Characteristics and Mortality Following Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction in Spain. Results From the TRIANA 1 (TRatamiento del Infarto Agudo de miocardio eN Ancianos) Registry

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Introduction and objectives. Although more elderly patients will experience acute myocardial infarction (AMI) in coming years, the best reperfusion strategy in these patients remains unknown.

Patients and method. The Spanish TRIANA (TRatamiento del Infarto Agudo de miocardio eN Ancianos) registry was set up to determine the feasibility of performing a randomized study of percutaneous coronary intervention (PCI) versus thrombolysis in AMI patients aged ≥75 years. The TRIANA 1 subregistry included consecutive patients of all ages with ST-segment-elevation AMI (≤12 h from onset) who underwent PCI in selected hospitals.

Results. In total, 459 TRIANA-1 patients were included at 25 hospitals over 3 months. Some 11% had cardiogenic shock. PCI was performed as rescue therapy in 24% and, in 15% because thrombolysis was contraindicated. After PCI, 83% had TIMI grade-3 flow without significant residual stenosis. Mortality at 1 month was 10.8%. Independent predictors of mortality identified by multivariate analysis were: cardiogenic shock at admission (OR=7.2; 95% CI, 2.2-23.3), age (OR=1.05 per year; 95% CI, 1.005-1.100), maximum creatine kinase MB fraction (OR=1.01; 95% CI, 1.004-1.270), and post-PCI TIMI grade <3 (OR=2.8; 95% CI, 1.0-8.3). Of 104 participants aged ≥75 years (mortality, 24%), 58 (55.7%) fulfilled criteria for inclusion in a randomized study.

Conclusions. *1)* The TRIANA 1 subregistry probably reflects the reality of PCI for AMI in Spain. *2)* Mortality at 1 month was associated with classic predictive factors. *3)* Some 50% of patients ≥75 years old who underwent PCI could be included in a randomized study. These findings indicate that randomized study to determine the best reperfusion strategy in elderly AMI patients is feasible.

Key words: *Acute myocardial infarction. Primary angioplasty. Rescue angioplasty.*

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Características y mortalidad del infarto agudo de miocardio tratado con intervencionismo coronario percutáneo primario en España. Resultados del Registro TRIANA 1 (TRatamiento πdel Infarto Agudo de miocardio eN Ancianos)

Introducción y objetivos. El número de pacientes de edad avanzada que presenta un infarto agudo de miocardio (IAM) se incrementará en los próximos años, sin que se conozca en la actualidad cuál es la mejor forma de reperfusión.

Pacientes y método. El Registro TRIANA (TRatamiento del Infarto Agudo de miocardio eN Ancianos) se diseñó para analizar la factibilidad de efectuar un estudio aleatorizado en España para comparar la eficacia del intervencionismo coronario percutáneo (ICP) con la trombólisis en el tratamiento del IAM en pacientes de edad avanzada (≥ 75 años). El subregistro TRIANA 1 evaluó a todos los pacientes consecutivos, con independencia de la edad, en los que se efectuaba un procedimiento de ICP en IAM

This study was jointly prepared by the Hemodynamics and Interventional Cardiology and Ischemic Cardiopathy Sections and Coronary Units of the Spanish Society of Cardiology.

*The researchers and hospitals participating in the TRIANA 1 Subregistry are listed in the Appendix.

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ABBREVIATIONS

AMI: acute myocardial infarction.
PCI: percutaneous coronary intervention.
OR: *odds ratio*.

con ST elevado (≤ 12 h de evolución) en una serie de hospitales seleccionados.

Resultados. En el subregistro TRIANA 1 se incluyó a 459 pacientes en 25 hospitales en un período de 3 meses. Un 11% de los pacientes se presentaron en shock cardiogénico. En un 15% la indicación del ICP fue por contraindicación a la trombólisis y en un 24%, por rescate. Se obtuvo un flujo TIMI 3 sin estenosis residual significativa post-ICP en el 83% de los pacientes. La mortalidad al mes fue del 10,8%. El análisis multivariado identificó la presencia de shock cardiogénico en el ingreso (*odds ratio* [OR] = 7,2; IC del 95%, 2,2-23,3), la edad (OR = 1,05 por año; IC del 95%, 1,005-1,100), el valor máximo de CK-MB (OR = 1,01; IC del 95%, 1,004-1,270) y el flujo TIMI < 3 post-ICP en la arteria causante (OR = 2,8; IC del 95%; 1,0-8,3) como factores predictivos independientes de la mortalidad. De los 104 pacientes incluidos con una edad ≥ 75 años (mortalidad del 24%), 58 pacientes (55,7%) cumplían criterios potenciales para ser incluidos en un estudio aleatorizado.

