**Coronary Arteries** 

# Magnetic Resonance Imaging Seems Safe in Patients with Intracoronary Stents

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## ABSTRACT

We elucidated whether exposure to cardiac magnetic resonance imaging (MRI) of patients with implanted intracoronary stents is associated with increased risk of stent-thrombosis, stent-restenosis, or other cardiovascular complications. Forty-seven patients admitted with acute myocardial infarction (AMI) were studied. Twenty-three were included in a serial cardiac MRI study, using 1.5-T scanners with standard gradient systems. The remaining patients were control subjects who were matched for age and gender with the MRI group. All patient had intracoronary stents implanted in connection with primary angioplastic treatment (PTCA) of AMI (n = 21), secondary PTCA procedures due to recurrent angina (n = 22), or both (n = 4). In the MRI group (n = 23, aged 58  $\pm$  10 yr), MRI was carried out one to five times in each patient a median of 166 days (range, 1-501) after stent implantation. The control group comprised 24 patients, ages  $59 \pm 11$  yr. The incidences of stent-thrombosis, stent-restenosis, and other cardiovascular complications did not differ statistically significantly between the two groups. In the MRI group, stent-related thrombosis (n = 1) or restensis (n = 7) was observed in eight cases a median of 102 days (range, 7-547) after MR examination and a median of 318 days (range, 138–713) after stent implantation, compared with nine cases in the control group (thrombosis, n = 1; restenosis, n = 8) observed a median of 147 days (range, 1–267) after stent implantation. No acute thromboembolic or other complication occurred in immediate connection with MRI. The follow-up time was  $21.3 \pm 4.5$  months. This small study shows no evidence of an MRIrelated risk of stent-restenosis or other cardiovascular complications, not even if cardiac MRI is performed early after stent implantation.

KEY WORDS: Acute myocardial infarction; Coronary stents; Magnetic resonance imaging; Safety.

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### INTRODUCTION

Magnetic resonance imaging (MRI) has become an important supplement to prevailing imaging methods (1), especially in patients with coronary artery disease (2). Potential hazards of MR could be related to the high static magnetic field, the varying gradient fields, the radiofrequency excitations, implanted ferromagnetic items in patients, projectile-like metallic items outside patients; further MR might cause thermal injuries and auditory damage (3,4). Whether MR could influence body temperature, nerve conductivity, electrocardiographic T waves, cardiac cycle length, blood sedimentation, susceptibility of genetic mutations, and neoplasia has also been considered, but so far no reports have appeared on observed harmful effects (4,5). Exposure to MR examination is generally considered safe if recommendations regarding field strength (<2-2.5 T) and ferromagnetic foreign bodies are followed (3).

At present, stainless steel stents are implanted during most coronary angioplastic procedures in patients with stable and unstable coronary syndromes. In patients with stainless steel stents, MRI has been reported to be safe 5-6 weeks after implantation, the stent being at that time safely incorporated in the vessel wall (6), but at present only limited experience exists in this field (7–9).

## MATERIALS AND METHODS

#### Aims

The purpose of the present study was to elucidate whether the exposure to MRI in patients with implanted intracoronary stents constitutes an increased risk of stentthrombosis, stent-restenosis, or other cardiovascular complications.

#### In Vitro Experiment

A coronary stent (Palmaz-Schatz®; Johnson & Johnson Interventional Systems, Warren, NJ) was placed in a 1.5-T magnet (Gyroscan; Philips Medical Systems, Best, The Netherlands). The stent was placed in the center of the scanner, where the chest of a person would be located during cardiac MRI. No spontaneous deflection was observed. Only when counteracting friction (i.e., making the stent move by tapping the tray on which it was lying) did the stent show deflection. Subsequently, the same coronary stent (Palmaz-Schatz) was exposed to MR examination. The stent was placed in a small quantity of ultrasound gel at room temperature. During simulated cardiac triggering at a heart rate of 105 beats/min, the stent was exposed to a series of five subsequent segmented k-space gradient-echo (turbofield, TFE) acquisitions, five TFE multiphasic gradient-echo acquisitions, five velocityencoded TFE sequences, and three T1-weighted spinecho sequences, each acquisition of approximately 1-min duration. Immediately before and after each type of imaging sequence, the temperature was measured in the gel surrounding the stent, in a control gel that was also located in the MR scanner, and in another control gel placed outside the scanner in the same room. A thermometer was used (Checktemp 2; Hanna Instruments, Inc., Woonsocket, RI; accuracy:  $\pm 0.3^{\circ}$ C). The temperature never differed in the three gels and at no time increased more than 0.4°C in the gel with the stent or in the other gels.

