

## Impact of Primary Angioplasty on the Indication for Implantable Cardiac Defibrillator in Patients With Myocardial Infarction

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**Introduction and objectives.** Implantable cardiac defibrillators (ICD) have been shown to improve survival in patients with myocardial infarction and LVEF  $< 0.30$  or LVEF  $< 0.40$  + nonsustained ventricular tachycardia + inducible sustained arrhythmias. However, these risk stratification criteria have not been evaluated in patients who are candidates for primary percutaneous transluminal coronary angioplasty (PTCA). The objective of this study was to assess the impact of both strategies on the indication for ICD in a consecutive series of post-infarction patients treated with primary PTCA.

**Patients and method.** One hundred and two consecutive patients with myocardial infarction (80 men, mean age  $63.6 \pm 11.5$  years) included in a single-center-based regional program of primary PTCA were included in the study. A 24-h continuous ECG recording was obtained 2 to 6 weeks after the acute event, and LVEF was determined by 2D-echocardiography one month after the infarct. Patients with nonsustained ventricular tachycardia and LVEF  $< 0.40$  underwent programmed ventricular stimulation using a standard protocol.

**Results.** Twenty-two patients (21.6%; 95% CI, 13.6-29.6) showed at least one episode of nonsustained ventricular tachycardia in the 24 h recording. Six of them had LVEF  $\leq 0.40$ , and sustained ventricular arrhythmia was induced in 2 out of 5. LVEF  $\leq 0.30$  was found in 3 patients, none of whom had nonsustained ventricular tachycardia. Thus, 5 patients had an indication for ICD according to either of the two risk stratification criteria.

**Conclusions.** The prevalence of nonsustained ventricular tachycardia in post-infarction patients treated with primary PTCA is high. However, because most of them have preserved ventricular function, primary prevention with an ICD is indicated in approximately 5% of the population.

**Key words:** Myocardial infarction. Coronary angioplasty.

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*Tachycardia. Defibrillator.*

**Impacto de la angioplastia primaria en la indicación de desfibrilador implantable en pacientes con infarto de miocardio**

**Introducción y objetivos.** El desfibrilador implantable mejora la supervivencia en pacientes postinfarto de miocardio con a) fracción de eyección  $\leq 0,30$  y b) fracción de eyección  $\leq 0,40$ , taquicardias ventriculares no sostenidas y arritmias ventriculares inducibles. Estos criterios no han sido evaluados en el contexto de la angioplastia primaria. El objetivo del estudio es evaluar el impacto de ambos criterios en las indicaciones de desfibrilador en pacientes con infarto revascularizados con angioplastia primaria.

**Pacientes y método.** Se estudió a 102 pacientes postinfarto (80 varones; edad,  $63,6 \pm 11,5$  años) incluidos en un programa regional de angioplastia primaria. Se realizó un registro Holter de 24 h entre las semanas 2 y 6 postinfarto, al mes, y se estimó la fracción de eyección por ecocardiografía practicando estimulación ventricular programada en el grupo con fracción de eyección  $\leq 0,40$  y taquicardia ventricular no sostenida.

**Resultados.** Un total de 22 pacientes (21,6%; intervalo de confianza [IC] del 95%, 13,6-29,6) presentaron taquicardia ventricular no sostenida en el Holter. Seis de ellos tuvieron fracción de eyección  $\leq 0,40$ , siendo inducibles 2 de 5 en el estudio electrofisiológico. La fracción de eyección fue  $\leq 0,30$  en 3 pacientes, ninguno de los cuales presentó taquicardia ventricular no sostenida. En total, 5 pacientes (4,9%) tuvieron indicación de desfibrilador aplicando alguno de los 2 criterios.

**Conclusiones.** La prevalencia de taquicardia ventricular no sostenida en pacientes con infarto tratados con angioplastia primaria es elevada. Sin embargo, la mayoría tiene una función ventricular conservada, por lo que la prevención primaria con desfibrilador estaría indicada en un 5% aproximadamente utilizando los criterios evaluados en este estudio.

