ICD-ON Registry for Perioperative Management of CIEDs: Most Require No Change

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Background: *There is significant variability in the perioperative management of patients with cardiac implanted electronic devices (CIEDs) undergoing procedures requiring electrosurgery.*

Methods: *We performed a multicenter registry from February 2014 to August 2015 at three suburban Chicago hospitals. Patients with transvenous CIEDs undergoing procedures requiring electrosurgery were assigned to one of three groups: (1) reprogram, (2) magnet, or (3) no change. Subjects with implantable cardioverter defibrillators (ICDs) or those pacemaker dependent having surgical procedures within 6 inches of their CIED were assigned to the reprogram group, whereby ICD therapies were programmed off with asynchronous pacing if pacemaker dependent. Subjects with ICDs ≥ 6 inches from their surgical site but above the iliac crest were assigned to the magnet group. All others were in the no change group. We evaluated electromagnetic interference (EMI) and postoperative device reset based on surgical location.*

Results: *All patients (n = 331) had pectoral CIEDs with mean age 73 years, 65% male, ejection fraction 56% for pacemaker subjects, 35% for ICD subjects with 22% pacemaker dependent. Assignments were n = 52 (16%) reprogram group, n = 51 (15%) magnet group, and n = 228 (69%) no change. There was EMI in 45% of thoracic cases, 35% of head/neck, 15% of upper extremity, and 3% of abdominal cases above iliac crest. There was no EMI in procedures below the iliac crest. There were no inappropriate therapies or device reset.*

Conclusion: *Results of the ICD-ON protocol demonstrate safe and efficient management of patients with CIEDs based on electrosurgery location, with 69% requiring no reprogramming or magnet application. (PACE 2017; 40:128–134)*

defibrillation, ICD, pacing, magnet, electrosurgery, EMI

Introduction

Patients with cardiac implanted electronic devices (CIED) are at risk of experiencing electromagnetic interference (EMI) from a variety of sources including electrosurgery. Monopolar electrosurgery is known to cause oversensing, potential for inappropriate implantable cardioverter defibrillator (ICD) therapies (i.e., shocks), pacing inhibition, and rarely device reset. However, improvements in noise detection, device filtering, and universal use of bipolar leads in current generation CIEDs make this risk very low.[1,2]

Several studies have been conducted demonstrating that EMI is unlikely in procedures where monopolar electrosurgery is used distant from the device.[3–10] In 2011, the Heart Rhythm Society/American Society of Anesthesiologists (HRS/ASA) published an Expert Consensus Statement on the Perioperative Management of CIEDs. They note that risk of EMI is considered so low for lower extremity procedures that "neither reprogramming nor magnet application are mandatory."[2] To this time, no studies have evaluated a "no change" approach to CIEDs during electrosurgery.

The risk of EMI during electrosurgery has traditionally been thought to be high and results in CIEDs being reprogrammed in the perioperative

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Table I.

ICD-ON Perioperative Management Protocol

- Pacemaker dependence and programmed magnet response evaluated preoperative
- Grounding pad on opposite side of ICD keeping electrosurgery path away from CIED

Surgical Procedure Above Iliac Crest	Surgical Procedure Iliac Crest and Below
≤6 inches from ICD: **Reprogram** therapies OFF w/ asynchronous pacing if PM dependent. ≤6 inches from PM: **Reprogram** asynchronous if PM dependent	ICD: **No change** PM: **No change**
> 6 inches from ICD: **Magnet**† > 6 inches from PM: **No change**†	
Bipolar cautery: **No change**	

†If PM dependent, observe for pacing inhibition. Minimize duration of electrosurgery if inhibition is seen. ICD = implantable cardioverter defibrillator; PM = pacemaker.

setting. It is important to note that this is not a benign practice. Som et al.[9] writes about an experience where a patient undergoing an ocular procedure had their ICD disabled, which lead to a delay to defibrillation and death from ventricular fibrillation. They concluded that ICD deactivation can usually be safely done by magnet application rather than ICD reprogramming, and that magnet use should be more liberally applied.[9]

We share Som's concern about disabling ICDs in all surgical cases. Therefore, in earlier work, we developed an ICD-ON perioperative management protocol for use in surgical procedures using monopolar electrosurgery greater than 6 inches from ICD generators. Use of this protocol resulted in significantly shorter time with ICD therapies off, fewer caregiver handoff communications, no risk of inadvertently discharging patient home with ICD therapies off, and no device reset.[6] In the current study, we expanded the ICD-ON protocol (Table I) to include pacemaker patients. This protocol is based on surgical location, pacemaker dependence, and programmed magnet response.

The consensus statement also recommends 1-month postoperative outpatient evaluation given concerns for device reset, though there is no evidence to support this time frame. We evaluated the use of routine postoperative outpatient CIED evaluations for those not requiring programming.

We hypothesized that a protocolized approach based on surgical location for perioperative management of CIEDs will promote better outcomes. Therefore, the purpose of this registry was to evaluate the effectiveness of the ICD-ON protocol for managing patients with CIEDs undergoing procedures with electrosurgery. Specifically, incidence of EMI based on surgical location, postoperative reprogramming needs for device reset, and reported pacing inhibition were analyzed. In the current study, we expanded the ICD-ON protocol to include pacemaker patients. In addition, we evaluated the use of routine postoperative outpatient CIED evaluation (either in office or remote) for those not reprogrammed. The goal of the ICD-ON protocol is to safely and efficiently manage CIEDs preoperatively, reprogramming CIEDs only when necessary based on the individual patient risk of EMI.

