Safety of Early Cardiac Magnetic Resonance Imaging in Acute Myocardial Infarction Patients With Stents

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Introduction and objectives. In general, magnetic resonance imaging is contraindicated when the patient has a ferromagnetic prosthesis or implant. With coronary stents, there is a theoretical concern that use of magnetic resonance imaging shortly after implantation will dislodge the stent, thereby increasing the risk of thrombosis. However, the risk may be overestimated because modern coronary stents are not ferromagnetic or are only weakly so. The objective of this study was to determine whether carrying out cardiac magnetic resonance imaging shortly after stent implantation is a safe procedure in acute myocardial infarction patients.

Methods. We carried out a retrospective study of 407 patients with ST-elevation acute myocardial infarction who were treated by stent implantation. Cardiac magnetic resonance imaging was performed in the first 14 (11) days after stent implantation in 86 of these 407 patients (group 1); it was not performed in the 321 patients in group 2. The occurrence of an adverse event, such as death, reinfarction, or revascularization, either in hospital or after 6 or 12 months was recorded.

Results. Three patients experienced subacute stent thrombosis, all in group 2. No statistically significant difference in any other variable was found. The combined rate of death, reinfarction, revascularization, or rehospitalization at 12 months was 14% in group 1 and 16% in group 2 (*P*=.7).

Conclusions. Carrying out cardiac magnetic resonance imaging shortly after stent implantation in acute myocardial infarction patients appears to be a safe procedure.

Key words: *Coronary stent. Cardiac magnetic resonance imaging. Acute myocardial infarction.*

Seguridad de la realización precoz de un estudio de resonancia magnética cardiaca en pacientes con infarto agudo de miocardio y revascularización con *stent*

Introducción y objetivos. La resonancia magnética está de forma general contraindicada cuando hay algún tipo de prótesis o implante de metal ferromagnético. En el caso del *stent* coronario, hay una teórica preocupación de que la realización precoz de una resonancia magnética produzca desplazamiento del *stent,* lo que aumentaría el riesgo de trombosis. Este riesgo puede estar sobrestimado, ya que los *stents* de última generación no son ferromagnéticos o lo son muy poco. El objetivo de este estudio es comprobar si la realización precoz de una resonancia cardiaca tras el implante de *stent* es un procedimiento seguro para el paciente tras un infarto agudo de miocardio.

Métodos. Estudio retrospectivo de 407 pacientes con infarto agudo de miocardio con elevación del segmento ST tratados con *stent.* Se realizó un estudio de resonancia cardiaca en los primeros 14 ± 11 días en 86 pacientes (grupo 1); el grupo 2 está formado por los 321 restantes. Se realizó un seguimiento de eventos adversos, incluidos el reinfarto, la muerte o la revascularización intrahospitalaria, y a los 6 y 12 meses.

Resultados. Se registraron 3 casos de oclusión trombótica subaguda del *stent,* todos en el grupo 2. No se encontraron diferencias significativas para el resto de las variables. El evento combinado muerte, reinfarto, revascularización y rehospitalización al año fue del 14% en el grupo 1 y del 16% en el grupo 2 (p = 0,7).

Conclusiones. La realización precoz de un estudio con resonancia magnética cardiaca parece ser un procedimiento seguro en pacientes que han sido tratados mediante implante de *stent* tras un infarto agudo de miocardio.

Palabras clave: Stent *coronario. Resonancia magnética cardiaca. Infarto agudo de miocardio.*

INTRODUCTION

Cardiovascular magnetic resonance (CMR) imaging allows overall assessment of the heart in anatomical, structural, and functional terms and is currently considered the non-invasive reference technique for the study of cardiovascular disease. The combination of several studies provided by CMR makes this technique an excellent tool for diagnosing patients with ischemic heart disease. In a single examination, it is possible to determine ventricular function, assess perfusion defects, and detect the presence of acute or chronic infarction by studying myocardial viability.[1-10] Thus, CMR is highly useful for diagnostic purposes, clinical decision-making, and determination of the prognosis in patients with ischemic heart disease.