Conclusiones. *1)* El Registro TRIANA 1 traduce posiblemente la realidad del ICP en el IAM en España y sugiere una selección en los pacientes tratados. *2)* La mortalidad se asoció a factores predictivos clásicos. *3)* La mitad de los pacientes ≥ 75 años expuestos a ICP primario serían potencialmente incluibles en un estudio aleatorizado. Estos datos apoyan la viabilidad de la realización de un estudio para determinar la mejor estrategia de reperfusión en pacientes ancianos con IAM.

Palabras clave: *Infarto agudo de miocardio. Angioplastia primaria. Angioplastia de rescate.*

INTRODUCTION

Elderly patients form a very large group out of all those hospitalized with a diagnosis of acute myocardial infarction (AMI),[1] and their numbers will steadily increase in the coming years.[2] In addition, this subgroup presents the highest risk and higher mortality. However, the best reperfusion strategy in these patients is still unknown. Thus, the benefit of thrombolytic treatment is a matter of controversy[3,4] and it remains unconfirmed whether or not primary angioplasty significantly improves its prognosis. Although multiple random studies have demonstrated the benefit of primary angioplasty versus thrombolysis[5] in younger patients, at present there is only one study in which the comparative efficacy of both strategies in the management of elderly patients has been evaluated under controlled conditions. However, only a small number of patients were enrolled.[6]

When setting up a study on the acute phase of myocardial infarction in this population special strategic and logistic requirements are needed. It should be a multicenter randomized study with minimal patient selection but where the population has high morbidity and mortality rates. The Hemodynamics and Interventional Cardiology and Ischemic Cardiopathy Sections and Coronary Units of the Spanish Society of Cardiology have set up periodic registries to determine some of the aspects related to specific events in patients with coronary heart disease and ways of managing them.[7-11] The TRIANA Registry (from the Spanish TRatamiento del Infarto Agudo de miocardio eN Ancianos) was created to determine the feasibility of carrying out a randomized study to compare the efficacy of percutaneous coronary intervention (PCI) versus thrombolysis in the treatment of AMI in elderly patients (age ≥75 years). To evaluate this aim 2 subregisters were set up: the TRIANA 1 subregistry where, regardless of age and over a preestablished study period, all the AMI patients would be analyzed who had been treated with PCI in a series of hospitals selected according to the number of primary angioplasties carried out; and the TRIANA 2 subregistry, in which all the elderly AMI patients (≥75 years) undergoing medical treatment would be analyzed who had been admitted to the same hospitals during the same period. The data and analysis presented in this study refer only to the TRIANA 1 subregistry which attempted to determine the strategies and outcomes of treating AMI with PCI in different hospitals and to analyze the specific characteristics of the population ≥75 years old treated with PCI.

PATIENTS AND METHODS

The TRIANA Registry was designed as an observational prospective study where Spanish hospitals with documented experience of treating AMI patients with PCI were selected. This was done according to data from the Annual Registry of the Spanish Hemodynamics and Interventional Cardiology Section[9] for 2001 (Registro Anual de la Sección de Hemodinámica y Cardiología Intervencionista). All the hospitals that had carried out ≥25 PCI procedures/year in the acute phase of AMI were invited to participate. The TRIANA 1 subregistry included all the consecutive patients of any age who had undergone a PCI procedure in the acute phase (≤12 h) of ST-segment elevation AMI or complete left bundle branch block in the selected hos-

pitals during the study period. Both primary angioplasty and rescue angioplasty patients were included, with no exclusion criteria. The criterion for carrying out rescue angioplasty was not specified. The patients who had undergone diagnostic coronary angiography with the aim of carrying out a primary PCI procedure, although their coronary anatomy made it inadvisable, were also included.

In-hospital mortality and mortality at 1 month were analyzed. A set of variables were prospectively identified and recorded in a standard data collection notebook (demographic variables, risk factors, background of coronary heart disease, concomitant diseases, AMI characteristics, arrival and procedure times, type of PCI, adjuvant treatment, angiographic and procedural variables, appearance and type of complication, need for additional in-hospital procedures, and events during hospitalization). PCI was considered successful when a TIMI 3 flow was obtained in the culprit artery, with a residual stenosis <50% and no major complications. A local researcher from each hospital periodically sent in the data collection notebooks to the coordinating center for data input purposes. These were evaluated via external audit. The data were analyzed individually and in case of inconsistency were sent back to the local researcher for reevaluation. Clinical follow-up at 1 month was done by telephone.

