ORIGINAL ARTICLE

CME

Argentine National Registry of Cardiogenic Shock (ReNa-SHOCK)

Registro Nacional Argentino de Shock Cardiogénico (ReNa-SHOCK)

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ABSTRACT

Background: Cardiogenic shock is a severe complication of myocardial infarction and constitutes one of the leading causes of death associated with this condition; yet, the information available in our country is limited.
Objective: The aim of this study was to learn the clinical characteristics, treatment strategies and in-hospital outcome of cardiogenic shock in Argentina.
Methods: A prospective, multicenter registry of patients hospitalized with cardiogenic shock in the context of acute coronary syndromes with and without ST-segment elevation was conducted in 64 centers of Argentina between 2013 and 2015.
Results: The cohort consisted of 165 patients with mean age of 66 (58-76.5) years; 65% were men. Seventy-five percent of cases were ST-segment elevation acute coronary syndromes; 8.5% were associated with mechanical complications and 6.7% had right ventricular involvement. Fifty-six percent presented with cardiogenic shock on admission. Ninety five percent of patients required inotropic agents, 78% mechanical ventilation, 44% Swan-Ganz catheter insertion and 37% intra-aortic balloon pump. Eighty-four percent of ST-segment elevation acute coronary syndromes (104/124 patients) were reperfused. Median time from symptom onset to admission was 240 minutes (132-720) and 80% of patients underwent primary percutaneous coronary intervention. Overall in-hospital mortality was 54% without differences between acute coronary syndromes with or without ST-segment elevation and neither were there differences between both syndrome presentations in the incidence of events and use of procedures.
Conclusions: The characteristics of cardiogenic shock in Argentina are similar to those of populations worldwide. Morbidity and mortality are high despite the use of available treatment strategies.

Key words: Cardiogenic Shock - Acute Coronary Syndromes - Registries

RESUMEN

Introducción: El shock cardiogénico es una complicación grave del infarto agudo de miocardio y constituye una de sus principales causas de muerte, pese a lo cual la información en nuestro medio es limitada.
Objetivo: Conocer las características clínicas, estrategias de tratamiento y evolución intrahospitalaria del shock cardiogénico en la Argentina.
Material y métodos: Se realizó un registro prospectivo, multicéntrico de pacientes internados con shock cardiogénico en el contexto de los síndromes coronarios agudos con y sin elevación del segmento ST entre los años 2013 y 2015 en 64 centros de la Argentina.
Resultados: Se incluyeron 165 pacientes, con una edad media de 66 (58-76,5) años; el 65% eran hombres. El 75% de los casos cursaban un síndrome coronario agudo con elevación del segmento ST. El 8,5% estuvieron asociados con complicaciones mecánicas y el 6,7% con compromiso del ventrículo derecho. El 56% presentaban shock cardiogénico al ingreso. Requirieron inotrópicos el 95%, asistencia respiratoria mecánica el 78%, catéter de Swan-Ganz el 44%, balón de contrapulsación intraaórtico el 37%. El 84% de los síndromes coronarios agudos con elevación del segmento ST (104/124 pacientes) se reperfundieron. La mediana de tiempo desde el inicio de los síntomas al ingreso fue de 240 minutos (132-720). El 80% recibieron angioplastia primaria. La mortalidad intrahospitalaria global fue del 54%, sin diferencias entre los síndromes coronarios agudos con o sin elevación del segmento ST. Asimismo, no hubo diferencia en la frecuencia de eventos y uso de procedimientos entre los síndromes coronarios agudos con o sin elevación del segmento ST.
Conclusiones: Las características del shock cardiogénico en la Argentina no difieren mucho de poblaciones de otras partes del mundo. La morbimortalidad es elevada a pesar de la utilización de las estrategias de tratamiento disponibles.

