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UPDATES ON CARDIAC DEVICES: MRI CONDITIONAL CARDIAC IMPLANTABLE ELECTRONIC DEVICES (CIEDS)

Shital Sharad Panchal*

Department of Pharmacology, Institute of Pharmacy, Nirma Univrsity, S.G. Highway, Chhaodi, Ahmedabad-382482.

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***Correspondence for Author**
Dr. Shital Sharad Panchal
Department of Pharmacology, Institute of Pharmacy, Nirma Univrsity, S.G. Highway, Chhaodi, Ahmedabad-382482.

ABSTRACT

It is imperative to monitor patients with the Implantable Electronic Devices viz. cardiac implantable electronic devices (CIEDs) comprising of pacemaker, Implantable Cardioverter Defibrillator (ICD) and cardiac resynchronization device. Magnetic Resonance Imaging (MRI) is the one of the approved techniques, may be required for such watch over at any point of life. Though CIEDs exhibit incompatible interference interactions during the MRI scan, changes in the devices are required to fabricate the compatible implantable devices. Currently in the field of cardiac implants, the MRI-conditional devices has shown great advancement ,which allow these devices being compatible with MRI imaging procedures and let the patients have the benefits of one of the important imaging technique MRI, provided that proper precautions are taken during the time of imaging.

KEYWORDS: CIEDs, MRI, ICDs.

INTRODUCTION

Cardiac Implantable Electronic Devices (CIEDs) are essential in the severe cardiac disorders and it becomes obligatory to implant them in such catastrophic condition for lifelong period. These devices comprise Implantable Cardioverter Defibrillator (ICDs), pacemakers as well as cardiac resynchronization device. Pacemaker implantation are suggested in various cardiac diseases like symptomatic sinus bradycardia, sick sinus syndrome, tachycardia-bradycardia syndrome, third degree (complete) atrioventricular block, atrial fibrillation with sinus node dysfunction, chronotropic incompetence, prolonged QT syndrome as well as cardiac resynchronization therapy with biventricular pacing.[1]

Cardioverter-defibrillator (ICD) implantation are advocated in numerous conditions. They can be allocated into 2 broad categories: primary prophylaxis and secondary prophylaxis against sudden cardiac death. An ICD is recommended as an initial therapy for secondary prophylaxis in survivors of cardiac arrest which are as a consequence of ventricular failure or hemodynamically unstable VT ICD implants are indicated as primary prophylaxis against sudden cardiac death.[1] ICDs have revolutionized the treatment of patients at risk of sudden cardiac death attributable to ventricular tachyarrhythmia. The FDA has approved four new heart pacing devices, i.e. the Dynagen Mini, Inogen Mini ICDs, the Dynagen X4, Inogen X4 cardiac resynchronization therapy defibrillators (CRT-Ds). The Mini ICDs are up to 24% thinner and 20% smaller by volume than other ICDs. ICD is explored as primary intervention for secondary prophylactic indication in victims of cardiac arrest which might attributable to VF or hemodynamically unstable VT. Published guidelines exclude implantation of devices in such cases where these conditions are "completely reversible".[2] Although this exclusion is somewhat controversial. Currently, most of the ICD implants are indicated for primary prophylaxis, even though the evidence for such implants is often less well established. Class I indications (i.e. the benefit greatly outweighs the risk, and the treatment should be administered) are, structural heart disease, sustained VT, syncope of undetermined origin, inducible VT or VF at electrophysiological study (EPS), left ventricular ejection fraction (LVEF) < 35% due to prior MI, at least 40 days post-MI, NYHA class II or III, LVEF ≤35%, NYHA class II or III, LVEF ≤30% due to prior MI, at least 40 days post-MI, LVEF < 40% due to prior MI, inducible VT or VF at EPS, etc. Class II a indications (i.e., the benefit outweighs the risk and it is reasonable to administer the treatment) are, unexplained syncope, sustained VT, nonischemic cardiomyopathy, normal or near-normal ventricular function, significant LV dysfunction, hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C), long QT syndrome, significant LV dysfunction, syncope or VT with beta-blockers, patients awaiting heart transplant, syncope or VT, brugada syndrome, giant cell myocarditis, catecholaminergic polymorphic VT, cardiac sarcoidosis, or Chagas disease.[1]

A permanent pacemaker is an implanted device that provides electrical stimuli, thereby causing cardiac contraction when intrinsic myocardial electrical activity is inappropriately slow or absent. In 1984, ACC (American College of Cardiology) and AHA (American Heart Association) published the first drafted clinical guideline for implantation of permanent pacemaker which were sequentially revised and published in collaboration with NASPE

(North American Society of Pacing and Electrophysiology), in 2002.[3] Primary indications for implantation of pacemaker placement are symptomatic sinus bradycardia, sick sinus syndrome, tachycardia-bradycardia syndrome, third degree (complete) atrioventricular block, atrial fibrillation, chronotropic incompetence, prolonged QT syndrome and cardiac resynchronization therapy. Secondary indications include cardiomyopathy and refractory neurocardiogenic syncope.

