
Short Title: Off Label MRI

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Abstract:

Both non-MRI conditional and MRI conditional systems are widely available. Physicians must choose which type of device to place. While off-label MRI can often be done safely, significant administrative and financial burdens remain to the physician posing a significant dilemma as to which device to choose. These issues are reviewed in a detailed direct manner.


In this issue of PACE, Emory University report their experience of both magnetic resonance imaging (MRI) of non-MRI conditional devices (often called, “legacy devices” or “off-label MRI”) and MRI conditional devices. (1) Using the metric that any difference in outcomes of off and on label MRI only be considered relevant if “clinically actionable”, Shah, et al. conclude “the findings presented may suggest equivalent low clinical risk when MR imaging is performed in patients with MRI conditional and non-MR conditional devices, under the specific protocol utilized”. (1) In their series of 96 off-label scans, small non-significant lead parameter changes did not require lead revision or programming changes and no device reset, or device failures were observed.

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Shah, et al. note that the average time from implant to MRI was 3 years emphasizing the importance that clinicians who must choose which device to implant today have impact on their patient’s future access to MRI. (1)

While only a comparatively small series of patients were evaluated, the authors show that a standardized protocol developed by experts elsewhere (2) can translate well to another center (Emory) allowing safe off label MRI of device patients. Others are implementing the eponymous “Hopkins Protocol” in a like fashion. (3) This signals to other institutions that they might embrace well vetted “recipes for off label scanning” should they wish to start scanning patients with non-MR conditional devices. Encouragingly, such protocols may provide a foundation to help break down professional and institutional barriers that may exist amongst Radiologists and hospital administration regarding the adoption of needed off-label scanning programs. Additional guidance will arrive with the release of the upcoming “HRS Expert Consensus Statement on MRI and Radiation Exposure in Patients with CIEDs” expected in the Spring of 2017, likely with areas of controversy remaining after its publication.

There is nothing particularly magical or difficult about the fundamentals of such protocols regarding device management before or supervision during MRI, as they all (2, 4, 5) advocate the same framework: appropriate programming before MRI tailored simply to the patient’s pacemaker dependency with all other device features off, redundant monitoring with both EKG and pulse oximeter during MRI, and usually, minimizing the systemic absorption rate (SAR) which is programmable through the MRI console. (6) It
may be helpful for the clinician to simply remember the essential features of safe MR of CIEDs as “MR; monitoring and reprogramming”. New work suggests that safe MRI of legacy devices may proceed with less monitoring, perhaps lessening the supervisory burden of MRI of selected CIED patients. (7)

Protocols for scanning increasingly available MR conditional devices are well defined by the manufacturer’s product labeling with some manufacturers products approved for scanning at both 1.5 and 3.0 Tesla (T). For active radiology services with both 1.5T and 3.0T scanners, the ability to scan at both field strengths offers additional flexibility when scheduling patients as well as the added resolution due to an enhanced signal-to-noise ratio that comes with 3T scanning. Little has been published regarding off-label scanning at 3.0 Tesla, leaving a gap in our understanding of how safe off-label MRI at 3.0T is and no MRIs in the report by Shah, et al were performed at 3 Tesla. However, the limited published experience suggests the outcome of off-label scanning at 3.0 Tesla will be little different from that at 1.5 Tesla: generally safe (6, 8), with an occasionally troublesome power-on-reset (9).

At this point in our understanding, it would appear there is only a small incremental safety advantage when scanning MR conditional vs. non-MR conditional devices although even strong advocates of continued implantation of non-MR conditional devices state there is “less risk of clinically significant or insignificant events” during MRI of MR conditional devices. (10) While not mentioned in an otherwise excellent recent review (10), scattered reports of misadventures during off-label scanning (often, but not always, the result of

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inadvertent scans or failure to program the device properly prior to MRI) (9, 11, 12, 13) continue to be published on a regular basis that may give pause to those with air-tight confidence that off-label MRI is unambiguously “safe”.

The forthcoming full publication of the results of the MagnaSafe registry (13) will only add fuel to the debate about which type of device to implant likely tipping the scales toward the continued implantation of non-MR conditional devices. MagnaSafe presents a series of largely safe off-label scans of a variety of devices performed at 21 centers. While Shah, et al saw no power-on-resets in their relatively small series presented in this issue (1), the 6 power-on-resets reported and one ICD replacement required after MRI in MagnaSafe (a far larger series of 1500 off-label MRIs) may somewhat temper the enthusiasm for implanting non-MR conditional devices. (13) As noted in a recent review “The greatest potential risk is that of power-on reset in pacemaker dependent patients, which may change the programmed mode from asynchronous to synchronous, permitting oversensing of CMR signals and inhibition of pacing output.” (14)

At least 2 looming issues remain when thinking about off-label MRI of CIED patients: the oppressive overarching supervisory service burden of off-label MRI and most importantly, payment for the off-label MRI itself. The supervisory burden of getting an off-label MRI scanning program off the ground can be a challenge consuming a great deal of time, with institutional barriers encountered from both radiology staff and administration that must be overcome in a collaborative manner. (4) No matter how many
interdisciplinary meetings are held, as the primary gatekeepers of the MRI facility, many radiologists may simply say “No” to off-label MRI despite being presented with the “significant amount of clinical data demonstrating the safety of MR with legacy devices in appropriate settings”. (10) Patients deserving of MRI simply may not get them.

