## Cardiovascular Catheters and Accessories: Ex Vivo Testing of Ferromagnetism, Heating, and Artifacts Associated With MRI

Frank G. Shellock, PhD • Vincent J. Shellock, BS

The purpose of this study was to evaluate the MR safety of cardiovascular catheters and accessories. Intravascular cardiovascular catheters and accessories were tested for MR safety at 1.5 T using previously described techniques with respect to the evaluation of magnetic field attraction (deflection angle method), heating (temperature measured immediately before and after performing MRI), and artifacts (using a fast spoiled gradient-recalled acquisition in steady state [GRASS] pulse sequence). Two devices were attracted (RV pacing lead and Oximetrix 3 SO<sub>2</sub> optical module) by the static magnetic field. Each of the other objects displayed no attraction. Heating was +0.2°C for the sample cardiovascular catheter tested (Opticath). Artifacts varied from moderate to severe, depending on the amount and type of metal present in the device. Despite these ex vivo test results, further safety consideration should be given to the cardiovascular devices that have a conductive wire component (ie, certain types of the cardiovascular catheters) because of the potential for inducing current and excessive heating in these devices during MRI, especially using a high-field-strength MR system. The cardiovascular

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catheters evaluated in this study or those with a similar design are not recommended for use in patients undergoing MRI procedures.

Index terms: Magnetic resonance, safety • Magnetic resonance, bioeffects

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**Abbreviations:** FOV = field of view, GRASS = gradientrecalled acquisition in steady state, MTC = magnetization transfer contrast, RF = radiofrequency, RV = right ventricular, SAR = specific absorption rate.

CARDIOVASCULAR CATHETERS and accessories are indicated for use in the assessment and management of critically ill or high-risk patients, including those with acute heart failure, cardiogenic shock, severe hypovolemia, complex circulatory abnormalities, acute respiratory distress syndrome, pulmonary hypertension, certain types of arrhythmias, and various other medical emergencies (1-5). In these cases, cardiovascular catheters are used to measure intravascular pressures, intracardiac pressures, cardiac output, and oxyhemoglobin saturation (1-4). Secondary indications include venous blood sampling and therapeutic infusion of solutions or medications (1-4). In addition, some cardiovascular catheters are designed for temporary cardiac pacing and intra-atrial or intraventricular electrocardiographic monitoring (5).

Because patients with cardiovascular catheters and associated accessories may require evaluation using MRI or these devices may be considered for use during MR-guided procedures, it is imperative that a thorough ex vivo assessment of MR safety be conducted for these devices to ascertain the potential risks of their use in the MR environment (6,7). Notably, there is at least one report of a cardiovascular catheter that melted in a patient undergoing MRI (8). Obviously, there are realistic concerns pertaining to the use of similar devices during MR examinations. Therefore, this study used ex vivo testing techniques to evaluate cardiovascular catheters and accessories with regard to magnetic

field attraction, heating, and artifacts associated with MRI.

#### MATERIALS AND METHODS

### Cardiovascular Catheters and Accessories

A total of 15 different cardiovascular catheters and accessories (Abbott Laboratories, Morgan Hill, CA) were selected for evaluation because they represent a wide variety of the styles and types of devices that are commonly used in the criticalcare setting (ie, the basic structures of these devices are comparable to those made by other manufacturers). Of these devices, the triple-lumen CVP catheter and CVP-PVC catheter (both used for central venous pressure monitoring, administration of fluids, and venous blood sampling; polyurethane and polyvinyl chloride, respectively), the thermoset-iced and thermoset-room catheters (both used as accessories for determination of cardiac output using the thermodilution method; plastic), and the Safe-set with in-line reservoir (used for in-line blood sampling; plastic) were determined to have no metallic components (Ann McGibbon, Abbott Laboratories, personal communications, 1997). Therefore, these devices were deemed safe for patients undergoing MR procedures and were not included in the overall ex vivo tests for MR safety. The remaining 10 devices were evaluated for the presence of magnetic field attraction, heating, and imaging artifacts associated with the use of a 1.5-T, 64-MHz MR system (Signa, General Electric Company, Milwaukee, WI). Table 1 provides a summary of these devices and their respective components.