DIAGNOSIS IN CIEDS IMPLANTATIONS

There are different non-invasive methods available for diagnosis of CIEC implants like transesophageal cardiograph, FDG-PET scanning or CT scanning, MRI etc. Scanning and diagnosis of internal structure of various organs along with its vital physiology at certain level can be accomplished by MRI. MRI is the most important diagnostic tool for identifications cardiovascular diseases. Together with the MRI and known signs and symptoms it becomes more convenient to confirm the cardiovascular disease, viz. Atherosclerosis, Cardiomyopathy, Congenital heart disease, Aneurysm, Valvular heart disease and Cardiac tumors.

During MRI, the patients is placed inside a very large magnet structure which is capable of generating magnetic field. As a part of the physiological processes, the applied radio frequency with magnetic field produces different plane cross-sectional images with high quality. The produced images are recorded by the connected computers which can be used for interpretations. [4] The steps involved in the production of an MRI study [4] include following processes 1.) Application of a uniform, powerful outward magnetic field for alignment of the random water containing tissues under examination. Further it is obligatory to introduce the optimum RF energy with appropriate frequency to induce resonance. 2.) Application of gradient or spatial magnetic field parallel to introduction of RF energy in the tissues which will modulate the RF of the patient. 3.) Measurement of the emitted signals and conversion of frequency formation by using Fourier transformation technique form each location. Once the RF is left, the emitted signals are measured. The magnetic field created, are different at different locations so it will produce tissue contrast, which can be helpful for interpretation of the generated image. MRI usage has various advantages i.e. it produces non ionizing radiation; means it is less harmful which promote its practice more frequently to examine children and pregnant women. Adding to this it is noninvasive, easy to use, and comfortable for patients. Generated images are with sufficient contrast as well as easy to interpret

moreover it provides three dimensional images i.e. sagittal, oblique, coronal and direct images. It has no reported adverse effects till date. However it has also certain disadvantages like it needs very expensive equipment and the patients are required to be constrained in the closed places for a longer time (may be up to one hour)in very noisy equipment, images may be distorted with the metal ornaments or metallic implants like stents. Bone structure cannot be detected well but bone marrow can be examined. Cancer whether benign or metastatic cannot be differentiated. Several advances in MRI has been reported which bring its newer applications now as days. Like volume imaging (3D imaging), flow imaging, Fast spin, chemical shift imaging, magnetization transfer contrast, electron spin resonance, MR elastography, etc.[5] Many reports indicate that the strong magnetic field, applied to the patients, may not be safe where certain activated (electrical, magnetic or mechanical) devices are implanted in the patients. These devices include artificial heart valves, cardiac pacemakers or implantable defibrillators. The imaging becomes necessary to diagnose and determine therapeutic interventions necessary for patients implanted with such medical devices and admitted in emergency care unit to advocate critical therapy. So device –MRI incompatibility interactions lead to exhibit severe life taking problems to the patients. CIEDs exhibit incompatible interference interactions during the MRI scan include, ventricular fibrillation induction, rapid atrial pacing and rapid ventricular pacing, asynchronous pacing, pacing output inhibition, changes in the programming and heating due to device damage.[8] MRI is considered to be contraindicated in patients with the pacemakers of cardiac devices owing to the generated magnetic frequency which can exhibit many effects i.e. device failure and several incompatibilities.[6.7] Since last few years physicians and device manufacturers have been concerning seriously for identification of malfunction of the pacing systems to be implanted. Countless new challenges are arising to manufacture over and above use of sophisticated and complex newer devices. So the MR-conditional devices are emerged with modifications in its design and geometry.

