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CARDIOGENIC SHOCK WITH ST-SEGMENT ELEVATION ACUTE CORONARY SYNDROME (ReNa-SHOCK ST)

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Abstract Cardiogenic shock (CS) in the setting of an ST-segment elevation myocardial infarction (STEMI) is a severe complication and constitutes one of the principal causes of death associated with this condition. The aim of this study was to describe the clinical characteristics, treatment strategies and hospital outcome of CS associated with STEMI in Argentina. The Argentine Registry of Cardiogenic Shock (ReNA-Shock) was a prospective and multicenter registry of consecutive patients with CS hospitalized in 64 centers in Argentina between July 2013 and May 2015. Only those with ST-segment elevation myocardial infarction (STEMI) were selected for this analysis. Of the 165 patients included in the ReNa-Shock registry, 124 presented STEMI. Median age was 64 years (IQR 25-75: 56.5-75) and 67% were men; median time from symptom onset to admission was 240 minutes (IQR 25-75: 132-720). 63% of the cases presented CS at admission. Eighty-seven percent underwent reperfusion therapy: 80% primary percutaneous intervention with a median door-to-balloon time of 110 minutes (IQR 25-75: 62-184). Inotropic agents were used in 96%; 79% required mechanical ventilation; a Swan Ganz catheter was inserted in 47% and 35% required intra-aortic balloon pumping. Most patients (59%) presented multivessel disease (MV). Hospital mortality was 54%. Multivariate analysis identified that time from symptom onset to admission (> 240 min) was the only independent predictor of mortality (OR: 3.04; CI 95%: 1.18-7.9). Despite using treatment strategies currently available, morbidity and mortality of STEMI complicated with CS remains high.

Key words: cardiogenic shock, myocardial infarction, registries

Resumen **Shock *cardiogénico en el síndrome coronario agudo con elevación del ST. Resultados del ReNa-Shock ST.*** El *shock* cardiogénico (SC) en el síndrome coronario agudo con elevación del ST (SCACEST), es una complicación grave y constituye una de las principales causas de muerte. El objetivo del registro fue conocer las características clínicas, estrategias de tratamiento y evolución intrahospitalaria del SC secundario a un SCACEST en Argentina. El Registro Argentino de *Shock* Cardiogénico (ReNa-*Shock*) fue prospectivo, multicéntrico y consecutivo de pacientes internados con SC en el periodo 2013/2015 en 64 centros de Argentina. Fueron incluidos 165 pacientes, de los cuales124 presentaban SCACEST. La edad (mediana) fue de 64 [RIC_{25-75}: 56-75] años, 67% hombres. La mediana de tiempo desde el inicio de los síntomas al ingreso hospitalario fue de 240 minutos [RIC_{25-75}: 132-720]. Un 63% de los casos tuvo SC desde el ingreso. El 87% recibió tratamiento de reperfusión, con un 80% de angioplastia primaria y un tiempo puerta-balón (mediana): 110 minutos [RIC_{25-75}: 62-184]. Requirieron inotrópicos un 96%, asistencia respiratoria mecánica el 79%, catéter de Swan Ganz 47%, balón de contrapulsación intraaórtico 35%. El 59% tenía lesión de 2 o 3 vasos. La mortalidad intrahospitalaria fue 54%. En el análisis multivariado, solo el tiempo de evolución al ingreso (345 min [RIC_{25-75}: 135-720] vs. 180 min [RIC_{25-75}: 85-420]; p: 0.03) fue la única variable predictora independiente de mortalidad. La morbimortalidad del SC complicando un SCACEST es elevada a pesar de la utilización de las estrategias de tratamiento actualmente disponibles.

Palabras clave: *shock* cardiogénico, infarto de miocardio, registro

Cardiogenic shock (CS) is not a frequent condition, but constitutes the leading cause of death in patients hospitalized with acute myocardial infarction. Its incidence ranges from 6% to 8% and is associated with a mortality rate of 40-50% despite myocardial revascularization and the use of intra-aortic balloon pumping (IABP)[1, 2]. The information currently available comes from studies and registries performed more than 10 years ago[3, 4]. In Argentina, the information is scarce and derived from registries of acute coronary syndromes performed by the Argentine Society of Cardiology (SAC)[5, 6].

