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Invasive Human Magnetic Resonance Imaging: Feasibility During Revascularization in a Combined XMR Suite

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Abstract

We tested the feasibility and safety of invasive magnetic resonance imaging (MRI) during peripheral angioplasty. Real-time MRI can image soft tissue and may potentially guide therapeutic procedures without ionizing radiation or nephrotoxic contrast. MRI-guided diagnostic catheterization has been described recently, but safe and conspicuous catheter devices are not widely available. An active guidewire, which serves as an MRI receiver antenna, might be useful to guide catheterization or even to image atheroma. We describe a combined interventional suite offering both X-ray fluoroscopy and real-time MRI. We used a 0.030" active guidewire receiver coil for invasive MRI after X-ray lesion traversal in patients undergoing percutaneous iliofemoral artery revascularization. Intravascular MRI was compared with noninvasive MRI, X-ray angiography, and intravascular ultrasound (IVUS). Seven eligible patients consented to participate, but three were excluded because of lengthy revascularization procedures. Four remaining patients safely underwent combined X-ray fluoroscopy and real-time magnetic resonance imaging (XMR) transport, continuous monitoring, and all imaging modalities. There was no device dislodgment, contamination or evidence of heating. The intravascular MRI coil was well visualized except at the tip, but did not provide superior mural imaging compared with IVUS. Therefore, because an adequate safety and workflow experience was obtained, enrollment was terminated after only four subjects. Invasive MRI is feasible and apparently safe during peripheral angioplasty. Patients can safely be transported and monitored in an XMR interventional suite. An active quarter-wavelength guidewire coil does not provide superior imaging compared with IVUS, but provides satisfactory guide-wire visualization. These tools may prove useful for advanced therapeutic procedures in the future.

Keywords

interventional magnetic resonance imaging; angioplasty; invasive imaging; catheterization; peripheral artery disease

INTRODUCTION

Magnetic resonance imaging (MRI) is potentially attractive to guide interventional procedures because of superior soft tissue imaging and lack of ionizing radiation and nephrotoxic radiocontrast. Real-time or fluoroscopic MRI is now technically feasible and may enable a range of therapeutic applications, including endoprosthesis deployment for congenital heart

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disease [1,2], vascular obstruction [3], abdominal aortic aneurysm [24], and targeted myocardial cell delivery [4]. In a recent landmark study, Razavi et al. [5] demonstrated the feasibility of diagnostic cardiovascular catheterization in 16 children and adults using MRI. They used passive plastic catheters filled with CO₂, which appear dark under MRI. However, safe catheter devices that appear bright under MRI are not widely available. Ferromagnetic catheter materials cause image distortion and may be displaced by the magnetic field. Conductive materials can heat from microwave exposure during MRI [6]. However, catheter devices may be modified to serve as MRI antennae so that they contribute to imaging or tracking [7] and yet are resistant to heating [8–10]. One such device, the Intercept guidewire (Surgi-Vision, N. Chelmsford, MA), is approved for invasive MRI by the U.S. Food and Drug Administration. Because this type of catheter imaging technology may be useful for future human interventional MRI procedures, we undertook a simple preliminary human experiment.

We tested the feasibility and safety of invasive MRI during clinical percutaneous peripheral artery revascularization in a combined interventional suite offering both X-ray fluoroscopy (XRF) and MRI modalities. We also detail the instrumentation and workflow we developed for this combined intervention suite.

MATERIALS AND METHODS

Study Design and Population

Protocol 02-H-0071 was approved by the National Heart, Lung, and Blood Institute (NHLBI) institutional review board. It was designed to test the safety and feasibility of invasive MRI and intermodality transport during clinical interventional procedures and to compare the value of intravascular MRI with intravascular ultrasound (IVUS). Subjects were recruited consecutively from adults undergoing percutaneous iliofemoral revascularization for intermittent claudication at the NHLBI. Subjects were excluded for any contraindication to MRI, pregnancy or lactation, serum creatinine greater than 2.0 mg/dL, or decompensated heart failure. All subjects gave written informed consent.

