
# Latin American Registry of Cardiogenic Shock in the context of Acute Coronary Syndromes (LATIN-Shock)

Version 2.0 - August 25, 2021

# Investigation area

# Argentine Society of Cardiology

**Index**

## Introduction:

Cardiogenic shock is a rare disease, but it constitutes the main cause of mortality in patients hospitalized for acute myocardial infarction. Its incidence ranges between 7 and 10% of infarction cases [1] and it is associated with a mortality of 40-50% despite revascularization and the use of intra-Aortic Balloon Contrapulsation [2-3-4].

Most of the bibliography on this topic is North American, it is already many years old [5-6] and the one that is currently published mainly shows the results of different ventricular supports that are not commonly used in our environment [7]. So far there is no record that reports the reality of Latin America. Only in Argentina, has carried out a national registry of cardiogenic shock in the context of acute coronary syndromes but have already spent more than 5 years since its publication[8]. In recent years have even changed management guidelines this pathology [9-10] and works have been published that could have changed previous behaviors [11].

This is a project of the Argentine Society of Cardiology to collect epidemiological data and current management of cardiogenic shock in Latin America.

## Objetives:

1- Determine the clinical characteristics of patients who are admitted to the coronary unit with acute coronary symptoms and present Cardiogenic Shock, either from admission or during their in-hospital evolution.
2- Analyze the treatment of patients with cardiogenic shock.
3- Observe the clinical in-hospital evolution.
4- Evaluates predictors of in-hospital mortality.
5- Compare the clinic, management and evolution characteristics in the different participating Latin American countries.

## Methods:

*Study design:*

It is an international, multicenter, observational, prospective and consecutive registry of patients with cardiogenic shock in the context of acute coronary syndromes, which will have a duration of 12 months starting on October 1, 2021. Coronary units from different Latin American countries will be invited to participate in the registry through the different cardiology societies. Each country and each participating center will be assigned a number and patients will be included in the registry in sequential order by center (1-2-3-etc) to maintain the confidentiality of the data. Since patient data will be extracted from medical records, records will be anonymous and there will be no follow-up, informed

consent will not be required. The names of the participating centers in the different countries will appear in a list at the end of the publications, under the collective name of “LATIN Shock group”.

Definition of cardiogenic shock (classic): Presence of systolic blood pressure ≤90 mm Hg for 30 minutes or requirement of vasopressors, inotropics and / or ventricular supports to maintain a blood pressure ≥90 mmHg, associated with signs of hypoperfusion and pulmonary congestion, in the absence of hypovolemia or arrhythmias that justify the clinical picture.

A new definition of cardiogenic shock has recently been proposed, which includes 5 categories[12]:

A- At risk: Patient who does not present signs or symptoms of cardiogenic shock but is at risk of presenting it. Includes acute myocardial infarction, previous infarction, decompensated acute or chronic heart failure.
B- Pre-shock: It is defined when there is tachycardia or hypotension without hypoperfusion. These patients must be closely monitored and carefully treated to avoid the development of classic cardiogenic shock.
C- Classic: Patient with hypoperfusion requiring intervention (inotropics, vasopressors, or mechanical support) despite fluid resuscitation to restore perfusion.
D- Worse: Patient similar to category C but worsening and unresponsive to initial interventions.
E- Extreme: Includes cases where the futility of the treatment is evaluated and palliative treatment should be considered.
In turn, all these categories are discriminated according to whether or not they have suffered cardiac arrest.

In this work, patients with cardiogenic shock C, D and E will be considered as a group. It will be recorded if they have presented cardiac arrest.

*Inclusion criteria:*

Patients of both sexes and older than 18 years, admitted to a coronary or polyvalent critical care unit, for an acute coronary syndrome with or without ST-segment elevation who present with cardiogenic shock from admission or develop it during hospitalization and who can be followed up in its evolution until hospital discharge

*Exclusion criteria:*

Non-ischemic cardiogenic shock (chronic heart failure, myocarditis, sepsis, tachycardiomyopathy, Takotsubo, etc.). Cardiogenic shock A and B of the new SCAI classification.

*Information gathering:*

The following variables will be analyzed: age, sex, risk factors and comorbidities, previous treatment, characteristics of the AMI that generated the shock, location of the infarction, Killip and Kimball on admission and evolution, time of evolution on admission, reperfusion strategies (fibrinolysis or angioplasty), if angioplasty was required: what type (primary, rescue, delayed), number of vessels operated, drug treatment instituted, hemodynamic monitoring and mechanical support (balloon pump, ECMO, mechanical ventilation, others).