The National Registry of Cardiogenic Shock (*Registro Nacional de Shock Cardiogénico*, Re-Na-*Shock*) was the

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first registry performed in Argentina[7] specially designed to determine the clinical characteristics, treatment strategies, and in-hospital events in patients admitted to the critical care units with ACS with or without ST-segment elevation and who present CS at the moment of admission or during hospitalization. This paper presents the data of cases with CS associated with ST-segment elevation myocardial infarction (STEMI)[7].

Materials and methods

Re-Na Shock patients with STEMI complicated with CS admitted to coronary care units from July 2013 to May 2015 were entered in the present analysis. Cardiogenic shock was defined as systolic blood pressure ≤ 90 mmHg for at least 30 minutes or requiring vasopressors or inotropic drugs to maintain a systolic blood pressure ≥ 90 mmHg, associated with clinical signs of hypoperfusion or pulmonary congestion in the absence of hypovolemia or arrhythmias which could account for the clinical condition[8].

Data were collected by the investigators of the different centers and entered in an *ad hoc* designed electronic worksheet containing the following variables: age, gender, risk factors, comorbidities, previous treatment, infarct location, Killip class, time from symptom onset to admission, reperfusion strategies (thrombolysis or angioplasty), number of vessels involved (coronary artery stenosis ≥ 70% or occlusion) and treated, drug therapy, invasive monitoring with a pulmonary artery catheter, mechanical support with intra-aortic balloon pump (IABP) and mechanical ventilation. Hospital outcome and complications (fever, sepsis, multiorgan failure, arrhythmias, angina, reinfarction, requirement of red blood cell transfusions and major or minor bleeding) were also recorded. Echocardiographic data and lab tests at admission and at 24 hours were analyzed. Severe bleeding was defined using the TIMI bleeding criteria of major bleeding[9] or the GUSTO scale of moderate or severe bleeding[10].

The protocol was organized and conducted by the SAC's Research Department and the Council of Cardiovascular Emergency Care and was approved by the SAC's Bioethics Committee.

A frequency table was constructed using 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 the 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 the Yates correction or the Fisher's exact test as applicable.

Contingency table analysis was used to compare the association or the independence of the variables. The presence of associations or independent predictions between the different variables involved and mortality was determined using multiple logistical regression analysis. Those variables with a p value = 0.10 at 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.

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). The registry included 165 patients, 124 (75%) were STEMI. The clinical characteristics are summarized in Table 1. Median time from symptom onset to admission was 240 minutes (IQR 25-75: 132-720) and 87% underwent coronary artery reperfusion: 80% primary PCI, 20% thrombolytic therapy (83% streptokinase) and 13% rescue PCI. Eighty percent of the procedures were successful, with a median door-to-balloon-time of 110 minutes (IQR 25-75: 62-184). Sixteen patients did not undergo reperfusion due to late hospital arrival (9 cases), unavailable reperfusion therapy (1 case) and non-reported causes in 6 patients.

During hospitalization, 87% of patients underwent coronary angiography. Most (59%) presented MV disease (28% two-vessel disease and 31% three-vessel disease). In 32% of MV disease patients, non-culprit vessels were also intervened, in most cases (95%) during the same procedure. Sixty-three percent presented CS at admission and 19% of the remaining patients were admitted in Killip class I, 12% in class II and 6% in class III and developed CS at a median time of 7 h (IQR 25-75: 1.2-28) after hospitalization. Finally, 14% presented CS after 24 hours of admission.

Inotropic agents or vasoactive drugs were used in 96% of the cases (norepinephrine 75%, dopamine 54%, dobutamine 56% and levosimendan 5%); 79% required mechanical ventilation and IABP was used in 35% of cases for a median of 3 days (IQR 25-75: 1-4.5). The complications associated with IABP occurred in 16%: stroke (n = 1); acute lower limb ischemia (n = 2), thrombocytopenia (n = 4) and severe bleeding (n = 1).