XMR Suite and Intermodality Transport

A clinical-grade interventional cardiovascular MRI suite has been constructed for investigational animal and human use. It consists of a floor-mounted single-plane digital X-ray fluoroscope (Axiom Artis FC; Siemens, Erlangen, Germany) collocated with a high-performance 1.5T cardiovascular MRI system (Sonata; Siemens). The two systems share a console control room and are separated by motorized lead-lined, radiofrequency energy (RF)-shielded doors (double sliding shielded door; ETS-Lindgren, Glendale Heights, IL). The 5 Gauss field line of the MRI system remains within the magnet room. Both rooms are ventilated under positive pressure without recirculation. The systems operate fully independently for traditional X-ray or MRI procedures or they can be operated simultaneously for combined XMR interventional procedures (Fig. 1).

Customization was required to allow smooth patient transport between X-ray and MRI. To avoid disrupting intravascular interventional devices during transport, we determined the subject should remain attached to a single elongated cradle or shell for use in both X-ray and MR environments. In collaboration with the vendor, we specified and installed a motorized X-ray table pedestal system (Miyabe; Siemens) on rails for docking and delivery of a patient cradle between the two systems. The cradle is designed for patients up to 200 kg, radiolucent for unattenuated X-ray transmission even at extreme oblique angulation, nonferrous and nonconducting for MRI compatibility and safety, having a foam comfort surface tolerable for awake patients during prolonged procedures (Tempur-Medical, Lexington, KY), yet thin enough for close proximity of posterior MR surface coils. The shell secures cables, pressure

transducers, sterile drapes, long intravascular devices, and supports intravenous pumps against dislodgment. The pedestal and shell move between modalities in approximately 50 sec (Fig. 2).

No commercial solution were available for satisfactory physiological monitoring of subjects during interventional MRI procedures. Dual X-ray and MRI 12-channel electrocardiogram (ECG) leads are not currently available because of the potential for inductive heating and their sensitivity to RF noise during MRI. Therefore, modality-specific ECG leads were reconnected to a single set of X-ray- and MRI-compatible electrodes (Radiolucent A10004; Vermed, Bellows Falls, VT) whenever the subject was transferred from one to the other. Intervention-quality physiologic monitoring capabilities were replicated using commercially available MRI hemodynamics monitor (Magnitude; Invivo Research, Orlando, FL) with customized cabling through an RF-filtered penetration panel to an analog-to-digital converter (Powerlab/16SP; ADInstruments, Colorado Springs, CO) and high-resolution in-laboratory video projection of instantaneous hemodynamics. This permitted uninterrupted monitoring of invasive blood pressure in addition to single-channel ECG, noninvasive blood pressure, and oximetry from the commercial system.

Real-time MRI sequences generate substantial audio noise (> 95 dB) because of continuous and rapid magnetic field gradient switching. This mandates hearing protection for staff and patients and makes verbal communications nearly impossible. In collaboration with commercial vendors (Phone-Or, Or-Yehuda, Israel, and Magnacoustics, Atlantic Beach, NY), we specified and installed a multichannel interventional MRI audio communications system using highly directional optical microphones, providing good noise suppression and open-microphone communications among staff. There is also a second channel for patient-staff communications.

In-laboratory systems control is modeled after conventional X-ray interventional laboratories. Three video streams are back-projected from custom-shielded inexpensive LCD projectors (InFocus, Wilsonville, OR) into the laboratory for display of real-time interventional images, scanner control, and instantaneous hemodynamics, respectively (Fig. 3). The scanner can be controlled either from the control room or in laboratory via wireless keyboards and mice.

The real-time MRI image reconstruction engine implemented by one of the authors (M.A.G.) has been described previously [4,11,12]. Briefly, a Linux-based multi-CPU computer extracts raw MR signals from the Siemens Sonata image reconstruction computer via Gigabit Ethernet for reconstruction and display to the operators with low latency (< 250 msec). Individual receiver channels are processed separately, for example, to adjust gain and to color-highlight signals associated with catheter devices. Additional interactive options include ECG-gating to freeze motion, variable temporal resolution by view sharing or altering the number of radial echoes incorporated into each image update [13], and device-only projection mode to disable slice selection and visualize the full extent of an out-of-plane catheter device similar to X-ray projection mode. Multiple slices may be imaged, individually manipulated, turned on or off, and combined with projection views. To visualize the complex relation of device position, function, anatomy, and delivered materials, a 3D rendering displays the slices at their respective locations in space.