Statistical Analysis

Between 350-400 patients were considered for inclusion in the TRIANA 1 subregistry. Data obtained from the Annual Registry of the Spanish Hemodynamics and Interventional Cardiology Section for 2001[9] showed that potentially between 25 and 30 hospitals could participate. Thus, between 90 and 120 patients/month could be registered at an average inclusion rate of 3-4 patients/month. Given these forecasts the inclusion period was programmed for 4 months. It was thought that this sample would provide enough information regarding primary PCI treatment strategies in the different hospitals as well as data on the percentage and specific characteristics of the population ≥75 years treated with PCI.

All the data were analyzed with SPSS software, version 11.0 (SPSS, Inc., 2001). Quantitative variables were expressed as mean±standard deviation (SD) or median and 25%-75% percentiles and were compared with the Student *t* test. Qualitative variables were expressed as absolute value and percentages; when necessary, these were analyzed with χ^2 test or Fisher's exact test. Independent factors related to mortality were identified via multivariate logistic regression analysis with a saturated model in which we initially introduced all the statistically significant variables related to mortality plus those not statistically significant but which were thought to have clinical relevance. The variables that did not contribute any predictive information were progressively withdrawn until a model was obtained with the smallest number of variables without decreasing its predictive value. Due to the large weight that cardiogenic shock has on mortality during admission, the multivariate analysis was repeated with and without this predictor in the model. A subanalysis was carried out on the patients ≥75 years old. A *P*-value <.05 was considered statistically significant.

RESULTS

The TRIANA 1 subregistry was begun on 18 March 2002 with 25 hospitals participating (see Appendix). Only 1 hospital declined the invitation to participate out of the hospitals selected. The inclusion period ended on 15 June 2002, 1 month before the expected date, since the calculated size of the sample had already been reached. During this period 459 patients were included (Figure 1). Table 1 shows the baseline characteristics, AMI location and Killip class of the included patients at presentation. Primary PCI was indicated in 76.2% of the patients and rescue PCI in 23.7%. Primary PCI was indicated in 15% of the patients due to a contraindication for thrombolysis.

Table 2 shows the different mean procedure times. The procedure was carried out during working hours in 45.4% of the patients. In 67% PCI was done within the first 6 h from onset of symptoms. Cardiac catheterization could not be done in three patients. PCI was not indicated in 15 patients (3.3%). Table 3 shows the different treatments administered before or during PCI. Most patients were treated with aspirin, thienopyridines and heparin, whereas 55.1% received a platelet glycoprotein IIb/IIIa receptor inhibitor which was usually abciximab.

Table 4 shows the baseline angiographic characteristics of the patients under study and the type of PCI procedure performed. Eighty-seven per cent of the patients had just one culprit artery revascularized, 2 arteries were revascularized in 9%, and 3 arteries in 1%. The procedure was considered successful in 83% of cases. Figure 2 shows changes in TIMI flow in the culprit artery after PCI. Regarding complications associated with the procedure, the loss of an important lateral branch was observed in 4% of the patients, and transitory or permanent flow reduction events in the culprit artery in the absence of significant lesions in 7%. Immediately before PCI, 51% of the patients showed angiographic images compatible with a thrombus in the culprit artery; after the procedure thrombus was suspected in 11%.

Mortality during hospitalization was 10.8% (Table 5), with no change at 1 month follow-up. Table 6 shows the different factors associated with hospital mortality in the logistic regression analysis. Cardiogenic shock at admission was identified as the main

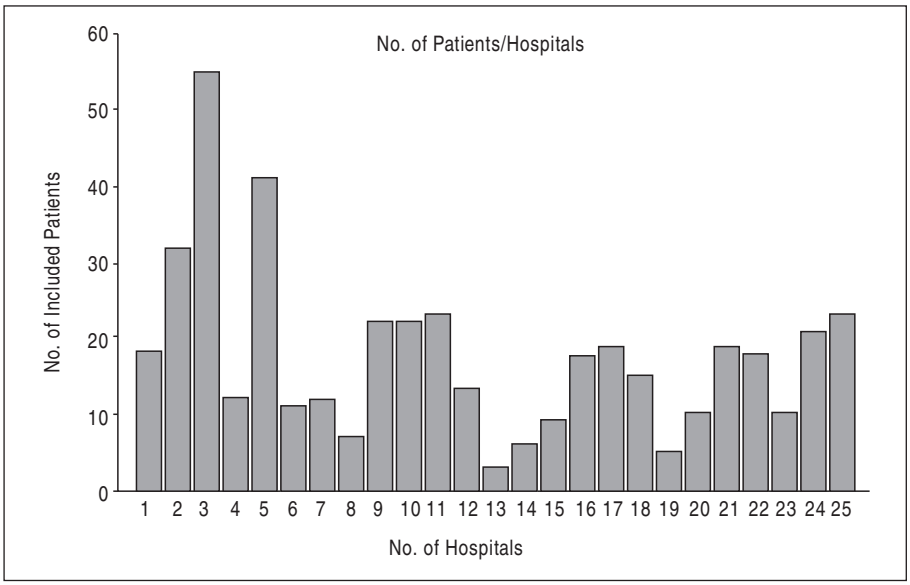

Figure 1. Individual distribution of the number of patients per center included in the 25 hospitals participating in the TRIANA 1 subregistry. Four hundred and fifty-nine patients were included over a 3-month period.

