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Effects of medically generated electromagnetic interference from medical devices on cardiac implantable electronic devices: A review

Barmore W et al. Medically generated EMI and CIED

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Abstract

As cardiac implantable electronic devices (CIED) become more prevalent, it is important to acknowledge potential electromagnetic interference (EMI) from other sources, such as internal and external electronic devices and procedures and its effect on these devices. EMI from other sources can potentially inhibit pacing and trigger shocks in permanent pacemakers (PPM) and implantable cardioverter defibrillators (ICD), respectively. This review analyzes potential EMI amongst CIED and left ventricular assist device, deep brain stimulators, spinal cord stimulators, transcutaneous electrical nerve stimulators, and throughout an array of procedures, such as endoscopy, bronchoscopy, and procedures involving electrocautery. Although there is evidence to support EMI from internal and external devices and during procedures, there is a lack of large multicenter studies, and, as a result, current management guidelines are based primarily on expert opinion and anecdotal experience. We aim to provide a general overview of PPM/ICD function, review documented EMI effect on these devices, and acknowledge current management of CIED interference.

Key Words: Electromagnetic interference; cardiac implantable electronic devices; Pacemaker; Implantable cardioverter defibrillator; Implantable cardioverter defibrillators; Permanent pacemakers; Cardiac implantable electronic devices; Left ventricular assist device; Endoscopy; Bronchoscopy; Electrocautery; Capsule endoscopy; Transcutaneous electrical nerve stimulators unit; Spinal cord stimulator

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Core Tip: There are several infrequent yet significant sources of electromagnetic interference (EMI) on cardiac implantable electronic devices (CIED). These include both implantable devices and procedures. Patients with cardiac devices often may need

another implanted medical device or specific medical procedures. The potential resulting EMI can be minimized in order to make these treatments safer and still provide patients with therapeutic relief. A large, prospective study is critical to provide more robust and consistent literature regarding EMI effects on CIED. This will provide a clearer assessment of risk of EMI associated with variety of sources in addition to the development of evidence based clinical guidelines regarding management of patients with CIED.

INTRODUCTION

Cardiac implantable electronic devices (CIED) include two main broad categories of devices, implantable cardioverter defibrillators (ICD), and permanent pacemakers (PPM)[1]. Over the last decade, the indications for the use of these devices have increased. Since 2019, over three hundred thousand devices have been implanted every year alone in the United States^[2]. Hence, it is important for clinicians to recognize challenges involved in the management of these devices. One of the biggest challenges with these is electromagnetic interference (EMI), which occurs as a result of exposure of a CIED to an electromagnetic signal from other devices such as a smartphone, metal detector, taser, headphones and less frequently from internal and external medical devices, and surgical procedures. EMI can lead to inappropriate CIED function and have catastrophic consequences[3]. EMI can be interpreted by PPM as an intrinsic cardiac signal and result in inhibition of pacing, leading to bradycardia, and potentially cardiac arrest³. Similarly, EMI in patients with ICD can lead to inappropriate shocks due to perceived ventricular tachyarrhythmia^[3]. The aim of this 2-part review article is to discuss the infrequent sources of EMI: (1) From implantable devices; and (2) Surgical procedures, its interactions with CIEDs, and management options to prevent these undesirable consequences.

CIED INDICATIONS AND OVERVIEW:

As PPM and ICD become more prevalent, it is important to briefly review indications and general functionality of these devices. According to the ACC/AHA/HRS guidelines, PPM are most commonly indicated for sinus node dysfunction, symptomatic bradycardia, and atrioventricular block^[4]. The indications for ICD placement are divided into primary and secondary prevention^[5,6]. Primary prevention focuses on those patients who are at high risk for sudden cardiac death as a result of ventricular tachyarrhythmias. This typically includes patients with cardiomyopathies who are classified in New York Heart Association functional classes II and III with a left ventricular ejection fraction of 35% or less. Secondary prevention is indicated for those

patients with documented prior episodes of hemodynamically unstable ventricular arrhythmias of unknown etiology and in patients with sustained ventricular arrhythmias and heart disease^[5,6].