Palabras clave: Shock cardiogénico - Síndromes coronarios agudos - Registros

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Abbreviations

ACS	Acute coronary syndrome	**NSTEACS**	non-ST-segment elevation acute coronary syndrome
CS	Cardiogenic shock	**SAC**	Argentine Society of Cardiology
IABP	Intra-Aortic Balloon Pump	**STEACS**	ST-segment elevation acute coronary syndrome

INTRODUCTION

Cardiogenic shock (CS) is an infrequent complication but remains the leading cause of death in patients hospitalized with acute myocardial infarction. Its incidence ranges between 6% and 8% and is associated with a mortality rate of 40-50% despite myocardial revascularization and use of intra-aortic balloon pump (IABP). (1, 2) The information available arises from studies and registries performed more than 10 years ago in other countries. (3, 4) In our country, the information is limited and comes from registries of acute coronary syndromes (ACS) performed by the Argentine Society of Cardiology (SAC). (5, 6)

This is the first registry carried out in Argentina, specially designed to determine the clinical characteristics, treatment strategies, and in-hospital events in patients admitted to critical care units with ACS and who present CS at the moment of admission or during hospitalization.

METHODS

A prospective, observational and multicenter registry of consecutive patients with ACS complicated with CS was conducted from July 2013 to May 2015.

Inclusion criteria were patients >18 years old, admitted to coronary care units or polyvalent intensive care units with ST-segment elevation ACS (STEACS) or non-ST-segment elevation ACS (NSTEACS) and presenting CS at admission or during hospitalization. Follow-up was restricted to hospital stay.

Cardiogenic shock was defined as systolic blood pressure ≤90 mm Hg for at least 30 min or vasopressor or inotropic drug requirement to maintain blood pressure (BP) ≥90mmHg, associated with clinical signs of hypoperfusion or pulmonary congestion in the absence of hypovolemia or arrhythmias.

Data were collected by the investigators of the different centers and entered in an ad hoc designed electronic worksheet containing the following variables: age, sex, risk factors, comorbidities, previous treatment, infarct location, Killip and Kimball classification on admission and during hospitalization, time from symptom onset to admission, reperfusion strategies (thrombolysis or angioplasty), numbers of vessels involved (coronary artery stenosis ≥70% or occlusion) and intervened, drug therapy, hemodynamic monitoring and mechanical support such as IABP and mechanical ventilation. In-hospital outcome and complications (fever, sepsis, multiorgan failure, arrhythmias, postinfarction angina, reinfarction, requirement of blood transfusion, and major or minor bleeding) were also recorded. In addition, echocardiographic data and lab tests at admission and at 24 hours were collected.

Severe bleeding was defined using the TIMI bleeding criteria of major bleeding or the GUSTO scale of moderate/severe bleeding. (8)

Statistical analysis

The information was entered into a database that was analyzed with the Epi-Info 3.5 software package. A frequency table was constructed for all the variables observed. Continuous variables with normal and non Gaussian distribution were presented as mean±standard deviation, or median and interquartile range (IQR 25-75), respectively, and were compared using Student's t test or the Wilcoxon rank sum test, as applicable. Discrete variables were expressed as percentages and were compared using the chi-square test with Yates correction or Fisher's exact test, as applicable.

Contingency tables were built to analyze the association or independence of the variables. The presence of association between the different variables involved and mortality was analyzed using linear regression or multiple logistic regression analysis. Variables with a p value=0.1 at the univariate analysis were included in the different regression models. The value corresponding to each covariate was expressed as adjusted odds ratio with its corresponding 95% confidence interval. A two-tailed p value <0.05 was considered statistically significant.

Ethical considerations

The protocol was organized and conducted by SAC's Research Area and the Council of Cardiovascular Emergency Care and was approved by SAC's Bioethical Committee. Patients were not asked to sign an informed consent form as the study was observational and covered only hospital stay. Patients' personal data were recorded as number of order and center to ensure the confidentiality of the information.

RESULTS

Sixty-four critical care units nationwide participated in the study (74% coronary care units, 17% intensive care units and 9% polyvalent intensive care units) (see Centers and Investigators). The median number of beds per center was 10 (8.5-17). The availability of complementary tests in the centers is detailed in Figure 1.

