Original Research

Long-Term Safety of Cardiac Magnetic Resonance Imaging Performed in the First Few Days After Bare-Metal Stent Implantation

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Purpose: To investigate the long-term safety of cardiac magnetic resonance imaging (CMR) performed one to seven days after coronary artery stent (bare metal) implantation.

Materials and Methods: We analyzed 119 consecutive patients with acute myocardial infarction (MI) who underwent emergency coronary stent implantation with a bare-metal stent. CMR using a 1.5T scanner was performed on 51 patients (42.9%) at a mean of 2.7 ± 3.1 days after stent implantation (CMR+ group), and the remaining 68 patients (57.1%) served as controls (CMR– group). The patients were followed up to six months for major adverse cardiac events.

Results: The average stent size was 3.3 ± 0.5 × 18.4 ± 6.7 mm, and 86% of the stents were made of 316L stainless steel. There were no significant differences between the CMR+ and CMR– groups in terms of infarct features, angiographic findings, or stent characteristics. Over a mean follow-up of 4.4 ± 2.1 months, 12 patients (10.1%) had 16 events (13.4%). Two patients had adverse events after early MRI scan (4.3%), a rate that is lower than the event rate in the patients who did not undergo MRI (16%, $P = 0.04$), and one of the two events was clearly not MRI related.

Conclusion: CMR on a 1.5T scanner can be safely performed within one to seven days after coronary bare-metal stent implantation and is not associated with an increased risk of adverse clinical cardiac outcomes. In the light of accumulating data, the guidelines by stent manufacturers should be revised.

Key Words: magnetic resonance imaging; heart; safety; stent; myocardial infarction
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PERCUTANEOUS CORONARY INTERVENTION (PCI) using stent implantation is routinely used in the management of patients with coronary artery disease. According to the 2001 ACC/AHA report (1), more than 500,000 PCI procedures are performed yearly in the United States, and it has been estimated that more than 1 million procedures are performed annually worldwide. In 2001, about 18 million magnetic resonance imaging (MRI) scans were performed in the United States. Cardiovascular magnetic resonance imaging (CMR) is a relatively new technology. However, CMR is increasingly being used for the clinical assessment of coronary artery disease patients, some of whom may have undergone coronary artery stent implantation. Additionally, noncardiovascular MRI is sometimes urgently needed for such patients based on clinical indications.

MRI has some theoretical risks for patients with coronary artery stents. The ferromagnetic force in the MRI environment may exert a pull on the stent, leading to stent displacement. Additionally, the radiofrequency (RF) waves used to excite the tissue for imaging may lead to heating of the stent. Both of these factors may predispose a patient to a risk of stent thrombosis or in-stent restenosis causing death, myocardial infarction (MI), or acute coronary syndrome. Based on these theoretical considerations, stent manufacturers (Guidant Corp., http://www.guidant.com; Medtronic, http://www.medtronic.com) have recommended waiting for at least eight weeks after implantation until the stent is completely endothelialized before performing an MRI scan. Despite these theoretical concerns, in vitro and animal studies (2–5) have demonstrated that the currently available stents show no or minimal ferromagneticity, heating, or stent migration. However, there are limited clinical data on the safety of MRI within eight weeks of stent implantation (6–8).

In patients with acute ST-segment elevation MI (STEMI) who had undergone emergency coronary artery stent implantation with a bare-metal or noncoated stent, we investigated the long-term safety of CMR performed within one week after the stent procedure. Patients with STEMI and coronary stents are potentially at higher risk for MRI-related complications due to the thrombotic milieu in the early postinfarction period;

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however, a preliminary study by Kramer et al (8) demonstrated the safety of performing MRI in this setting. We hypothesized that patients with recent coronary-artery bare-metal stents could safely undergo MRI procedures. Since CMR utilizes higher gradient strength and RF excitation compared to some noncardiac MRI studies, we envisioned that the demonstrable safety of CMR in high-risk STEMI patients with bare-metal stents would be applicable to a lower-risk patient population undergoing noncardiac MRI.

