The results confirm that biventricular involvement represents a more advanced stage of isolated RV disease. Our study corroborates the association between LV involvement and a more advanced functional class. Certainly, previous studies have established the relationship between LV involvement and an increased mortality rate due to heart failure.[1,5,6] However, although the analysis of our series does not demonstrate a significant association, it does shows a trend: the 2 patients who died from heart failure and the single patient who received a transplant were all from the biventricular involvement group. The lack of significance is probably due to an insufficient sample size. Regarding the risk of arrhythmia, of the group with isolated RV involvement, 4 patients had ICDs as secondary prevention compared with only 2 in the biventricular group. In contrast, all ICDs implanted as primary prevention were in patients with biventricular involvement, because their risk profile was higher based on the presence of significant LV dysfunction[3] (Table 1). These differences could explain why the incidence of arrhythmic events was similar in both groups at follow-up, even though a relationship with the presence of LV dysfunction would have been expected.

We can conclude that LV dysfunction is associated with greater RV dysfunction, worse functional class, and an increased tendency to events due to heart failure. No clear relationship was found between LV involvement and an increased rate of arrhythmic events, although there was an association with an increased burden of family history of SCD.

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Incidence and Prognosis of Mechanical Complications of STEMI After Primary Angioplasty: Data From a Single-center Registry of an Infarction Code Program

Incidencia y pronóstico de las complicaciones mecánicas del IAMCEST sometido a angioplastia primaria: datos de un registro unicéntrico de Código Infarto

To the Editor,

Mechanical complications (MC) of ST-segment-elevation acute myocardial infarction (STEMI) are an important cause of morbidity and mortality and dramatically worsen prognosis. The introduction of early reperfusion therapy has significantly reduced the classical incidence of MC (5%-10%).[1,2] In particular, the widespread use of primary angioplasty (PA) has reduced its current incidence to between 1% and 2%.[3,4] The implementation of regional PA programs has decreased reperfusion times and improved prognosis, most likely due to the decreased incidence of MC. We evaluated the incidence, treatment, course, and predictors of MC in a cohort who underwent PA under a STEMI emergency treatment protocol, in which fibrinolysis was only used when there were delays or logistic difficulties.

Four researchers retrospectively reviewed the medical records of 950 consecutive patients who underwent PA between 2005 and 2012 with hospital and 30-day follow-up. Qualitative variables are expressed as percentages and quantitative variables as mean or median ± standard deviation according to the normality of the distribution. The Student *t* test was used to compare means and chi-square for percentages. Univariable and multivariable analyses were used to identify the predictors of MC. A *P* value of $< .05$ was used as a cutoff for statistical significance.

The incidence of MC was 2.02% (19 patients). Of these patients, 14 (73.6%) had free wall rupture (FWR), 2 (10.5%) had interventricular septal rupture (IVSR), and 3 (15.8%) had papillary muscle rupture (PMR). Most MCs occurred within 24 hours of admission (52.6%) and a significant proportion (26.3%) occurred after 96 hours. Table 1 shows the baseline characteristics of the patients and Table 2 shows the characteristics of the patients with MCs. The

Table 1
Baseline Characteristics of Patients With and Without Mechanical Complications and Their Comparison

	MC (n = 19)	Without MC (n = 931)	*P*
Age, y	76.8 ± 8.9	65 ± 13.5	<.01
Men, %	52.6	80.2	<.01
BMI	25.3	28.2	.54
HT, %	52.6	59.5	.54
DM, %	36.8	26.4	.77
Dyslipidemia, %	57.9	42.9	.19
Smoking, %	41.2	21.1	.12
Previous ischemic heart disease, %	5.3	11.7	.38
Peripheral artery disease, %	0	8.3	.19
CCR < 60 mL/min, %	20.1	17	.22
Site of AMI			.35
Anterior/septal, %	61.1	44.4	
Inferior/posterior, %	16.7	25.7	
Lateral, %	3.3	9.8	
Other, %	18.9	20.1	

Table 1 *(Continued)*
Baseline Characteristics of Patients With and Without Mechanical Complications and Their Comparison

	MC (n = 19)	Without MC (n = 931)	*P*
Culprit artery			.79
LMCA, %	0	0.4	
AD territory, %	57.9	43.7	
RC territory, %	31.7	44.2	
Cx territory, %	10.4	11.7	
Killip class ≥ III, %	68.8	12.1	<.01
Multivessel disease, %	57.9	57.6	.97
Total ischemia time, min	360 [210-448]	240 [170-350]	.62
Door-to-balloon time, min	87 [46-210]	70 [36-120]	.18
IABPC, %	5.3	2.2	.37
Hospital mortality, %	36.8	4.0	<.01