General population

The registry included 165 patients, 124 (75%) of whom were STEACS and 41 (25%) were NSTEACS. In 8.5% of cases, the ACS was associated to mechanical complications (n=14) and in 6.7% to right ventricular (RV) involvement (n=11). The clinical characteristics of the general population and according to the type of ACS are summarized in Table 1. Patients with NSTEACS were older, and had more prevalence of diabetes, peripheral vascular disease and chronic kidney failure. In this population, the prevalence of CS at admission was lower.

Fifty-six percent of the patients presented CS at admission (n=93/165). In the rest of the patients, 21% were admitted with Killip and Kimball class A, 14%

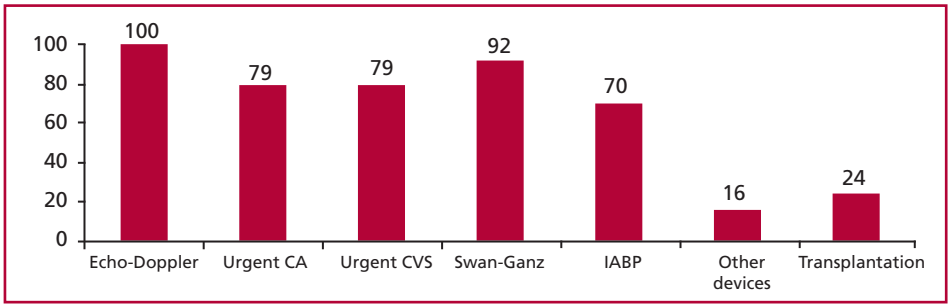

Fig. 1. Availability of complementary tests (%) in the participating centers. CA: Coronary angiography. CVS: Cardiovascular surgery. IABP: Intraaortic balloon pump. Other devices: Ventricular assist devices other than IABP.

Table 1. Clinical characteristics of the general population and according to the type of ACS at admission.

	Global (n=165) n (%)	STEACS (n=124) n (%)	NSTEACS (n=41) n (%)	p
Age, (median), years	66 (58-76.5)	64 (56.5-75)	71 (63-79.5)	**0.02**
>75 years	50 (30)	35 (28)	14 (34)	0.23
Male gender	107 (65)	84 (68)	23 (57)	0.09
Hypertension	115 (70)	87 (70)	32 (77)	0.18
Diabetes	50 (30)	31 (25)	19 (46)	**0.005**
Dyslipidemia	76 (46)	53 (43)	23 (57)	0.07
Current smoker	61 (37)	50 (40)	11 (27)	0.063
Previous myocardial infarction	38 (23)	25 (20)	13 (32)	0.07
Previous stroke	9 (5.5)	6 (5)	2 (6)	0.4
Peripheral vascular disease	12 (7.3)	5 (4)	7 (17)	**0.001**
Chronic kidney failure	14 (8.5)	7 (6)	7 (17)	**0.03**
KK D classification at admission	93 (56)	78 (63)	16 (39)	**0.003**

STEACS: ST-segment elevation acute coronary syndrome. NSTEACS: Non-ST-segment elevation acute coronary syndrome. KK: Killip and Kimball.

class B and 9% class C, and developed CS at a median time of 8 h (1.2-24) after hospitalization. Twenty-six percent of patients presented CS 24 h after myocardial infarction.

Inotropic or vasoactive drugs were used in 95% of the patients (norepinephrine 89%, dopamine 54%, dobutamine 70% and levosimendan 9.5%); 78% required mechanical ventilation and IABP was inserted in 37% of the cases and was withdrawn after a median period of 3 (1-4) days. Complications associated with IABP occurred in 13% of the patients: stroke (n=1); acute lower limb ischemia (n=2), thrombocytopenia (n=4) and severe bleeding (n=1). In patients with IABP support, mortality was 58% (n=35/60).