Coronary stent implantation is currently considered the technique of choice in percutaneous revascularization procedures. In 2004, 91% of the interventional procedures carried out in our country involved stent implantation.[11] Magnetic resonance (MR) imaging is generally contraindicated when the patient has some type of ferromagnetic prosthesis or implant because of the risk of displacing or heating the device, and the potential for producing image artifacts.[12] In the case of coronary stents, there is a theoretical concern that the use of MR imaging shortly after stent placement might displace the device, and thereby favor exposure of platelets to the metal, which could increase the risk of thrombosis, myocardial infarction, and the need for urgent revascularization.[13] This risk is minimized once endothelialization of the stent is complete. Therefore, in their user information guidelines, the manufacturers of these devices recommend waiting 8 weeks following implantation before MR imaging is undertaken.[4,15]

The potential for displacement and heating of the stent has been investigated in vitro[16] and in experimental animal models.[17,18] The findings from these studies have shown that the devices are safe even in magnetic fields stronger than those used clinically. Several clinical studies,[18-22] all of them retrospective, have indicated that MR is safe in patients with these devices, because the incidence of adverse effects in patients bearing a stent was similar to the expected rate. Nonetheless, these studies have been carried out in small populations and the MR examination used in some of them was not cardiac MR, a fact that detracts from the value of the results.[19] In addition, the interval between stent implantation and CMR imaging

in most of them was not limited to the first few days following placement of the device.[22]

Therefore, the theoretical risk of arterial lesion might be overestimated, particularly because the majority of last-generation stents are not ferromagnetic or only very weakly so. Moreover, these indications contrast with what is done in actual clinical practice in many cardiology departments,[6,23] where CMR imaging is performed immediately after coronary stent implantation.

The aim of this study is to determine whether the use of CMR imaging in the first few days following stent implantation is a safe procedure for acute myocardial infarction patients.

METHODS

Patients

From March 2000 to January 2005 in Hospital Clínico Universitario de Valladolid, 407 revascularization procedures involving coronary stent implantation were performed in patients with ST-segment-elevation acute myocardial infarction (AMI). The patients' mean age was 61 (12) years and 85% were men. The infarction was in an anterior location in 43% of the cases. Treatment consisted of primary angioplasty in 24% of the patients and facilitated angioplasty (thrombolytic therapy followed by angioplasty in the first 12 hours) in 76%.

Among the 407 patients, CMR was performed in 86 of them as part of a substudy of the GRACIA 1 study[24] (n=500, 191 patients with a stent, 13 undergoing CMR), GRACIA 2 study[25] (n=212, 176 patients with a stent, 33 undergoing CMR), and TECAM study[26] (n=45, 40 patients with a stent and 40 undergoing CMR). Participation of the patients in the substudy was based on the availability of the MR unit and the willingness of patients to collaborate. All the participants in the substudy had previously signed the corresponding informed consent form to participate in the GRACIA 1, GRACIA 2 or TECAM clinical trials, which had been approved by the Ethics Committee of Hospital Clínico Universitario de Valladolid.

Patients with the following criteria were excluded: those bearing a pacemaker, automatic implantable defibrillator, cochlear implant, or aneurysm clip, pregnant women, hemodynamically unstable persons, and those with claustrophobia.

The mean interval between stent implantation and CMR imaging was 14 (11) days, with a range of 2-58 days. The median was 10 days (range, 7-18 days), a fact indicating that the CMR study was undertaken before day 10 in 50% of patients and before the first month in 91% of patients.

As a part of the protocol design, the GRACIA 1 study[24] used the stainless steel Giudant Multi-Link™ stent, and the GRACIA 2 study[25] the cobalt-chrome Guidant Vision™ stent. In the initial phase, the TECAM

study[26] used cobalt-chrome stents (Vision™ from Guidant, or Driver™ from Medtronic) and stainless steel stents (Jostent™ from Abbott, Lekton™ from Biotronik, or Phytis™ from Phitis Corp.) Later, rapamycin- or paclitaxel-eluting stents were employed (Cypher™ from Cordis or Taxus™ from Boston Scientific). Thus, the material used in the stents implanted in patients who underwent a CMR study was 316L stainless steel in 58% and cobalt-chrome in 42%. The percentage of drug-eluting stents used in this group of patients was 15% of the total of stents implanted (Table 1).

Follow-up was performed before hospital discharge and later all patients were checked in the consultation room or by telephone contact at 6 and 12 months after the AMI episode.

Cardiac Magnetic Resonance Examination Protocol

All CMR imaging studies were performed on a 1.5 Tesla unit (General Electric Signa 4.0) with phased-array surface coils and body coils, and electrocardiogram (ECG)-gating. The study protocol included only acquisition of cine MR images.