#### Assessment of Magnetic Field Attraction

To assess magnetic field interaction for the cardiovascular catheters and accessories, the devices were suspended by a 30-cm length of silk suture (4.0 silk), attached at the estimated center of mass from a specially constructed device (a plastic protractor mounted on a wooden stand), so that the angle of deflection from the vertical could be measured, as previously described (9–16). The accuracy of

From the University of Southern California, School of Medicine, Los Angeles, CA (F.G.S.). Received March 13, 1998; revision requested May 6; revision received May 14; accepted May 15. Address reprint requests to F.G.S., 7511 McConnell Avenue, Los Angeles, CA 90045.

Device	Description and Metallic Content		
1. Transpac IV	Intended use for direct hemodynamic pressure monitoring, including arterial, left atrial, monary artery, and venous pressures. Disposable transducer monitoring kit with continu flush device and drip container. Metals include the following: Connector: bronze alloy with gold-plate finish Sensor: gold wire with aluminum bonding pads and silver paladium Leadframe: beryllium, copper, tin, and gold plate		
2. Opticath Catheter Model U400	Fiberoptic intravascular catheter that provides continuous in vivo monitoring of oxyhemo globin saturation without blood sampling and recording of intravascular pressures. Metals include the following: tantalum wire, stainless steel wire. Calibration component: stainless steel wire.		
3. Opticath PA Catheter with Ex- tra Port	Fiberoptic intravascular catheter that provides continuous in vivo monitoring of oxyhemo globin saturation without blood sampling and recording of intravascular pressures and ther modilution cardiac output. In addition, there is an extra port that can be used for infusion of fluid or medication. Metals include the following: Resistor leads: tin, copper, nickel Thermistor leads: nickel alloy Connector pins: brass, gold Solder: tin, lead Calibration component: stainless steel		
4. Opticath PA Catheter with RV Pacing Port	Fiberoptic intravascular catheter that provides continuous in vivo monitoring of oxyhemo globin saturation without blood sampling and recording of intravascular pressures and ther modilution cardiac output. In addition, there is a component to permit temporary pacing of the right ventricle. Metals include the following: Resistor leads: tin, copper, nickel Thermistor leads: nickel alloy Connector pins: brass, gold Solder: tin, lead Calibration component: stainless steel Pacing component: stainless steel, tantalum		
5. Opti-Q SvO <sub>2</sub> /CCO flow-di- rected thermodilution fiberop- tic continuous cardiac output pulmonary artery catheter	Intended for use as a system for assessment of the hemodynamic status of a patient, including the measurement of hemodynamic pressures (right atrium, pulmonary artery, and pulmonary capillary wedge pressures), cardiac output (thermodilution method), and venous blood sampling. In addition, this catheter provides continuous in vivo monitoring of oxyhemoglobin saturation without blood sampling. Metals include the following: Resistor leads: tin, copper, nickel Connector pins: brass, gold Thermistor leads: nickel alloy Solder: tin, lead Heater coil and lead wire: copper Calibration component: stainless steel		
6. TD Thermodilution Flow-di- rected Pulmonary Artery Cath- eter	Intended for use as a system for assessment of the hemodynamic status of a patient, including the measurement of hemodynamic pressures (right atrium, pulmonary artery, and pulmonar capillary wedge pressures), cardiac output (thermodilution method), and venous blood sam pling. Metals include the following: Resistor leads: tin, copper, nickel Connector pins: brass, gold Thermistor leads: nickel alloy Solder: tin, lead		
7. Torque-line Flow-directed Ther- modilution Pulmonary Artery Catheter	Intended for use as a system for assessment of the hemodynamic status of a patient, including the measurement of hemodynamic pressures (right atrium, pulmonary artery, and pulmonary capillary wedge pressures), cardiac output (thermodilution method), and venous blood sam pling. This catheter is designed to provide a high degree of directional control to facilitate insertion through the vascular and heart chambers. Metals include the following: Resistor leads: tin, copper, nickel Connector pins: brass, gold Thermistor leads: nickel alloy Solder: tin, lead		
8. TDQ CCO Flow-directed, Ther- modilution Continuous Car- diac Output Pulmonary Artery Catheter	Intended for use as a system for assessment of the hemodynamic status of a patient, including the measurement of hemodynamic pressures (right atrium, pulmonary artery, and pulmonary capillary wedge pressures), cardiac output (thermodilution method), and venous blood sam pling. Metals include the following: Resistor leads: tin, copper, nickel Connector pins: brass, gold Thermistor leads: nickel alloy Solder: tin, lead Calibration component: stainless steel Heater coil and lead wire: copper		
9. RV Pacing Lead	Intended for use in temporary right ventricular pacing and can also be used for intraventric ular ECG monitoring. It is bipolar and constructed of coaxial round wire and a Teflon-coated coiled flat wire. Metal: stainless steel		
10. Oximetrix 3 SO <sub>2</sub> Optical Mod- ule	Optical module intended for use with Opticath catheters for continuous in vivo monitoring o oxyhemoglobin saturation without blood sampling. Metals include the following: Circuit board and cabling: tin, copper, stainless steel, lead Connector pins: brass, gold		