MATERIALS AND METHODS

Patients

We analyzed all patients with acute STEMI who presented between August 2002 and February 2004 to a community hospital emergency room and underwent primary coronary intervention (PCI) with bare-metal stent implantation. Patients were only enrolled if they had chest pain of less than 12-hour duration associated with ST-segment elevation on electrocardiogram. Patients were excluded if they were too unstable to undergo CMR or had any of the standard MRI contraindications (e.g., pacemaker, defibrillator, intracranial aneurysm clips, or severe claustrophobia). Patients who underwent CMR more than one week after PCI were also excluded from the analysis based on the study design.

CMR

CMR was performed on a 1.5T MR scanner (Signa CV/*i*, GE Medical Systems, Milwaukee, WI, USA; maximum gradient = 40 mT/m, slew rate = 180 mT/m/s, operating in research mode) using a four-element cardiac phased-array coil. All patients underwent ECG-gated cine CMR, a first-pass perfusion study, and delayed enhancement for imaging of MI. Cine CMR images were acquired using a steady-state free precession (SSFP) technique in multiple parallel short-axis planes, with 8-mm-thick slices separated by 3-mm gaps, as well as in two-, three-, and four-chamber long-axis views (12 views per segment, matrix = 192 × 160, typical field of view (FOV) = 28–36 cm, breath-hold = 12–15 seconds, receiver bandwidth = ±125 kHz, TR/TE/flip = 3.5 ms/1.3 ms/45°). First-pass perfusion imaging in the short-axis plane (basal, mid, and apical left ventricle (LV)) was performed after injection of 0.1 mmol/kg of gadolinium diethyltriaminepentaacetic acid (Gd-DTPA, Magnevist, Berlex) using a segmented echo-planar sequence (slice thickness = 8 mm, TR = 6.1 ms, TE = 1.4 ms, matrix = 128 × 96). MI imaging was performed by delayed enhancement technique using an inversion-recovery fast gradient-echo sequence triggered every other heartbeat approximately 10–15 minutes after another intravenous injection of 0.1 mmol/kg Gd-DTPA (total dose = 0.2 mmol/kg). Imaging was performed at end-expiration and lasted about 12 heartbeats (16 views per segment, matrix = 256 × 128, 8-mm slice thickness with 3-mm gap, TR/TE/flip = 6.5ms/3.2ms/20°). The same slices were acquired for both functional imaging and delayed enhancement in order to match wall-motion abnormality and infarct location.

Follow-Up

Patients were contacted for follow-up at 30 days and at six months after the CMR examination regarding the occurrence of death from any cause, MI, acute coronary syndrome requiring hospitalization, congestive heart failure, and coronary angiography performed for clinical indications.

Statistics

Data are presented as the mean ± SD. Patients who underwent CMR (CMR+) were compared with patients who did not undergo CMR (CMR–) by means of Student's *t*-test. The cutoff for statistical significance was $P < 0.05$.

RESULTS

A total of 119 consecutive patients with STEMI who satisfied the inclusion criteria for the study were analyzed. Of these, 51 patients (42.9%) underwent CMR at a mean of 2.7 ± 3.1 days after coronary stent implantation (the CMR+ group). The remaining 68 patients (57.1%) who did not undergo CMR served as controls for comparison (the CMR– group). CMR was performed as part of a research study and was offered to all STEMI patients. However, the patient recruitment was based on referral from the attending physicians and the absence of MRI contraindications. All patients tolerated the CMR study well without any complications during the scan.

The baseline characteristics of the study patients are outlined in Table 1. The mean age of the patients was 66.0 ± 13.5 years, and two-thirds of the patients were male. Patients who underwent CMR were younger (63.1 ± 12.9 years vs. 68.1 ± 13.6 years, $P = 0.04$) and mostly men (84.3% vs. 66.2%, $P = 0.03$), compared to patients who did not undergo CMR. The incidence of major risk factors and a history of coronary artery disease was similar in both groups.

The majority of the MIs were inferior in location, followed by anterior and lateral locations (Table 2). The median peak troponin-I was 48.6 ng/ml (normal range = <0.4 ng/ml), and the peak MB fraction of Creatine Kinase (CK-MB) was 108.0 mg/ml (normal range = <2.37 mg/ml). Infarct location, peak troponin-I, and CK-MB levels did not significantly differ between the CMR+ and CMR– groups.