Scout views were first taken to determine the imaging planes for the cine studies. Two long-axis views and 6-8 short-axis views were obtained to guarantee total coverage of the left ventricle. An ultrafast balanced gradient echo sequence was performed. Each of the sections acquired was performed with breath-holding of 8-14 s. The typical parameters used were as follows: 6-mm thickness with a 4-mm space between slices, repetition time=one RR interval, flip angle 15-30°, echo time 5 ms, 20 phases per cardiac cycle, matrix 128 160 (phase encoding steps) ? 256 (readout points), field of view 300-350 mm. Oversampling in the phase encoding direction was used to avoid wrap around artifacts. Images were analyzed with Mass 4.0.1 software (Medical Imaging System, Leiden, The Netherlands). Quantitative analysis of the ejection fraction, and left ventricular volumes and mass were done for each patient. Calculation of the volumes and ejection fraction was performed by manual detection of the endocardial contour at end-systole and end-diastole in each slice and application of the Simpson's rule (Σ[thickness+space between sections]). In addition, qualitative analysis of segmental contractility was carried out using the standardized, 16-segment model for segmental study of the myocardium from the American Heart Association.[27] Each segment was scored according to the following scale: 1=normal, 2=hypokinesia, 3=akinesia, 4=dyskinesia, or aneurysm.

Mean duration of the CMR studies was 25 (12) min. Each imaging study was interpreted by two experienced independent observers, using measurements for the analysis determined by consensus.

TABLE 1. Characteristics of the Stents Implanted

Variables	Group 1 (With CMR) n=86	Group 2 (Without CMR) n=321	P
Stainless steel stents (316L), n (%)	50 (58)	178 (55)	.6
Cobalt-chrome stents, n (%)	143 (44)	36 (42)	.6
Drug-eluting stents, n (%)	16 (13)	0 (0)	<.01
No. stents/patient, mean (SD)	1.5 (0.82)	1.4 (0.7)	.32
Length area covered per stent, mean (SD), mm	26 (14)	27 (14)	.44

CMR: cardiac magnetic resonance; SD: standard deviation

Follow-Up

The follow-up of events before hospital discharge included death, reinfarction, and the need for revascularization. At 6 and 12 months, the incidence of death, reinfarction, revascularization, and rehospitalization was assessed by medical consultation or telephone contact.

Reinfarction was defined as chest pain of more than 30-min duration and creatine kinase MB isoenzyme (CK-MB) elevation, with or without ST-segment changes. The enzyme elevation had to meet one of the following criteria: a) when chest pain occurred within the first 48 hours after the initial infarction, enzyme re-elevation was considered positive if it appeared in the descending phase of the enzyme curve and reached at least 150% of the prior determination; b) if chest pain occurred more than 48 hours after the initial infarction, CK-MB re-elevation was considered positive if it reached a peak at least 3-fold higher than the normal values of the isoenzyme; and c) if chest pain occurred within the first 48 hours following angioplasty or revascularization surgery, CK-MB re-elevation was considered positive if it reached a peak at least 5-fold higher than the normal values. Acute stent thrombosis was defined on the basis of angiographic evidence of total or partial occlusion of the artery at the level of the implanted stent occurring in the first 24 hours, subacute thrombosis on the basis of the same criteria occurring during the first month postimplantation, and chronic thrombosis as occlusion occurring after the first month postimplantation.

Ischemia-guided revascularization was defined as any type of revascularization procedure (percutaneous or surgical) affecting any diseased artery after identifying severe ischemia by at least one of the following criteria: a) angina at rest with ECG changes; b) grade III/IV exertional angina (Canadian classification); or c) stress test while under treatment with beta blockers demonstrating unequivocal ECG changes, segmental contractility alterations, or perfusion defects.

Statistical Analysis

Continuous variables were expressed as mean (standard deviation) and categorical variables as absolute value and percentage. The between-group comparison of continuous variables was done with Student t test. Categorical variables were compared with the chi-square test or Fisher's exact test, when appropriate.

P-values of <.05 were considered statistically significant. Data were analyzed with the SPSS 12.0 statistics package (SPSS Inc. Chicago, Illinois).

RESULTS

The study population was classified into two groups based on whether or not a CMR examination was performed: Group 1 included patients who underwent CMR (n=86) and Group 2 patients who did not undergo CMR (n=321). There were no statistically significant differences with respect to demographic variables and risk factors between the patient groups, except for mean age, which was higher in Group 2 (Table 2).

A comparison of the characteristics of the infarction and the treatment received by the two groups is shown in Table 3. It is worth highlighting that patients who underwent CMR had a higher percentage of infarctions in an anterior location, a lower ejection fraction, and a higher CK-MB peak than patients in Group 2. The characteristics of the stents implanted in both groups of patients are summarized in Table 1.

No complications, including chest pain, dyspnea, or arrhythmias, were recorded during or immediately after the CMR examination. In all patients the study was completed satisfactorily and suitable images for calculating the ventricular function parameters were obtained.

