

Physician Survey

e Management of Cardiac Implantable Electrical Devices in Patients Undergoing Radiofrequency Ablation for Spine Pain: Physician Survey and Review of Guidelines

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Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received:
01-07-2020
Accepted for publication:
02-03-2020

Free full manuscript:
www.painphysicianjournal.com

Background: More patients with cardiac implantable electrical devices (CIEDs) are presenting to spine and pain practices for radiofrequency ablation (RFA) procedures for chronic pain. Although the potential for electromagnetic interference (EMI) affecting CIED function is known with RFA procedures, available guidelines do not specifically address CIED management for percutaneous RFA for zygapophyseal (z-joint) joint pain, and thus physician practice may vary.

Objectives: To better understand current practices of physicians who perform RFA for chronic z-joint pain with respect to management of CIEDs. Perioperative CIED management guidelines are also reviewed to specifically address risk mitigation strategies for potential EMI created by ambulatory percutaneous spine RFA procedures.

Study Design: Web-based provider survey and narrative review.

Setting: Multispecialty pain clinic, academic medical center.

Methods: A web-based survey was created using Research Electronic Data Capture (REDCap). A survey link was provided via e-mail to active members of the Spine Intervention Society (SIS), American Society of Regional Anesthesia and Pain Medicine, as well as distributed freely to community Pain Physicians and any receptive academic departments of PM&R or Anesthesiology. The narrative review summarizes pertinent case series, review articles, a SIS recommendation statement, and multi-specialty peri-operative guidelines as they relate specifically to spine RFA procedures.

Results: A total of 197 clinicians participated in the survey from diverse clinical backgrounds, including anesthesiology, physical medicine and rehabilitation, radiology, neurosurgery, and neurology, with 81% reporting fellowship training. Survey responses indicate wide variability in provider management of CIEDs before, during, and after RFA for z-joint pain. Respondents indicated they would like more specific guidelines to aid in management and decision-making around CIEDs and spine RFA procedures. Literature review yielded several practice guidelines related to perioperative management of CIEDs, but no specific guideline for percutaneous spine RFA procedures. However, combining the risk mitigation strategies provided in these guidelines, with interventional pain physician clinical experience allows for reasonable management recommendations to aid in decision-making.

Limitations: Although this manuscript can serve as a review of CIEDs and aid in management decisions in patients with CIEDs, it is not a clinical practice guideline.

Conclusions: Practice patterns vary regarding CIED management in ambulatory spine RFA procedures. CIED presence is not a contraindication for spine RFA but does increase the complexity of a spine RFA procedure and necessitates some added precautions.

Key words: Radiofrequency ablation, neurotomy, cardiac implantable electrical device, zygapophyseal joint, spondylosis, neck pain, low back pain, chronic pain

Pain Physician 2020; 23:E335-E342

With the aging population, the prevalence of patients with cardiac implantable electrical devices (CIEDs) is increasing (1-4). Symptomatic zygapophyseal (z-joint) osteoarthritis is also frequently encountered in older patients (5) and often treated with radiofrequency ablation (RFA) of the medial branch nerves. Thus the interventional pain physician must understand the risks of RFA procedures in patients with CIEDs and be prepared to manage them.

Several guidelines exist for perioperative management of CIEDs, but they do not specifically address RFAs for spinal pain; instead, these guidelines address the perioperative management of CIEDs with reference to ablation within solid organs typically undertaken in an operating room environment, and are not specifically targeted to providers who perform RFA procedures in an ambulatory clinic or otherwise nonoperative setting, in which the support of a licensed anesthesia provider may not be available (2,6-8). Only recently have publications, such as the Spine Intervention Society (SIS) Patient Safety Committee report, provided guidance specifically to the interventional spine physician (9). This report clarifies that the presence of a CIED is not a contraindication for spinal RFA, but recommends that additional precautions be taken, namely communication with the patient's primary cardiologist in advance of the procedure, and discussing the risks of RFA to patients with CIEDs during the informed consent. This report also describes some procedural and postprocedural precautions, including maintaining at least 15 cm between the grounding pad and CIED sensing leads, considering magnet use, reprogramming, and/or involving a device representative or electrophysiologist for the procedure or postprocedure monitoring (9). Although useful as an overview, this report still lacks details to serve as a decision-aid considering the varied combinations of CIEDs and types/levels of RFA procedures commonly encountered.

