Acute Myocardial Infarction Mortality in Continuous ARGEN-IAM-ST Registry. Its Relationship with Different Reperfusion Therapies

Mortalidad por infarto agudo de miocardio en el registro continuo ARGEN-IAM-ST. Su relación con las diferentes terapias de reperfusión

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ABSTRACT

Background: Reperfusion treatment is the most effective therapy to reduce ST-segment elevation acute myocardial infarction (STEMI) mortality, and its effectiveness is inversely proportional to total ischemic time. The greatest challenge is to implement its application in real life and continuously correct the deviations or barriers that arise in daily practice.

Objectives: The aim of this study was to assess mortality with different reperfusion modalities, their effectiveness and the relationship of mortality with treatment time.

Methods: A national prospective, multicenter study was carried out including patients, with STEMI up to 36 h since symptom onset (ARGEN-IAM-ST continuous registry).

Results: A total of 2464 patients from 78 centers were included in the study from 2015 to 2019. In 88.5% of cases, patients received reperfusion treatment. Overall mortality was 8.68%; in patients with reperfusion therapy, mortality was 7.81% vs. 15.38% without reperfusion treatment (p < 0.001).

Mortality was 7.51% with primary angioplasty, 9.03% with thrombolytics, 2.99% with a pharmacoinvasive strategy and 9.40% with rescue angioplasty, with no statistically significant difference between primary angioplasty and thrombolytics (OR 0.81; 95% CI 0.56-1.18, p = ns).

Deceased patients were older and with a higher proportion of women and heart failure. Reperfusion treatment and admission to the institution within 3 hours of symptom onset were associated with lower mortality. Patients with primary angioplasty who died had a longer total ischemic time (378 min vs. 285 min, p <0.001).

Conclusions: Mortality from STEMI was associated with access to reperfusion treatment and its early implementation. It was much higher in non-reperfused patients, and lower when reperfusion was carried out early within 3 hours of symptom onset. In patients treated with primary angioplasty, mortality increased with longer total ischemic time. This registry of the actual practice of infarction treatment reinforces the need for a better management of the care system to reduce times and use the best timely strategy.

Key words: Myocardial infarction - ST segment elevation myocardial infarction - Mortality – Reperfusion- Coronary balloon angioplasty – Fibrinolysis

RESUMEN

Introducción: El tratamiento de reperfusión es la terapéutica de mayor eficacia para reducir la mortalidad del infarto agudo de miocardio con elevación del segmento ST (IAMCEST), y su efectividad es inversamente proporcional al tiempo total de isquemia. El mayor desafío es instrumentar su aplicación en la vida real y corregir en forma continua los desvíos o las barreras que se presentan en la práctica cotidiana.

Objetivos: Evaluar la mortalidad con las diferentes modalidades de reperfusión, su relación con el tiempo de tratamiento y su efectividad en un registro prospectivo multicéntrico del mundo real de Argentina.

Métodos: estudio prospectivo, multicéntrico de carácter nacional, incluidos los pacientes con IAMCEST hasta las 36 h del comienzo de los síntomas (ARGEN-IAM-ST registro continuo).

Resultados: participaron 2464 pacientes de 78 centros entre 2015 y 2019. El 88,5% recibió tratamiento de reperfusión. La mortalidad fue de 8,68%. Los pacientes tratados con reperfusión tuvieron una mortalidad de 7,81% versus 15,38% sin tratamiento (p < 0,001).
La mortalidad con angioplastia primaria fue 7,51%, con trombolíticos 9,03%, con estrategia farmacoinvasiva 2,99% y con angioplastia de rescate 9,40%, sin diferencia estadísticamente significativa entre angioplastia primaria y trombolíticos (OR 0,81 IC 95% 0,56-1,18, p = ns).

Los pacientes fallecidos fueron de mayor edad, con mayor proporción de mujeres e insuficiencia cardíaca. El tratamiento de reperfusión e ingreso a la institución dentro de 3 horas del comienzo de los síntomas se asoció a menor mortalidad. Los pacientes con angioplastia primaria fallecidos tuvieron mayor tiempo total de isquemia (378 minutos versus 285 minutos, p < 0,001).

Conclusiones: La mortalidad por IAMCEST se relacionó con el acceso a la reperfusión y su precocidad. Fue mucho mayor en los pacientes no reperfundidos, y menor cuando la reperfusión se efectuó en forma precoz dentro de las primeras tres horas del comienzo de los síntomas. En los pacientes tratados con angioplastia primaria la mortalidad se incrementó con mayor tiempo total de isquemia. Este registro de la práctica real del tratamiento del IAMCEST refuerza la necesidad de una mejor articulación del sistema de atención para bajar los tiempos y utilizar la estrategia mejor y más oportuna.