# Table 2 Summary of Test Results for Magnetic Field Deflection Angle, Artifact Grade, and Heating of Cardiovascular Catheters and Accessories Tested for MR Safety

Device	Magnetic Field Deflection Angle (°)	Artifact Grade (+1 to +4)	Heating (°C)	
1. Transpac IV	0	+4		
2. Opticath Catheter Model U400	0	+3	+0.2	
3. Opticath PA Catheter with Extra Port	0	+4		
4. Opticath PA Catheter with RV Pacing Port	0	+4		
5. Opti-Q SvO <sub>2</sub> /CCO Catheter	0	+4		
6. TD Thermodilution Catheter	0	+4		
7. Torque-line Thermodilution Catheter	0	+4		
8. TDQ CCO Catheter	0	+4		
9. RV Pacing Lead	90	+4		
<ol> <li>Oximetrix 3, SO<sub>2</sub> Optical Module*</li> </ol>	90	+4		
*Quality assurance testing conducted by technicians at Abbott Laboratories on the Optical Module indicated that it did not meet the established specifications for this device after it was exposed to the MRI environment.				

this measuring apparatus is  $\pm 0.5^{\circ}$  (based on the ability to read the protractor and the actual alignment of the protractor as it was positioned in a 1.5-T MR system with the aid of axial, coronal, and sagittal positioning lights) (10.12.14,15). The deflection angle was determined at the position of maximal gradient field force in the 1.5-T MR system, according to recommendations indicated by Kagetsu and Litt (17). This position was approximately 35 cm from the entrance of the bore of the MR system. The deflection angles for the cardiovascular catheters and accessories were measured twice and averaged.

#### Assessment of Heating

The assessment for the possible production of heat during MRI is only important for the cardiovascular catheters, since they would be in the immediate patientrelated area during operation of the MR system. Furthermore, because the metallic materials used for the Opticath Model U400 cardiovascular catheter were considered to represent a worst-case condition with respect to the conductive qualities of the materials, only this catheter was selected and utilized for the evaluation of heating. The wire component of the Opticath was exposed to permit surface temperatures to be recorded directly from this metal.