**Palabras clave:** Infarto de miocardio. Angioplastia coronaria. Taquicardia. Desfibrilador.

## ABBREVIATIONS

ICD: implantable cardioverter defibrillator.  
 LVEF: left ventricular ejection fraction.  
 MADIT-II: Multicenter Automatic Defibrillator Implantation Trial II.  
 MUSTT: Multicenter UnSustained Tachycardia Trial.  
 NSVT: nonsustained ventricular tachycardia.  
 PTCA: percutaneous transluminal coronary angioplasty.

## INTRODUCTION

Recent studies have shown that an implantable cardioverter defibrillator (ICD) can be effective in the primary prevention of sudden death following myocardial infarction.<sup>1-3</sup> The MADIT<sup>1</sup> and MUSTT<sup>2</sup> studies reported a decrease in overall mortality with ICD implantation in patients with myocardial infarction, left ventricular ejection fraction (LVEF)  $\leq$  0.35-0.40, spontaneous nonsustained ventricular tachycardia (NSVT) and inducible sustained ventricular tachyarrhythmia with programmed stimulation that could not be suppressed with antiarrhythmic agents. More recently, the MADIT-II<sup>3</sup> study has shown that ICD implantation reduces mortality in patients who are at least one month post myocardial infarction with LVEF  $\leq$  0.30. Implantation of devices in this large cohort would have a considerable impact on healthcare costs.<sup>4,5</sup> The use of primary angioplasty (PTCA) to treat acute infarction may reduce the proportion of patients who fulfill these criteria for an ICD. Various studies have shown that percutaneous revascularization, in comparison with thrombolysis, increases the number of patients with a patent artery on angiographic follow-up, reduces the size of the infarct area, improves ventricular function and decreases subsequent remodeling,<sup>6-9</sup> effects that may reduce the arrhythmogenic potential in these patients.<sup>10-12</sup> Nevertheless, we found no data in the literature on the incidence of spontaneous NSVT and its relationship with ventricular function in patients with acute myocardial infarction treated with primary angioplasty.

The purpose of this study was to determine the incidence of patients with an indication for ICD based on the MUSTT (Multicenter UnSustained Tachycardia Trial) criteria (LVEF  $\leq$  0.40, spontaneous NSVT and inducible sustained ventricular tachyarrhythmia) and MADIT-II (Multicenter Automatic Defibrillator Implantation Trial II) criteria (LVEF  $\leq$  0.30) in a consecutive series of post-myocardial infarction patients enrolled in a regional primary angioplasty program.