TABLE 1.– *Clinical characteristics of the patients included*

Variable		
Age, (median) years	64 (56-75)	
	n	%
Age > 75 years	35	28.2
Male sex	84	67.7
Hypertension	87	70.0
Diabetes	31	24.4
Dyslipemia	53	42.9
Current smoking	50	40.1
Previous MI	25	20.3
Previous stroke	6	5.1
Peripheral vascular disease	5	4.0
Chronic renal failure	7	5.6
Killip class IV at admission	78	62.9
Anterior location MI	83	66.1
RV involvement	11	8.9

MI: Myocardial infarction; RV: right ventricle

A Swan-Ganz (SG) catheter was inserted in 47% of the treated: 62% within the first day, 18% between 24 and 48 hours and 20% after 48 hours for a median of 3 days (IQR: 2-5). The catheter was inserted as a routine practice or to guide treatment in most cases, and for diagnostic purposes in 15%. There were no differences in age, gender, infarct location, time from symptom onset to admission, type of reperfusion strategy or right ventricle involvement between patients with a SG catheter inserted and those without.

Main events during hospitalization are presented in Table 2.

The incidence of bleeding was 11% and it was severe in 7 patients. Twenty-one percent required transfusion of red blood cells (< 2 units: 23%, 2 to 4 units: 54% and > 4 units: 23%). Twenty-nine patients were successfully resuscitated and 52% survived and were discharged.

The echocardiographic data were analyzed in 96 cases. Forty-seven percent of the echocardiograms were performed within 24 hours of admission. Echocardiography was not performed in 23% (70% of these patients had died within the first 48 h of admission).

Ventricular function was visually estimated by echocardiography: 58% evidenced severe and 29% moderate dysfunction, while the remaining 21% had normal or near normal of left ventricular function. Wall motion abnormalities corresponded to a single vascular territory in 38% of the cases and to 2 or more in 62%. The characteristics of wall motion in remote territories were reported in 70 patients: 54% presented a preserved wall motion, 41% abnormal and 4% evidenced hyperkinesis. Systolic pressure in the pulmonary artery could be measured in 31 patients with a median value of 39 mm Hg (IQR 25-75: 22-48). Five patients presented mitral regurgitation and 1 had a ventricular septal defect.

Hospital mortality was 54% (46% of them within the first 48 h). The most frequent causes of death were ventricular failure (53%), arrhythmias (25%), infections (12%) and neurological complications (4%). Mortality rate was 51% in reperfused patients and 75% in those without reperfusion (p = 0.05), 37% in patients with one-vessel disease versus 54% in those with MV disease (p = 0.05). In patients undergoing MV PCI, mortality was 67% while in those with MV disease who underwent PCI of the culprit vessel mortality was 36% (p = 0.01). There were no differences in mortality according to the use of IABP. On the other hand, mortality was significantly higher in those who were not monitored with a SG catheter (55% vs. 45%; p = 0.004).Cumulative survival was 0.85 for patients lasting 120 minutes from symptom onset to admission and 0.74 when it was 240 minutes (Fig. 1).

At univariate analysis, age > 75 years, previous stroke, time from symptom onset to admission, reperfusion and multivessel disease were associated with higher mortality (Table 3). At multivariate analysis time from symptom onset to admission > 240 minutes, was the only independent predictor of mortality (OR: 3.04; CI 95%: 1.18-7.9; p = 0.021) (Fig. 2).

TABLE 2.– *Events during hospitalization*

Events	n	%
Revascularization	108	87.0
Mortality	67	54.0
Angina	5	4.0
Reinfarction	2	1.6
Arrhythmias	83	66.9
AF	40	32.2
VT-VF	63	50.8
AV- block	17	13.7
Temporary pacing	26	20.9
Electric cardioversion	48	38.7
Fever	61	49.1
Dialysis	8	6.5
Ventricular assistance	4	3.5
Heart transplantation	3	2.4

AF: Atrial fibrillation; VT/VF: Ventricular tachycardia/ventricular fibrillation; AV block: Atrioventricular block.