The coronary angiography and PCI findings are summarized in Table 3. Consistent with infarct location, coronary angiography revealed the right coronary artery (RCA) to be the most common culprit vessel, followed by the left anterior descending and circumflex arteries. The majority of patients had single-vessel disease. Only bare-metal stents were used, the average stent size was 3.3 ± 0.5 × 18.4 ± 6.7 mm, and the Penta stent (Guidant Corp., USA) was the most commonly used stent. The stent type used in seven patients was not recorded. There was no significant difference between the CMR+ and CMR– groups in terms of the culprit vessel involved, use of stents, or stent size. The Zeta stent (Guidant Corp., USA) was used more commonly in the CMR+ group than in CMR– group (43.1%

Table 1
Baseline Characteristics

Variable	All *N* (%)	CMR+ *N* (%)	CMR– *N* (%)	*P*-value
Number	119	51 (42.9)	68 (57.1)	
Age	66.0 ± 13.5	63.1 ± 12.9	68.1 ± 13.6	0.04
Male	88 (73.9)	43 (84.3)	45 (66.2)	0.03
Prior history				
Hypertension	68 (57.1)	29 (56.9)	39 (57.4)	0.96
Diabetes mellitus	29 (24.4)	14 (27.5)	15 (22.1)	0.50
Smoking	49 (41.2)	19 (37.3)	30 (44.1)	0.46
Hyperlipidemia	56 (47.1)	24 (47.1)	32 (47.1)	1.00
Prior MI	10 (8.4)	4 (7.8)	6 (8.8)	0.85
Prior PCI	16 (13.4)	6 (11.8)	10 (14.7)	0.64
Prior CABG	4 (3.4)	0 (0)	4 (5.9)	0.08

MI = myocardial infarction, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft surgery.

vs. 17.6%, $P = 0.002$). Other stent types (Pixel, Tetra, Ultra, Vision, and Tristar, all from Guidant Corp.) were more commonly used in the CMR– group compared to CMR+ group (15.7% vs. 35.3%, $P = 0.02$). Despite the difference in stent types, the majority of the stents (85.7%) were made of 316L stainless steel. The exception was the Vision stent (10.1%), which is made of a cobalt-chromium alloy.

Follow-up was completed for 107 patients (89.9%), with an average follow-up duration of 4.4 ± 2.1 months (Table 4). Four patients in the CMR+ group and eight patients in the CMR– group were lost to follow-up. A total of 12 patients (11.2%) had 15 outcome events (14.0%). The total number of events (6.4% vs. 21.7%, $P = 0.03$) and the number of patients with events (4.3% vs. 16.9%, $P = 0.02$) was higher in the CMR– group. One patient in the CMR+ group died, and two in the CMR– group died.

The person from the CMR+ group who died was a 79-year-old male who had been admitted with acute anterior STEMI. Coronary angiography showed the left anterior descending artery as the culprit vessel, and triple-vessel disease. He underwent complex intervention with stent implantation to the left anterior descending artery and balloon angioplasty to the diagonal artery. CMR was performed two days after stent implantation (Fig. 1) and showed a septal rupture causing a ventricular septal defect. The patient also developed acute renal failure. He was considered to be a poor surgical candidate and was managed medically. He experienced a sudden cardiac arrest two days later and could not be resuscitated. Prior to the cardiac arrest the patient did not report any chest pain, and no ST segment elevation were noted on the monitor. The family declined a request for autopsy. This death was categorized as unrelated to the CMR scan.

The second patient in the CMR+ group who experienced an adverse event was a 60-year-old male with acute inferior MI who underwent emergency cardiac catheterization that demonstrated proximal RCA 100% occlusion and proximal left circumflex artery with 90% stenosis with thrombus. Stenting to the proximal and distal RCAs, and balloon angioplasty of the left circumflex artery were performed. He underwent repeat cardiac catheterization three months later for a positive stress test and was found to have in-stent restenosis of the proximal RCA with a patent distal RCA stent and circumflex artery. Another stent was placed in the proximal RCA without complications. It is possible that this in-stent restenosis event was related to the CMR scan, but this leads to an event rate that is as good or better than the reported 10–20% in-stent restenosis incidence after bare-metal stent implantation.