TABLE 1. **Demographic Characteristics, Baseline Clinical Data, and Location of the Infarction in the 459 Patients Included in the TRIANA 1 Subregistry***

	n (%)
Age, years (mean±SD)	62±13
Male	373 (81.2)
Coronary risk factors	
Smoking habit	200 (43.5)
AHT	207 (45)
Dyslipidemia	202 (44)
Diabetes	105 (22.8)
Background of coronary heart disease	
Previous heart attack	74 (16.1)
Unstable angina	106 (23)
Stable angina	37 (8)
Previous PCI	33 (7.1)
Previous coronary surgery	7 (1.5)
Peripheral vasculopathy	22 (4.8)
Previous stroke	39 (8.4)
Kidney failure	8 (1.7)
Systolic blood pressure, mm Hg (mean±SD)	126±29
Diastolic blood pressure, mm Hg (mean±SD)	74±16
Heart rate, beats/min (mean±SD)	78±20
Location of the AMI with ECG	
Anterior	251 (54.6)
Inferior	190 (41.3)
Lateral	18 (3.9)
Killip class at admission	
I	312 (68)
II	71 (15.4)
III	26 (5.6)
IV	53 (11.5)
Indication for PCI	
Primary PCI	350 (76.2)
Due to contraindications for thrombolysis	69 (15)
Rescue PCI	109 (23.7)

*AHT indicates arterial hypertension; AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; ECG, electrocardiogram; SD, standard deviation.

TABLE 2. **Procedure Time in the 459 Patients Included in the TRIANA 1 Subregistry***

Time from onset of symptoms-hospital (min)	
Mean (percentile 25-percentile 75)	122 (70-240)
Time door-guidewire, min	
Mean (percentile 25-percentile 75)	102 (60-190)
Time symptoms-guidewire, min	
Mean (percentile 25-percentile 75)	260 (180-415)
Time from onset of pain-PCI	
≤6 h	308 (67.1%)

*PCI indicates percutaneous coronary intervention.

TABLE 3. **Adjuvant Treatment Administered Prior to or During PCI. Patients Included in the TRIANA 1 Subregistry***

	n (%)
Aspirin	432 (94.1)
Thienopyridines	427 (93.6)
Low-molecular-weight heparin	206 (44.9)
Unfractionated heparin	223 (48.6)
Glycoprotein IIb/IIIa receptor inhibitors	253 (55.1)
Abciximab	233 (92)
Tirofiban	12 (4.8)
Fibrinolysis	109 (23.7)
TNK	82 (75.2)
rTPA	21 (19.2)
Streptokinase	3 (2.7)
Other	3 (2.7)
Nitroglycerin IV	244 (53.2)
Beta-blockers IV	21 (4.6)
Pre-PCI beta-blockers	107 (23.3)
Diuretics	131 (28.5)
Inotropics	96 (20.9)
Intra-aortic balloon pump	47 (10.2)

*GP indicates glycoprotein; PCI, percutaneous coronary intervention.

TABLE 4. **Baseline Angiographic Characteristics and PCI Procedures in the 456 Patients† Included in the TRIANA 1 Subregistry Who Underwent Coronary Angiography***

	n (%)
No. of vessels with significant lesions (≥50%)	
1	245 (53.7)
2	124 (27.1)
3	86 (18.8)
Common trunk	14 (3)
Culprit artery	
Anterior descending	239 (52.4)
Right coronary	150 (32.8)
Circumflex	43 (9.4)
Common trunk	6 (1.3)
Not identified	18 (3.9)
Pre-PCI TIMI flow in the CA	
0	322 (73)
1	23 (5)
2	39 (8.9)
3	57 (13)
No. of patients treated with PCI	441 (96%)
1 lesion	350 (76.7)
2 lesions	77 (16.8)
≥3 lesions	21 (4.6)
Implantation of ≥1 stent	410 (92.9)
Mean stent diameter, mm$	3.1±.4
Mean stent length, mm$	17.7±6
Post-PCI TIMI flow	
0	12 (2.7)
1	12 (2.7)
2	23 (5.2)
3	394 (89.3)
Pre-PCI stenosis, %$	97±7
Post-PCI stenosis, %$	7±18
Complete revascularization	256 (58)
Procedural success	381 (83)
Failure with complications	18 (4)
LV ejection fraction, %$	50±13
Maximum CK‡	1969 (1005-3236)
Maximum CK-MB‡	219 (104-370)