# **Clinical Study**

During an 18-month period (11/9/95 to 10/2/97), consecutive patients  $\leq$ 75 yr admitted with a first-time diagnosis of acute myocardial infarction (AMI) were screened for inclusion in a 1-yr serial cardiac MRI study. All patients with AMI were treated by coronary angioplasty when admitted during the day and by thrombolysis when admitted during the evening and weekends, according to the guidelines of the Department of Cardiology at that time. Forty-seven AMI patients underwent intracoronary stent implantation either in connection with primary angioplastic treatment (PTCA) of an acute coronary occlusion or during a secondary PTCA procedure due to recurrent angina pectoris after thrombolytic or angioplastic treatment. Adjunctive antithrombotic medical treatment comprised aspirin, heparin, dalteparin, and ticlopidin.

Twenty-three AMI patients participated in the prospective 1-yr cardiac MRI study (MRI group). The remaining 24 patients, matched for age and gender with the MRI group, constituted the control group. They were admitted in exactly the same period but could not be included in the MRI study because of reluctance to participate, claustrophobia, increased body mass, or for other practical reasons.

Medical files, including information on readmissions, visits to the outpatient clinic, and coronary angiograms, were reviewed after a follow-up of  $21.3 \pm 4.5$  months for information on recurrent angina pectoris, repeated angiography or revascularisation therapy, stent-related restenoses (defined as  $\geq$ 70% stenosis, i.e., in-stent-restenoses or stent-restenoses in juxtaposition, defined as restenoses just proximally or distally to the stent), stent-

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unrelated restenoses, thromboembolic complications, recurrent AMI, or death.

# **Cardiac MRI**

The patients in the MRI group underwent serial cardiac MRI 3-9 days and 3, 6, and 12 months after infarction. An additional MR examination was performed in five patients for reproducibility analysis. Cardiac imaging was performed in whole body 1.5-T systems (Philips Gyroscan HP/S15 with 10 mT/m, 10 mT/m/ms gradients, and Philips Gyroscan NT with 15 mT/m, 17 mT/ m/ms gradients). Electrocardiographic triggering was used with the patient resting in the supine position. Multiple TFE gradient-echo images (Philips Gyroscan NT) or T1-weighted spin-echo images (Philips Gyroscan HP/ \$15) of the heart were made in the coronal, sagittal, and transversal planes. Using these scouts as points of reference, two fast-field echo (FFE; Philips Gyroscan HP/ S15) or TFE (Philips Gyroscan NT) long-axis gradientecho cine-loops were acquired, followed by two-phase contrast acquisitions using FFE. The acquisition parameters appear in Table 1. The duration of each biplane MR examination was 40-60 min. In 13 patients, multislice imaging was performed in addition. Using the apical

long-axis gradient-echo images as points of reference, 8– 14 FFE or TFE gradient-echo short-axis MRI cine-loops were acquired. The duration of one multislice MRI examination was an additional 10–30 min.

## **Statistical Analysis**

Data were analyzed retrospectively and are presented as means  $\pm$  SD or as median values with range, when appropriate. Student's unpaired two-tailed *t*-test was used for comparisons between groups when normal distribution could be assumed; otherwise, unpaired nonparametric analysis was used (Mann-Whitney test). Analysis of differences of binary variables between groups was made using the chi-squared test or by Fisher's exact test, when appropriate. p < 0.05 was considered statistically significant.

# Ethics

The study complied with the Second Helsinki Declaration and was approved by the local Scientific Ethics Committee. The patients were included in the MRI study when informed written consent was obtained.

MRI Acquisition Parameters						
Imaging Type	TR/HPI (msec, range)	TE (msec, range)	Flip Angle (degrees)	Spatial Resolution (matrix)	Scan Percentage	
Biplane FFE gradi- ent-echo (Philips Gyroscan HP/S15)	28-62	11–25	30	128 × 128	80 or 100	
Biplane TFE gradi- ent-echo (Philips Gyroscan NT)	35-74	3.1-6.7	35	256 × 256	88	
Phase-contrast FFE (Phillips Gy- roscan HP/S15)	25-34	9–12	45	128 × 128	100	
Phase-contrast TFE (Philips Gyroscan NT)	26-33	5-8	35	128 × 128	85-100	
Multislice multiphase TFE gradient-echo (Philips Gyroscan NT)	5689	6.1-8.3	30	128 × 128	75 or 80	

Table 1

TR, repitition time; HPI, heart phase interval; TE, echo time.