A Swan-Ganz catheter was inserted in 44% (n=73) of the patients: 62% within the first day, 18% between 24 and 48 h and 20% after 48 h. In 80% of the cases, a Swan-Ganz catheter was used in patients with STEACS, and remained placed for a median time of 3 (2-5) days. The catheter was inserted to guide treatment in most cases and in 15% for diagnostic purposes. The mortality rate in patients with a Swan-Ganz catheter was 48%. There were no differences in the clinical characteristics and in the outcome of patients with IABP support and/or Swan-Ganz catheter vs. those without these devices.

The main events during hospitalization are presented in Table 2.

The incidence of bleeding was 11% and was severe in 7 patients. Twenty-one percent of the patients required transfusion of red blood cells (<2 units: 23%, 2 to 4 units: 54% and >4 units: 23%).

In 111 patients without mechanical complications, coronary angiography revealed significant one-vessel disease in 37% of the cases, two-vessel disease in 30% and three-vessel-disease in 33%. In 70 patients with more than one-vessel disease, 47 (67%) underwent percutaneous coronary intervention (PCI) of the culprit vessel, while in 18 patients (26%) and 5 patients (7%) two and three arteries were intervened, respectively. Most multivessel PCIs (95%) were performed during the same procedure and in the remaining 5% a second procedure was required during hospitalization. The procedure was successful in 83% of the cases.

Global in-hospital mortality was 54% (46% within the first 48 h). The most frequent causes of death

	Global (n=165) n (%)	STEACS (n=124) n (%)	NSTEACS (n=41) n (%)	p
Revascularization	130 (79)	108 (87)	23 (56)	**0.001**
Mortality	89 (54)	67 (54)	23 (56)	0.39
Postinfarction angina	6 (3.6)	5 (4)	1 (2.5)	0.35
Reinfarction	4 (2.4)	2 (2)	2 (5)	0.15
Arrhythmias	109 (66)	83 (67)	25 (62)	0.4
AF	40 (24)	40 (32)	22 (54)	**0.04**
VT/VF	80 (48)	63 (51)	15 (38)	0.13
AV block	30 (18)	17 (14)	7 (17)	0.45
Temporary pacemaker	35 (21)	26 (21)	8 (19)	0.43
Electric cardioversion	64 (39)	48 (39)	14(36)	0.37
Fever	84 (51)	61 (49)	23 (56)	0.21
Dialysis	11 (7)	8 (6.5)	4 (10)	0.22
Ventricular support	4 (2.4)	4 (3.5)	0	0.15
Heart transplantation	4 (2.4)	3 (2.4)	1 (2.5)	0.47

STEACS: ST-segment elevation acute coronary syndrome. NSTEACS: Non-ST-segment elevation acute coronary syndrome. AF: Atrial fibrillation. VT/VF: Ventricular tachycardia/ventricular fibrillation. AV: Atrioventricular.

Table 2. Revascularization and events during hospitalization in the general population, and comparison between STSEACS and NSTSEACS.

were ventricular failure (53%), arrhythmias (25%), infections (12%), neurological complications (4%) and other causes (6%).

After excluding patients with mechanical complications, univariate analysis revealed that age, history of stroke, arrhythmias, time of ACS evolution at admission, reperfusion and multivessel disease were associated with greater mortality (Table 3). However, none of these variables had an independent predictive value at multivariate analysis, even when restricted to patients with STEACS.

Patients with STEACS (n=124)

In 67% of the cases infarctions were located in the anterior wall. Median time from symptom onset to admission was 240 (132-720) minutes and 87% of patients underwent coronary artery reperfusion: 80% received primary PCI, 20% thrombolytic therapy (83% steptokinase) and 13% rescue PCI. Eighty percent of the procedures were successful, with a median door-to-balloon-time of 110 minutes (62-184). In-hospital mortality of STEACS was 54%. Mortality rate was 51% in patients reperfused and 75% in those without reperfusion (p=0.05). Sixteen patients did not undergo reperfusion due to late hospital arrival (n=9), lack of available reperfusion strategies in 1 patient and the causes were not reported in 6 patients.