AD, anterior descending; AMI, acute myocardial infarction; BMI, body mass index; CCR, creatinine clearance rate; Cx, circumflex; DM, diabetes mellitus; HT, hypertension; IABCP, intra-aortic balloon counter pulsation; LMCA, left main coronary artery; MC, mechanical complication; RC, right coronary.
Unless otherwise specified, values are expressed as mean ± standard deviation or median [interquartile range].

median total times of ischemia (symptoms-to-balloon) and door-to-balloon were nonsignificantly higher in the MC group. Regarding treatment and in-hospital course, 7 patients died (36.8%) and 10 patients (52.6%) were referred to cardiac surgery. One patient died before surgery, but the remaining 9 patients survived. All patients with PMR or IVSR underwent surgery, whereas 5 (35.7%) of the patients with FWR underwent surgery and 5 with FWR (35.7%) underwent intensive medical treatment. Patients with IVSR did not undergo percutaneous treatment due to its lack of availability. These treatment options were not applicable in the remaining patients with FWR (28.6%), because of sudden death. Logistic regression analysis showed that the only independent predictors of events were female sex (odds ratio [OR] = 4.03; confidence interval 95% [95%CI], 1.2-14.9; $P = .022$) and Killip class III-IV (OR = 1.95; 95%CI, 1.9-4.5; $P < .0001$).

The incidence of MC was similar to that described in the literature[1,2], but clearly lower than its incidence (5%-10%) in the period before widespread implementation of systematic reperfusion. Some characteristics have already been described as predictors of MC: female sex and longer ischemia times.[4] In our series, Killip class III-IV was also an independent predictor of MC.

Current guidelines[5] recommend surgery as the treatment of choice; however, some patients are not candidates for emergency surgery because of instability, age, and comorbidity. In addition, the optimal timing of surgical treatment remains to be established. Surgical mortality in these patients is considerable and is clearly influenced by those who survive the first days of stabilization under intensive measures, which constitutes a selection bias in most of the reported results. In our series, 52.6% of patients were referred to surgery, and around half of the patients with FWR received intensive medical treatment with acceptable results. Most of these patients had subacute FWR, which successfully responds to nonsurgical treatment.[6]

Table 2
Characteristics of Patients With Mechanical Complications

Patient	Type of MC	Year of MC	Moment of MC[a]	Sex	Age, y	CA	Killip class at admission	LVEF at admission, %	Successful PCI[b]	TTI, min	DBT, min	CVS	Mortality	
													Hospital	30 d
1	FWR	2005	3rd day	Woman	82	RCd	IV	60	No	460	320	No[c]	Yes	—
2	IVSR	2006	1st day	Man	85	ADi	I	40	Yes	420	NA	Yes	Yes	
3	FWR	2006	4th day	Woman	83	ADi	IV	NA	No	210	90	No	Yes	—
4	FWR	2007	1st day	Man	74	RCp	I	55	Yes	360	180	Yes	No	No
5	FWR	2007	11th day	Man	43	ADp	III	25	Yes	> 48 h	NA	Yes	No	No
6	FWR	2008	2nd day	Man	79	RCp	IV	55	Yes	210	30	Yes	No	No
7	FWR	2008	1st day	Man	77	ADp	IV	35	Yes	360	220	No	No	No
8	PMR	2009	1st day	Man	87	RCi	IV	60	Yes	240	45	Yes	Yes	—
9	FWR	2009	8th day	Man	83	ADp	II	35	Yes	300	50	No	No	No
10	FWR	2010	1st day	Woman	79	ADi	IV	30	Yes	420	40	No[c]	Yes	—
11	FWR	2010	1st day	Woman	73	OM2	II	NA	Yes	240	180	No[c]	Yes	—
12	FWR	2010	3rd day	Woman	80	ADp	IV	30	No	360	75	No	No	No
13	FWR	2010	5th day	Woman	83	ADd	II	45	No	390	100	Yes	No	No
14	FWR	2011	4th day	Man	80	ADp	IV	30	Yes	210	90	Yes	No	No
15	FWR	2011	1st day	Man	76	ADp	I	NA	No	330	—	No[c]	Yes	—
16	FWR	2012	3rd day	Woman	81	RCp	I	55	Yes	150	45	No	No	No
17	PMR	2012	1st day	Man	79	CX-OM1	III	70	Yes	90	75	Yes	No	No
18	PMR	2012	1st day	Woman	68	RCi	IV	60	Yes	510	55	Yes	No	No
19	IVSR	2012	1st day	Woman	78	ADi	IV	50	Yes	720	120	Yes	No	No

AD, anterior descending; CA, culprit artery; CVS, cardiovascular surgery; CX-OM1, circumflex-first marginal; d, distal; DBT, door-to-balloon time; FWR, free wall rupture; i, intermediate; IVSR, interventricular septal rupture; LVEF, left ventricular ejection fraction; MC, mechanical complication; NA, not available; OM2, second marginal; p, proximal; PCI, percutaneous coronary intervention; PMR, papillary muscle rupture; RC, right coronary; TIMI, Thrombolysis in Myocardial Infarction; TTI, total time of ischemia.
[a] Time of MC after admission.
[b] PCI was considered successful if it was possible to revascularize the culprit artery without complications and with TIMI III flow.
[c] CVS not scheduled due to abrupt clinical presentation of MC as sudden death.