PPM and ICD are composed of a few components: generator, lead(s), an electrode at the tip of each lead, and, if an ICD, a shocking coil(s). The generator is located in the subcutaneous tissue of the upper chest wall or under the pectoralis major and is responsible for the generating a current that is transmitted by the leads. Leads may be inserted into one or more chambers of the heart depending on the type of CIED that is indicated. Each lead tip is in direct contact with the cardiac myocytes (Figure 1), and these leads are either unipolar or bipolar (Figure 2). A unipolar lead is a single conductor lead that transmits electricity in a unidirectional fashion, meaning the generator serves as the anode and the lead tip as the cathode with electrons flowing from anode to cathode (Figure 2A)^[7]. A bipolar lead has two isolated conductors on the tip with one serving as the anode and the other as the cathode (Figure 2B).

CIED RESPONSE TO INTERNAL AND EXTERNAL DEVICES:

There has been longstanding concern and scrutiny throughout the electrophysiology, chronic pain management, and physical rehabilitation communities in regard to potential electrical interference amongst internal and external medical devices, in particular left ventricular assist devices (LVADs), CIED, deep brain stimulators, transcutaneous electrical nerve stimulation (TENS) units, and spinal cord stimulators. We have summarized some of these concerns in Table 1. In regard to LVADs, Erquo *et al*^[8] presented the case of 60-year-old female patient with doxorubicin-induced dilated cardiomyopathy status post cardiac resynchronization therapy defibrillator who underwent LVAD pump exchange. The intraoperative exchange was uncomplicated; however, postoperatively it was noted that the patient was in complete heart block with her pacemaker no longer consistently pacing. The loss of consistent pacing was found to be secondary to increased RV lead sense amplification from the LVAD's pump rotation speed. To mitigate the pacemaker's oversensing, the low frequency attenuation filter

was disabled, which allowed the device to function without further inhibition. Additionally, Pfeffer *et al*^[9] outlined additional LVAD-ICD interference; however, this case differs from Erquo *et al*^[8] as it described the interaction between subcutaneous ICD and LVAD. This case involved a 42-year-old male with nonischemic cardiomyopathy who received 31 ICD shocks one hour after LVAD placement. This adverse interaction was due to superimposed electric noise from the LVAD in the setting of diminished R waves. This mixing of electrical noise was perceived as a shockable rhythm by the S-ICD. This patient's S-ICD was removed and a transvenous ICD was placed, which resulted in regular device function and no further ICD shocks on 6-month follow-up.

In addition, deep brain stimulators (DBS) and spinal cord stimulators (SCS) are becoming more prevalent as well. However, their adverse interactions with PPM and ICD are not well-documented. There are case reports that demonstrate a safe coexistence between CIED and DBS or SCS. Obwegeser et al^[10] demonstrates the safety of DBS in a patient being treated for essential tremor in the setting of a previously implanted ICD for sustained monomorphic ventricular tachycardia. This patient's DBS pulse generator was in close proximity of the ICD (10.5 cm away); however, after thorough testing, there was no inappropriate sensing by the ICD. The safety of DBS and ICD is further supported by Elliot et al[11], who analyzed 20 case reports with subclavicular DBS and PPM/ICD (some locations not stated) and found no effect of the DBS on a cardiac device; however, in one case a single ICD shock resulted in the deactivation of bilateral DBS devices. SCS also appear to safely coexist with PPM/ICD as demonstrated by Schimpf et al^[12]. They noted no oversensing of the impulses from the SCS by ICD or SCS device failure after an ICD-shock. Unipolar or bipolar stimulation from the SCS in different voltages or impulse rates resulted in no oversensing or adverse interaction with ICD function. There was potentially some concern for SCS used at the cervical level to induce probable interference with ICD/PPM given their proximity; however, a report by Thomas et al[13] found no potential interaction between cervical SCS with ICD in five swine models. No reports of cervical SCS adverse interactions with ICD are available in human patients.