Hypothesizing substantial practice variability, physicians were surveyed regarding practice patterns related to RFA in patients with CIEDs. The literature was also reviewed to provide practical background information on CIEDs, specifically for the interventional spine physician. This summary will provide pertinent information to assist in management of CIEDs before, during, and after spine RFA procedures, including monitoring, magnet use, and reprogramming, depending on the particular CIED and procedure location.

METHODS

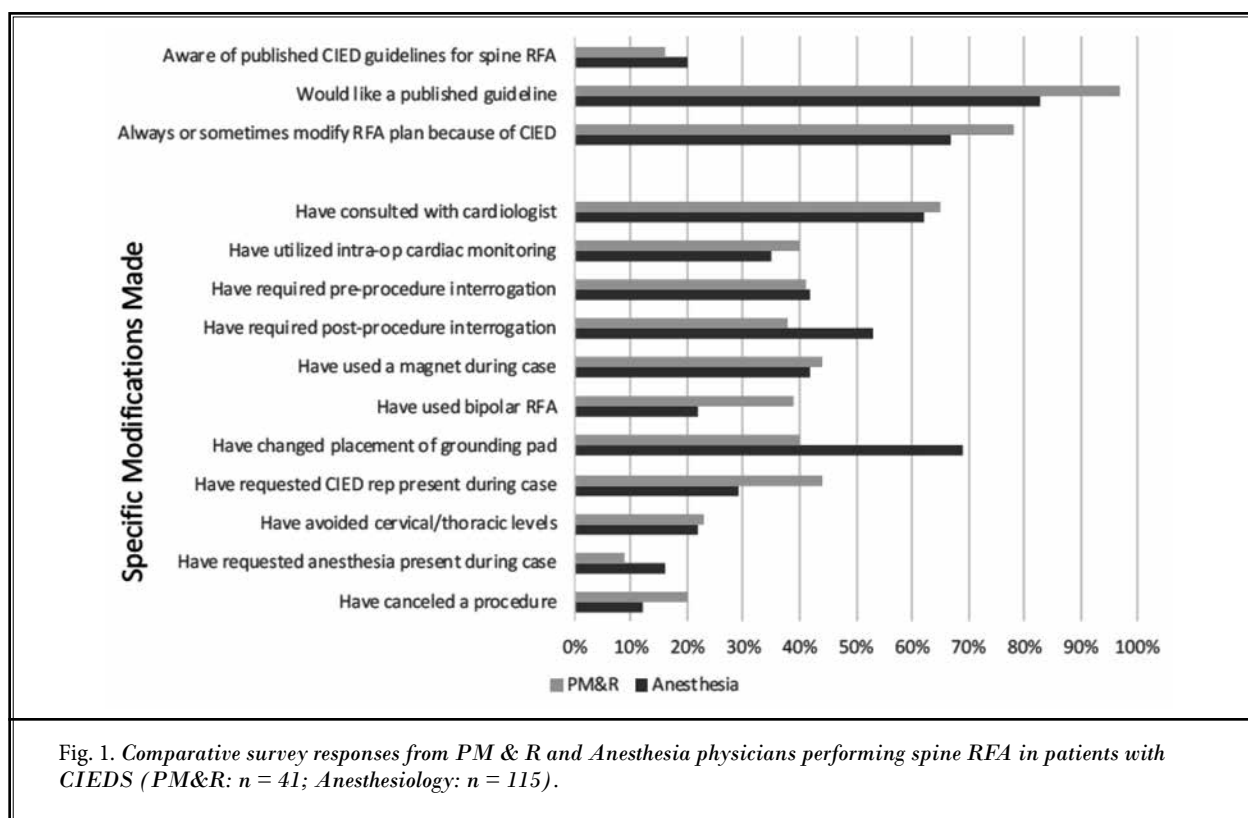
A web-based institutional review board–approved survey was created utilizing Research Electronic Data Capture (REDCap) (REDCap, Vanderbilt University, Nashville, TN) open from January 2019 to June 2019. The complete survey is included Appendix A. Surveys were distributed to members of the SIS, American Society of Regional Anesthesia and Pain Medicine (ASRA), as well as additional interventional spine providers from physical medicine and rehabilitation (PM&R) and anesthesiology in various academic and private practice clinics within the United States. For the narrative review, perioperative guidelines for management of CIEDs for noncardiac surgeries were reviewed (2,6-8), in addition to pertinent review articles (1,3,10-13) and case series, specifically relating to spine RFA (14,15). The only known recommendation statement pertaining specifically to spinal RFA comes from the SIS Patient Safety Committee (9).