The Surgi-Vision Intercept guidewire has a caliber of 0.030" and a length of 100 cm. It is insulated with polyester and coated with silicone. The distal 9 cm contains the imaging coil and spring tip; the proximal hub connects to an MRI interface box. The interface box consists of a balun, tuning/matching, and decoupling circuit. The interface is connected via a 100 cm coaxial cable (avoiding inadvertent coiling) to the Siemens Flex adaptor and thereby to the receiver chain of the scanner. In manufacturer phantom tests, the guidewire was associated

with trivial heating of a vascular phantom ($< 0.3^{\circ}\text{C}$) over 10 min of continuous fast-spoiled gradient echo scanning using a high flip angle (A.C. Lardo, personal communication).

Workflow

All staff were instructed formally on MRI safety and specifically to check clothing for unsecured ferromagnetic material before entering the XMR suite. Subjects received parenteral conscious sedation with midazolam and fentanyl according to institutional guidelines. Ferromagnetic materials were omitted from the instrument table except for puncture needles and introducer guide-wires, which were discarded immediately after use.

Subjects first underwent a baseline MRI with gadolinium contrast-enhanced 3D magnetic resonance angiography (MRA) and were permitted to rest off the table before the invasive procedure began in the XRF laboratory. Patients were prepared for sterile groin access with neck-to-foot sterile drapes and underwent standard transfemoral arterial runoff digital subtraction radiocontrast angiography (DSA) using calibrated marker catheters. Unfractionated heparin was administered to achieve an activated clotting time of 250–300 sec as desired. Target iliofemoral lesions were crossed retrograde or antegrade via iliac crossover using 0.018" or 0.035" steerable guidewires and exchanged for a 0.014" guidewire. IVUS was conducted using a solid-state phased-array transducer (Avanar, Jomed/Volcano Therapeutics) and automated pullback starting from an anatomic reference point (e.g., femoral bifurcation). Next, nonbraided sheaths (Brite-Tip, Cordis, Miami, FL, or Flexor Balkan, Cook, Bloomington, IN) were sutured into place and an unbraided (nonferromagnetic) 4 or 5 Fr Kumpe or multipurpose shape catheter (Angiodynamics, Queensbury, NY) was connected to a Tuohy-Borst hemostatic valve, advanced to the aortoiliac junction (or wherever), and used to exchange for the 0.030" Surgi-Vision guidewire coil. The guidewire coil was positioned under XRF before the distal 15 cm were unsheathed for MRI visualization by withdrawal of the exchange catheter. The coaxial connector cable was attached using a sterile plastic sleeve. The entire sterile field was covered with a clear sterile drape. ECG leads were changed before each transfer for otherwise uninterrupted monitoring. The MRI bore entrance and controls were covered with clear sterile drapes. Anterior MRI surface coils were placed inside clear sterile bags, positioned on top of the covered sterile field, and then secured with ordinary system belts. Transfer between modalities was accomplished with at least one sterile operator and at least two nonsterile assistants to control cable, lead, and intravenous connections. Patients and staff donned protective communications headsets before MRI scanning. After the MRI was completed, the patient was returned to the XRF system for completion of the percutaneous intervention using standard techniques.

Imaging

MRI was performed using a standard 3D gradient echo sequence (VIBE [14]) with the following parameters: field of view (FOV), 360×270 mm; matrix, 256×144 ; slice thickness, 2 mm; bandwidth (BW), 200 Hz/pixel; repetition time (TR), 6.2 msec; echo time (TE), 2.3 msec; yielding $1.4 \times 1.9 \times 2$ mm voxels. Real-time steady-state free precession (SSFP) MRI used TR/TE, 2.84/1.42 msec; BW, 800 Hz/pixel; FOV, 400×300 mm; matrix, 144×80 ; slice thickness, 6 mm; yielding $2.8 \times 3.8 \times 6$ mm voxels.

For quantitative angiographic analysis, target blood vessel sites were selected in relation to distance from upstream bifurcations (iliac or femoral). Images from all modalities were assessed offline for lumen area and diameter, reference area and diameter, lesion length using native vendor applications (for X-ray: Quantcor.QCA v4.0/CAAS II, PIE Medical, Maastricht, Netherlands; for MRI: Leonardo VB30A, Siemens; for IVUS: InVision Gold v4.0.1, Jomed/Volcano Therapeutics, Rancho Cordova, CA).