In contrast to DBS and SCS, there are more reported adverse interactions between CIED and TENS units. Both Singh *et al*^[14] and Shenoy *et al*^[15] reported EMI from a TENS unit that resulted in an ICD shock. Singh et al^[14] details a S-ICD shock after a patient underwent TENS therapy in the neck, axilla, and back. This adverse interaction was likely due to the relatively superficial location of the S-ICD and its increased susceptibility to EMI, which ultimately led to an ICD shock after the device detected low-amplitude and high frequency signals^[14]. Shenoy et al^[15] further documents ICD and TENS interaction even in a patient with a transvenous ICD, who underwent TENS therapy in an unreported anatomic location. A single shock occurred during TENS therapy. Device interrogation revealed low-amplitude sinusoidal electrical activity during the patient's muscle therapy, leading to an ICD shock^[15]. These two reports support the increased risk of EMI-induced shock delivery from an ICD whether subcutaneously or transvenously placed. Similarly, past reports have analyzed a potential interaction between TENS units and pacemakers, and a general consensus was contraindication of TENS units in individuals during synchronous pacing but safety while use in those with asynchronous pacing.

In summary, the above studies suggest a low risk of EMI from DBS or SCS on CIED function. However, there is a greater risk of EMI arising from LVADs on pacemakers and defibrillators, and from TENS unit on defibrillators and certain older generation pacemakers as summarized in Table 2.

In order to minimize the interaction between stimulators (DBS, TENS unit, SCS) and CIED that is implanted, the parameter for each device should be assessed under "worst case scenario" settings. The stimulator is programmed to its maximally tolerated output while the cardiac device is programmed to its maximal sensitivity to assess for the effect of EMI. Once this effect is determined, the output from the stimulator should be decreased to the minimal value that will achieve therapeutic benefit and the sensitivity of the CIED is also decreased to prevent detection of stimulator output yet recognize underlying cardiac activity. In regard to LVAD, following the optimization of the LVAD function, the sensitivity of the CIED is adjusted to minimize detection of

EMI, sense R waves and allow for differentiation of R waves from T waves. Furthermore, in LVAD patients, RV pacing is preferential over biventricular pacing, as RV pacing has been associated with improved functional status, better quality of life, fewer arrhythmias, and potentially less EMI^[16].

SURGICAL PROCEDURES ASSOCIATED EMI WITH CIED:

Over the years, numerous studies have been conducted aiming to better understand the role of electromagnetic interference from surgical procedures with CIED. In this section, we will review the available literature relating to the EMI caused by various surgical procedures including endoscopy, bronchoscopy, electrosurgery and its interaction with CIEDs.

Endoscopies have revolutionized the field of gastroenterology by allowing clinicians to effectively diagnose and manage diseases of the gastrointestinal tract. Radiofrequency energy modality is commonly utilized by gastroenterologists during endoscopies to achieve hemostasis. This therapeutic modality has been a cause of concern for clinicians as a potential source of EMI that can interfere with CIED. To elucidate this potential interaction, Samuels at el. performed a Manufacturer and User Facility Device Experience (MAUDE) query between 2009-2019, and noted 45 reports of EMI causing CIED malfunction during endoscopy, which included 26 inappropriate shocks (65%), and less frequently, bradycardia, and asystole^[17]. In contrast, there have been smaller individual retrospective and prospective studies performed to evaluate EMI during endoscopy in patients with CIED which found no adverse interaction. In a study by Guertin et al^[18], 41 patients with ICDs underwent endoscopies with ICDs programmed to detection-only with abortive (or therapeutic) tachyarrhythmia therapies off. Post-procedural device interrogation noted no EMI or arrhythmic events triggered during the procedure^[18]. Similarly, in a large cohort study of 92 patients by Cheng at al. there were no observed adverse events on patients with defibrillators. Among the patients with a pacemaker, they observed three cases of EMI that was interpreted by the pacemaker as rapid atrial activity, which resulted in mode switching from dual

