection

The main purpose of this study is to demonstrate the descriptive properties, clinical characteristics, and incidence of mortality data of CCU patients in Turkey. Therefore, to ensure adequate geographic diversity according to population densities, we invited centers from 7 geographical regions of Turkey. Fifty of these invited centers having 24-hour follow-up care for CCU patients from all 7 regions accepted to participate in the study. The geographic distribution of hospitals across the country and the overall profile of the participating CCUs will be representative of the national setting in Turkey.

Prior to patient enrollment, the study coordinators held several meetings about the basic design, methodology, and short- and long-term outcomes. In these meetings, the basic concepts were defined, and then the template of the study form was sent to all participants for review. After participants reviewed the form, 2 online meetings were conducted to receive suggestions and brief participants on the importance, inclusion and exclusion criteria, and the accuracy of the study. A social media platform (WhatsApp group) was set up to ensure the necessary communication before and during the study and to inform and support all participants with questions or problems.

Sample Size and Power Analysis

The study was primarily designed as a descriptive study to find out the incidence and predictors of mortality and was planned to describe the clinical properties of CCU patients in Turkey. However, selecting eligible patients from all over the country would be difficult. Therefore, at least 50 centers representing all geographical regions were determined to reflect the whole country. It was decided to use stratified sampling together with the random sampling method according to the weights of the centers.

The power analysis of the study was performed by GPower 3.1.9.2. (Universitaet Kiel, Germany) software. The test family was chosen as "Exact" and the statistical test as "Proportion: Difference from constant (binomial test, one sample case)" since the mortality rate was given about 10% (5%-13%) in the literature. The effect size was determined using the approximate mortality rate (10%) as proportion $P2$ versus $P1 = 0.50$. Considering the type-I error rate as 0.05 and the power as 0.95, the effect size was calculated as 0.05.

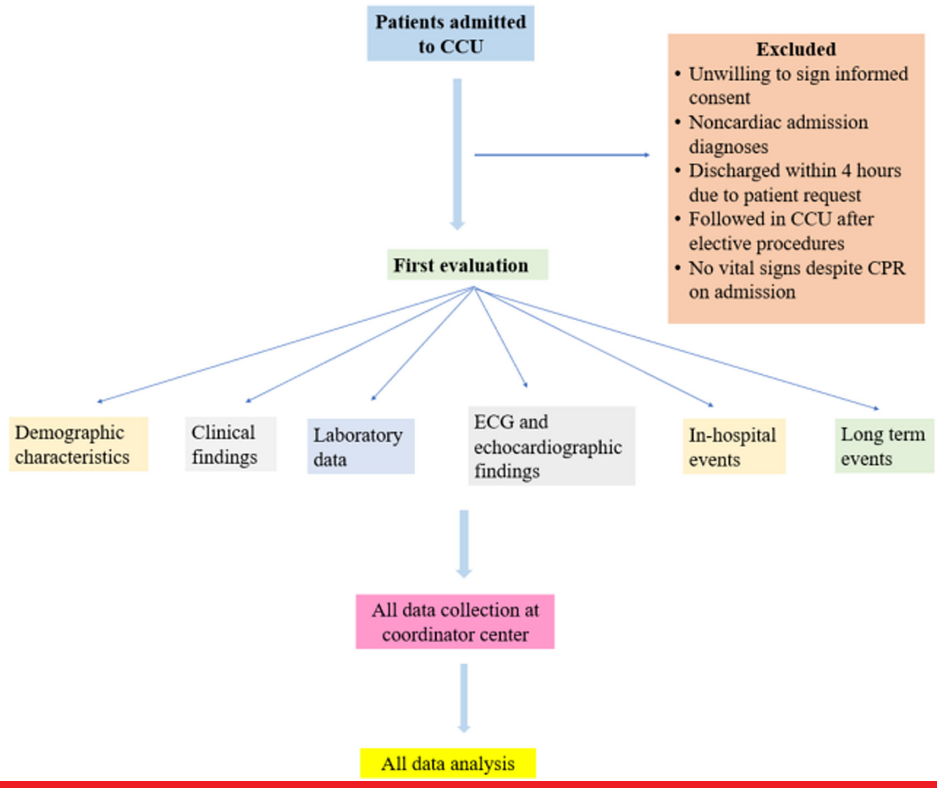

Figure 2. Flow diagram illustrating patients meeting entry criteria.