*AMI indicates acute myocardial infarction; CA, culprit artery; LV, left ventricle; PCI, percutaneous coronary intervention; CK, creatine kinase; CK-MB, creatine kinase MB isoenzyme.
†Catheterization could not be done in 3 patients.
‡Mean (percentile 25-percentile 75).
$Mean ± standard deviation.

predictor of mortality (odds ratio [OR]=7.2; 95% confidence interval [CI], 2.2-23.3; *P*<.001) when this was included as a variable in an initial model. Age, elevated creatine kinase MB isoenzyme (CK-MB) and the presence of a postprocedure TIMI flow <3 in the culprit artery were also identified as main predictors of mortality (Table 7). However, hospital mortality was 42% and 7% in the patients who were admitted with and without cardiogenic shock, respectively. When all the patients were included in the model and the analysis repeated, but cardiogenic shock excluded, the presence of a postprocedure TIMI flow <3, age, the magnitude of CK-MB elevation and heart rate at admission were identified as independent predictors of mortality (Table 7).

TABLE 5. **Events Occurring During Hospitalization***

	n (%)
Death	50 (10.8)
Cause of death	
Cardiogenic shock	32 (64)
Mechanical complication	3 (6)
Other causes	15 (30)
Cardiogenic shock	65 (14.1)
Reinfarction	7 (1.5)
Need for coronary revascularization	45 (9.8)
New PCI	35 (77.7)
Coronary surgery	10 (22.2)
Non-coronary heart surgery	3 (0.7)
Stroke	5 (1)
Major hemorrhage	33 (7.1)
Need for transfusion	23 (5)

*PCI indicates percutaneous coronary intervention.

A comparative analysis was done regarding indications for PCI. Rescue PCI was indicated in 109 patients (24%), whereas primary PCI was indicated in the 350 remaining patients. The patients with indications for rescue PCI had a longer procedure time (onset of symptoms-PCI, 7±4 vs 5.3±4.2 h; *P*<.001) and better TIMI 2/3 flow in the pre-PCI culprit artery (39 vs 16%; *P*<.0001). There were no differences in presentation time, Killip class at admission, the extent of coronary heart disease and PCI success rates (91 vs 90%; *P*=NS) regarding the patients who had indications for primary PCI. Neither were there significant differences (7.3 vs 7.2%; *P*=NS) regarding the rate of

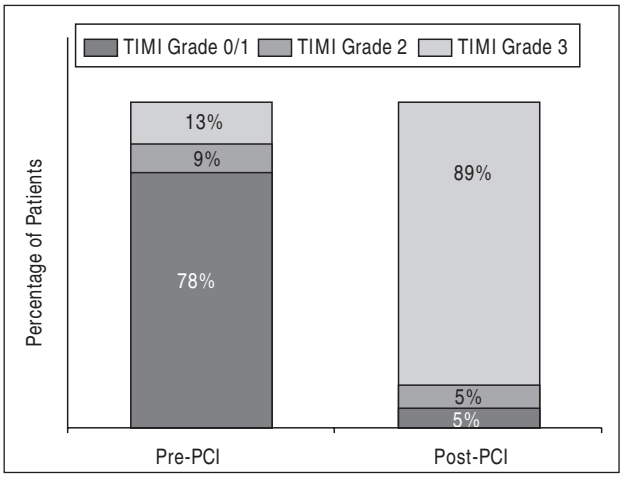

Figure 2. Changes in the TIMI flow in the culprit artery after PCI (right) compared to the pre-PCI baseline values (left).
AMI indicates acute myocardial infarction; PCI, percutaneous coronary intervention.