Ninety-seven patients with STEACS and without shock secondary to mechanical complications underwent coronary angiography during hospitalization. In this group, 41% had one-vessel disease, 28% had two-vessel disease and 31% had three-vessel disease. Mortality rate was 37% in patients with one-vessel disease versus 54% in those with two- or three-vessel disease (p=0.05). In 32% of the patients with multivessel disease, other non-culprit vessels were also intervened, in most cases (95%) during the same procedure. In this group of patients, mortality was 67% while in those with multivessel disease undergoing only PCI of the culprit vessel, mortality was 36% (p=0.01 vs. multivessel angioplasty).

Patients with NSTEACS (n=41)

Fifty-six percent of the patients underwent revascularization with PCI. The prevalence of multivessel disease was higher in NSTEACS: 92% vs. 59% in STEACS (p <0.005). Five patients underwent coronary artery bypass graft surgery.

DISCUSSION

Cardiogenic shock is the most serious complication of myocardial infarction and is still its leading cause of death. Historically, the incidence of CS was 5 to 15%, but, many registries have reported that the implementation of reperfusion strategies has fortunately reduced this number across the years. (9-11) In our country, the incidence of CS is 6% according to the 2011 registry of the Argentine Society of Cardiology, and when the data from the same centers is compared in different periods (2005-2001), its incidence has decreased from 12% to 8%. (5)

In our registry, similar to other reports, most CSs were secondary to STEACS. Although the prevalence of men with CS was higher than that of women, the proportion of women was higher compared with populations with ACS and without shock, as reported by

Table 3. Univariate analysis of predictors of mortality*

	Dead (n=83) n (%)	Alive (n=67) n (%)	p
Age (median, IQR), years	69 (62,5-77,5)	62 (54,5-75)	0,03
Male gender	56 (67,5)	46 (68,66)	0,49
Diabetes	26 (31,7)	18 (26,8)	0,19
HTN	61 (76)	44 (66)	0,07
Current smokers	38 (45,6)	37 (54,4)	0,08
CKF	11 (12,8)	4 (6,15)	0,16
Previous stroke	8 (9,46)	1 (1,5)	0,02
Previous myocardial infarction	23 (28,05)	13 (19,4)	0,07
KK class D at admission	47 (56,6)	39 (58,46)	0,33
PIA	2 (2,41)	3 (4,48)	0,16
Reinfarction	3 (3,6)	1 (1,5)	0,23
Arrhythmias	61 (73,17)	40 (59,7)	0,04
Time from symptom onset to admission (median, IQR), minutes	345 (120-720)	180 (75-420)	0,04
Anterior wall infarct	56 (68)	47 (70)	0,41
STEACS	61 (74)	51 (76)	0,39
RV involvement	5 (6)	6 (9)	0,28
Reperfusion	58(70)	56 (84)	0,016
Multivessel disease (2 or more)	58 (70)	38 (57)	0,05

*Population: 150 patients (excluding patients with mechanical complications).
IQR: Interquartile range. HTN: Hypertension. CKF: Chronic kidney failure. KK: Killip and Kimball.
PIA: Postinfarction angina. STEACS: ST-segment elevation acute coronary syndrome. RV: Right ventricular.

other registries. (3, 4, 7, 13, 14)

In addition, patients with CS hospitalized for NSTEACS were older than patients with STEACS, a finding that is similar to the one reported by international registries. (10)

Time to shock

In the context of an ACS, CS may be present at hospital admission (<20%), (3, 4) or may develop during hospitalization. In our registry, 56% of the patients presented CS since hospitalization and the rest of the patients evolved with CS at a median of 6 h, similar to other reports. (3, 15, 16) The difference in the prevalence of shock at the time of hospital admission in our study might be explained by the shorter time from symptom onset to the first medical contact of patients without shock in other registries (1.5 h vs. 6 h). Nevertheless, in our study as in previous registries, (3, 4) most patients (74%) presented CS within the first 24 h.