Unfortunately, even with the radiologist’s blessing, sometimes risk adverse administrators may pose a significant barrier to implementing a program of off-label scanning. Such barriers to MR-conditional device scanning simply do not exist after implanting a device that is already labeled MR-conditional as these devices have the all-important imprimatur of FDA approval, clearly stated pathways for scanning, and significantly, a flawless track record of safety when used as the labeling directs. While some CIED systems may gain retroactive FDA labeling as MR conditional, many systems implanted today will not.

Once the off-label MRI program is up and running, burdens remain. Despite claims to the contrary (10) suggesting no difference in the supervisory burden of on-label and off-label MRI, the additional supervisory burdens of off-label MRI continues during the run up to the off-label scan itself with centers typically reporting “all MRI requests in patients with pacemakers or ICDs are reviewed jointly by cardiac electrophysiology and radiology physicians” and “scans are limited to 1.5 Tesla machines”. (15) At Emory University, Shah, et al relate in their manuscript “All patients underwent formal, face-to-face evaluation with a cardiac electrophysiologist” (1) While it is hoped the appropriateness of all MRIs are reviewed, it goes without saying that such
burdensome collaborative risk-benefit assessment efforts are not required when scanning MR-conditional patients as the risk of mishap has been deliberately engineered out of the product.

While some have mentioned in passing the uncomfortable truth of the “lingering administrative issues related to compensation, medicolegal consequences, and compliance” (10) of off-label MRI, the fact remains as Do and Boyle note, “the Center for Medicare and Medicaid Services (CMS) are not reimbursing for MRI studies performed in patients with non-MRI conditional devices, which are still considered off-label, except under a research protocol. Given these significant financial barriers, most centers will not perform MRI on patients with non-MRI-conditional devices.” (15) In a companion publication from Emory, the investigators state off label MRIs performed are enrolled in an approved protocol: “However, since this institutional review board–approved study ended at our institution, in our practice Medicare patients with conventional CIEDs have been asked to sign a waiver, because Medicare will not pay for the MRI examination. Patients who choose to sign the waiver and proceed with MRI are billed for the study. In addition, coordination with billing is now necessary to ensure that for Medicare beneficiaries with conventional devices, these examinations are charged as a non-billable examination owing to the presence of the conventional CIED.” (16)

Notably, “CMS issued a NCD that provided coverage of MRI for beneficiaries with implanted pacemakers (PMs) or implantable cardiac defibrillators through Coverage with Evidence Development (CED)/Coverage with Study Participation
(CSP) in approved clinical studies of MRI.” (17) For centers who wish to receive payment for off-label MRI, development of a registry that satisfies CMS CSP requirement appears to be a way forward providing a “work around” for the problem of non-payment with at least 6 centers in the United States having an active registry up and running as of January of 2017. (3, 17) Some registries are not expected to complete enrollment until late 2021 (18) Some protocols ask referring physicians to complete forms “about the effect of the MRI clinical management strategy, planning of treatments and interventions, as well as if/how the MRI results prevented other diagnostic studies or interventions, and other exposures (such as to ionizing radiation or iodinated contrast from CT scans)” (19) Other protocols are single center and exclude pacemaker dependent patients (18) while others are “by invitation only” (20) all of which make it difficult for most patients with non-MR conditional devices to gain reliable, unburdened, affordable access to the MRIs their clinician’s believe they need, not to mention imposing additional paperwork burdens on the busy clinician. In short, unless a physician champions an IRB approved protocol that satisfies CMS requirements at the facilities at which you practice, there will be no payment for off-label MRI of CIED patients perpetuating the limited access issues that patients with non-MR conditional CIEDs now face.

Why in 2017, after nearly 10,000 off-label scans reported in the literature, the vast majority of which have proceeded uneventfully, have we reached this state of affairs, particularly when pretty much everyone believes that off-label MR when done properly is for the most part safe? From an administrative perspective, hospitals already stressed by razor thin margins, must engage in the unrelenting hiring of a cadre of costly administrative staff (none of whom...
provide direct reimbursable care to patients) that must be hired simply for compliance to gain payment for off-label scans. Alternatively, if such staff are not employed, clinicians involved in direct patient care must have their attention directed toward the burdensome task of filling out yet another form thereby taking them away from their important duties. Finally, by their nature of including essentially any pulse generator-lead combination, none of these CMS approved registries will ever have the statistical power to show that any particular pulse generator-lead combination is MR conditional, alone or when taken in aggregate. Whether CMS will grant payment outright for off-label MRI (perhaps in the next decade) without using the “work around” of Coverage with Study Participation registries now being used is, to say the least, unknown in an era where the future of health care financing itself is uncertain. It goes without saying, every non-MR conditional device placed tomorrow will simply add to this problem.

It is hard to know what we will learn from such registries other than what is already known; namely, off-label MRI can be done with a very large certainty that it will proceed safely with the exception of the infrequent, but sometimes serious consequences of power-on-reset and device and lead dysfunction. Frankly, CMS should simply pay for off-label MRI without the cumbersome work arounds that are now being implemented to gain payment as there is little to be learned from any registries.

In the end, the article by Shah, et al (1) in this issue of PACE adds to the growing confidence that off-label MRI can be done safely leaving physicians at a “fork in the road” (21) as to which type of the device they will place
tomorrow in their CIED patients who will likely need an MRI in the future. Physicians can be certain of their patients having unburdened, safe, reliable access to MRI tomorrow through the choices they make today. Let common sense prevail.
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