Ethical Considerations

All participants were provided a written informed consent and could opt out of the survey at any time. The Colorado multiple institution review board (COMIRB) approved the consent, survey, and protocol.

RESULTS

Approximately 9,800 physicians received an e-mail with an active survey link and nearly 50% viewed the e-mail. A total of 342 physicians clicked on the link, and 197 physicians volunteered to participate in the survey. Of these respondents, 92.3% reported current usage of RFA in their practice and the majority reported more than 10 years of experience (60%) with RFA procedures, followed by 5 to 10 years of experience in 20% of the respondents, 1 to 5 years of experience in 16%, and only 4% with less than 1 year of experience. Survey participants were from a variety of primary specialties, including anesthesiology (70%), PM&R (25%), radiology (1.2%), neurosurgery (1.2%), and neurology (0.6%), with 81% reporting fellowship training. Most fellowship-trained clinicians reported training in pain medicine (91.3%), followed by sports medicine (6.8%), interventional radiology (0.6%), and spine surgery (0.6%). There were a variety of reported practice settings, including academic medical centers (31%), private practice (42%), hospital-employed or health maintenance organization (18%), and mixed practice type (9%). Eighty-four percent of respondents reported practicing in the United



States, whereas 16% reported practices outside of the United States. In the United States, the majority of clinicians were located in Colorado (14%), California (10%), Ohio and Illinois (5.3% each). There is currently wide variability in provider management of CIEDs before, during, and after RFA for z-joint pain. Figure 1 compares the responses in PM&R-trained physicians versus anesthesiology-trained physicians. An overwhelming majority of respondents indicated that they would like more specific guidelines to aid in management and decision-making around CIEDs and RFA procedures.

DISCUSSION

The results of the physician survey demonstrate variability in care for patients with CIEDs receiving RFA procedures for spinal pain, and consensus that there is a need for more readily available information on CIED management for interventional pain procedures. Although this article does not represent a consensus guideline, it does provide an evidence-based management review relevant to the interventional spine physician.

CIED Background Information Relevant to the Interventional Spine Physician

CIEDs include permanent pacemakers (PPMs), implanted cardiac defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. These devices serve to treat cardiac dysrhythmias and heart failure, as well as prevent sudden cardiac death. Although explanation of all the different device subtypes and settings is beyond the scope of this article, understanding some basic terminology can facilitate proper monitoring and management of these devices during percutaneous spine procedures. This section will categorize and define device types, electromagnetic interference (EMI), oversensing/inhibition, unipolar versus bipolar sensing, and inappropriate shock.

The primary concern around spine RFA procedures and CIEDs is the potential consequence of oversensing EMI: PPM inhibition in a pacemaker-dependent patient and inappropriate shock in a patient with an ICD. Phantom-reprogramming, in which EMI causes a change in the device settings, is not a concern with contemporary devices (7). PPMs can be atrial, ventricular, or "dual-chamber," and can be set to various modes depending

on the need. PPMs can both sense and deliver electrical activity. Asynchronous modes pace at a programmed rate, regardless of any intrinsic cardiac activity, whereas inhibitory modes sense intrinsic electrical activity and pace only if the intrinsic cardiac rate falls below the programmed capture rate. A triggered mode means the device is programmed to sense certain events, such as atrioventricular (AV) node delay, before initiating a pacing impulse. ICDs can detect and terminate ventricular tachyarrhythmias through delivery of a high-energy shock, but may also have pacemaker functions. CRT devices are a less common form of pacing, often specifically indicated for left bundle branch block or heart failure, to coordinate function of the left and right ventricles. These devices may or may not have a defibrillator function.