chamber pacing to ventricular pacing and two cases of detection of EMI as rapid ventricular activity resulting in inhibition^[19]. Even though these cohort studies have shown the safety of the use of CIED during endoscopy, Samuels *et al.* study clearly demonstrates a small risk of CIED dysfunction and inappropriate shock that was not observed in the aforementioned studies. These three studies demonstrate the potential effects of EMI during endoscopy with electrocautery on both pacemaker and ICD function. Therefore, until large multicenter studies are performed, clinicians should be aware of the potential risk of an CIED adverse event during these procedures. To mitigate the risk, reprogramming the device or magnet therapy is recommended, which will be discussed later in more detail.

The introduction of capsule endoscopy has transformed the field of gastroenterology as well; however, similar concerns of EMI during this procedure have been raised. Reassuringly, in a cohort study by Harris *et al*^[20] of 118 patients undergoing capsule endoscopy, no interference with CIED was reported. To further support the safety of capsule endoscopy, Bandorski *et al*^[21], performed an in-vitro investigation, in which they placed capsules used during the procedure at various distances to the lead and ICD device, and monitored device activity continuously. Interestingly, even at the closest proximity to the ICD (on top of the device), no interference was observed. However, similar to traditional endoscopy, no large studies have been performed evaluating EMI with CIED, therefore reprogramming the device may be appropriate during the procedure.

Over the last two decades, the field of interventional pulmonology has rapidly expanded. Procedures and modalities such as laser therapy, argon plasma coagulation, electrocautery, and electromagnetic navigational bronchoscopy (ENB) are being performed at higher rates than ever before. These procedures use heat and electrical energy and can produce an electromagnetic field which can generate EMI and affect devices in the vicinity, especially CIED. There are concerns of APC and electrocautery causing EMI given its configuration of current delivery. Electrocautery during bronchoscopy has two main modes of current delivery: monopolar and bipolar. In

monopolar configuration, current "entry" is delivered by the cauterizing instrument and leaves through the "ground" electrode, that is typically placed somewhere on the body (often the legs). In the monopolar configuration, the current has to pass through a large body surface area and can cause significant EMI, and ICDs can spuriously interpret the EMI as a tachyarrhythmia and result in an unnecessary shock. EMI in PPM can lead to inhibition of pacing, mode-switching, or reprogramming. EMI can be avoided if bipolar current configuration is used as the "entry" and "exit" electrodes are located at the tip of the cauterizing instrument, allowing for a very narrow EMI field. Similar to the monopolar configuration of the electrocautery, APC only has monopolar circuitry, causing a high risk of EMI. Lastly, per CHEST guidelines, ENB is contraindicated in patients with CIEDs given the electromagnetic field that it creates around the subjects^[22]. To better understand EMI from ENB, an in-vitro test was subsequently performed by Magnani et al^[23]. They noted insignificant EMI, with no interaction with CIEDs. However, this test was performed using a human torso simulator, with no replicative studies performed in humans due to the theoretical risk of CIED dysfunction given the large electromagnetic field that is created during these procedures. Overall, clinicians must be aware of the potential EMI leading to CIED malfunction during bronchoscopies.

Similar to bronchoscopy, electrosurgery is commonly used during surgical procedures to cut or coagulate tissue. The current configuration of electrosurgery is either monopolar or bipolar as stated above. Therefore, individuals undergoing any surgical intervention including general surgery, cardiac surgery, abdominal surgery, etc. are at risk of EMI with CIEDs, if monopolar current configuration is used by the operator. In addition to the monopolar current configuration, another factor that increases the likelihood of EMI with CIEDs is the distance between the surgical field where electrosurgery is being performed and the location of the CIED. In a study of 171 patients with ICDs, EMI was noted with monopolar configurations in 9 of 22 procedures above umbilicus, but in none of fifty-three patients below umbilicus^[3]. For procedures in close proximity to the CIED, temporary reprogramming is recommended

and will be discussed in the subsequent section. Recent HRS/ASA guidelines suggest that for procedures below the umbilicus, given the low concern for EMI, reprogramming is not recommended^[24]. Further detailed management of CIED interference will be discussed in the following section.