# RESULTS

The demographic characteristics of the patients appear in Table 2. The MRI group and the control subjects did not differ statistically significantly regarding clinical variables, medical history, or use of medication. In the control group, 2 of 26 patients were excluded from analysis from the start because of sudden death and cerebral infarction, respectively, immediately after coronary angioplasty with stenting. In the MRI group, no deaths occurred. Similar incidences of cardiovascular complications in relation to AMI were observed in the MRI group and the control group; in each group two patients developed clinical heart failure and one patient unstable angina after initial thrombolytic treatment.

In the MRI group, the number of MR examinations performed in each patient, after intracoronary stent implantation, were one (n = 2 patients), two (n = 4), three (n = 5), four (n = 11), or five (n = 1). The time interval between coronary stenting and MR examination was 166 days (range, 1-501). In 13 patients, MRI was performed within 1 month of stent implantation and in 11 patients within 1 week.

Table 3 shows the distribution and characteristics of the angioplastic procedures, the use of stents, and the observed incidences of restenosis and thrombosis. In the MRI group, one patient suffered acute coronary artery

occlusion distally to a previously stented segment 148 days after an MR examination. This was successfully treated by repeated primary angioplasty, without increase of cardiac enzymes or other complications. In the control group, one patient died after acute coronary bypass surgery, after a coronary thrombotic complication during angioplasty of an in-stent-restenosis.

The incidences of stent-thrombosis, in-stent-restenosis, or non-in-stent-restenosis did not differ statistically significantly between the groups (Table 3). In the MRI group, stent-thrombosis or stent-restenosis were observed 102 days (range, 7-547) after MR examination. No acute thromboembolic or other complication occurred in connection with MR examination. In the subgroup of patients (n = 13) in whom MRI was performed within 1 month of stent implantation, two patients later developed in-stentrestenoses and two patients later developed stent-restenoses in juxtaposition. In these patients, the time interval between MRI and the diagnosis of restenosis was 303 days (range, 257-436). Compared with the control group, a statistically significantly longer time passed in the MRI group before repeated coronary angiography was considered indicated and a significantly longer time passed before the stent-restenoses were diagnosed.

Two of four diabetic patients experienced stent-stenosis, one in each group; in the diabetic patient in the control group, stent-restenosis occurred three times. Stents

Demographics				
	MRI Group	Control Group		
Number of patients (males/females)	23 (21/2)	24 (21/3)		
Age (yr) (mean ± SD)	$58 \pm 10$	$59 \pm 11$		
Peak CK-MB (U/l) (median, range)	64 (17-253)	69 (7-320)		
Time to reperfusion (hr) (median, range)	3 (1-31)	2 (1-8)		
Anterior infarction (n)	15	12		
History of angina (n)	8	9		
History of hypertension (n)	6	5		
History of diabetes (n)	2	2		
Hypercholesterolaemia (n)	11	9		
Tobacco smokers (n)	16	14		
Use of medication (in addition to aspirin,	ticlopidin, daltepar	rin, and heparin)		
Thrombolysis (n)	7	7		
ACE inhibitors (n)	11	10		
Beta-blockers (n)	19	20		
Calcium blockers (n)	5	2		
Nitrates (n)	4	5		
Diuretics (n)	4	6		

Table 2

Demo	gra	ph	ics

CK, creatine kinase; ACE, angiotensin-converting enzyme.

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Table 3
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Results

	MRI Group	Control Group
Primary PTCA (n)	13	17
Primary PTCA with stenting (n)	11	14
Secondary PTCA with stenting (n)	13	13
Time after AMI (days) (median, range)	99 (2-307)	60 (2-398)
Total number of stenosed arteries (n)	41	39
Total number of stents (n)	33	40
Length of stent (mm) (mean $\pm$ SD)	$14.1 \pm 4.4$	$13.6 \pm 4.8$
Diameter of stent (mm) (mean $\pm$ SD)	$3.6 \pm 0.5$	$3.7 \pm 0.4$
Maximum pressure (atm) (mean $\pm$ SD)	$14.7 \pm 2.2$	$15.0 \pm 3.4$
Repeated angiography (n)	18 (12 patients)	26 (15 patients)
In-stent-thrombosis (n)	1)	1)
In-stent-restenoses (n)	3 { (8 patients)	6 (5 patients)
Stent-restenoses in juxtaposition (n)	4	2
Stent-unrelated-restenoses (n)	8 (7 patient)	9 (5 patients)
Time to diagnosis of stent-restenosis (days) (median, range)	318 (138–713)	147 (1-267)*
Time to need of reangiography (days) (median, range)	309 (62-713)	136 (1-505)*