Discussion

Cardiogenic shock is the most life-threatening complication of MI and remains the leading cause of death. Historically, the incidence of CS ranged between 5 to 15% but many registries have reported that the implementation of reperfusion strategies reduced the incidence of this complication[11-13]. In Argentina, CS incidence is 6% according to the 2011 registry of *the Sociedad Argentina*

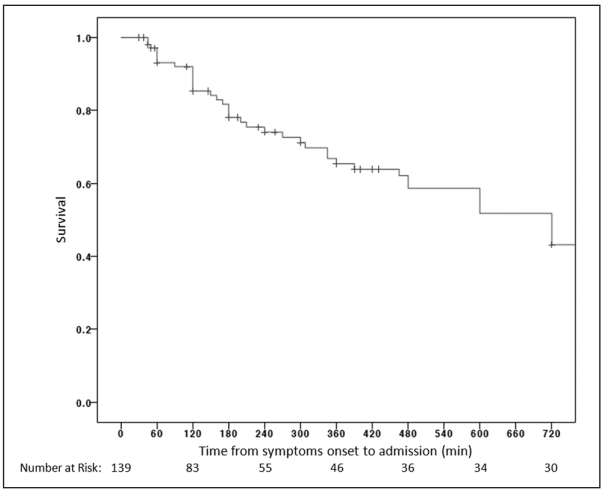

Fig. 1.– Cumulative survival according to time (minutes) from symptoms onset to admission

TABLE 3.– *Mortality predictors: univariate analysis*

	Dead n = 66	Alive n = 57	p
Age (median, IQR) years	66 [60-76]	62 [54-71]	0.01
> 75 years	24 (36.4)	11 (19.3)	0.01
Male sex	43 (65.1)	41 (71.9)	0.25
Diabetes	17 (26.7)	13 (22.8)	0.33
Hypertension	43 (66.1)	38 (66.7)	0.27
Current smokers	22 (33.3)	26 (45.6)	0.09
Chronic renal failure	11 (16.7)	4 (7.0)	0.16
Previous stroke	6 (9.1)	1 (1.7)	0.04
Previous MI	15 (22.7)	10 (17.5)	0.29
Killip class IV at admission	55 (83.3)	49 (85.9)	0.4
Angina	2 (3.0)	3 (5.3)	0.28
Reinfarction	1 (1.5)	1 (1.7)	0.46
Arrhythmias	47 (71.2)	35 (61.4)	0.12
Time from symptom onset to admission (median, IQR), minutes	345 (135-720)	180 (85-420)	0.03
Time from symptom onset to admission > 240 minutes*	34 (60.7)	21 (42.9)	0.05
Anterior location MI	44 (66.7)	37 (64.9)	0.5
RV involvement	5 (7.6)	6 (10.5)	0.3
Reperfusion	52 (78.8)	51 (89.5)	0.005
Mutivessel disease	31 (46.9)	26 (45.5)	0.05
IABP	23 (34.8)	20 (35.1)	0.48
Fever	31 (46.9)	29 (50.9)	0.33

RV: Right ventricle; IABP: Intra-aortic balloon pump
**: 240 minutes was the median time from onset to admission.*

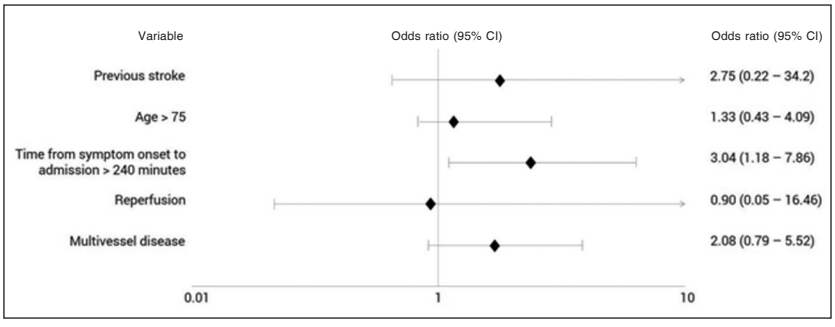

Fig. 2. Multivariate analysis of death

de Cardiología; when data from the same centers were compared in different time intervals from 2001 to 2005 the incidence decreased from 12% to 5%[5].

In our registry and in line with other reports, most CS admitted were due to STEMI[14]. Also, the prevalence of males with CS was greater than that of females but the relative proportion of women was greater than that of men´s when compared with populations with ACS without shock in accordance with the reports of all the registries available[3, 4, 15, 16].