EMI is any electrical signal from an external source, such as RFA, that falls within the sensing spectrum of the CIED. Oversensing can occur when the CIED detects a noncardiac electrical signal. In the case of a PPM, oversensing of EMI can cause inhibition of pacing as the device spuriously detects EMI as intrinsic cardiac electrical activity. PPMs and ICDs can have either unipolar or bipolar sensing configurations. In the case of ICDs, EMI within the device's detection zone has the potential of tricking the device into applying an inappropriate shock as it senses EMI as a ventricular arrhythmia. Unipolar sensing configurations are more susceptible to EMI as the detection zone lies between the sensing electrodes and the generator just under the skin. The detection zone is much smaller in bipolar sensing configurations between 2 relatively close leads. Some select (brand-specific) CIEDs may contain a noise-reversion mode, which offers some protection against EMI (4): when high frequency EMI (such as RFA) is applied near a CIED with noise-reversion mode setting, the device automatically converts to asynchronous pacing. Noise-reversion is not available on all CIEDs.

RFA is a known cause of EMI and disruption of CIED function, especially when applied to the heart and thoracic cavity (4). Although there are no reported cases of RFA to the spine causing PPM or ICD dysfunction severe enough to cause serious injury or death, interference and inappropriate shock is possible (9). Taking specific precautions before, during, and after the RFA procedure can reduce risk.

Preprocedural Planning for Patients with CIEDs Receiving Spine RFA

Because of the known potential risks of RFA in patients with CIEDs, all patients scheduled for spine

RFA should be screened for the presence of a CIED, ideally no later than the medial branch anesthetic block or on review of response to this block. Individualized care and communication with the primary team that manages the device is critical to plan procedural management (2,6-9). Thus the primary device team needs to be identified either through patient query or from the electronic medical record. In cases in which there has not been a recent device interrogation (within 6 months for PPMs and within 3 months for ICDs), then the patient should be directed for follow-up with their primary cardiology office for device interrogation prior to undergoing the RFA procedure (7). If documentation of a recent device interrogation is available, then the interventional spine team should seek a device management prescription from the cardiology office. The device prescription should be readily available to the provider to review before and at the time of the procedure and should include device manufacturer, model, device type (PPM and/or ICD), PPM-dependency, magnet effects, underlying rhythm, date of last interrogation, and any patient-specific recommendations. The following patient would be considered especially high-risk for EMI, based on their device type and the planned procedure: PPM-dependent and ICD present and planned RFA above the umbilicus (at or cephalad to the L3 vertebral level). For these specific patients, an electrophysiologist or electrophysiology technician should be scheduled to be available on the procedure day to potentially reprogram the device before and after the procedure. It is important to understand that a device prescription is distinct from a device interrogation. Although an industry device representative can interrogate a device to produce a print-out of the device function, they cannot provide a device prescription or any medical decision-making for device reprogramming. This service should be performed by a cardiologist or a specifically trained representative from a cardiology or electrophysiology department (7,8).

Procedural Management of CIEDs in Patients Undergoing Spine RFA

Awareness of risks of EMI and risk mitigation strategies is critical to optimal management of CIEDs during an RFA procedure. The interventional pain physician should know in advance of the procedure the type and location of the device, and should have reviewed the preprocedural device prescription. Potential consequences of EMI oversensing should be discussed with the patient as part of the informed

consent, including the need for continuous monitoring, potential effects of EMI oversensing, and potential magnet application to inhibit ICD function or make a PPM function independent of intrinsic cardiac activity (i.e., asynchronous mode). The interventional spine physician should verify the immediate availability of the device magnet and discuss the device management plan with the procedure care team. All patients should be placed on continuous telemetry (with pacer-capture mode) with pulse-oximetry monitoring throughout the procedure.