For the assessment of heating associated with MRI, the Opticath was placed in a "straight-to-curved" configuration, with the wire exposed (ie, the curved portion was approximately a 3.5-cm radius shape, similar to its shape and use in an in vivo condition) in a Plexiglas phantom filled with physiologic saline. Physiologic saline was used in the phantom to provide a means of surrounding the catheter with fluid that had a similar conductivity to that of the fluids of the human body. MRI of the device was performed using a T1weighted spin echo, magnetization transfer contrast (MTC) pulse sequence. The body coil was used to transmit and receive radiofrequency (RF) energy for a total imaging time of 60 minutes (12,15,16). The estimated whole-body averaged specific absorption rate (SAR) was 1.1 W/kg, and the spatial peak SAR was 5.2 W/kg, which

represents a relatively high level of exposure to RF energy. SAR values were based on the calculations provided by the MR system's software. The imaging parameters were as follows: TR/TE = 100/25 msec; flip angle =  $60^\circ$ ; field of view = 30 cm; matrix size =  $256 \times 128$ ; number of excitations = 10; section thickness = 1.0 mm. The above-described experimental conditions were selected in order to produce a "worst-case" condition with regard to the heating related to the use of MRI. Since there is no heat transfer from blood flow associated with this experimental method, it further simulates a worst-case condition.

Surface temperature was measured from the wire surface of the cardiovascular catheter immediately (within 5 seconds to prevent cooling before measurement of temperature) before and after MRI. Heat dissipation within 5 seconds (ie, the time it took to remove the phantom and measure the catheter/wire) is presumed to be negligible in consideration that there was no "blood flow" present and given the thermal inertia of this experimental model. A noncontact infrared thermometer (Medi-Therm, Fullerton, CA) (12,15,16) was used to record temperature. This infrared thermometer has an accuracy and resolution of 0.1°C.

#### **Assessment of Artifacts**

Artifacts were assessed by performing MRI with the devices individually placed inside a 2-lb beef phantom to simulate tissue interaction. The imaging plane was oriented to pass through the metallic portion of the devices in a perpendicular fashion. MRI was conducted using a send/receive, quadrature-polarized head coil and a fast multiplanar, spoiled GRASS pulse sequence, as follows: TR/TE = 100/7.1 msec; flip angle =  $30^\circ$ ; field of view = 20 cm; matrix size =  $256 \times 128$ ; number of excitations = 2; section thickness = 5 mm.

Artifacts were characterized using a previously published methodology as follows: neg = no artifact; +1 = artifact less than size of the metal in the device; +2 = artifact same size as the metal in the device; +3 = artifact slightly larger than size of the

#### • RESULTS

Based on the assessment of the magnetic field attraction, the RV pacing lead and the Oximetrix 3 SO<sub>2</sub> optical module demonstrated substantial magnetic field attraction (ie, the deflection angles were 90°). Quality assurance testing conducted by technicians at Abbott Laboratories on the Optical Module indicated that it did not meet the established specifications for this device after it was exposed to the MRI environment. Since the electromagnetic fields of the MR system substantially affected the function of the Optical Module, it is not recommended for use if it is exposed during an MR procedure.

The remaining devices were unaffected by exposure to the 1.5-T static magnetic field of the MR system (ie, the deflection angles were 0°). Quality assurance testing conducted by Abbott Laboratories technicians demonstrated that the Transpac IV was unaffected after exposure to the MRI environment (ie, the operational and functional parameters met the established specifications for the device).

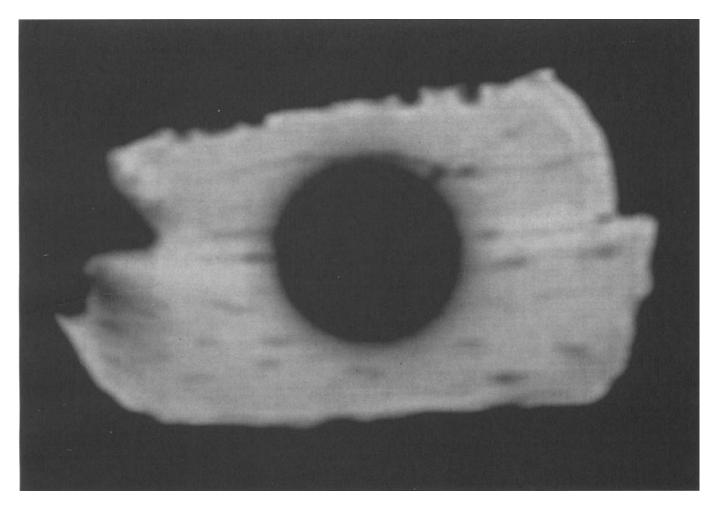
The temperature change measured for the exposed wire of the Opticath catheter was  $+0.2^{\circ}$ C after 60 minutes of MRI using the T1-weighted pulse sequence. The temperature of the physiologic saline in the phantom increased  $+0.1^{\circ}$ C.