PERI-PROCEDURAL MANAGEMENT OF CIED INTERFERENCE

Due to the potential detrimental effects that EMI can cause with CIEDs, this section will discuss the interventions that can be applied to minimize and/or prevent EMI in CIEDs. The recommendations are generally based on expert opinion as there are no large multicenter studies performed to address EMI that occurs in patients with CIED.²⁵

Prior to any procedure, patients with CIED should undergo CIED interrogation within 6 to 12 mo to identify the type of cardiac device implanted and if the patient is device dependent^[17,25], which will ultimately dictate intraoperative and postoperative management.

The ACC/AHA guidelines recommend placing the device into an asynchronous mode for the entire duration of the procedure in device dependent patients who are undergoing EMI-generating procedures, whereas ASGE suggests it should be reserved only for prolonged (no specific length of time provided) endoscopy procedures in these patients^[17]. Asynchronous modes include dual chamber asynchronous pacing, asynchronous ventricular pacing, or asynchronous atrial pacing. These modes mitigate the potential adverse EMI that can result in intermittent of loss of pacemaker function via delivery of a constant, fixed stimulus without sensing capability. The pulse generator will then send a constant pacing stimulus regardless of external electrical influence. In addition, reprogramming or inactivating the tachyarrhythmia detection/management of ICDs is recommended. If this is not feasible, placing a cardiac magnet over the pulse generator is an alternative method^[26]. All CIED are fitted with a reed switch comprised of two magnetic metal strips that are separated. When these strips are activated via the application of a magnetic field, they come into contact, preventing sensing by a pacemaker resulting in asynchronous pacing and inhibition of

ventricular tachyarrhythmia detection and prevention of shock delivery by an ICD^[25,26]. Once the magnet is removed, the device will return to its pre-magnetic application modes/settings. Post-procedure management involves CIED interrogation and restoration of the devices to their original settings and pre-procedural therapeutic thresholds and sensing if they were reprogrammed before the procedure^[25].

In addition, the expert consensus statement by HRS/ASA further recommends any procedures associated with EMI that are performed geographically above the umbilicus, such as bronchoscopy, should also undergo the post-procedure management as described above^[25].

LIMITATIONS

While there is evidence to support concern for EMI on CIEDs, the literature primarily is comprised of case reports or small case series reviews. Therefore, the data regarding the risk of EMI from medical devices or procedures is often sparse and inconsistent. For instance, the MAUDE query performed by Samuels *et al*^[17] demonstrates a small risk of EMI on CIEDs during endoscopic procedures. However, given the limited quality of data available in the database it is difficult to identify the exact etiology of and clinical scenario surrounding each reported CIED malfunction^[17]. There are also conflicting studies reporting no adverse events during endoscopic procedures, thus it is challenging to conclude the true risk of significant EMI during endoscopy. Similar conflicting reports exist for a number of interventions suspected to interfere with CIEDs. Additionally, as a result of limited data, consensus recommendations from the HRS/ASA regarding management of CIED interference are heavily reliant on personal experience of prior patient management.

CONCLUSION

There are several infrequent yet significant sources of EMI on CIED. These include both implantable devices and procedures. Patients with cardiac devices often may need another implanted medical device or specific medical procedures. The potential

resulting EMI can be minimized in order to make these treatments safer and still provide patients with therapeutic relief. A large, prospective study is critical to provide more robust and consistent literature regarding EMI effects on CIED. This will provide a clearer assessment of risk of EMI associated with variety of sources in addition to the development of evidence based clinical guidelines regarding management of patients with CIED.

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