DISCUSSION

This study indicates that performing MRI scans on patients one to seven days after acute STEMI and bare-metal stent implantation may be safe and is associated with a very low risk of future adverse cardiac events. In this study the patients who underwent CMR were slightly younger, predominantly male, and less likely to have undergone coronary bypass surgery compared to the control subjects; however, there were no significant differences in relation to other cardiac risk factors, location, and size of infarction, and culprit coronary artery. The higher event rate in the CMR– group is a reflection of referral bias, as more sick or unstable pa-

Table 2
Infarct Characteristics

Variable	All, *N* (%)	CMR +, *N* (%)	CMR –, *N* (%)	*P*-value
Infarct location				
Inferior	66 (55.5)	27 (52.9)	39 (57.4)	0.64
Anterior	48 (40.3)	19 (37.3)	29 (42.6)	0.56
Lateral	6 (5.0)	5 (9.8)	1 (1.5)	0.04
Peak troponin (ng/mL),median (range)	48.6 (0.62–286.2)	44.0 (1.04–286.2)	58.5 (0.62–251.6)	0.80
Peak CK-MB (mg/mL), median (range)	108.0 (1.4–706.7)	96.4 (4.87–706.7)	111.5 (1.4–585.0)	0.71

Table 3
Percutaneous Coronary Intervention

Variable	All *N* (%)	CMR+ *N* (%)	CMR– *N* (%)	*P*-value
Stent site				
Left anterior descending	43 (36.1)	22 (43.1)	21 (30.9)	0.17
Left circumflex	13 (10.9)	6 (11.8)	7 (10.3)	0.80
Right coronary	57 (47.9)	20 (39.2)	37 (54.4)	0.06
Two vessels	6 (5.0)	3 (5.9)	3 (4.4)	0.72
Stent characteristics				
Diameter (mm)	3.3 ± 0.5	3.3 ± 0.5	3.2 ± 0.5	0.37
Length (mm)	18.4 ± 6.7	17.6 ± 5.2	18.9 ± 7.7	0.30
Type–Zeta	34 (28.6)	22 (43.1)	12 (17.6)	0.002
Penta	46 (38.7)	19 (37.3)	27 (39.7)	0.79
Other stent types	32 (26.9)	8 (15.7)	24 (35.3)	0.02
316L stainless steel	102 (85.7)	46 (90.2)	56 (82.4)	0.17

tients after STEMI were not referred for CMR. The CMR sequences for cine, perfusion, and viability used in this study represent the current practice of scanning these patients. Importantly, SSFP cine MRI is a method that pushes the scanner gradients and RF deposition to FDA limits, and thus is a good test case for problems that might arise due to the scan. The presence of recently implanted coronary artery stents was not associated with any increased incidence of adverse clinical events compared to the control group.

Clinical studies that performed MRI in patients with coronary stents are summarized in Table 5. Gerber et al (6) reported a case series of 111 patients with coronary artery stents who underwent MRI scans. The mean time interval from stent placement to MRI was 21 ± 17 days (range = 0–54 days), and only 15 patients underwent MRI within two days of stent placement. All of these scans were noncardiac MRI studies, which often use lower gradient strength or RF power than CMR. The adverse cardiac event rate was low (5%), including four noncardiac deaths and three repeat PCI procedures. Schroeder et al (7) studied 23 patients with acute MI who underwent CMR a median of 166 days (range = 1–501 days) after stent implantation, and compared their outcomes with those of an age- and gender-matched control group ($N = 24$). They did not find any evidence of an MRI-related risk of stent-restenosis or other cardiovascular complications.

In a preliminary study, Kramer and colleagues (8) studied 13 patients, in comparison with a control group of 17 patients, who underwent CMR on day 3 ± 1 after stent implantation for acute MI. Only one patient developed in-stent restenosis after CMR with a mean follow-up of 7 ± 2 months, compared to three cases of in-stent restenosis in the control group.

Our results are in agreement with the above-cited studies, even though we used a higher-risk population. Our study included only patients with acute STEMI who were treated with primary bare-metal stent implantation and underwent CMR 24 hours to 7 days after the procedure. This patient population might be expected to be at high risk of cardiac complications due to the thrombotic milieu associated with recent acute MI. However, no increased risk of events associated with CMR was seen. We believe that these safety findings can be extrapolated to lower-risk situations, such as cardiac or noncardiac MRI scanning in patients with chronic coronary artery disease and recent bare-metal stent implantation.