Analysis and Statistics

Images derived from the intravascular guidewire coil were corrected for sensitivity inversely proportional to distance from the coil center. Signal-to-noise ratio (SNR) was calculated as $SNR = SI_{ROI}/\sigma_{noise}$, where SI_{ROI} is the mean signal intensity in a given region of interest and σ_{noise} is the standard deviation of noise in a nonsignal region.

The primary comparisons were between IVUS and each of DSA, surface coil MRI, and intravascular MRI. First ANOVA compared all four measurements and then Dunnett's correction was applied for multiple comparisons with IVUS. SNRs were compared using Student's *t*-test but was not corrected for multiple comparisons. Continuous parameters are expressed as mean $\pm$ standard deviation.

RESULTS

Subjects

Seven subjects were enrolled. Three did not undergo intravascular imaging because, in the judgment of the investigators, clinical procedure duration was excessive. Four remaining subjects were enrolled with a mean age of 65 ± 17 . Two subjects underwent contralateral femoral access to external iliac and superficial femoral artery stenoses, and one each retrograde femoral access to ipsilateral common iliac artery stenosis and occlusion, respectively.

Safety

The first subject was transported between modalities using a Teflon sliding board and a free-moving gurney. This proved cumbersome, slow, and jarring. Thereafter, the motorized pedestal and sliding shell were employed as described above. Shell transfer without a patient requires 50 sec. However, during these clinical procedures, shell transfer required approximately 5 min for preparation and 5 min for transfer. Uninterrupted hemodynamic monitoring was successful in all subjects. Because MRI causes artifact on ECG tracings, intra-arterial pressure monitoring provided a useful adjunct to ECG rhythm monitoring.

There were no apparent complications of intravascular MRI. Specifically, there were no cases of wire dislodgment during transfer, assessed by XRF. There was no evidence of RF-induced heating of the guidewire coil, nor of heating-associated thrombus formation. No patient reported discomfort during MRI acquisition. There was no evidence of contamination of the sterile field nor of infection at 2-week follow-up.

Imaging

Artery measurements were indistinguishable between all four imaging modalities (Table I). Intravascular MRI confirmed intraluminal guidewire location in all cases. In the case of XRF-guided recanalization of chronic total common iliac artery occlusion, the guidewire coil demonstrated the subintimal position (Fig. 4D–G). In longitudinal slabs, the intravascular guidewire received adequate MR signal to be conspicuous along its entire shaft but not the distal several centimeters.

Both intravascular and conventional noninvasive MRI visualized adventitial borders. Both MRI techniques and IVUS identified external elastic lamina and lumen borders, while DSA identifies only lumen (Fig. 4A and C). Signal from the surface coil provided anatomic context (Fig. 4D), while the intravascular guidewire had a comparatively reduced field of view (Fig. 4E). Signal detected by the intravascular guide-wire coil was inversely related to distance from the coil; indeed, the high local signal interfered with image interpretation [7]. Comparing the target artery imaged using the two different MRI techniques, SNR was 52 ± 16 using the surface coil alone compared with 133 ± 53 using the intravascular coil ($P = 0.04$). In spite of this higher

SNR, without proximity correction, qualitative vessel wall imaging was not improved by the intravascular coil. Proximity correction (Fig. 4G) significantly improved artery imaging. However, conventional IVUS provided superior mural imaging in real-time (Fig. 4B) compared with nonreal-time surface-coil or intravascular-coil MRI, enabling identification of intimal and medial components.

In longitudinal slabs, the intravascular guidewire was conspicuous along its entire shaft but not the distal several centimeters. In real-time MRI sequences, which provide high temporal resolution at the expense of spatial resolution, color highlighting of signal from the intravascular guidewire coil (Fig. 5) provided good device visualization

Study Termination

Indeed, since mural imaging using Surgi-Vision 0.030" guidewires was not superior to IVUS, the protocol was terminated due to futility of further enrollment.