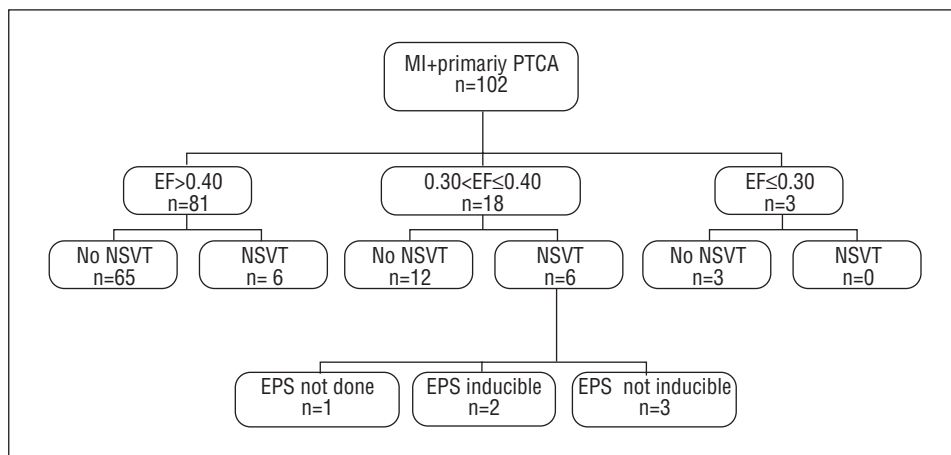
## PATIENTS AND METHODS

This prospective study included consecutive patients from our hospital's catchment area, admitted between January and December 2001 for acute myocardial infarction of 12 hours' evolution or less who survived the hospital phase. The hospital has a regional primary angioplasty program, and therefore all patients underwent emergency coronary angiography and, where appropriate, percutaneous revascularization of the infarct. In the initial patient assessment, acute myocardial infarction was defined as ST segment elevation of 0.1 mV in two adjacent frontal plane leads, 0.2 mV in the precordial leads, or new complete left bundle branch block with chest pain lasting more than 30 minutes. Revascularization consisted of percutaneous transluminal coronary angioplasty, with subsequent stent placement for the culprit lesion. Complete revascularization was attempted only in patients with cardiogenic shock. After the procedure, all patients received pharmacological therapy with 2 antiplatelet drugs (acetylsalicylic acid and clopidogrel) plus statins, angiotensin-converting enzyme inhibitors and beta-blockers according to the usual recommendations.<sup>13</sup> If any significant lesions were not resolved during the primary angioplasty, percutaneous or surgical revascularization was attempted after the acute phase, depending on evidence of persistent ischemia.

After discharge, 24-hour Holter monitoring was done 2 to 6 weeks after the infarction to assess the presence of NSVT, defined as three or more consecutive premature ventricular beats with a heart rate above 100 bpm. In addition, all patients underwent echocardiography approximately one month after the acute episode, with ejection fraction estimated by the area-length method and manual delineation of the borders. Electrophysiological study with programmed ventricular stimulation was recommended in patients who showed NSVT on Holter monitoring and left ventricular dysfunction (EF  $\leq$  0.40) on echocardiography performed 4 weeks postinfarction. A standard protocol (2 points, 2 cycle lengths in the basic drive train and up to 3 extrastimuli) with minimum coupling interval of 180 ms was used for programmed ventricular stimulation. Specific response was defined as induction of sustained monomorphic ventricular tachycardia, and induction of ventricular fibrillation with one or 2 extrastimuli. Electrophysiological study was not performed in patients older than 80 years who had intercurrent illnesses and a compromised short-term prognosis, or in patients who had not given written informed consent.

## Statistical analysis

Based on the additional tests, the number of patients



**Fig. 1.** Patient selection procedure, based on MUSTT and MADIT-II criteria. EPS indicates electrophysiological

who met the MUSTT (LVEF≤0.40+spontaneous NSVT+inducible sustained ventricular tachyarrhythmia) and MADIT-II (LVEF≤0.30) criteria was estimated and expressed as a percentage (95% confidence interval [CI]). The relationships between categorical variables were evaluated by the  $\chi^2$  test or Fisher’s exact test, when appropriate.

**RESULTS**

The study included 102 predominantly male patients with a mean age of 63.6 years (Table 1). Fifteen percent of the patients had experienced a previous infarction, and most presented one or more cardiovascular risk factors: smoking (52%), hypertension (49%), dyslipidemia (44%) and diabetes (28%, type 1 in 6 patients). Mean time between the onset of symptoms and TIMI 3 flow in the infarct artery was 190 minutes. In four patients (3.9%), angioplasty was not performed because of spontaneous patency of the vessel at the time of the angiography. Fifty-nine patients had significant lesions in one coronary vessel, 24 in 2 vessels and 15 in all 3. On echocardiography performed at 1 month, the mean LVEF was 0.52±0.1, where LVEF>0.40 in 81 patients (79.4%; 95% CI, 71.6-87.2), 0.30 to 0.40 in 18 (17.6%; 95% CI, 10.3-24.9) and ≤0.30 in 3 patients (2.9%; 95% CI, 0-6.1). Holter monitoring showed sinus