The presence of the cardiovascular catheters and devices in the beef phantom caused a moderate (+3) to severe (+4) amount of distortion of the MR image that appeared as a signal void (Table 2). Figure 1 shows a representative example of a severe artifact (+4) caused by the presence of a cardiovascular catheter (Opticath).

#### DISCUSSION

Cardiovascular catheters and accessories are indicated for use in critically ill or high-risk patients (1-5). MRI, angiography, and spectroscopy procedures may play an important role in the diagnostic evaluation of these patients. Furthermore, the performance of certain MR-guided interventional procedures may require the utilization of cardiovascular catheters and accessories to monitor patients during biopsies, interventions, or treatments, Therefore, it is crucial to determine the MR safety and artifacts for these devices before they are considered to be acceptable for use in patients in the MR environment (6-19).

The ex vivo test designed to assess magnetic field attraction for the cardiovascular catheters and accessories indicated that two of the devices, the RV pacing lead and Oximetrix 3 SO<sub>2</sub> optical module, were attracted to the 1.5-T static magnetic field. Typically, it is not necessary for the Oximetrix 3 SO<sub>2</sub> optical module to be in the MR environment during a procedure, and therefore, this device should not present a problem. Of further note is that the RV pacing lead resides within the RV pacing catheter when in use. The RV pacing catheter is anchored in place by means of



**Figure 1.** Example of MRI of cardiovascular catheter (Opticath, 7Fr) using a fast spoiled GRASS (axial plane, TR/TE = 100/7.1; flip angle = 30°; FOV = 20 cm) pulse sequence. The presence of the catheter caused a severe (+4, artifact larger than twice the size of the metal in the device) signal void relative to the size and shape of the metal present.

applying a few sutures and a surgical dressing when used for an in vivo application. In addition, once the proper placement of this catheter has been verified, the RV pacing lead is secured within the catheter using a specialized valve (Touhy-Borst) at the proximal end of the pulmonary artery catheter. These collective procedures should serve to counterbalance the attractive force of a 1.5-T MR system and retain the device in position within the patient. Therefore, under the routine patient management conditions that are recommended in the product inserts for cardiovascular catheters (eg, "The catheter should be well secured to the patient to prevent inward and outward movement."), the attractive force from the static magnetic field of 1.5-T MR systems or less should not present a problem with regard to movement or dislodgement. However, this remains to be verified by additional testing of the effect of the counterforce relative to the magnetic attractive force acting on the catheter.

In this study, only a minor temperature increase of +0.2°C was recorded for the cardiovascular catheter selected for evaluation (Opticath) in association with MRI using a relatively high exposure to RF energy. This temperature level will not pose a risk to a patient undergoing MRI and is considered to be representative of the other cardiovascular catheters because of their similar design components. However, there are other concerns relative to heating of this device that should be recognized.

Excessive heating of bioimplants or devices made from conductive materials has been reported to be a hazard for patients who undergo MR procedures (6-8,19-22). This is particularly a problem for devices that are in the form of a loop or coil, because current can be induced in this shape during operation of the MR system, to the extent that a first-, second-, or third-degree burn can be produced (6,7,19-22). The additional physical factors responsible for this hazard have not been identified or well characterized (eg, the imaging parameters, specific gradient field effects, and size of the loop associated with excessive heating). For this reason, the present study did not attempt to investigate the effect of various "coiled" catheter shapes on the development of substantial heating during an MR procedure, particularly since there are many additional factors besides the shape of the catheter with a conductive component that can also influence the amount of heating that occurs during an MR procedure.