DISCUSSION

We explored the safety and utility of intravascular MRI both for the potential to track active catheters in humans during investigational therapeutic procedures and for the possibility of enhancing atherosclerosis imaging by close apposition of the MRI coil with the target tissue.

Intravascular Loopless Guidewire Coil Designs for Artery Imaging

Most MRI data are acquired as an amalgam of frequencies encoded onto specific positions of excited magnetic spins in space. Images are created by Fourier transformation of these frequency data, which assumes that all waveforms are periodic. When selected fields of view are too narrow, image elements suffer Nyquist aliasing or wrap-around artifact. The geometry of external MRI coils makes them ill-suited for narrow field of view imaging without some other compromise to overcome this Nyquist aliasing. In contrast, intravascular MRI coils may be positioned more closely to tissue of interest. Because coils like the one we employed are sensitive only for a few millimeters in any axial dimension, very narrow fields of view can be used for axial images without aliasing artifact. Unfortunately, in our experience, this potential advantage was offset by the relatively small incremental SNR provided by the loopless guidewire coil. SNR is the ultimate determinant of the achievable increase in spatial resolution or reduction in scan time. Other investigators report similar results in swine vessel wall imaging [15].

Using this intravascular coil design, the signal intensity is inversely related to distance from the guidewire surface. Satisfactory interpretation of guidewire coil images requires proximity correction of signal intensity, which is straightforward for cross-sectional images. Other investigators address this problem by positioning guidewire coils into veins neighboring the arteries of interest [7,16]. In spite of higher maximum SNR and CNR values, the end result was invasive imaging that was not dramatically superior to noninvasive imaging using conventional phased-array surface coils, even in deeper iliac arteries. Moreover, these nonreal-time MRI techniques generated images inferior to conventional real-time IVUS.

The loopless or quarter-wave design of the Surgi-Vision guidewire coil used here can be improved in more complex intravascular designs [16–19]. Some of those designs suffer other important limitations [20], such as inability to view or profile the entire shaft of the intravascular device for navigation under real-time MRI or difficulty with miniaturization. The loopless design also suffers in that coil sensitivity falls to zero near the tip, making it unsuitable for interactive navigation through obstructed or tortuous anatomy without further modification

[8]. However, we found the guidewire coil was well visualized along its sensitive region during real-time MRI.

Heating is another important safety consideration when using conductive intravascular devices [6,21], which can induce thermal injury or coagulation. The Surgi-Vision device we employed is specifically designed to suppress inductive heating, an important element of its regulatory approval package [22]. While we did not conduct in vivo thermometry, there was no palpable heating on the external or withdrawn wire, nor was there clinical evidence of severe heating such as thrombus accumulation on the intravascular guidewire coil.

These guidewire coils are not optimal for invasive imaging. However, their safety and visibility make them attractive for their originally intended application, which is to guide investigational interventional procedure under real-time MRI.

Combined XMR Suites

We have specified and assembled a combined XMR suite suitable for investigational XRF and MRI procedures in humans. Both laboratories operate independently of each other for simultaneous unrelated procedures; both can operate in conjunction for combined XMR procedures. The only major incremental capital outlay was for the motorized transfer table and for the RF and lead-shielded doors separating the laboratories. Therefore, such installations may be justifiable at research centers even while MRI-guided procedures remain investigational. Additional control, monitoring, communications, image display, and reconstruction functionality required relatively inexpensive additional equipment, although few commercial solutions are available.

While our goal is to conduct therapeutic procedures wholly under real-time MRI guidance, we believe egress should be available for bailout XRF treatment in case of unanticipated cardiovascular emergencies. This resembles the policy, common during the early years of percutaneous coronary angioplasty, of keeping cardiac surgery teams available on standby.

We describe a workflow that resembles ordinary XRF cardiovascular catheterization with minor alterations for MRI safety. While intermodality transport was safe in this small series and did not disrupt intra-vascular device position, multiple external devices and connections required careful supervision and several minutes of preparation when moving in either direction. Emergency egress drills, however, could be completed in less than 1 min.