rhythm in all but two patients who were in atrial fibrillation. Mean heart rate was 65.4±10.1 bpm. More than 10 premature ventricular beats per hour were detected in 20 patients (19.6%; 95% CI, 11.9-27.3), couplets in 43 (42.2%; 95% CI, 31.5-50.9) and nonsustained ventricular tachycardia in 22 (21.6%; 95% CI, 13.6-29.6). Patients with NSVT on Holter monitoring had a mean of 1.5 episodes (range: 1-5) and a mean of 5.8 beats per episode (range: 3 to 19). There was a higher percentage of patients with NSVT in the group with LVEF≤0.40 (6 of 21; 28.6%) than those with LVEF>0.40 (16 of 81; 19.8%), although the difference was not statistically significant. No significant relationship was found between the presence of nonsustained ventricular tachycardia and the time elapsed between infarction and Holter monitoring. Five of the 6 patients with LVEF≤0.40 and NSVT underwent electrophysiological study (the sixth was excluded because of lung carcinoma); sustained monomorphic ventricular tachycardia was induced in two of these patients. According to the MUSTT and MADIT II criteria, ICD was indicated in 2 and 3 patients, respectively. No patient was selected by both sets of criteria, as the 3 patients with LVEF≤0.30 did not have nonsustained ventricular tachycardia on Holter monitoring. Figure 1 indicates the number of patients selected in each study phase. Similar results were obtained when patients with a prior history of infarction (n=16; 15.7%) were excluded from the analysis: 2 patients met the MUSTT criteria and another 2 had LVEF≤0.30.

**TABLE 1. Patient characteristics (n=102)**

Age, years	63.6±11.5
Sex, male/female	80/22
Number of risk factors	1.7±0.9
Diabetes	29 (28.4%)
Previous MI	16 (15.7%)
Anterior location	46 (45.1%)
No. of affected vessels	1.5±0.8
No. of revascularized vessels	1.0±0.38
Time to TIMI 3*	190 (135-298)
Beta-blocker therapy	85 (83.3%)

\*Median (range). MI indicates myocardial infarction.

**DISCUSSION**

Routine use of the MUSTT and MADIT-II criteria in a postinfarction population with primary angioplasty identified about 5% of the patients with a potential indication for ICD. Simultaneous application of both risk criteria (LVEF≤0.40+NSVT+inducibility and LVEF≤0.30) seems warranted, as they apparently do

not select the same patients in this population.

Left ventricular dysfunction has long been known to be a major risk factor for sudden death<sup>14-16</sup>. The MADIT-II study recently showed a significant decrease in mortality in this group of patients when ICD implantation was associated with conventional pharmacological treatment.<sup>3</sup> With the availability of thrombolytic drugs, the percentage of postinfarction patients with severely depressed LVEF varies according to the series. In a recent study, 16% of the patients had LVEF $\leq$ 0.35.<sup>17</sup> Andresen et al<sup>18</sup> found that 34.2% of the patients had LVEF $\leq$ 0.40 and 15.3% had LVEF $\leq$ 0.30. In Spain, a prospective multicenter registry has suggested that 21% of the patients have LVEF $\leq$ 0.40.<sup>19</sup> Fast, effective restoration of coronary flow in the infarct artery is associated with better ventricular function and a better prognosis in patients treated with thrombolytics.<sup>20</sup> Treatment with primary PTCA achieves earlier, more complete revascularization, decreasing the size of the infarction and thereby improving global and regional ventricular function.<sup>8</sup> In a large series of postinfarction patients randomized to primary angioplasty or thrombolysis, a much smaller percentage of patients with LVEF $\leq$ 0.40 was found in the primary angioplasty group than in the thrombolysis group (14% vs 26%).<sup>21</sup> It has also been observed that ventricular function can improve during the months after angioplasty.<sup>9</sup> These results suggest that widespread use of primary PTCA for revascularization in acute infarction would reduce the number of patients eligible for an implantable defibrillator according to the MADIT-II criteria, and also explain the low percentage (2.9%) of patients with LVEF $\leq$ 0.30 in our series.