Coronary-artery bare-metal stents are made of different materials, including 316L stainless steel (the most common material), nickel-titanium, tantalum, and cobalt-chromium L605. In our study the majority of coronary stents used (85.7%) were made of 316L stainless steel. The new-generation stents show no or weak ferromagnetic properties, and our data suggest that wait-

Table 4
Outcome Events

Variable	All *N* (%)	MRI+ *N* (%)	MRI– *N* (%)	*P*-value
Follow-up duration (months)	4.4 ± 2.1	4.7 ± 2.0	4.4 ± 2.1	0.19
Total patients with events	12 (11.2)	2 (4.3)	10 (16.6)	0.04
Total events	15 (14.0)	2 (4.3)	13 (21.7)	0.03
Death	3 (2.8)	1 (2.1)[a]	2 (3.3)	0.73
Reinfarction	2 (1.8)	0 (0)	2 (3.3)	0.21
Acute coronary syndrome	6 (5.3)	0 (0)	6 (10.0)	0.03
Heart failure	1 (0.9)	0 (0)	1 (1.7)	0.37
Stent thrombosis	1 (0.9)	0 (0)	1 (1.7)	0.37
In-stent restenosis	2 (1.8)	1 (2.1)	1 (1.7)	0.87

[a]The one death in the MRI + group was considered not related to the MRI scan as it occurred in the patient with a ventricular septal rupture after myocardial infarction which was already present at the time of the examination.