Palabras clave: Infarto de miocardio - Infarto de miocardio con elevación del ST - Mortalidad –Reperfusión - Angioplastia coronaria con balón – Fibrinolíticos

INTRODUCTION
Acute myocardial infarction is one of the main causes of death in Argentina. (1) The organization of registries by disease or syndrome has the great advantage of including all the spectrum patients representing the usual medical practice, thus allowing the evaluation of the effectiveness, efficacy and safety of treatments. (2) Clinical trials are extremely useful to define safety and efficacy, but their external validity is often questioned. (3) Our greatest challenge is to implement the adequate application of the best treatments recommended by clinical practice guidelines in real life.

Reperfusion treatment of ST-segment elevation acute myocardial infarction (STEMI) is time dependent. Survival improvement, which implies not only the application of the best reperfusion treatment but doing it within the recommended time frame, requires prehospitalization logistics. (4) Our main objective was to discriminate which are the components of overall mortality according to the different subgroups of patients receiving or not reperfusion treatment, and their relationship with delays and total ischemic time (TIT).

METHODS
The ST- Segment Elevation Acute Myocardial Infarction Continuous Registry (ARGEN-IAM-ST) (2) is a nationwide, prospective, multicenter, study, with data collection through a website platform shared by all participating centers. Patients with up to 36 hours of STEMI evolution since symptom onset were included in the study. Data was collected regarding delays up to effective treatment, which were defined as:

1) Pain-to-admission time: time from symptom onset suggestive of coronary ischemia to hospital admission.
2) Time-to-reperfusion: time interval between arrival to a medical center and start of reperfusion treatment.
   a) In case of fibrinolytics
      • Time frame or total TIT: time interval in minutes from symptom onset to start of fibrinolytic therapy infusion.
      • Door-to-needle time (DNT): time interval in minutes from hospital arrival to start of fibrinolytic therapy infusion.
   b) In case of percutaneous coronary intervention (PCI)
      • Time frame or TIT: same as for fibrinolytics, but until balloon inflation.

   • Door-to-needle time (DNT): time interval in minutes from hospital arrival to balloon inflation.

Data was collected via a website, in an electronic form specially designed by the FAC Medical Teleinformatics Center (CETIFAC).

The reperfusion treatment refers to patients who received thrombolytics and/or PCI.

Ethical considerations
The protocol of the ARGEN-IAM-ST registry was approved by the Ethics Committee of the Argentine Society of Cardiology and of each participating center. This registry does not require the need for an informed consent, which is left to the discretion of each participating center.

Statistical analysis
Qualitative variables are expressed as frequencies and percentages, with their 95% confidence intervals (95% CI) and quantitative variables as mean ± standard deviation or median and interquartile range (IQR 25-75), according to their distribution.

Continuous variables were analyzed using contingency tables and the chi-square test or Fisher’s exact test, and continuous variables using Student’s t test or the Kruskal Wallis test for unpaired data, or the analysis of variance (ANOVA), as appropriate. Multiple logistic regression was used for the independent analysis of in-hospital mortality quantified by the odds ratio (OR) and its 95% CI. A p value <0.05 was considered as statistically significant. Epi Info 7.2.2.6 software package was used to perform the statistical analysis. The protocol was registered in ClinicalTrial.gov under number NCT2458885.

RESULTS
A total of 2464 patients from 78 centers in 19 provinces of Argentina and the Autonomous City of Buenos Aires participated in this study from January 1, 2016 to September 10, 2019, with the following medical coverage: public (31%), prepaid and private (16%) social security (40%) and Integral Health Care Program (PAMI) (13%). Seventy-three percent of patients corresponded exclusively to coronary care units and 65% to centers with PCI availability. Table 1 shows population characteristics.

In-hospital mortality was 8.68%. Deceased patients were older, a third were women, and with greater...
prevalence of history of coronary heart disease, heart failure and risk factors, except for smoking and family history. In 75% of cases, deceased patients suffered from heart failure, according to the admission Killip score (Table 1).

**Differentiated mortality**

Mortality of patients who did not receive reperfusion treatment doubled that of those who received reperfusion (OR 2.14, 95% CI 1.5-3.0, p <0.001) (Figure 1). Most patients received primary PCI, with 7.51% mortality, or fibrinolytics, with 9.03% mortality, without significant difference between both strategies (OR 0.81, 95% CI 0.95-1.18, p=ns). Rescue PCI was performed in 33% of thrombolized patients, with 9.40% mortality, and the pharmacoinvasive therapy was only performed in a small proportion of thrombolized patients (15%) and with very low mortality (2.99%) (Figure 1).