The follow-up of adverse events included reinfarction, death, and the need for revascularization during

TABLE 2. Demographic Data and Risk Factors

Variables	Group 1 (With CMR) n=86	Group 2 (Without CMR) n=321	P
Age, y mean (SD)	58.3 (11.8)	61.7 (11.8)	.018
Men, n (%)	74 (86)	273 (85)	.8
Prior AMI, n (%)	2 (2)	21 (6)	.18
Prior PCI, n (%)	3 (3)	3 (4)	.99
DM, n (%)	0 (12)	61 (19)	.1
Hypercholesterolemia, n (%)	37 (43)	116 (36)	.25
HT, n (%)	28 (33)	119 (37)	.43
Family history, n (%)	11 (13)	61 (19)	.17
Smoker, n (%)	63 (73)	239 (74)	.82

AMI: acute myocardial infarction; CMR: cardiac magnetic resonance; DM: diabetes mellitus; HT: hypertension; PCI: percutaneous coronary intervention; SD: standard deviation

TABLE 3. Infarction Characteristics and Treatment Received

Variables	Group 1 (With CMR) n=86	Group 2 (Without CMR) n=321	P
AMI anterior location, n (%)	58 (67)	117 (36)	<.001
AMI inferior location, n (%)	26 (30)	190 (59)	<.001
Primary PCI, n (%)	23 (28)	76 (24)	.44
Facilitated PCI, n (%)	60 (72)	245 (76)	.44
CK-MB (g; mean [SD])	344 (301)	294 (213)	.09
Baseline EF (mean [SD])	51 (11)	55 (11)	.008
No. of diseased vessels=3, n (%)	24 (7)	2 (2)	.13
Clopidogrel or ticlopidine, n (%)	72 (84)	258 (80)	.77
Aspirin, n (%)	83 (96)	304 (95)	.48
Beta blockers	80 (93)	252 (82)	.01
ACEI	56 (65)	177 (56)	.16

ACEI: angiotensin-converting enzyme inhibitor; CK-MB: creatine kinase MB isoenzyme; CMR: cardiac magnetic resonance; EF: ejection fraction; PCI: percutaneous coronary intervention; SD: standard deviation

hospitalization and at 6 and 12 months. Three cases of subacute thrombotic stent occlusion were recorded, all in Group 2 patients (no CMR), and all took place in the first ten days following stent implantation. No statistically significant differences were found for the remaining variables studied (Table 4). The combination of events, *death, reinfarction, revascularization of the stented vessel, and rehospitalization at one year* was 14% in the group of patients who underwent CMR and 16% in Group 2 (*P*=.7).

DISCUSSION

This comparative study indicates that it is safe to perform a CMR examination in the early phase following stent implantation. None of the 86 patients studied with CMR in the acute phase of AMI presented events after the examination, nor were there any immediate adverse effects attributable to the CMR study. Lastly, and despite the fact that the baseline characteristics of the group undergoing CMR showed a significantly higher risk profile than the control group (higher percentage of anterior infarctions, lower ejection fraction, and higher CK-MB peak), the one-year rate of combined events was similar in the two groups.

In their user information guidelines, stent manufacturers recommend waiting 8 weeks before performing an MR examination.[14,15] This recommendation is based on the time considered necessary for complete endothelialization of the device, which would avert possible dislodging if the stent were submitted to a magnetic field. The valuable information provided by CMR is particularly important for the clinician in the acute phase of coronary disease; hence, the 8-week waiting period seems excessive. Thus, it is necessary to accurately establish the interval of time

TABLE 4. Events at 12-Month Follow-Up

Variables	Group 1 (With CMR) n=86	Group 2 (Without CMR) n=321	P
Death, n (%)	0	11 (3)	.13
Reinfarction, n (%)	2 (2)	7 (2)	.99
PCI, n (%)	4 (5)	19 (6)	.79
Surgery, n (%)	0	3 (1)	.99
Revascularization, n (%)	4 (5)	21 (6)	.69
Rehospitalization, n (%)	8 (9)	32 (10)	.99
MACE 1, n (%)	2 (2)	17 (5)	.38
MACE 2, n (%)	6 (7)	32 (10)	.52
MACE 3, n (%)	12 (14)	50 (16)	.71

CMR: cardiac magnetic resonance; MACE (major adverse coronary events) 1: death or reinfarction; MACE 2: death or reinfarction or revascularization; MACE 3: death or reinfarction or revascularization, or rehospitalization; PCI: percutaneous coronary intervention

required following stent implantation to undertake a CMR study without exposing the patient to the risk of stent displacement.