Thus, the minimum required sample size was calculated as 1092. As more patients would be better to reflect the whole country to determine the short- and long-term mortality rate in CCU, we planned approximately 3000 patients to be included in the study during this period.

Definitions and Outcomes

The definitions of ACS are based on the guidelines of the European Society of Cardiology. ST-elevation MI is diagnosed when troponin levels are elevated, symptoms consisted of myocardial ischemia and significant ST-elevation in at least two contagious leads or suspected new left bundle branch block on 12-lead electrocardiogram (ECG). Non-ST-elevation MI is diagnosed when symptoms consisted of myocardial ischemia with no ST-elevation and high troponin levels on 12-lead ECG.

Acute HF is defined as the rapid or gradual onset of symptoms or signs of HF, severe enough to require patients to seek urgent medical attention, resulting in unplanned hospitalization or an emergency department visit.[14] Rapid ventricular rate AF was defined as causing the patient to seek urgent medical attention with or without hemodynamic compromise with irregular R-R intervals on ECG without distinct p waves. Sustained ventricular tachycardia was defined as tachyarrhythmia lasting longer than 30 seconds or hemodynamic instability occurring in less than 30 seconds with wide QRS complex on ECG. Bradyarrhythmia was defined as a heart rate lower than 60 bpm with a rhythm other than sinus rhythm requiring intervention or close follow-up. Cardiogenic shock has been defined as severe impairment in myocardial performance resulting in decreased cardiac output, end-organ hypoperfusion, and hypoxia; presenting clinically as hypotension refractory to volume resuscitation with end-organ hypoperfusion, cardiogenic shock requires pharmacological or mechanical intervention.[15] Pericarditis and myocarditis were defined as the inflammation of the pericardial layers or myocardium supported by laboratory results and imaging modalities in patients presenting with similar symptoms.

In addition to primary admission diagnoses, we will also record CV risk factors of admitted patients such as a family history of coronary artery disease, smoking status, history of diabetes mellitus, hypertension, hyperlipidemia (HL), chronic kidney disease, peripheral artery disease, and HF. Cardiovascular medications used during admission will also be questioned and recorded (Table 1).

Baseline and Follow-Up Data

All participant centers will collect and record data on a previously prepared and shared "The MORCOR-TURK Study Google Form" online. Basic data to be included in the form will be demographic and clinical characteristics, CV risk factors and primary admission diagnoses, Killip class, basic ECG findings, blood pressure, heart rate, follow-up time in CCU (hours), CV medications on admission, in-hospital, and at discharge, basic echocardiographic findings, biochemical test results, complete blood count, lipid profile, and troponin level. In-hospital and long-term outcomes (1st, 6th, and 12th months) will include death, rehospitalization, AF occurrence, ischemic-hemorrhagic stroke, acute renal failure, major-minor bleeding, and recorded malignant arrhythmias. Adverse event information after hospital discharge

Table 1. Summary of the MORCOR-TURK Survey Questionnaire

Baseline Demographic Characteristics	Admission Complaint and Diagnosis	Treatments	Echocardiographic and Laboratory Measurements	Events in Hospital
Age Sex Height (cm) Weight (kg) Medical history • Coronary artery disease • PCI history • Myocardial infarction history • Bypass surgery history • Peripheral artery history • Atrial fibrillation history • Heart failure history • Hypertension • Diabetes mellitus • Dyslipidemia • Smoking status • Family history CAD • Cardiac device • Stroke history • Prior major bleeding history • Chronic kidney disease • CHA_2DS_2VASc score	Chief complaint • Chest pain • Dyspnea • Syncope/near syncope • Palpitation • Sudden death • Acute ischemic leg pain Main admission diagnosis • STEMI • NSTEMI • USAP • Acute pulmonary edema • Decompensated HF • Arrhythmia • Cardiac arrest • Critical limb ischemia • Complication during intervention Killip class Admission rhythm • Sinus rhythm • Atrial fibrillation • Other SVTs • AV block • Ventricular tachycardia • Ventricular fibrillation • Cardiac arrest • Pacemaker rhythm Acute ischemic changes on ECG Systolic blood pressure Diastolic blood pressure Heart rate Saturation	Prehospital treatment • Acetylsalicylic acid • Other platelets • Oral anticoagulants • Beta-blockers • ACEI/ARB • Calcium channel blockers • Statins • Proton pump inhibitors In-hospital treatment • Acetylsalicylic acid • Other platelets • Low molecular weight heparin • Positive inotropes • Gp IIb/IIIA inhibitors • Thrombolytic treatment • Invasive treatment • Beta-blockers • ACEI/ARB • Calcium channel blockers • Statins • Proton pump inhibitors • Others	Echocardiography EF Valve pathologies Laboratory • Troponin • Peak troponin • Lipids (LDL, HDL, TG) • Liver enzymes, • TSH • WBC • Hemoglobin • Hematocrit • Platelet count • Creatinine	Death Death type Stroke Atrial fibrillation VF/VT Mechanical ventilation Acute renal failure Bleeding CCU follow-up