The in-hospital evolution and eventual complications (fever, sepsis, COVID 19, multiorgan failure, arrhythmias, reinfarction, post-infarction angina, mechanical complications, transfusion requirement, major and minor bleeding) will be studied. Laboratory data will be collected upon admission and at 24 hours. Hemodynamic measurements will be recorded at the time of Swan Ganz catheter placement and at 24 hours (if used) and echocardiogram data. The follow-up will only be in-hospital.

The data will be collected by the researchers from the different participating centers through an electronic file developed ad hoc in Red Cap and the data will be analyzed by the executive committee that will be made up of members of the research area of the Argentine Society of Cardiology.

The Red Cap platform is a secure web application for online data management. The data will be stored securely on a server at the Argentine Society of Cardiology. For centers without Internet access, it is possible to collect data offline through Red Cap using the Red Cap mobile application that is downloaded to a tablet or mobile device. With the app, data can be collected offline and then synced with Red Cap's server. While Attachment 1 can also be printed and used to collect data for subsequent electronic submission, direct collection of electronic data is preferable to avoid transcription errors.

As it is a study that involves different countries, the data will be analyzed globally and by country initially. Different sub-studies may be carried out with the information obtained. Each participating country has the right to submit ideas for conducting sub-studies. In that case, they must be formally presented to the Executive Committee, who will carry out the analysis and provide the data if the proposal is accepted. The sub-studies should be re-evaluated by the ethics committee.

Each participating Scientific Society will receive an Excel with the data of their country once the study is finished (anonymized data) that they can present at conferences or for publication as national experiences. Each participating center

will have available immediately statistical reports (automatically generated) of the patients who have entered their center.

File in Red Cap: http://redcap.sac.org.ar/redcap/surveys/?s=RMCAYAXMF3

*Statistic analysis:*

The information obtained will be incorporated into a database that will be analyzed using the statistical programs Epi-info and / or IBM SPSS. For each of the observed variables, a frequency table will be constructed.

Continuous variables will be expressed as mean and standard deviation for those with a normal or Gaussian distribution and as a median with an interquartile range 25% -75% for those without such distribution. The comparison between these variables will be carried out using the Student's t test or the Wilcoxon ranksum test, as appropriate.

Discrete variables will be expressed as percentages. Statistical comparisons between them will be made using the chi-square test with Yates correction or Fisher's exact test, as appropriate.

Contingency tables will be constructed to analyze the association or independence of the variables. The analysis of the existence of associations and / or independent predictions between the different variables involved and the end points will be carried out by means of linear regression analysis and / or multiple logistic. The variables of univariate statistical significance will be entered for evaluation in the different regression models. The value corresponding to each covariate of the aforementioned analysis will be expressed as adjusted Odds Ratio and its corresponding 95% confidence interval. All statistical comparisons will be two-tailed, and p values <0.05 will be considered statistically significant.

*Consent of the patient*

LATIN-Shock, as an observational study, only requires data that has already been collected and is available in the patient's medical record. It does not require sensitive data. It does not involve specific interventions and there is no follow-up after discharge, therefore, informed consent is not required. However, this could be adjusted according to local regulations of the participating countries.

*Ethical considerations*

The protocol and the registration form will be submitted for approval by the ethics committee of the Sociedad Argentina de Cardiología, Azcuénaga 980, CABA. The study will be carried out in accordance with national and international ethical standards (CABA Law No. 3301, Declaration of Helsinki, and others).

As it is a descriptive study in which the data will be those normally collected in this pathology and there will be no identification of the patient or out-of-hospital follow-up, the signing of informed consent will not be required.

**Study organization:**

**Executive committee:**

Directors: Yanina Castillo Costa - Víctor Mauro

Scientific and organizational secretariat: It is responsible for the organization of research, control, management and preparation of data analysis reports. It will be made up of: Heraldo D´Imperio, Mauro García Aurelio, Flavio Delfino.

Each participating Latin American Society of Cardiology will be represented by one / two members (designated by its president) and they will be the ones who appear in the final document and receive the database of their country at the end of the study.

Collaborators: This is the name given to the members of the centers where the inclusion of the participants takes place. The head of each center where the investigation is carried out and another doctor designated by him will be specially invited, who will be in charge of preparing the registration forms.

Participating Centers:

Other Spanish-speaking Latin American Cardiology Societies will be invited to participate and they will designate the coronary units where the registry will be carried out.