TABLE 6. **Factors Related to Hospital Mortality Identified by Univariable Analysis in the Patients Included in the TRIANA 1 Subregistry***

	Dead (n=50)	Live (n=409)	*P*
Age, years	68±15	61±13	<.01
Heart rate, beats/min	90±24	76±19	<.001
Systolic blood pressure at admission, mm Hg	110±31	128±28	<.001
Maximum CK, U/L	5514±6642	2495±2662	<.001
	Mortality, n (%), According to		
	Variable Present	Variable Absent	
Diabetes type 1	7 (29)	9 (11)	.025
Smoking habit	12 (6)	32 (14)	.007
Previous myocardial infarction	13 (18)	37 (10)	.047
Previous HF	5 (31)	44 (10)	.007
Previous stroke	9 (23)	41 (10)	.01
Cardiogenic shock	22 (42)	28 (7)	<.0001
Contraindication for thrombolytic treatment	16 (23)	34 (9)	<.0001
Outcome of PCI			
Post-PCI TIMI flow <3 in the CA	19 (31)	28 (7)	<.0001
PCI failure	14 (28)	20 (5)	<.001
LV ejection fraction <0.30	15 (30)	11 (4)	<.0001

*CA indicates culprit artery; CK, creatine kinase; HF, heart failure; PCI, percutaneous coronary intervention; LV, left ventricle.

TABLE 7. **Odds Ratio and Confidence Intervals of the Predictive Factors of Mortality Identified by Multivariate Analysis in the Patients Included in the TRIANA 1 Subregistry***

Variable	*Odds ratio*	95% CI	*P*
Model including cardiogenic shock at admission			
Age	1.05†	1.005-1.10	.05
Cardiogenic shock	7.2	2.2-23.3	.001
Post-PCI TIMI <3 flow in the CA	2.8	1.00-8.3	.05
Maximum CK-MB	1.01‡	1.004-1.27	.009
Model excluding cardiogenic shock at admission			
Age	1.07†	1.02-1.12	.07
Heart rate at admission	1.053‡	1.03-1.07	.05
Post-PCI TIMI flow <3 in the CA	4.02	1.26-12.7	.018
Maximum CK-MB	1.013$	1.002-1.25	.01

*CA indicates culprit artery; PCI, percutaneous coronary intervention; CK-MB, creatine kinase MB isoenzyme.
†Increase in risk per year of age.
‡Increase in risk per beat/min.
$Increase in risk per every 100 U/L.

major hemorrhagic complications. Mortality per month was also similar (rescue PCI, 9.6%; primary PCI, 11.8%; *P*=NS). When patients in shock and indications for rescue PCI were excluded, mortality in the remaining patients was 6.6%.

Of the 459 patients included, 104 (22.6%) were ≥75 years old. Table 8 shows comparative data between the younger (<75 years old) and the older patients (≥75 years old) in the study. Almost one-third of the older patients were women and the incidence of risk factors was higher. Compared to the younger patients, they presented a more difficult initial hemodynamic situation and indications for PCI were more frequent given that thrombolysis was contraindicated. Mortality per month and the in-hospital complication rate were significantly higher. When 46 patients were excluded from the group of elderly patients due to contraindications for thrombolysis (n=24), dementia (n=3), shock at admission (n=8), and delay >6 h (n=11), 58 patients ≥75 years old (55.7%) could have been potentially included in a randomized study on reperfusion strategies. In this subgroup of patients, the combined event rate was 12.8%, with a mortality rate of 10.2%, reinfarction 0% and stroke 2%.

DISCUSSION

The TRIANA 1 subregistry was set up to analyze

TABLE 8. **Comparative Data Between the Younger Patients (<75 Years) and the Older Patients (≥75 years) Included in the TRIANA 1 Subregistry***

	Younger Patients (n=355)	Older Patients (n=104)	*P*
Age, years†	59 (50-67)	79 (76-81)	–
Females	54 (15)	32 (31)	<.001
Coronary risk factors			
Smoking habit	190 (54)	17 (18)	<.001
AHT	145 (41)	68 (66)	<.001
Dyslipidemia	177 (50)	37 (36)	.02
Diabetes	74 (21)	37 (36)	<.01
Partial/total dependency	8 (2)	27 (26)	<.01
Previous myocardial infarction	50 (14)	24 (23)	.03
Previous PCI	18 (5)	14 (14)	<.01
Previous stroke	25 (7)	14 (14)	.04
Heart rate at admission, beat/min‡	75±20	80±19	NS
Previous location of the AMI	187 (53)	64 (61)	NS
Killip I class at admission	259 (73)	55 (54)	<.001
Cardiogenic shock at admission	43 (12)	11 (11)	NS
Indication for PCI			
Primary PCI	259 (73)	92 (88)	.001
Due to contraindications for thrombolysis	39 (11)	31 (30)	<.001
Rescue PCI	97 (27)	12 (12)	.001
Time door-guidewire, min†	100 (58-200)	105 (60-155)	NS
Adjuvant treatment			
Low-molecular-weight heparin	163 (46)	46 (45)	NS
GP IIb/IIIa receptor inhibitors	205 (58)	48 (46)	.027
Diuretics	92 (26)	41 (39)	.007
Inotropics	65 (18)	31 (30)	.013
3-vessel coronary disease	68 (19)	18 (17)	NS
Procedural success	297 (86)	84 (84)	NS
LV ejection fraction <0.40	99 (28)	29 (28)	NS
Maximum CK†	2103(1114-3350)	1545(701-2880)	.009
Events during hospitalization			
Death	25 (7)	25 (24)	<.001
Cardiogenic shock	45 (13)	20 (20)	.093
Reinfarction	6 (2)	1 (1)	NS
Mechanical complication	0 (0)	3 (3)	.009
New PCI	21 (6)	13 (12)	.028
Stroke	2 (.6)	3 (3)	.045
Major hemorrhage	21 (6)	12 (12)	.053