Magnet Use

Only a minority of patients with CIEDs should require use of a magnet during percutaneous spine RFA procedures. A quick reference for CIED scenarios is provided in Table 1. Indiscriminate magnet use is not recommended as a magnet applied to a patient with a strong competing intrinsic rhythm (i.e., not PPM-dependent) could potentially trigger an arrhythmia (7). Furthermore, prone positioning during the RFA procedure may require a nurse, assistant, or device-representative to maintain magnet placement. The magnet has variable effects depending on the device (Table 2). In patients with ICDs, magnet application will turn-off tachy-therapy (shock) function. Normal ICD function will be restored with magnet removal. For patients with PPMs only (without ICDs), magnet application will activate asynchronous pacing mode at the predetermined manufacturer-specific rate (Table 2), and revert back to normal patient-specific settings on magnet removal. In patients with ICD and PPM, magnet

application will have no effect on the PPM function and will only suspend ICD function. This is especially important to understand in the patient who has an ICD and is PPM-dependent because magnet application will not protect the PPM from oversensing EMI with the potential consequence of asystole (2,7).

The interventional pain provider should consider using a magnet when the patient has an ICD, recognizing the risk of inappropriate shock is lower when the procedure is performed below the umbilicus (at or caudal to L3 vertebral level) or bipolar RFA is utilized. The exception is the patient with an ICD who is PPM-dependent and receiving RFA cephalad to the umbilicus (L3 vertebrae), in which reprogramming should be considered. In this situation, an electrophysiologist should be involved in the procedural care to reprogram the device before and immediately after the procedure (7,8).

Patients with PPMs without ICDs can generally be managed with continuous telemetry monitoring, immediate device-magnet availability, and risk mitigation strategies (see section later). The potential exception in this case is the PPM-dependent (no ICD) patient receiving RFA cephalad to the umbilicus (L3 vertebrae) in which provider discretion and shared decision-making is needed, along with recommendation from the primary cardiologist. Preemptive magnet use is reasonable in this scenario, but may not always be required in circumstances in which PPM-inhibition can be carefully monitored and risk-mitigation strategies (e.g., bipolar lesioning) can be applied. Regardless of the location of the procedure, if PPM-inhibition is observed during

Table 1. Decision-aid for spine radiofrequency ablation procedures in patients with cardiac implantable electrical devices (CIEDs)*.

Device/Dependency status	Procedure caudal to umbilicus (L3 vertebrae)	Procedure cephalad to umbilicus (L3 vertebrae)
PPM (no ICD)/ Non-dependent	Monitor	Monitor
PPM (no ICD)/Dependent	Monitor	Monitor or apply magnet Consider risk mitigation (i.e. bipolar RFA)
ICD (no PPM)	Apply magnet Monitor	Apply magnet Monitor
ICD and PPM/Non-dependent	Apply magnet to deactivate ICD (no effect on PPM) Monitor	Apply magnet to deactivate ICD (no effect on PPM) Monitor
ICD and PPM/Dependent	Apply magnet to deactivate ICD (no effect on PPM) Monitor	Reprogramming needed by cardiology before AND after procedure Monitor

*Decision-aid still requires clinical discretion as exceptions can occur based on individual clinical scenarios.

Table 2. Magnet Information for Common Devices*.

Device	Magnet Placement	Magnet Removal
PPM (no ICD)	Asynchronous pacing Medtronic: 85 bpm Boston Scientific: 100 bpm St. Jude: 96-100 bpm Biotronik: 90 bpm	Reactivation of previously programmed PPM function
ICD (no PPM)	Suspends tachytherapy Audible tone: Medtronic and Boston Scientific No tone: St. Jude and Biotronik	Tachytherapy re-activated Audible tone: Medtronic and Boston Scientific No tone: St. Jude and Biotronik
PPM and ICD	Suspends tachytherapy No effect on PPM	Tachytherapy re-activated No effect of PPM

*Some exceptions possible in older devices

RFA, then the RFA should be immediately ceased and a magnet applied with confirmation of asynchronous pacing mode before RFA is continued. Confirmation of asynchronous mode can be made through audible tones with magnet application in the case of Medtronic and Boston Scientific devices, or through pacer-capture setting on telemetry matching the manufacturer-specific rate (Table 2).

Reprogramming

Typically, CIED reprogramming should only be needed in patients with an ICD who are PPM-dependent and receiving RFA cephalad to the umbilicus (L3 vertebrae). In this case, the PPM will probably be set to asynchronous mode and ICD tachy-therapy may be suspended. Reprogramming should only be performed under the specific direction of a cardiologist or cardiac electrophysiologist (7,8). The industry-device representative cannot make reprogramming decisions. If reprogramming is performed, then external defibrillation equipment needs to be immediately available. Furthermore, it is the physician's responsibility to ensure the device is reprogrammed back to the preprocedure settings, including reactivation of tachy-therapy. Failures to restore tachy-therapies after surgical procedures have resulted in patient deaths (7,8).

