Clinical Safety of Magnetic Resonance Imaging on Recently Placed Coronary Artery Stents

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BACKGROUND: Because of uncertainty regarding safety, most manufacturers of coronary artery stents have recommended waiting a period of 8 weeks after stent placement before magnetic resonance imaging (MRI). At least one manufacturer of a drug-eluting stent (DES) has pursued Food and Drug Administration (FDA) approval for MR imaging early after stent placement through *in vitro*, non-clinical testing (1). However, little clinical data regarding stent MR safety has been published (2,3,4).

PURPOSE: Our purpose was to examine the incidence of adverse cardiac events in patients who underwent cardiac MR (CMR) imaging acutely after coronary artery stent placement using a variety of coronary artery stents. Safety information was extracted from a phase 2, FDA dose ranging study performed to evaluate the safety and efficacy of an MRI contrast agent to identify the presence, location and extent of myocardial infarction (MI).

METHODS: A phase 2, randomized, double blinded, FDA dose ranging study was conducted at 21 clinical sites in North & South America and Europe from February 2003 to April 2004. In this study, 285 patients underwent delayed contrast-enhanced CMR within 16 days of acute MI, using a gadolinium-based MRI contrast agent (OptiMARK®, Tyco Healthcare/Mallinckrodt), to determine optimal dose of contrast agent needed to detect MI. Patients were scanned on 1.5 Tesla whole body MRI scanners using a segmented inversion-recovery gradient echo pulse sequence prior to and then 10 and 30 minutes after intravenous injection of contrast agent. Patients were eligible for the study if they had acute MI defined by either peak troponin I level ≥ 0.5 ng/mL, or CK-MB > three times the upper limit of normal and had only single vessel disease shown on coronary x-ray angiography (no other vessel ≥ 60% diameter stenosis). Coronary angiography data was reviewed from all clinical sites, providing stent placement information in 211 patients (165 M; 54 +/- 29 yrs) who received a total of 258 stents to the single culprit vessel. Stents were either stainless steel or cobalt chromium and included both bare metal (BMS;157/258) and drug eluting (DES; 42/258) stents (59/258, unknown). In 86% (181/211) of patients, stents were placed within 48 hours of the presenting event. In an independent analysis, we extracted cardiac-related safety data, including EKG, from the safety monitoring information on the 211 patients for whom stent placement information was available. As part of the FDA safety information, patients were queried immediately and at 24 hours after the MRI for adverse events, to include signs and symptoms of cardiac ischemia. EKG and vital signs were obtained prior to, immediately after, and 24 hours after the MRI. Additionally, for the 20 patients enrolled at our institution, we reviewed charts for adverse cardiac events 12 months post-MRI.

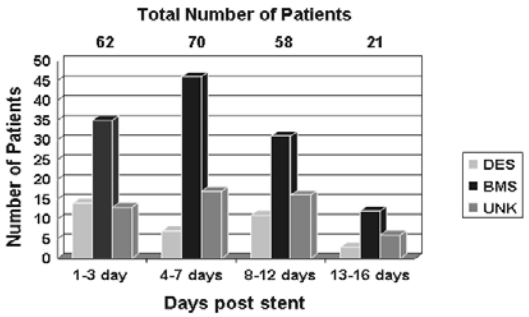
RESULTS: In all 211 patients cardiac MRI was performed within 16 days after stent placement. Fifteen of the 211 patients underwent MRI within one day of stent placement. Sixty-two of the 211 patients had their MRI within 3 days of stenting **(Figure)**. There were no serious adverse cardiac events within the first 24 hours after MRI in all 211 patients. On EKG, one of the 211 patients was noted to have asymptomatic, mild, transient ST segment and T wave changes that resolved within 24 hours. Of the 20 patients with 3 month clinical follow-up data, none had adverse cardiac events. Additionally, eight of the 20 patients at our institution had clinically indicated repeat cardiac catheterization within one year of their MRI at the request of their cardiologist. Two of the 8 patients had in-stent restenosis at four & five months, respectively. Six of the 8 showed patent stents.

DISCUSSION: There were no adverse cardiac events within the first 24 hours after the MRI. EKG's and vital sign measurements demonstrated no significant changes pre and post MRI. No adverse clinical events occurred in any of the 20 patients followed out to 3 months. Two of 20 patients enrolled at our institution demonstrated clinically significant in-stent restenosis late after MRI. This incidence is consistent with previously reported occurrence rates of in-stent restenosis, and bears no obvious link to the MRI early post-stenting. This clinical stent safety information supports the conclusions of *in vitro* stent assessment (1,5), retrospective pilot BMS (2), and smaller prospective clinical studies (3,4).

SUMMARY: No adverse cardiac events occurred in all 211 patients who underwent cardiac MRI between 1 and 16 days after coronary artery stent placement for acute myocardial infarction.

CONCLUSION: It is safe and feasible to perform MRI early after coronary stent placement, using a wide variety of stents.

Figure: Number of patients and stent types by days post stent placement after which MRI was performed.



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