CAD, coronary artery disease; CCU, critical care unit; HDL, high-density lipoprotein; HF, heart failure; LDL, low-density lipoprotein; TG, triglyceride; TSH, thyroid-stimulating hormone; WBC, white blood cell; PCI, percutanous coronary intervention; STEMI, ST elevation myocardial infarction; NSTEMI, Non-ST elevation myocardial infarction; USAP, unstable angina pectoris; SVT, supraventricular tachycardia; ACEI/ARB, angiotensin converting enzyme inhibitor/angiotensin receptor blocker; EF, ejection fraction; VF, ventricular fibrillation; VT, ventricular tachycardia; CCU, coronary care unit.

will be collected in each outpatient clinic control. No extra visits other than routine outpatient visits will be planned. If the patient is lost to follow-up, phone calls, electronic medical records, and a national database system will be used to reach outcomes (Figure 3).

Data Management

All study centers will enter the data into the previously built-up Google forms. All data will be automatically converted to excel spreadsheets and checked for missing or mismatched data. In case of incompatibility, the coordinators will contact the participants to resolve the problem. After reviewing and completing all shortcomings, the last remaining data will be analyzed and interpreted according to the protocol and design of the study.

Mortality Scoring System

The MORCOR variables will be selected within the first 24-hour admission to CCU. Patients' demographic characteristics including age, gender, admission diagnosis, CV

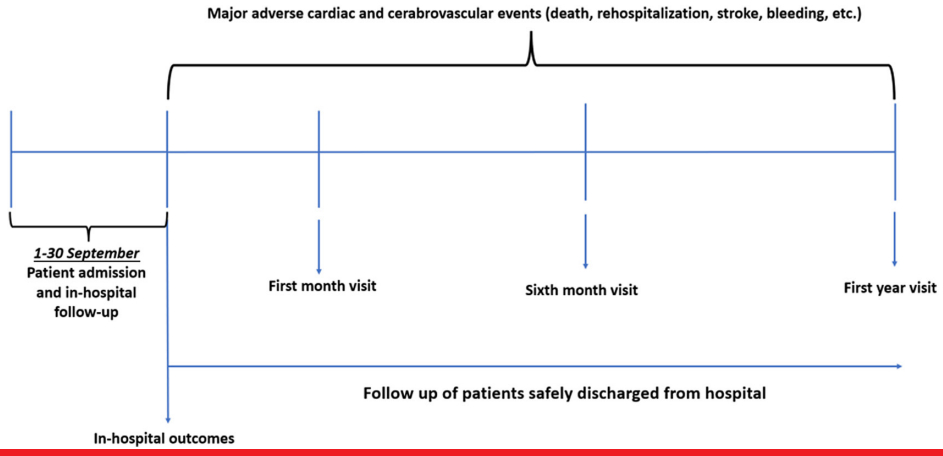

Figure 3. Timeline of the MORCOR-TURK study. MORCOR-TURK, MORtality predictors in CORonary care units in TURKey.

risk factors, vital signs (heart rate, blood pressure, and oxygen saturation), and laboratory findings (serum creatinine, sodium, potassium, calcium and magnesium levels, glomerular filtration rate, white blood cells, hemoglobin, and platelet levels) will be recorded. Thereafter, all demographic and clinical variables will be tested in LR analysis and crude hazard ratios and 95% confidence intervals will be computed. The variables which were found statistically significant will be added to multivariable LR analysis to provide final model for predicting in-hospital mortality. The mean area under the receiver operating characteristic curve will be used to test the discriminative power of the final model (C-statistic). Moreover, predictive accuracy of the models will be tested separately in large subgroups of the patients such as ACS and acute/decompensated HF.