Invasive physiological monitoring and high-resolution hemodynamic recordings are possible in both XRF and MRI environments, although a single seamless commercial system is not available. A universal monitoring lead interface, wired or wireless, would be attractive and would facilitate more rapid intermodality transport. More troublesome is the problem of monitoring for myocardial ischemia. Blood moving through the high magnetic field markedly distorts ECG signals. Filtered ECG signals may be satisfactory for QRS detection but not for monitoring repolarization (ST segment) changes. This has important implications for myocardial interventional procedures under MRI. During our animal experiments, our surrogate for ST segment ischemia monitoring is real-time MRI monitoring of myocardial wall motion.

This preliminary experience is a first step toward investigational human interventional MRI procedures. Applications might include targeted myocardial cell delivery, endoluminal valve placement, recanalization of totally occluded iliac arteries, or simple angioplasty procedures in children, who are more sensitive to late sequelae of radiation [23]. The Surgi-Vision *Intercept* coil is conspicuous during real-time MRI but will require improved tip visibility to guide complex therapeutic procedures. We have demonstrated satisfactory imaging, patient

handling, and monitoring. The biggest remaining obstacle is the paucity of commercially available clinical-grade devices suitable for real-time MRI.

In this limited experience, invasive MRI with an active device appears feasible and safe during peripheral angioplasty. Patients can safely be handled and monitored in an XMR interventional suite. A loopless quarter-wavelength guidewire coil provides good signal-to-noise for device visualization but adds little to images of iliofemoral arteries compared with IVUS. Further development of conspicuous catheter devices may enable advanced therapeutic procedures guided by real-time MRI.

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Fig. 1.

Schematic diagram of XMR suite showing the relationship of the X-ray and MR equipment. A: MRI system. B: X-ray system. C: Entrance. D: 5 Gauss magnetic field line. E: Patient access, outside 5 Gauss line. F: Staff access, inside 5 Gauss line. G: Common control room. H: Shielded window into X-ray laboratory. I: Shielded window into MRI laboratory. J: Rails for table pedestal. K: Shielded RF/X-ray pocket doors. L: X-ray instrument room. M: MRI instrument rooms. Diagram provided by Hannes Seissl.

Fig. 2. Intermodality patient transfer. Image from NHLBI cardiovascular interventional XMR suite. The shielded doors separating the independently operating X-ray and MRI units open under motorized control. The fluoroscope C-arm is rotated away. The X-ray pedestal is mounted on motorized rails and conveys the patient, transport shell, and associated equipment directly into the magnet bore.

Fig. 3.

In-room hemodynamics and image display. Image from inside the interventional MR scanner suite showing in-room display of three video streams back-projected from LCD projectors. The ceiling-mounted screen shows real-time interventional images (lower left), interactive scanner control (lower right), and instantaneous hemodynamics (top).

Fig. 4. Comparison of imaging modalities. A: Baseline digital subtraction radiocontrast angiogram shows occluded left common iliac artery. B: Intravascular ultrasound through 5 Fr catheter inside recanalized total occlusion. Marks are 1 mm apart. C: Final postrevascularization radiocontrast angiogram. D: SSFP MRI with only surface coil signal displayed. E: SSFP MRI with only the intravascular MRI guidewire coil signal displayed. F: Image combining surface and intravascular signal shown on B and C. Note the high local signal from the intra-vascular coil confounds image interpretation. G: Proximity-corrected version of intravascular image on E.

Fig. 5. Three-dimensionally rendered real-time MRI image (in which spatial resolution is sacrificed for high temporal resolution) demonstrating intraluminal guidewire (green) as it enters the common femoral artery and extends across common iliac artery. Top image contains anatomic labels.

TABLE I

Lesion Measurements by Imaging Modality*

Patient	Angiogram MLD,% ,LL	IVUS MLD, %, LL	Intravascular MRI MLD, %, LL	Surface MRI MLD, %, LL
2	1.1, 95, 18.6	1.3, 92, 18.5	1.2, 90, 19.0	1.4, 88, 20.0
3	5.7, 51, 12.1	4.1, 60, 12.0	4.0, 55, 15.0	5.0, 45, 18.0
5	1.3, 71, 71.2	1.9, 77, 77.6	2.0, 73, NA	2.1, 70, 90.0
7	0, 100, 32	0, 100, 32	0, 100, NA	0, 100, NA

* MLD, minimal lumen diameter, mm; %, percent stenosis; LL, lesion length, mm.