*AHT indicates arterial hypertension; AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; NS, not insignificant; LV, left ventricle; GP, glycoprotein; CK, creatine kinase. Results by numbers (percentage in brackets), except in indicated cases.
†Median (percentiles 25-75).
‡Mean ± standard deviation.

all the consecutive AMI patients treated with PCI in a group of hospitals selected in Spain over a set period.

Data extrapolated from Spanish registries regarding the treatment of transmural AMI suggest that in 2002 only 10%-15% of patients admitted to hospitals were reperfused via primary angioplasty.[10-13] However, in the TRIANA 1 subregistry, the inclusion of patients had to be interrupted 1 month before the end of the estimated time because the calculated size of the sample had already been reached. A total of 459 patients from 25 hospitals were included over 3 months. The baseline characteristics of the patients were similar to other populations with similar selection criteria, with two exceptions: 11.5% of the patients were admitted in cardiogenic shock, a remarkably high proportion when compared to other series of AMI patients,[14-20] and there was a high incidence of previous stroke (8%), probably related to contraindication for fibrinolysis, which was the indication for PCI in 15% of cases. However, the percentage of patients with kidney failure or peripheral vasculopathy was low. These data suggest that there was a certain degree of selection regarding patient inclusion.

Procedure Time and Initial Treatments

The delay from the onset of symptoms until PCI

was done was similar to other registries[14,15] and slightly longer than recommended in recent guidelines.[16,17]

An interesting fact is that, in a large number of patients, the PCI procedure was done while the patient was undergoing anticoagulant treatment with low-molecular-weight heparin. Similarly, it should be pointed out that in up to 56% of the patients glycoprotein IIb/IIIa receptor inhibitors were administered prior to or during PCI. This rate of platelet aggregation inhibitor use is markedly higher than that used in Spain during non-AMI PCI procedures.[10]

Results of PCI

PCI was carried out successfully in 83% of cases, with improvements in the perfusion level of the culprit artery similar to those described in other studies.[21-23] Intracoronary stents were implanted in 92.9% of the patients. Stent implantation during PCI for AMI is currently done systematically since this facilitates the initial outcome of the procedure and consistently reduces the later incidence of restenosis.[24]

Some 10.8% of the patients died during the hospital admission period, without additional mortality during the follow-up month. The leading cause of death was cardiogenic shock. Patient mortality in the TRIANA 1 subregistry was moderately high compared to that described in primary PCI studies,[5] possibly due to some degree of patient selection in certain hospitals, since it is likely that in some hospitals PCI is only indicated in patients with high-risk AMI or with contraindications for thrombolysis. The highly variable number of patients included in each center suggest this interpretation. It has been found that there is a relationship between the number of cases of primary PCI per year and mortality.[25] The treatment of AMI patients with primary angioplasty in low-volume hospitals (<25 primary PCI/year) does not seem to offer additional benefits compared to thrombolytic treatment.[25] Documented mortality in the patients ≥75 years was 24.5%, similar to the rate described in other studies.[26-28] Nearly half the patients ~75 years included in the TRIANA 1 subregistry could have been potentially included in a randomized study to determine the best reperfusion strategy for them.

Mortality Predictors

Logistic regression analyses consistently identified four predictors of hospital mortality: hemodynamic situation at admission, age, extent of the infarction and outcome of PCI. These factors have been reported in previous studies.[29-33] Of these, the main determinant of mortality is cardiogenic shock at admission. When this variable is not included in the model, a TIMI flow <3 in the culprit artery (i.e. obtaining suitable reperfusion is impossible) is the most important predictor, with heart rate at admission becoming another predictor. Primary angioplasty failure and the extent of the infarction have been identified as predictive factors of mortality.[29,30] Old age is a factor consistently associated with a high risk of mortality in patients with AMI.[31] Higher initial heart rate is a marker of initial hemodynamic situation, which can reflect a more significant functional disorder. Both parameters have been used in recent initial evaluation scales to calculate risk in AMI patients.[32,33]