Ethical Considerations

The study protocol has been reviewed and approved by the Local Ethics Committee (No: 2022/9-422; Date: 05/08/2022). The study will comply with the good clinical practices protocol and Declaration of Helsinki principles. Written informed consent will be obtained from all participants or their relatives.

DISCUSSION

The MORCOR-TURK study will be the largest registry to demonstrate current mortality rates and predictors of CCU patients in Turkey. Furthermore, it will show the incidences of in-hospital adverse events, including acute renal failure, AF occurrence, ischemic/hemorrhagic events, and bleeding in this population. It will also enlighten the independent predictors of long-term mortality in patients discharged from CCU. In addition, it will provide data for building a new CCU mortality score.

The first CCUs were formed in the early 1960s, after the introduction of defibrillation and continuous electrocardiographic monitoring in clinical practice. The most important purpose was to rapidly identify and terminate the peri-infarction malignant arrhythmias developing during acute MI.[16,17] Multiple studies have shown that close follow-up of acute MI patients in CCU has ensured a 15%-20% decline in in-hospital mortality.[1,18] Furthermore, besides continuous monitoring and trained personnel support, progress in interventional techniques (right heart catheterization, etc.) and echocardiographic imaging have caused favorable prognostic results in all critical cardiac patients. Given these positive results, the importance of CCU in clinical cardiology practice has become indisputable.

However, the patient profile admitted to the CCU has changed over time. In addition to STEMI, patients with more complications such as acute pulmonary edema, decompensated HF, life-threatening arrhythmias and patients with advanced age and high comorbidities have increased in number in CCUs. Katz et al[4] reported relative change in odds of STEMI was −7% and non-STEMI 13%, while non-ACS diagnosis and interventions increased steadily within the Duke University CCU from 1989 to 2006. Due to the increase in the mortality risks of hospitalized patients in parallel with technological developments and the increase in clinical experience, a negligible decrease was observed in CCU mortality (Supplementary Figure 1).[19]

With the evolution in capabilities of CCUs and changes in patient profiles, different countries have shared their CCU experiences and mortality rates. However, most of these data were shared in the 1990s and early 2000s. For example, in a report from Canada, the mortality rate for patients admitted to CCU was 13%; in other reports from Israel, it was 5.4%; and in the United States, 7%-8%.[2-4] Nevertheless, there has not been up-to-date data on the predictors and rates of CCU mortality. Furthermore, although multicenter and national studies have been conducted in Turkey in different patient groups, including AF, ACS, direct oral anticoagulants, drug interactions, and HL, no previous national study has been conducted to investigate the CCU mortality.[20-25] Therefore, we designed the MORCOR-TURK study to eliminate this deficiency, shed light on the literature, and present the current data of our country in this field.

Risk scores have been established for different patient populations to predict mortality. Especially, different mortality scoring systems such as Acute Physiologic Score and Chronic

Health Evaluation (APACHE), and Simplified Acute Physiology Score (SAPS) have been tested in ICU patients, and they successfully predicted in-hospital mortality.[26,27] But CCU patients were mostly excluded from prediction analysis of these scoring systems. Besides, different scoring systems such as TIMI (Thrombolysis in Myocardial Infarction) and GRACE (Global Registry of Acute Coronary Events) have been used for mortality prediction in ACS patients.[28,29] The most recent studies on mortality predictors and new scoring systems in CCU patients were performed by Bagaswoto et al[11] and Pramudyo et al. [12] However, these studies are limited due to their single-center and retrospective design. Furthermore, the latter one included only ACS patients. Another recent study in this area was conducted by Blatter et al.[13] Despite its prospective design, this study included only cardiac arrest patients in a single center. Moreover, in this study, instead of forming a new scoring system, previously accepted risk scores were compared to each other. Therefore, with the current multicenter study, we are planning to contribute to the literature by generating a new scoring system for all CCU patients.