\* *p* < 0.05.

atm, athmosphere.

that occluded did not differ statistically significantly from stents that did not, with respect to length, diameter, or implantation pressure. Stents that were occluded or stenosed were as follows: Palmaz-Schatz stents (Johnson & Johnson Interventional Systems), 8 among 40 implanted stents; Freedom stents (Boston Scientific Corporation, Boston, MA), 2 among 8 implanted; and Multilink stents (Guidant, Copenhagen, Denmark), 1 among 2 implanted. Other stents used in which no stenoses were observed comprised Micro stents (n = 10; Medtronic, Vicare, Vedbæk, Denmark), NIR stents (n = 8; Boston Scientific Corporation), and Crossflex stents (n = 5; Cordis, Dallas, TX).

### DISCUSSION

In patients with stable and unstable coronary syndromes, arterial implantation of stainless steel stents is frequently used during angioplastic procedures to avoid acute complication and to reduce vascular restenosis (10,11). Restenosis or reocclusion may occur early (e.g., due to thrombosis or elastic recoil) or later, after neointimal proliferation or vascular remodeling. MRI offers the advantage of being a noninvasive coronary imaging method without the hazards of instrumentation, infection, and radiation. It could thus be repeated several times, and in selected cases it is being used for the evaluation of coronary artery patency (8,9,12). In theory, unwanted effects of MRI in the presence of intravascular stents comprise dislocation of the stent by magnetic forces, heating, or induction of electric currents in the coiled stents by the magnetic gradients. The latter could possibly cause thermal injury to the endothelium, inducing thrombosis, restenosis, or maybe even development of arrhythmogenic foci.

In the present in vitro experiment, a stainless steel stent in a 1.5-T magnetic field only showed deflection when friction was offset. Thus, the impact of the magnetic field is much weaker than what would be expected by the forces exerted by heart motion and shear stress. This experiment confirms similar studies (13–15). Moreover, no heating of the stent was observed during exposure to MRI. Another in vitro study reported short-time exposure of 23 different types of pacemaker electrodes to MR (16). Heating of the tip of the electrode of >15°C was observed in 28% of cases, to a lesser degree, however, in saline solution than in air. So far, two studies have reported lack of heating of various types of stents that were implanted in pig coronary arteries (17,18).

This study is one of the first clinical follow-up studies

of patients with intracoronary stents being exposed to MR. The study population of first-time AMI patients was chosen to obtain a relatively homogenous population without a long history of coronary artery disease. Even in this high-risk population with recent myocardial infarction, a low incidence of restenosis was observed. Another MRI study that evaluated the patency of intracoronary stents did not report cardiovascular complications (9). The present study shows that even early after stent implantation, the exposure to MR, using standard gradient systems, probably does not constitute any risk of stent restenosis or thrombosis. No increased incidence of stentrestenosis, thromboembolic, or other cardiovascular complications was observed in patients exposed to MRI. Thus, stent-restenosis or occlusion is presumably related to mechanical factors in the interaction between stent and artery, such as the length of the stent and possible inherent propensity of the vessels to restenosis (e.g., caused by diabetes) rather than being related to mechanical interaction with the magnetic field.

## Limitations

The present study is limited by a low number of patients and by being retrospective and nonrandomized. The two patient groups were very similar, however, and the reasons the control group did not participate in the MRI study were not related to factors that are likely to influence the propensity to develop vascular restenosis. Moreover, only gradient strengths up to 15 mT/m with slew rates of 17 mT/m/ms were used. Control angiography was not performed in all patients, only in those with symptoms of angina. Thus, stent-restenoses may have been undetected. There is, however, no reason to believe that the two groups would differ in this respect.

The in vitro study was only conducted once, with a Palmaz-Schatz stent. In theory, the result might be different with other stents. However, because other in vitro studies did not report differences for various stents regarding motion and heating (14,18), it was considered prudent to conduct the in vivo study without testing all the stents in vitro.

In conclusion, in patients with coronary artery disease exposed to MRI after the implantation of an intracoronary stent, no increased incidence of stent-restenosis or thromboembolic complications were observed. Cardiac MRI does not seem to induce inadvertent impact on coronary arteries in patients with earlier or even recently inserted coronary artery stents. Schroeder et al.

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