Sample: It is estimated to include approximately 500 patients in one year.

**Publications**

The results of the study will be presented initially in the Congress of the Argentine Society of Cardiology and later in the different Congresses of Cardiology of the participating Societies. The publication will bear the names of all the researchers participating in the study and the members of the secretariat and the executive committee, who will be called the “LATIN Shock group”.

Individual centers and countries are encouraged to publish their results.

Each center coordinator is responsible for giving permission for the analysis, writing and publication of the individual LATIN Shock data. Site coordinators are requested to ensure that this data is not released prior to the release of the main LATIN Shock document.

LATIN SHOCK Principal Investigators are committed to ensuring that the main article is published in a timely manner (to facilitate the previous point).

## Bibliography

[1] AHA Scientific Statement. Invasive management of Acute Myocardial Infarction Complicated by Cardiogenic Shock. Circulation 2021; 143: 00-00.

[2] Thiele H, Zeymer U, Neumann FJ, Ferenc M, Olbrich HG, Hausleiter J et al. IABP-SHOCK II Trial Investigators. Intraaortic balloon support for myocardial infarction with cardiogenic shock. *N Engl J Med* . 2012; *367* : 1287-1296. doi: 10.1056 / NEJMoa1208410 .

[3] Menon V, Hochman J, Stebbins A, Pfisterer A, Col J, et al. Lack of progressin cardiogenic shock: lessons from the GUSTO trials. Eur HeartJ2000; 21: 1928-1936.

[4] Kolte D, Khera S, Aronow WS, Mujib M, Palaniswamy C, Sule S et al. Trends in incidence, management, and outcomes of cardiogenic shock complicating ST-elevation myocardial infarction in the United States. *J Am Heart Assoc* . 2014; *3* : e000590. doi: 10.1161 / JAHA.113.000590.

[5] Hochman JS, Sleeper LA, Webb JG, Sanborn TA, White HD, Talley JD, et al. Early revascularization in acute myocardial infarction complicated by cardiogenic shock. NEnglMed. 1999; 341: 625-634

[6] Hochman JS, Buller CE, Sleeper LA, Boland J, Dzavik V, Sanborn TA, et al. Cardiogenic shock complicating acute myocardial infarction - etiologies, management and outcome: a report from the SHOCK Trial Registry. Should we emergently revascularize Occluded Coronaries for cardiog é nico shocK? JAmCollCardiol 2000 Sep; 36 (3SupplA): 1063-70.

[7] Rihal CH, Naidu S, Givertz MM, Szeto WY, Burke JA, Kap N et al. 2015SCAI / ACC / HFSA / STS clinical expert consensus statement on the use of percutaneous mechanical circulatory support devices in cardiovascular care. Cathet. Cardiovasc. Intervent., 85: E175-E196.https: //doi.org/10.1002/ccd.25720.

[8] Castillo Costa Y, Garcia Aurelio M, Mauro V, Villareal R, Piombo A et al. Argentine National Registry of Cardiogenic Shock (ReNa-SHOCK). RevArgentCardiol 2016; 84: 228-235. http://dx.doi.org/10.7775/rac.es.v84.i3.7825

[9] Zeymer U, Bueno H, Granger C, Hochman J, Huber k, and cols . Acute Cardiovascular Care Association position statement for the diagnosis and treatment of patients with acute myocardial infarction complicated by cardiogenic shock: A document of the Acute Cardiovascular Care Association of the European Society of Cardiology. European Heart Journal: Acute CardiovascularCare1–15.

[10] van Diepen S, Katz JN, Albert NF, Henry TD, Jacobs AK et al. Contemporary Management of Cardiogenic Shock: A Scientific Statement From the American Heart Association. Volume 136, Issue 16, 17 October 2017, Pages e232-e268

[11] Thiele H, AkinI, Sandri M, Fuernau G, de Waha S, Meyer-Sarae R. CULPRIT-SHOCK Investigators. PCI Strategies in Patients with Acute Myocardial Infarction and Cardiogenic Shock. N Engl J Med 2017; 377: 2419-2432. DOI: 10.1056 / NEJMoa1710261

[12] Baran DA, Grines CL, Bailey S, et al. SCAI clinical expert consensus statement on the classification of cardiogenic shock: This document was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), the Society of

Critical Care Medicine (SCCM), and the Society of Thoracic Surgeons (STS). Catheter Cardiovasc Inter2019; 94: 29–37