OVERVIEW

Previously, non-MR compatible devices were considered as contraindicated for MRI scanning because of numerous device associated incompatibilities i.e device failure, lead tip heating, miss interpretation by the device and patient discomfort have been of concern. [9] Recent advancement in the devices i.e. newer MRI compatible devices can overcome these limitations. Certain changes were made in the devices to overcome the limitations for the MRI scanning difficulties, which are reduction in the use of the ferromagnetic materials to

overcome the magnetic field interactions and circumvent the device damage, shielding of the device to reduce the effects of the electromagnetic radiations on device, changing of the reed switch to the hall sensors and winding of lead wires to decrease the device- MRI interference as well as cardiac tissue and device heating due to the effect of the magnetic radiations and electrical conduction between the lead and the MRI [10]further activation of device telemetry functions by magnetic field may cause inappropriate battery consumption.[11]

Currently available leads are having very large diameter, stiffness which is uncomfortable for active fixation. New MRI-compatible devices have been developed which are polyurethane coated further they are thinner and tiny as well as safe for use as compared to previous non MRI compatible devices. [13]Some specific precautions are also required to be taken into account while device related changes have been made. i.e. maintenance of field strength, setting of the device in MRI compatible mode, after imaging reprogramming of the device, requirement of constant ECG monitoring, pulse oximetry and resuscitation facilities for the well-controlled circumstances.[14] In addition to all these precautions, it should (must and should doesn't come together) be performed under the supervision of the competent staff. Due to prerequisite of durable, conducive and biocompatible material, the choice of non-ferromagnetic materials is very limited. To reduce the effect of MRI on the cardiac device, maximization of the distance between the scanner and cardiac device is very helpful to decrease magnetic field interactions. [12]

Several study factors are suggested which should be considered during the MRI scanning of the patient having implantation of CIEDs. [15] The factors are mentioned below.

MR system: Horizontal as well as cylindrical bore magnet with static magnetic field around 1.5-T is the key need.Gradient magnetic fields with slew rate of 200-T/m/s must be used.

Patient screening: Patients with their implanted systems should be screened for fulfilling the following requirements like, the implanted device consisted of a sure scan device as well as sure scan leads because other combination can result in to hazard for the patient during MRI scans. Previously implanted (active or abandoned) medical devices, leads and lead extenders or adaptors should not be there. History of broken leads or leads with intermittent electrical contact should be taken to avoid such cases. The MRI-compatible pacing system implantation duration should be minimum of 6 weeks. The threshold values for the pacing should not be ≥2 V at 0.4ms pulse width. The lead impedance value should not be ≤200Ω and ≥1,500 Ω.

Patient positioning: The patient should be positioned within the bore properly so the isocenter is superior or inferior to the C1 vertebra or the T12 vertebra respectively.

Patient monitoring: Proper patient monitoring is required during the scanning. Verbal and visual contact should be maintained with the patient. The ECG and pulse oximetry is also required.

Pacemaker staff: Programming and Scanning should be performed in presence of a healthcare professional who is well trained for cardiology surescan.

Imaging staff: A healthcare professional with completed radiology Surescan training should be present during the MRI scan.

Based on the above condition Medtronic, Inc., Minneapolis, Minnesota has studied the MRI effect on devices and found no electrical reset, reported arrhythmias, generator output inhibition, or sensations (related with magnetic field interactions or pain). There were no significant changes have been observed in pacing parameters like sensing, threshold and impedance change) as compared to controls. Risk and benefits of the MRI conditional devices depends on the individual device manufacturing company. Because there are no specific guidelines regarding scanning beyond the specified limitations of an individual MR-conditional device, reliance on the current literature and the guidance of institutional review bodies regarding the risks and benefits in these situations are important considerations. [16, 17] One of the most considerable issue regarding the working efficiency of such MRI compatible devices include combination of the MRI compatible pulse generator and MRI compatible leads. Hence it becomes critical to select the compatible devices since their components remain only compatible with respective devices developed by individual manufacture company i.e. some manufacturers claim that there pulse generator works well with their company leads. In the cases where patients has been already implanted with the non MRI compatible devices required to be replaced with the device compatible with MRI should be acquired from the same manufacturer to prevent device related incompatibility. Many patients prefer to extend their device replacement date as long as possible due to the complications associated with the re-operation and also financial constraints. Reported data till date has good results when compared to that of non MRI compatible devices with the MRI compatible one and can be helpful in the patients with the CIEDs requiring MRI scanning.

CONCLUSION

These new MRI-compatible devices has outweighed the limitations of MRI and has shown great advancement in the field of cardiac implants allowing patients to take the benefit of one of the important imaging technique MRI, provided that proper precautions are taken during the time of imaging.

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