Revascularization

One of the benefits of myocardial infarction reperfusion is the reduction in the incidence of CS by limiting infarct size. (17, 18) The high mortality rate of patients with myocardial infarction complicated with CS and the results of the SHOCK trial (3) in terms of mortality reduction with early reperfusion have motivated the American, (19) European (20) and local guidelines (21) to strongly recommend urgent revascularization in patients with CS. Even more, revascularization of all the vessels with critical stenosis that can affect wall motion in the remote territories is recommended despite the lack of studies supporting this indication. Multivessel disease is very frequent in patients with CS: 64% in our study and between 60% and 78% in the literature. (4, 22)

Despite the guidelines' recommendations, only the culprit vessel is revascularized in most patients with CS. In our registry, similarly to others, (20) the other non-culprit vessels were also revascularized in only one third of the patients with multivessel disease. In this group of patients, mortality was 67% while in those who underwent PCI only of the culprit vessel, mortality was 36%. In the same sense, the results of the German ALKK-PCI registry (23) have been recently published, reporting that patients undergoing immediate multivessel PCI presented increased mortality compared with patients only with culprit lesion intervention (46.8% vs. 35.8%), and this difference persisted in multivariate analysis. Yet, the interpretation of data derived from registries has to be cautious, as the patients with the most severe disease could have received complete revascularization, and

the highest mortality could be attributed to the severity of the disease rather than to revascularization per se. The ongoing CULPRIT-SHOCK trial will address the question of optimal revascularization strategy in patients with multivessel disease and CS.

Mechanical circulatory assistance

In our study, IABP was used in 37% of patients and was not associated with higher mortality.

Even though intra-aortic balloon counterpulsation has been the mainstay for the treatment of CS since its introduction in clinical practice in 1960, and has been considered a Class I recommendation in American and European guidelines, its use in clinical practice varies between 15 and 40%. (7, 10) An analysis of the National Registry of Myocardial Infarction in the United States showed that the use of IABP was 36.5% in 1998 and 13.4% in 2008, and this reduction is similar to the one reported by other registries. (11) Despite the theoretical virtues of the device in the management of CS, the IABP-SHOCK II trial (25) which is the only randomized trial published so far, could not demonstrate significant differences in the mortality of patients treated with IABP and thus its use is currently a class II recommendation in some guidelines (26, 27) and even a class III recommendation in the last guideline published. (28)

The use of other ventricular support devices was 2.4% in our study and similar to previous reports. (14) Probably, the use of other ventricular assist devices (ECMO, Impella) may increase in a near future, as many studies have reported better clinical outcomes associated with their use. (29, 30)

Mortality

Although a few studies have reported a decline in mortality associated with CS over the years, (31, 32), it still remains high and varies according to different variables: age, sex, (33) the anatomy of coronary arteries found during angiography (number of vessels involved or left main coronary artery disease), angiographic patency, successful revascularization, type of ACS (with or without ST-segment elevation), or early vs. late CS. (13) In most cases, mortality is between 40 and 60%; (11, 20, 21) in our study, overall mortality was 54%. The ARGEN-IAM-ST registry reported 60% mortality in patients with CS. (34)

We did not find any independent variable predicting mortality of patients once CS has developed.

Study limitations

The present registry represents the real treatment of patients with CS in Argentina mostly recruited in high complexity centers; thus, these results cannot be extrapolated to CS at admission or developed during hospitalization in other type of centers. As this was not a registry of myocardial infarction, we could not determine the incidence of CS in the population studied.

CONCLUSIONS

The characteristics of CS in Argentina are similar to those of populations worldwide. In our registry, CS was more frequent since admission, probably associated with longer time delays to the first medical contact. Despite all the available treatment strategies, mortality is very high.

Measures for health promotion should be implemented to allow the population to seek rapid medical advice in the presence of symptoms suggestive of myocardial infarction. In the same sense, management of myocardial infarction should be optimized and adapted to the reality of each community to allow more efficient treatment strategies and thus avoid this severe complication.

Conflicts of interest

None declared. (See authors' conflicts of interest forms in the website/Supplementary material).

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