**Treatment time**

Patients admitted to a center within 3 hours of symptom onset (61%) presented 7.07% mortality compared with 11.1% in those who were admitted later (OR 0.60, 95% CI 0.45-0.80, p <0.001). Table 2 summarizes the different admission times.

Deceased patients with primary PCI had a longer admission time and TIT than those who survived, without differences in door-to-balloon time, although this was prolonged according to clinical practice guideline recommendations (Figure 2A). No differences were detected in patients treated with fibrinolytics, despite door-to-needle time and TIT were increased according to recommendations (Figure 2B).

Deceased patients who received rescue PCI had very prolonged door-to-balloon time and TIT with respect to those who survived (647 min vs. 320 min, p=0.04 and 800 min vs. 516 min, p=0.06, respectively). Patients treated with a pharmacoinvasive strat-

<table>
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<th>Variable</th>
<th>Total (n = 2464) %</th>
<th>Alive (n = 2250) %</th>
<th>Dead (n = 214) %</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>p</th>
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<td>60 (RIC 52-67)</td>
<td>64 (RIC 58-74)</td>
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<td>-</td>
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<td>25.7</td>
<td>2.2</td>
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<td>&lt;0.001</td>
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<td>50</td>
<td>0.60</td>
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<td>&lt;0.001</td>
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</table>

egy had a TIT of 800 min (IQR 495-1274); the two deceased patients had a lower door-to-balloon time (215 min vs. 800 min, \( p=0.07 \)) and a lower TIT (687 min vs. 800 min, \( p=ns \)). Given the low number of patients and low mortality, inclusion biases cannot be ruled out.

**Multivariate analysis**
Age, female sex, and heart failure expressed as admission Killip >1 were the variables independently associated with greater mortality, and reperfusion treatment and hospital admission within 3 hours of symptom onset were protective variables (Table 3).

**DISCUSSION**
The ARGEN-IAM-ST registry incidence of in-hospital mortality is 8.7%, as a result of averaging primary PCI (7.5%), thrombolytic treatment (9.0%), rescue PCI (9.0%), pharmacoinvasive treatment (3.0%) and non-reperfused patients (15.4%). This mortality rate has not changed in the last 10 years in the Argentine Society of Cardiology and the Argentine Federation of Cardiology registries. (5-9) Recently, the comparison of mortality between the United Kingdom and Sweden was published, including 842 897 patients with ST-segment elevation or non-ST-segment elevation acute coronary syndromes between 2003 and 2013. In Sweden, it included 60 712 patients (SWEDEHEART) and in the United Kingdom 263 159 patients (MI-NAP) with STEMI. (10) These data do not reflect the current situation in the United Kingdom, but may be useful to compare some aspects with our registry.

The United Kingdom reported lower rates of revascularization (primary PCI or CABG) compared with Sweden (43.8% vs. 74.9%, respectively). However, reperfusion from primary PCI or fibrinolitics was higher in the United Kingdom (78.9% vs. 75.7%, \( p <0.05 \)). The standardized net probability of death between admission and 1 month was greater in the United Kingdom: 8.0% (95% CI 7.4-8.5) vs. 6.7% (95% CI 6.5-6.9) in Sweden. Mortality in the ARGEN-IAM-ST registry is higher, despite our population is much younger than that of Sweden or the United Kingdom (60.2±11.7 years vs. 68.9±12.6 and 65.8±13.6 years, respectively) and the reperfusion rate in our registry is higher (88%).

Probably our registry includes high-quality care centers, affiliated to scientific societies and are not representative of our community. Nevertheless, our mortality was higher. These data correlate with the prolonged ischemic times both in survived and deceased patients.

The registry is a key tool to assess treatment effectiveness and understand the discrepancy between the evidence and clinical practice. (11, 12) Without this
universal instrument we will certainly be unable to establish national public policies.

ST-segment elevation myocardial infarction belongs to the group of pathologies in which survival is time-dependent: it ideally requires that the patient seeks medical care within 3 hours of symptom onset and that reperfusion treatment is applied as soon as possible, either with thrombolytic therapy, with a door-to-needle time below 30 minutes, or with primary PCI, with a door-to-balloon time below 90 minutes. It is very difficult to achieve these times in the real world. (13) The registry shows that 40% of patients consult beyond the time frame of 180 minutes, which is associated with greater mortality. (14) Currently, the way to solve this complex problem is to work in prehospital logistics and regionalization, as demonstrated by the Stent-Save a Life! initiative in our country, (15) with a low mortality rate (3.5%) in patients treated within 3 hours of symptom onset. However, global mortality is still high (7%), similar to that of patients from our registry treated with primary PCI (7.5%).

