Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Examinations*

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In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with heart valve prostheses [including *transcatheter* aortic *valve* replacements (*TAVR*), *transcatheter* aortic *valve* implantation (*TAVI*) devices, percutaneous aortic *valve* replacement (PAVR) implants, *transcatheter heart valves* (THV), as well as other similar heart valve implants used in association with minimally invasive procedures] and annuloplasty rings (1-21).

MRI labeling information exists for numerous heart valve prostheses and annuloplasty rings. By following the MRI labeling information (i.e., presented in the *Instructions for Use*, Patient Identification Card, etc.), patients with heart valve prostheses and annuloplasty rings have, have safely undergone MRI examinations, including those performed using MR systems operating up to 3-Tesla (5, 16, 21). Notably, there has never been an adverse event reported in association with performing MRI in patients with these implants.

Unfortunately, the standard policy that MRI labeling information is required before allowing the use of MRI in patients with heart valve prostheses and annuloplasty rings limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. However, in consideration of the relevant peer-reviewed literature and other related documents (1-21), it is acceptable and safe to perform MRI examinations in patients with heart valve prostheses and annuloplasty rings by following specific guidelines developed by taking into consideration possible safety concerns (i.e., magnetic field interactions and MRI-related heating) for these implants.

By adhering to these conservative MRI conditions, patients with heart valves and annuloplasty rings can benefit from the diagnostic imaging information provided by this important noninvasive imaging modality.

Guidelines. A patient with a heart valve prosthesis or an annuloplasty ring may undergo MRI using the following guidelines:

- 3-Tesla or les
- No restriction on the direction of the static magnetic field

- No restriction on the value of the spatial gradient magnetic field
- Whole body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating in the Normal Operating Mode for the MR system)
- Maximum imaging time, 15 minutes per pulse sequence (multiple pulse sequences per patient are allowed)

*Important Note: The "Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Examinations" should only be implemented for use after the careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

Important Note: Any deviation from the above MRI conditions requires prior approval by a supervising physician.

Important Note: These guidelines must be reviewed on an annual basis to confirm that no heart valve prosthesis or annuloplasty ring has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe.

References

(1) Ahmed S, Shellock FG. Magnetic resonance imaging safety: Implications for cardiovascular patients. Journal of Cardiovascular Magnetic Resonance 2001;3:171-181.

(2) Edwards MB, Taylor KM, Shellock FG. Prosthetic heart valves: Evaluation of magnetic field interactions, heating, and artifacts at 1.5-Tesla. J Magn Reson Imag 2000;12:363-369.

(3) Frank H, Buxbaum P, Huber L, et al. *In vitro* behavior of mechanical heart valves in 1.5-T superconducting magnet. Eur J Radiol 1992;2:555-558.

(4) Hassler M, et al. Effects of magnetic fields used in MRI on 15 prosthetic heart valves. J Radiol 1986;67:661-666.

(5) Karamitsos TD, Karvounis H. Magnetic resonance imaging is a safe technique in patients with prosthetic heart valves and coronary stents. Hellenic J Cardiol 2019;60:38-39.

(6) Levine GN, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices: An American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization. Circulation 2007;116:2878-2891.

(7) Maragiannis D, et al. Functional assessment of bioprosthetic aortic valves by CMR. JACC Cardiovasc Imaging 2016;9:785-93.

(8) Myers PO, et al. Safety of magnetic resonance imaging in cardiac surgery patients: Annuloplasty rings, septal occluders, and transcatheter valves. Ann Thorac Surg 2012;93:1019.

(9) Pruefer D, et al. *In vitro* investigation of prosthetic heart valves in magnetic resonance imaging: Evaluation of potential hazards. J Heart Valve Disease 2001;10:410-414.

(10) Randall PA, et al. Magnetic resonance imaging of prosthetic cardiac valves *in vitro* and *in vivo*. Am J Cardiol 1988;62:973-976.

(11) Saeedi M, Thomas A, Shellock FG. Evaluation of MRI issues at 3-Tesla for a transcatheter aortic valve replacement (TAVR) bioprosthesis. Magnetic Resonance Imaging 2015;33:497-501.

(12) Shellock FG. Biomedical implants and devices: Assessment of magnetic field interactions with a 3.0-Tesla MR system. J Magn Reson Imag 2002;16:721-732.

(13) Shellock FG. Prosthetic heart valves and annuloplasty rings: Assessment of magnetic field interactions, heating, and artifacts at 1.5-Tesla. Journal of Cardiovascular Magnetic Resonance 2001;3:159-169.

(14) Shellock FG, Morisoli SM. Ex vivo evaluation of ferromagnetism, heating, and artifacts for heart valve prostheses exposed to a 1.5-Tesla MR system. J Magn Reson Imaging 1994;4:756-758.

(15) Shellock FG, Shellock VJ. MRI Safety of cardiovascular implants: Evaluation of ferromagnetism, heating, and artifacts. Radiology 2000;214:P19H.

(16) Shellock FG. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2020 Edition. Biomedical Research Publishing Group, Los Angeles, CA, 2020.

(17) Shellock FG. Biomedical implants and devices: Assessment of magnetic field interactions with a 3.0-Tesla MR system. J Magn Reson Imag 2002;16:721-732.

(18) Soulen RL. Magnetic resonance imaging of prosthetic heart valves [Letter]. Radiology 1986;158:279.

(19) Soulen RL, Budinger TF, Higgins CB. Magnetic resonance imaging of prosthetic heart valves. Radiology 1985;154:705-707.

(20) Shellock FG, Crues JV. MR procedures: Biologic effects, safety, and patient care. Radiology 2004;232:635-652.

(21) <u>www.mrisafety.com</u>

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