There are no data on the incidence of NSVT in postinfarction patients treated by primary angioplasty. In series of patients treated with thrombolytics, the incidence is highly variable, ranging between 6.8 and 21%.<sup>17,22-24</sup> Our figure (21.6%) is high and does not suggest a decrease in the incidence of NSVT with primary angioplasty, despite the improved revascularization rate with this technique as compared to conventional thrombolytic treatment.<sup>21,25</sup> Other authors have found similar incidences of NSVT in patients with patent or occluded infarct arteries.<sup>17</sup> With regard to ventricular function, some studies suggest that patients with depressed LVEF have a higher incidence of NSVT. A prospective registry in Spain found a 32.4% incidence of NSVT in patients with LVEF $\leq$ 0.40.<sup>19</sup> A study conducted by Hohnloser et al<sup>17</sup> reported an NSVT episode on Holter monitoring prior to discharge in 15% of the patients with LVEF $\leq$ 0.35 versus 7.6% in the group with LVEF $>$ 0.35. Our results appear to suggest a similar relationship between depressed ventricular function and NSVT, although this was not statistically significant, probably because our sample was small.

The use of a combined selection criterion (LVEF

$\leq$ 0.35 and the presence of NSVT on 24-hour Holter monitoring) selected between 2.4% and 9% of postinfarction patients treated with thrombolytics.<sup>8,17,26</sup> In a recent multicenter registry,<sup>19</sup> a criterion of LVEF $\leq$ 0.40 yielded a prevalence of 6.8%, somewhat higher than the 5.9% obtained in our study. Sustained ventricular tachyarrhythmia is induced with programmed stimulation in approximately half of these patients,<sup>27-29</sup> implying that 3%-4% of the patients would be eligible for defibrillator implantation if this selection criterion were used. This figure could be reduced if the device were indicated only in patients who do not respond to procainamide therapy.

The reference population for ICD implantation at our hospital is the population for primary PTCA. During the study period, 30 defibrillators were implanted for indications other than primary postinfarction prevention. These figures suggest that routine use of the selection criteria we studied could increase the number of implants at our hospital by 16%. It is also necessary to consider the costs of Holter monitoring in 18% of the patients (those with LVEF between 0.30 and 0.40) and electrophysiological study in 5% of the postinfarction population under 80 years of age. Studies with more patients are needed to establish the cost-effectiveness of this approach using primary angioplasty.

### Limitations of the study

The main limitation of our study was the relatively small number of patients. Because only a subset presented high-risk criteria, small changes in the absolute number of patients could cause a substantial difference in the percentage results. This limitation is common to most studies that use the combined criteria of Holter monitoring and electrophysiological study for risk stratification in these patients. Secondly, the prevalence of NSVT was established on the basis of a 24-hour electrocardiograph recording. A longer monitoring period may have led to a noticeably higher prevalence, as the reproducibility of this finding is apparently low, at least in patients who receive thrombolytic therapy.<sup>29</sup>

### CONCLUSIONS

Our results indicate that the prevalence of NSVT in patients with myocardial infarction treated with primary angioplasty is high, and is apparently no lower than in series of patients on thrombolytics. Most patients in our series had preserved ventricular function, and therefore electrophysiological study to evaluate the inducibility of sustained tachyarrhythmia was indicated only for a small percentage of the total population. Because the percentage of patients with severely depressed ejection fraction ( $\leq$ 0.30) was also low, approximately 5% of the post-myocardial infarction patients treated with primary

angioplasty were eligible for an implantable defibrillator according to the stratification criteria assessed in this study.

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