At present, the pharmacoinvasive treatment has proved to be successful and comparable to primary PCI, as long as tenecteplase (TNK) is available and a rescue PCI is performed to a third of patients with no reperfusion criteria. (16)

The STREAM study showed approximately 4.5% mortality in patients with TIT of 100 minutes for pharmacoinvasive treatment and 179 minutes for primary PCI. Total ischemic time in our registry was about 180 minutes for thrombolytics and 285 minutes for primary PCI in surviving patients, and 378 minutes in deceased patients. It is evident that the double mortality rate correlates with very prolonged TIT.

It is remarkable that in a country with such long
distances as Argentina, the use of pharmacoinvasive treatment is so low, and that it has not been a strategic option. (17, 18) Even though in our registry patient mortality with a pharmacoinvasive strategy was low, its application was restricted to a very selected group of patients. The use of this strategy at a community level has not been evaluated in Argentina.

A total of 443 patients received thrombolytic treatment, and 33% of them, rescue PCI with TIT of 8.9 hours, which explains the elevated mortality compared with the aforementioned randomized studies and the low mortality in patients reperfused with thrombolytics undergoing PCI (TIT=13.3 h). However, a pharmacoinvasive treatment cannot be considered without taking into account those patients who are not reperfused and need a procedure in less than 2 hours.

Argentina is a country with more than 300 hemo-dynamics centers (19) and, paradoxically, mortality is very high. Lack of public policies that allow acting in the emergency of an acute myocardial infarction probably explains this health problem. The recently published REGIBAR study (20) puts this issue into perspective, since in a projection of the total number of acute myocardial deaths in the country (21) we observe that in-hospital mortality only represents 15% of global infarction mortality.

Limitations
The main limitation of the ARGEN-IAM-ST registry is that it does not represent the global situation of the country, as participation is voluntary and associated to centers affiliated to scientific societies. In addition, it does not have an external audit to validate the results.

CONCLUSIONS
This registry leaves open some relevant problems which require a community solution in line with the Sumar plan proposal. (22)

1) Public policies should be applied stimulating early consultation.

2) Centers administering thrombolytics should reduce by half the door-to-needle delay.

3) Centers applying primary PCI should significantly reduce door-to-balloon times.

4) Thrombolytic therapy should be the first option when delay for referral to PCI is longer than 120 minutes in order to reduce TIT.

Conflicts of interest
None declared.

(See authors' conflict of interests forms on the web/Additional material.)

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REFERENCES


SUPPLEMENTARY MATERIAL

APPENDIX

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Clínica Santa Isabel – Victor Mauro/Yanina Castillo Costa
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Sanatorio San Carlos – Matías Calandrelli
Sanatorio Allende Nueva Córdoba – Julio Bono
Centro Privado de Cardiología – Eduardo G. Hasbani
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Centro Modelo de Cardiología – Juan Muntaner
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Sanatorio Privado Gatti – Pablo Moreno
Sanatorio Pasteur – María Pía Marturano
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Hospital Ramón Carrillo– David Marcelo Krivich
Hospital Córdoba – Marcos De la Vega
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Hospital San Felipe San Nicolás – Raúl Alejandro Quijano
Hospital El Carmen, Mendoza – Oscar Fernando Vidal
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Sanatorio de la Trinidad, San Isidro, Bs. As. – Juan Taccari/Walter Nieto
Hospital Italiano de Buenos Aires, CABA – José Luis Navarro Estrada/Francisco José Romeo
Hospital Británico de Buenos Aires, CABA – Horacio Alberto Avaca/Mauro Gastón Gingins
Hospital Mi Pueblo, Florencio Varela, Buenos Aires – Santiago Tur/Federico Bodega
Hospital Pablo Soria – Franz Rivero Paz
Sanatorio Allende Cerro, Córdoba – Roberto Miguel A. Colque
Hospital Privado del Sur – Raúl Cermesoni/Marcelo Guimarenz
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Clínica San Martín – Pablo Maldonado
Hospital Italiano de La Plata – Cecilia Beltrano
Hospital Irarte – David Parisi
HIGA Gral. San Martín – Luis Medesani
HIGA Rossi – Carlos Martínez
Hospital Pirovano – Ricardo Mejail
Hospital Español de Rosario – Daniel Edgardo Miraglia
Clínica Yunes – Edgar Aguilar
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Policlínico Modelo de Cipolletti – Diego Figoni
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Clínica Del Valle – Miguel Salva
Hospital Zonal Bariloche – Germán Santamaría
Hospital de Alta Complejidad J. D. Perón – Christian Smith/Nicolás Areco
Hospital L. Molas, Santa Rosa, La Pampa – Fabián Kubaruk
Sanatorio Mitre – Hernán Cohen Ariazi