Rescue PCI

Rescue PCI was indicated in 24% of the patients after thrombolysis failed. In 39% of these patients, the culprit artery had TIMI 2/3 flow immediately before PCI. Although some patients with adequate flow in the culprit epicardial artery can still show clinical signs of lack of reperfusion due to compromised microcirculation,[34] criteria for rescue PCI were not specified in the protocol. This means that the clinical criteria of the hospitals could have differed regarding such indications. Furthermore, no significant differences were found in the clinical evolution of these patients compared to those with indications for primary PCI. Both aspects suggest that facilitated angioplasty could be included among the rescue PCI procedures patients were assigned to. The proportion of our patients with AMI only treated with PCI compared to those treated with post-thrombolysis PCI is similar to the proportion documented for European patients in the GRACE registry.[35]

Younger Patients Versus Older Patients

More elderly patients (≥75 years) presented baseline clinical and infarction characteristics indicative of higher risk than the younger patients. Despite presenting identical procedure times, similar PCI success rates and a similar degree of AMI, mortality and incidence of major hospital complications were significantly higher in the older patient group.

LIMITATIONS

The results of the procedure were evaluated by each local investigator. The data were not submitted to external audit, although individual confirmation was required when anomalous data were provided. Furthermore, when dealing with a registry of AMI patients treated with PCI there could be a selection bias, since the indication for PCI was done according to each hospital's criteria. Taking into account variations in the number of patients included in the different hospitals, it is possible that primary PCI was indicated exclusively in patients with high-risk AMI in

some of the participating hospitals, whereas in others it may have been done only during daily working hours or even only in patients with early AMI. Similarly, there was an additional limitation due to criteria for rescue PCI not being specified. Predictive factors of mortality identified in this registry should be interpreted within the context of the highest risk AMI population. The incidence of cardiogenic shock at admission and hospital mortality confirms this assumption.

CONCLUSIONS

The TRIANA 1 subregistry probably reflects how PCI is currently approached in the acute phase of myocardial infarction in Spain. This registry was set up with an excellent patient inclusion rate, clearly higher than expected. Some of the baseline characteristics of the patients and the number of patients included per hospital suggest a degree of selection regarding the indications in different hospitals. Mortality among the patients included was associated with easily identifiable factors at admission and with the degree of reperfusion immediately obtained via PCI in the culprit artery. Nearly 50% of the patients ≥75 years old could have been included in a randomized study. In addition to reflecting how AMI is treated in Spanish hospitals with a primary angioplasty strategy, the high number of hospitals participating in this registry and the high recruitment rate strongly support the feasibility of a future randomized study comparing primary angioplasty with fibrinolysis in the treatment of elderly patients with AMI.

APPENDIX. **Researchers (in Alphabetical Order) and Hospitals Participating in the TRIANA 1 Subregistry**

A. Amaro, Hospital Clínico Universitario de Santiago, Santiago; J. Ángel, Ciutat Sanitaria Vall d'Hebron, Barcelona; J. Bermejo, Hospital Clínico de Valladolid, Valladolid; A. Bethencourt, Hospital Universitario Son Dureta, Palma de Mallorca; A. Cequier, Hospital Universitario de Bellvitge, L'Hospitalet de Llobregat; J. Cubero, Hospital Virgen de la Macarena, Sevilla; J.A. Diarte, Hospital Universitario Miguel Servet, Zaragoza; F. Fernández, Complejo Hospitalario de León, León; E. García, Hospital Gregorio Marañón, Madrid; J. Goicolea, Hospital do Meixoeiro, Vigo; J.M. Hernández, Hospital Virgen de La Victoria, Málaga; R. Hernández, Hospital San Carlos, Madrid; A. Iñiguez, Fundación Jiménez Díaz, Madrid; R. Lezaún, Hospital de Navarra, Pamplona; X. Mancisidor, Hospital de Cruces, Baracaldo; L. Martínez-Elbal, Hospital Universitario de La Princesa, Madrid; R. Melgares, Hospital Universitario de Las Nieves, Granada; J. Moreu, Hospital Virgen de la Salud, Toledo; C. Morís, Hospital Central de Asturias, Oviedo; J. Pey, Hospital Ramón y Cajal, Madrid; S. Romani, Hospital Clínic, Barcelona; J.C. Tascon, Hospital 12 de Octubre, Madrid; J. Valencia, Hospital General Universitario d'Alacant, Alicante; N. Vázquez, Hospital Juan Canalejo, A Coruña; J. Zueco, Hospital Marqués de Valdecilla, Santander.

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