The age of our population was similar to that of international registries[11]. In the setting of an ACS, CS may be present at hospital admission (< 20% of the cases)[3, 4], or may develop during hospitalization. In our registry, 63% of the patients presented CS from admission and the rest of the patients developed CS at a median of 7 hours from admission, data comparable to other reported findings[2, 3, 17].The different prevalence of CS at the time of hospital admission in the present study compared to other registries may be related to a longer time from symptom onset

to first medical contact (6 h vs. 1.5 h). Nevertheless, the majority of our patients with CS were admitted during the first day of symptoms similar to data published in previous registries[3, 4].

One of the benefits of reperfusion therapy is to reduce the incidence of CS by limiting infarct size[18, 19]. The high mortality rate of MI patients complicated with CS and the results of the SHOCK trial[3] as regards reduction of mortality with an early reperfusion therapy have motivated the American[20], European[21] and local[22] guidelines to strongly recommend prompt revascularization in patients with CS. Moreover, a complete revascularization in cases of multivessel disease that can jeopardize remote left ventricle wall motion is recommended despite the lack of strong evidence warranting this indication. Multivessel disease is very frequent in patients with CS: 64% in our study and between 60% and 78% in reported evidence[4, 23].

Despite the recommendations of the guidelines, the single culprit vessel is treated in most CS patients. Similarly to other registries[23], the non-culprit vessels were treated in only one third of the patients with MV disease in our study but with a higher mortality compared with patients who underwent single revascularization of the culprit vessel. In addition, the results of the German ALKK-PCI registry that have been recently published[24], reported that patients undergoing immediate multivessel PCI evidenced an increased mortality compared with patients undergoing single culprit vessel revascularization (47% vs. 36%) that persisted after multivariate analysis. Yet, data registry must be interpreted with caution as patients with a more extensive coronary disease could have received a complete revascularization and thus the higher mortality in this group can be attributed to a higher clinical risk rather than to the revascularization procedure *per se.* The ongoing CULPRIT-SHOCK trial[25] will address the question of the optimal revascularization strategy in CS patients with multivessel disease.

The use of IABP was not associated with differences in mortality rate. Despite IABP has been a mainstay of treatment of CS since it was introduced in clinical practice in 1960 and was recommended by the American and European guidelines as a class I indication, its use in clinical practice varies between 15% and 40%[11]. An analysis of the National Registry of Myocardial Infarction in the United States[26] showed that the use of IABP decreased from 36.5% in 1998 to 13.4% in 2008, and this reduction is similar to reports from other registries[12]. Despite the theoretical virtues of the device in the management of CS, the IABP-SHOCK II trial[27] which is the only randomized trial to address this issue so far, could not demonstrate significant differences in mortality of patients treated with IABP and thus its use is currently a class II recommendation[21, 28] and even a class III in the last guideline published[29].

The use of other ventricular assist devices was 2.4% in our study and similar to previous reports[15]. Probably, the use of other ventricular assist devices (ECMO, Impella) may increase in the near future, as many studies have reported a better clinical outcome associated with their use[30, 31].

Although a few studies have reported a decline in mortality associated with CS throughout the years[8, 32], it still remains very high with differences related to variables such as age, gender[33], extension of coronary artery disease, angiographic patency, successful revascularization, type of infarction and early or late CS development[14].

Most reports of CS evidenced a mortality ranging from 40 to 60%[12, 34, 35], in line with the one observed in our study that was 54%. Finally, the time from the onset of symptoms to admission was the only independent predictor of mortality in our population.

The limitation of this study is that the present registry represents the real treatment of CS associated with STEMI in Argentina in patients mostly recruited in tertiary care centers; thus, these results cannot be extrapolated to CS at admission or developed during hospitalization in other type of centers.

Finally, the characteristics of CS in Argentina are similar to those of populations worldwide. In our registry, CS was more frequent at admission, probably related to longer time delays from symptom onset to first medical contact. Only one third of our patients with mutivessel disease underwent a complete revascularization procedure with a high mortality despite all the treatment strategies available.

Conflict of interests: None to declare

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