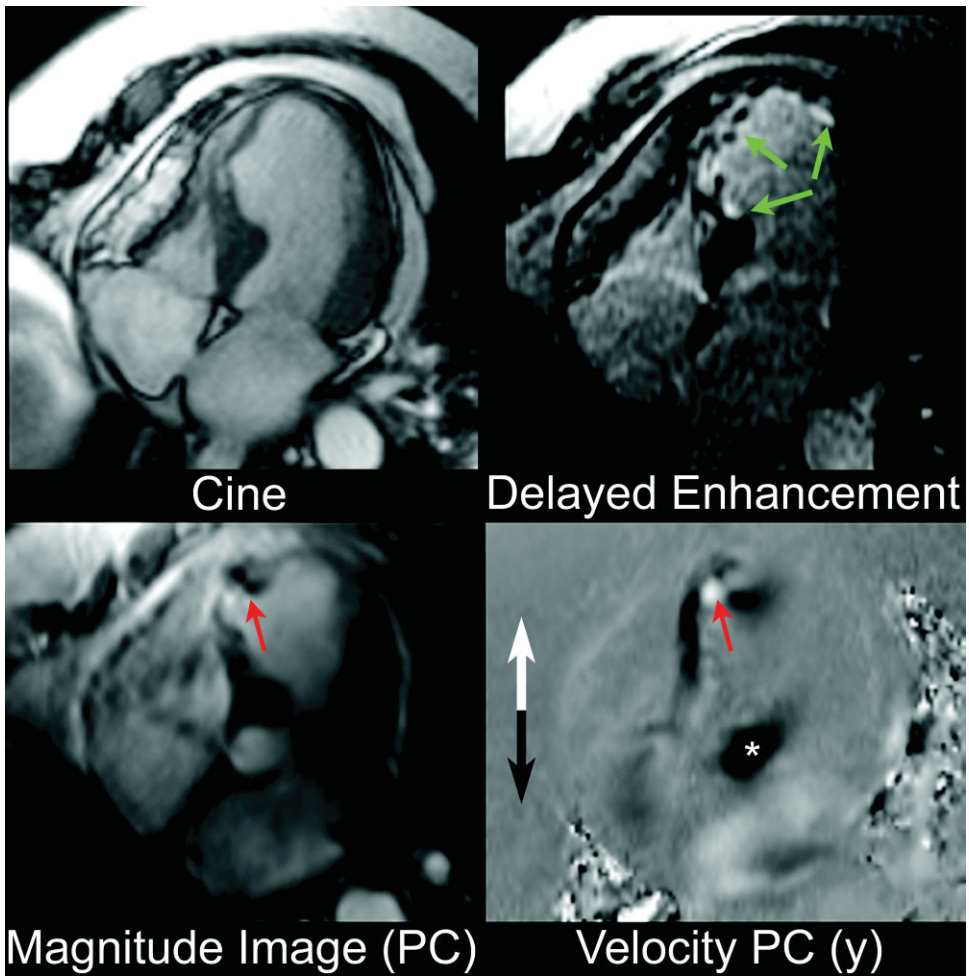

Figure 1. The one patient in the CMR+ group who died had a post MI ventricular septal rupture at the time of the MRI and thus was categorized as a non-MRI-related death. Four systolic images are provided: SSFP cine MRI (upper left), delayed enhancement (upper right), magnitude image from velocity-encoded acquisition (lower left), and y-velocity-encoded image (lower right). All images are in the four- or five-chamber view. The y-velocity-encoding direction lines up with flow in the vertical direction of the image, and the white/black arrows indicate the direction of flow. The green arrows point to the transmural MI with some area of microvascular obstruction. The red arrow on the image at lower left points to turbulence through the interventricular septum. The red arrow at lower right points to a white patch that was interpreted as blood flow with a primary vector that is directed more toward the apex of the heart. The black jet in the right ventricle corresponds to redirection of the ventricular septal defect (VSD) jet toward the tricuspid annulus. There is a smaller black patch in the LV cavity near the VSD that we interpret as blood flow from the apex toward the VSD. The transition from black to white near the VSD goes through a gray area, which represents a primary vector that is mostly perpendicular to the velocity-encoding direction. The other black patch (asterisk) represents blood flow in the LV outflow tract.

ing for the stents to endothelialize is unnecessary. We believe that a stent that is fully expanded in the vessel wall is unlikely to be displaced during an MRI scan performed at 1.5T.

Limitations

Referral bias likely contributed to some of the differences between the CMR+ and CMR– groups. The patient recruitment was based on referral from the attending physicians and the absence of MRI contraindications. We performed CMR 24 hours after the stent implantation to avoid moving patients out of the coronary intensive care unit unnecessarily, and to allow some time for hemodynamic and symptomatic stabilization immediately after the infarction and stent implantation. The safety of MRI within 24 hours of stent implantation has not been formally studied. We followed patients clinically for adverse cardiac events, and could not exclude subclinical stent thrombosis or in-stent restenosis, since angiographic follow-up was not mandated. CMR was performed on a 1.5T scanner and therefore the safety data cannot be extrapolated to higher-field-strength MRI systems. The safety of higher-field-strength imaging (≥3T) in patients with coronary-artery stents is not known at present. The RF energy deposition increases substantially between 1.5T and 3T scanners, so safety studies will need to be performed at higher field strengths as well.

We did not include the recently introduced drug-eluting stents in our study. The two commercially available drug-eluting stents—Cypher (Cordis/Johnson & Johnson, USA) and Taxus (Boston Scientific, USA)—are both made of 316L stainless steel and thus

Table 5
Summary of MRI Safety Studies

Authors	Patient numbers	Patient type	Study type	MRI type	Mean time to MRI	Follow-up	Events CMR+	Events CMR–
Gerber et al (8)	111	CAD	Case series	Head and neck 39%, spine 21%, abdomen/pelvis 14%, extremities 10%, chest 9%, combined 7%	21 ± 17 days	30 days	5%	N/A
Schroeder et al (9)	47	AMI	Case (*N* = 23) Control (*N* = 24)	Cardiac	166 days	21.3 ± 4.5 months	34.8%	37.5%
Kramer et al (10)	30	AMI	Case (*N* = 13) Control (*N* = 17)	Cardiac	3 ± 1 day	7 ± 2 months	7.7%	29.4%
Present study	119	AMI	Case (*N* = 51) Control (*N* = 68)	Cardiac	2.7 ± 3.1 days	4.4 ± 2.1 months	4.3%	21.7%

CAD = coronary artery disease, AMI = acute myocardial infarction.

are similar to bare-metal stents. One concern is the potential effect of heating the drug-eluting stents, which could alter the activity or timing of delivery of the drug to the endothelium. However, Strohm et al (4) found no evidence of significant stent heating during MRI on a 1.5T scanner. The FDA recently approved both drug-eluting stents for MRI scanning soon after implantation. It now appears that it is also safe to perform an MRI scan shortly after implantation of bare-metal coronary stents.

In conclusion, our study suggests that CMR on a 1.5T scanner can be safely performed in stable patients one to seven days after primary PCI with coronary-artery bare-metal stent implantation, and is not associated with an increased risk of adverse clinical cardiac outcomes. Our data and those from other studies do not support delaying an MRI study for six to eight weeks after bare-metal stent implantation.

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