In general terms, MR studies are considered contraindicated in patients with ferromagnetic implants, mainly because of the potential risk of dislodgment, induction of electric currents, and excessive heating of the device, and because of the potential for erroneous interpretation of the images due to artifacts produced by the object. Several factors determine the relative risk incurred by patients with metal implants: 1) the strength of the magnetic field and the gradients; 2) the degree of ferromagnetism of the implanted device; 3) the geometry of the material implanted, and 4) the location and orientation of the material during the MR study.

The safety and artifacts associated with various types of coronary stents have been assessed in experimental studies using a 1.5-Tesla MR unit and comparing several imaging sequences (turbo spin-echo, gradient-echo, and echo-planar) in porcine models.[16,17] Nineteen different types of stents with a longitude of 8 to 25 mm and a diameter of 3.0 to 4.5 mm were assessed. The researchers investigated potential migration of the stents caused by the force of the magnetic field and the heating cause by the radiofrequency waves. The greatest ferromagnetic force was observed in stents having the largest mass, whereas the lightest stents showed no ferromagnetism. Even though there may be a minimum of ferromagnetism with heavier stents, the ferromagnetic force would be too weak to cause migration of the stent during MR study on a 1.5-Tesla unit. Moreover, the force applied to a stent due to rapid cardiac motility, with acceleration and deceleration during cardiac contraction and relaxation, is much greater than that produced by the magnetic field.

The expanded stent acts as a closed circuit and it would be expected that the magnetic field changes associated with the ultrafast pulsed gradients used in MR imaging might produce an electric current and therefore, local heating. Nevertheless, even when radiofrequencies much higher than those generally used in clinical MR imaging studies were applied to 19 stents in the study by Hug et al,[16] no increase in temperature was recorded in any of them.

Strohm et al[17] assessed the dynamics of stent displacement in 14 types of stent implanted in porcine arteries. On the basis of the results, the authors concluded that there was no visible movement in any of the stents.[18]

The same parameters were tested in a recent study by Shellock et al[28] evaluating the safety of drug-coated stents in a 3-Tesla magnetic field. This in vitro study concluded that because of the observed absence of interactions with the magnetic field, it would be safe to perform CMR imaging immediately after implantation of a drug-coated cobalt-chrome stent.[28]

With regard to clinical studies, Gerber et al[19] reported a retrospective analysis of adverse events in 111 patients who underwent MR studies in 1.5-Tesla fields (the magnetic field generally used in clinical practice) during the first 8 weeks following stent implantation (median, 18 days). The risk of cardiac death, myocardial infarction, and the need for revascularization due to stent thrombosis was very low and was consistent with the current rate of adverse events (0.5%-1.9%) described for patients submitted to coronary angioplasty and stent placement. It is important to mention that the reason for stenting was an acute coronary syndrome in only 60% of patients in that study, whereas the remaining patients had stable ischemic heart disease.

Other retrospective studies limited by the small number of patients included (from 11 to 33 cases) indicate that CMR is safe in patients with AMI treated by stenting.[20,21] The follow-up of adverse events in these studies was, moreover, limited to the period of hospitalization.

In 94 patients who had undergone percutaneous cardiac revascularization with stent placement, Kim et al[22] performed a CMR study on a 1.5-Tesla unit a mean of 2.3 (1.8) days following the procedure. The indication for stent implantation was acute coronary syndrome in 90% of the patients. Two events documented during hospitalization were unrelated to the arteries in which the stents were implanted. There were no events at 3 months, no deaths at 6 months, two AMIs were recorded (neither in the territories of the stented arteries) and two patients had in-stent stenosis. The authors concluded that MR study during the first 7 days following stent implantation is safe and that the risk of death or AMI due to stent thrombosis is low. In contrast to our study, only 68% of the patients in the study by Kim had ST-segment elevation and, moreover, there were no data from a control group.

The present study, which strongly supports the conclusions of the aforementioned reports, presents several particularities relative to them: *a)* the study population is homogeneous, including only patients in the acute phase of myocardial infarction who received a coronary stent; *b)* the study population is larger; *c)* comparison is performed with a control group; and *d)* the study of events is performed not only during hospitalization, but also at long term (12 months). However, we are also conscious of the limitations inherent to its retrospective, non-randomized design.

CONCLUSIONS

This study indicates that CMR imaging examination is safe in AMI patients who have been treated by stent implantation. Delaying acquisition of the valuable and extensive information provided by CMR is, in our opinion, unnecessary. Nevertheless, prospective, randomized studies should be performed to confirm the safety of the technique in this population.

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