Although a thermodilution Swan-Ganz catheter (specific manufacturer unknown) is constructed of nonferromagnetic materials that include a conductive wire, a report indicated that a portion of this catheter that was outside the patient melted during MRI (8). It was postulated that the high-frequency electromagnetic fields generated by the MR system caused eddy current-induced heating of either the wires within the thermodilution catheter or the radiopaque material used in the construction of the catheter (8). This incident suggests that patients with this catheter or a similar device that has conductive wires or other components could be potentially injured during an MR procedure.

Furthermore, heating of the wire or lead of a temporary pacemaker (eg, the RV pacing lead) is of at least a theoretical concern for any similar wire in the bore of an MR system (6,7). Cardiac pacemaker leads are typically intravascular for most of their length, and heat transfer and dissipation from the leads into the blood may prevent dangerous levels of lead heating to be reached or maintained for the intravascular segments of pacemaker leads. However, for the extravascular segments of these leads, it is at least theoretically possible that sufficient power deposition or heating may be induced within these leads to result in local tissue injury or burn during an MR procedure (6,7). A recent ex vivo study conducted by Achenbach et al (23) substantiates this contention, whereby temperature

increases of up to  $63.1^{\circ}$ C were recorded at the tips of pacemaker electrodes during MRI performed in phantoms.

Chou et al (24) also assessed RF-induced heating for an electrically conductive device with a wire component. In this study, the investigators exposed a spinal fusion stimulator to RF energy levels far in excess of what would occur during a typical MR procedure. The results indicated that heating was within acceptable levels for patients. However, if one of the metallic leads was broken, a substantial temperature increase could occur that would pose a substantial hazard to the patient. Therefore, it was suggested that a careful radiological examination using X-ray be performed to ensure that there are no broken leads before performing an MR procedure in a patient with this electrically conductive device (24).

Recently, Ladd et al (25) studied actively visualized catheters designed for use in interventional MRI procedures and noted that heating was a function of many variables. The variables included the static magnetic field strength, the cable length, and the position of the cable in the MR system, as well as other factors. These authors reported a justifiable concern about using such devices in vivo at 1.5 T due to concerns about excessive heating.

Because of these obvious deleterious and unpredictable effects, patients referred for MR procedures with cardiovascular catheters and accessories that have internally or externally positioned conductive wires or similar components should not undergo MR procedures because of the possible associated risks (6-8,23). Further support of this recommendation is based on the fact that inappropriate use of monitoring devices during MR procedures is often the cause of injuries to patients (6-8,19-22). Numerous first-, second-, and third-degree burns have occurred during MR procedures that have been directly attributed to the improper use of physiologic monitoring equipment (6-8,19-22). These burns have primarily occurred in the MR environment in association with the use of devices that utilize a conductive wire interface to the patient; eg, electrocardio-graphic leads, wires, "hard-wire" pulse oximeters, and cables (6-8,19-22). The cardiovascular catheters and accessories evaluated in this study contained metallic materials that are good electrical conductors, which in turn could potentially present a hazard for a patient undergoing an MR procedure (22,23).

With regard to the artifact tests, the cardiovascular catheters and accessories produced artifacts that were moderate to severe, as shown by the ex vivo evaluation that was performed using a fast spoiled GRASS pulse sequence. From a diagnostic MRI standpoint, the presence of one of these devices may prevent adequate diagnosis if the device is located in the immediate area of interest. However, if the imaging area of interest is remote from the site of the catheter or accessory, it should not present a problem for interpretation of MR procedures. Nevertheless, this is a moot point because, as previously indicated, it is recommended that patients with the cardiovascular catheters and accessories evaluated in this study should not undergo MR examinations. Additionally, catheters and accessories from other manufacturers made from a similar design (ie. with conductive wire components, etc) are also likely to present problems to patients in the MR environment.

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