Regardless of treatment, prognosis is clearly worse in these patients and depends on the type of MC. In a series published by French et al.,[4] in-hospital survival and 90-day survival were 97% and 96% in patients without MC, respectively. However, in-hospital survival and 90-day survival were 43% and 27% in patients with FWR, 73% and 73% in those with PMR, and 60% and 20% in those with IVSR, respectively. Overall 30-day survival was 63.2%, which varied according to the type of MC: 64.3% in FWR, 66.6% in PMR, and 50% in IVSR.

In conclusion, the incidence of MC has decreased in the era of PA, but remains associated with high mortality; however, the mortality rate could decrease in a group selected for surgery. Early diagnosis and treatment would be improved by remaining alert to the specific characteristics of each patient. The incidence of MC could be reduced by the widespread use of PA protocols with shorter ischemia times. Multicenter registries with more patients are needed to better understand the predictors of MC and to determine which subgroups would derive the most benefit from surgical treatment.

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Quality of Methods and Results Reporting in Cost-effectiveness Analyses of Cardiovascular Interventions

La calidad en la presentación de métodos y resultados de los análisis de coste-efectividad de intervenciones cardiovasculares

To the Editor,

Cardiovascular diseases are the principal cause of death in most economically developed countries, including Spain, and cause significant loss of health.[1] Cost-effectiveness analysis is an important tool that can help clinicians, researchers, and policy makers to determine the efficiency of health care interventions, establish financing priorities for health services, and evaluate the effectiveness of these services in terms of health benefits and costs.[2] The information provided by cost-effectiveness analysis thus has the potential to impact public health. Therefore rigor in clinical practice and health care policy requires careful evaluation of methods and results reporting in cost-effectiveness analyses to establish their validity. Previous studies systematically evaluated the methodology and general results of cost-effectiveness analyses that express their results as the cost per quality-adjusted life year (QALY) gained.[3,4] However, to date, there has been no sufficiently detailed cost-effectiveness analysis of cardiovascular interventions in Spain. Such an analysis could provide comprehensive information about the state of research at a national level; the completeness of information reporting at this level is generally less well understood, even though specific health care priorities and research requirements are often established nationally. Here, we examine the quality of methods and results reporting in cost-effectiveness analyses of cardiovascular interventions in Spain.

Source data for this analysis were obtained from a previous systematic literature review of cost-effectiveness analyses of health care interventions published in Spain between 1989 and 2014.[4] This literature review was conducted in PubMed and complementary databases (Scopus, ISI Web of Science, databases from the University of York Centre for Reviews and Dissemination, *Índice Médico Español*, *Índice Bibliográfico Español en Ciencias de la Salud*, and technology evaluation reports). From this review, we identified cost-effectiveness analyses of cardiovascular interventions that used QALYs as an outcome measure carried out in Spain up until December 2014. Based on existing documents and the review team's experience,[4] we identified the basic elements of correct methods reporting in cost-effectiveness analyses. Data from each study were extracted by 2 reviewers. All data analysis was conducted with STATA v. 13 (StataCorp LP; College Station, Texas, United States).

In total, 47 cost-effectiveness analyses were included. The studies are grouped by publication year in the Figure of the supplementary material, and the main study characteristics are summarized in the Table of the supplementary material. Most studies (n = 45 [95.7%]) did not indicate the research protocol used or provide access to it; moreover, most studies (n = 43 [91.5%]) used mathematical simulations. Fewer than half the analyses (n = 21 [44.7%]) provided a suitable description of the population characteristics. The interventions examined in most analyses (n = 30 [63.8%]) were classified as pharmacological therapies, and half the analyses (n = 24 [51.1%]) included an active alternative as the comparator. Data on intervention efficacy came from a single study of 21 analyses (44.7%), and only 9 analyses (19.1%) used synthetic estimates derived from systematic reviews and meta-analyses,[5] even though such evidence is considered to be of high quality and scientifically rigorous. The methods used to calculate QALYs gained are shown in the Table. Few analyses (n = 5 [10.6%]) presented a complete description of the methods used to calculate QALYs. Most of the reports (n = 31 [66.0%]) stated that the evaluated intervention produced "more cost and more QALYs" than the comparator. Most of the analyses (n = 42 [89.4%]) reported favorable results. The main source of funding was the private sector, which supported 27 (57.4%) of the analyses. In 17 studies (36.2%) there was no declared conflict of interest.