Study Limitations

The results of this study should be interpreted with some caution because of several limitations. The first limitation is that we did not include all CCU-capable centers to analyze the data. But since the centers were selected according to the regional distribution of Turkey, it is unlikely to adversely affect the results. The second limitation is that the interventional facilities of the centers and the skills and experience of the operators may affect the results of the procedures and therefore the mortality rates. However, in this study, we aimed to reveal the national data of Turkey, not the differences between the centers and operators. Final limitation is an additional uncontrolled factor is a possibility that the study has a cross-sectional observational design that could affect bias and confounding. Notwithstanding these limitations, this study offers insight into current data on mortality predictors of CCU in Turkey.

CONCLUSION

The findings of the MORCOR-TURK study will have several contributions to the current literature. First, it will give the current CCU mortality data in Turkey. Furthermore, it will help to enlighten the most important predictors of mortality in CCU. Thus, it will increase our awareness of taking precautions against the risk factors. Second, it will give information about the distribution of each diagnosis. Moreover, subgroup analyses will show the highest and lowest mortality rates according to the diagnoses. Third, with the help of this national data, we will be able to contribute to the literature with a new scoring system about mortality.

Ethics Committee Approval: Study has been approved by the Ethics Committee of Afyonkarahisar University of Health Sciences, Afyon, Turkey (No: 2022/9-422; Date: 05/08/2022).

Informed Consent: Written informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

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Supplementary File 1

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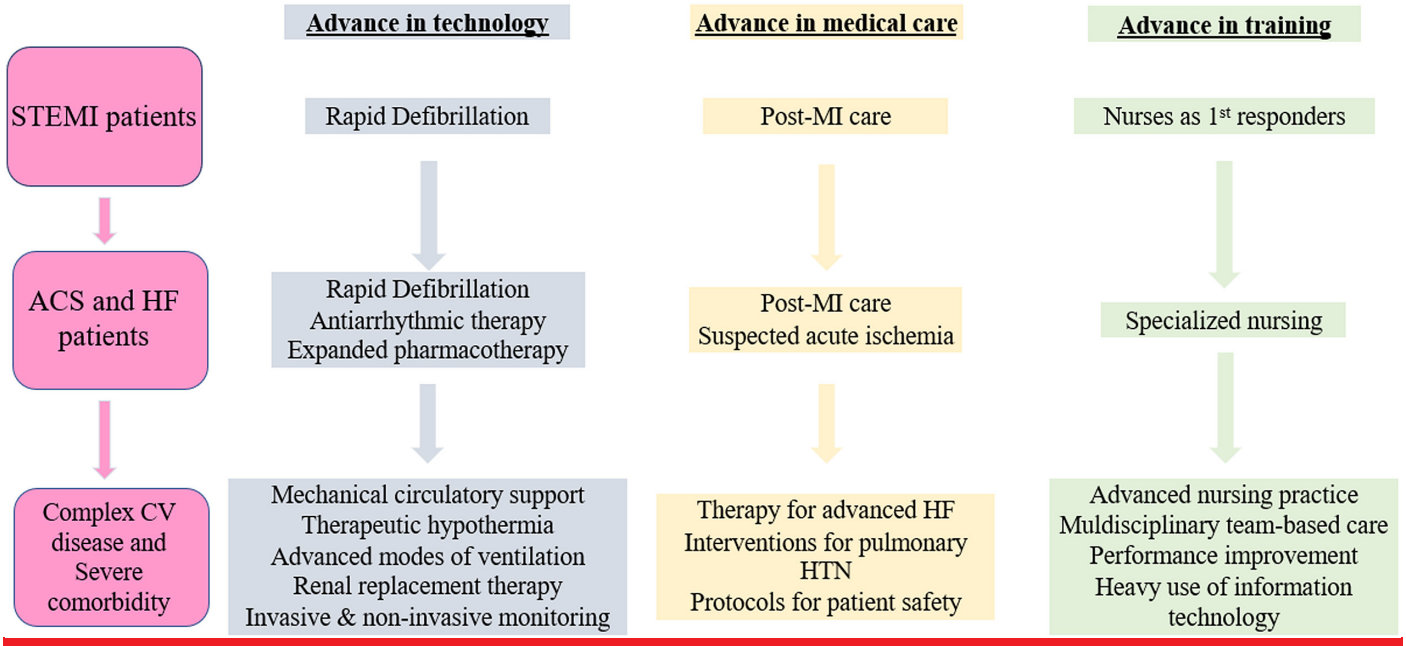

Supplementary Figure 1. Clinical and technological change of the coronary care unit.