Sedation

Rapid-acting medications used for sedation, such as diazepam and fentanyl, can increase cardiac conduction block, which is important in patients with sinus or AV node dysfunction. In some cases, the non-PPM-dependent patient may become PPM-dependent once sedated (2,7). This requires the provider administering sedation to closely monitor telemetry, ensure a magnet is immediately available, and be able to manage the PPM-dependent scenarios.

Risk Mitigation Strategies

Multiple risk-mitigation strategies exist to help the interventional pain physician complete a successful RFA procedure in patients with ICDs. Obtaining a device prescription is perhaps the best strategy to determine in advance of the procedure what is likely to be needed: monitoring, magnet application, or reprogramming. The procedural set-up can also reduce risk. The risk of EMI is low when the entire radiofrequency (RF) circuit (i.e., needle to grounding pad) is at least 15 cm away from the CIED components (2,4,7,9). The best method to reduce the RF circuit size is by utilizing bipolar RFA, instead of the more traditional monopolar. If monopolar is used, then the RF circuit (RF needle to grounding pad) should be minimized, kept as far from the CIED as possible, and arranged so that the current path does not cross the CIED or leads. During the procedure, use of pacemaker detection and careful monitoring of telemetry for bradycardia during stimulations and RFA can help identify PPM oversensing of EMI and the need for magnet use. Of course, if a significant arrhythmia, hypoxemia, chest pain, palpitations, or shortness of breath presents, the RFA should be immediately discontinued and appropriate medical management applied.

Postprocedural Management

In most cases, minimal additional postprocedural management should be required beyond the typical protocols for patients without CIEDs. However, post-procedure CIED management is needed at least in the following scenarios: (1) Preprocedure reprogramming occurred; (2) abnormal cardiac rhythms were noted during the procedure; (3) any potential CIED-related or cardiac complications occurred during the procedure (such as telemetry or cardiovascular abnormalities or patient-reported symptoms); and (4) cardiology device prescription recommends postprocedure interrogation.

In the first scenario, reprogramming back to preprocedural settings is critical and cannot be overemphasized. In the other 3 scenarios, postprocedure interrogation should be performed at a minimum, with cardiology consultation needed for any persistent symptoms or CIED abnormalities.

Limitations

Unique clinical situations encountered in the interventional pain clinic require individualized treatment and shared-decision making with the patient and the patient's cardiology team. Although this article strives to offer some clarity to a complex topic, it cannot provide a recipe for all possible clinical situations. Furthermore, a review such as this should not be confused as a multistakeholder clinical practice guideline.

CONCLUSIONS

Percutaneous RFA is a substantially beneficial procedure for some patients with disabling spinal z-joint arthritis. As the population ages, an increasing proportion of patients selected for spine RFA will have CIEDs. Although the presence of a CIED is not a contraindication for a spine RFA procedure, it does increase the complexity of decision-making before, during, and after the procedure. At a minimum, the interventional pain provider will need communication with the car-

diology team overseeing the device in the form of a device prescription, but should also understand basic principles of device function and management. RFA can be performed safely in patients with CIEDs when precautions and risk mitigation strategies are understood and applied.

ACKNOWLEDGMENTS

Author contributions: Drs. Friedrich and Itano had full access to all the data in the study and take responsibility for the integrity of the data analyses. Drs. Friedrich and Itano designed the study protocol. Dr. Friedrich managed the literature searches and summaries of previous work and wrote the first draft of the manuscript. Drs. Itano, Rzasa Lynn provided revision for intellectual content and final approval of the manuscript. We appreciate the University of Colorado Hospital electrophysiology department for their input and content review of the manuscript.(REDCap, Vanderbilt University) We would also like to show our gratitude to the professional societies who graciously distributed our institutional review board-approved survey to their member database, including the SIS, and the ASRA. We thank all of the physicians who volunteered to participate in our survey and take the time to provide meaningful feedback.

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