Methods

This study was a prospective multicenter observational registry for perioperative management of patients with CIEDs. The trial protocol was reviewed and approved by respective site institutional review boards and consent was obtained from each subject. CIED management was based on surgical location (Table I) described in the procedure section below.

Patient Population

Adult patients with transvenous CIEDs undergoing a procedure with anticipated electrosurgery were considered for enrollment. Patients with devices manufactured by Medtronic, Plc. (Minneapolis, MN, USA), Boston Scientific (St. Paul, MN, USA), or St. Jude Medical (Sylmar, CA, USA) were included, since they composed the vast majority of implanted devices at the enrolling centers. Subjects with a Boston Scientific ICD under the Product Advisory related to magnet performance were excluded; however, no such subjects were screened. Subjects with two electrosurgery operators were excluded, but again, no subjects were screened. From February 2014 to August 2015, 355 subjects were enrolled in the registry at three suburban Chicago community hospitals. Per protocol, subjects remained in the

study up to and including their postoperative interrogation.

Procedure

Preoperative

Once the subject was enrolled, magnet response and pacemaker dependence were reviewed remotely preoperatively. Pacemaker dependence was defined as either absence of intrinsic R waves less than 40 beats/min documented in device clinic records or history of atrioventricular nodal ablation. Distance of surgical location from CIED generator was determined. Based on the ICD-ON protocol (Table I), subjects were assigned to one of three groups: reprogramming group, magnet group, or no change group. Any ICD in the magnet group programmed to "ignore magnet" or "change tachy response with magnet" was to be reprogrammed to allow magnet use. However, no such subjects with this programming were screened or enrolled in the study.

Subjects with ICDs undergoing procedures requiring monopolar electrosurgery ≤6 inches from an ICD were programmed with therapies off. Boston Scientific ICDs were programmed with monitor only. Medtronic ICDs were programmed with detection on and therapies off, and St. Jude ICDs were programmed with therapies off. If ICD subjects were pacemaker dependent, they were reprogrammed asynchronous.

Pacemaker subjects undergoing procedures requiring monopolar electrosurgery ≤6 inches from pacemaker and who were pacemaker dependent were reprogrammed to asynchronous pacing. There were no changes to rate responsiveness or other sensors. There were no programming changes to CIEDs for those in the magnet group or no change group preoperatively. There was no programming or magnet application for those using bipolar electrosurgery.

Intraoperative

Placement of current return pad was per routine care, placed on the opposite side of the CIED, if possible. For left pectoral devices, the return pad was placed on the right. A whole body universal return pad (Megadyne Inc., Draper, UT, USA) was used if this was part of routine care for the procedure. Type and duration of electrosurgery was left to the discretion of the surgeon. Subjects were placed on continuous electrocardiogram monitoring and oximetry with emergency resuscitation equipment available per routine care.

For those ICD subjects requiring monopolar electrosurgery in the magnet group, a standard donut magnet (77 mm × 14 mm with 30-mm hole) was secured to the chest with tape over the ICD generator prior to electrosurgery and removed once electrosurgery was complete. Procedure time was recorded in the medical record and extracted during data collection for the study.

Postoperative

For those in the reprogramming group, CIEDs were reprogrammed back to preoperative settings immediately postoperatively. Subjects in the magnet group or no change group had their device interrogated at their next routine follow-up visit whether office or remote.

All postoperative interrogations were reviewed to determine if there was device reset and/or EMI. Programmed parameters were compared to preoperative interrogations to evaluate for device reset. Stored episodes/events from the date and time of surgery were collected. High ventricular rate episodes, mode switch episode with high ventricular rates, noise reversion, or stored arrhythmias that correlated with the date and time of the surgery were considered for EMI. EMI was defined as nonphysiologic oversensing. Electrograms and markers that correlated with date and time of surgery were reviewed by each manufacturer's respective qualified industry representative to confirm EMI.

For Medtronic subjects with ICDs in the magnet group, magnet application suspends detection and therefore no EMI episodes/events are stored. In these circumstances, the Medtronic Sensing Integrity Counter (SIC) was used to identify nonphysiologic short v-v intervals. Any SIC > 0 was evaluated by Medtronic technical services and considered EMI if they correlated with the date and time of the procedure.

Data Analysis

Baseline demographics and procedural data were summarized as means with standard deviation where appropriate. The primary outcome, EMI frequency, was determined separately for each of the five surgical regions (head/neck, thorax, upper extremity, abdomen/pelvis above iliac crest, and iliac crest and below). Based on earlier research, we anticipated that a sample size of 350 patients would provide standard errors of less than 10% for each surgical region.[6]

Results

A total of 355 subjects with transvenous CIEDs were enrolled. There were a total of 21 subjects withdrawn. Reasons included cancellation of procedure (5), no electrosurgery during procedure (14), and lost to follow-up (2). The two lost to follow-up are known to be alive but noncompliant with the study follow-up protocol.

Table II.

Subject Device Characterization

	Pacemaker Subjects	ICD Subjects
N	174	157
EF (SD)	56% (±10)	35% (±15)
PM dependent	n = 59 (35%)	n = 23 (15%)
Indications	Sinus node dysfunction n = 114 (66%) AV block n = 60 (34%)	Ischemic cardiomyopathy n = 88 (56%) Nonischemic cardiomyopathy n = 54 (34%) Other n = 15 (10%)

AV = atrioventricular; EF = ejection fraction; ICD = implantable cardioverter defibrillator; PM = pacemaker; SD = standard deviation.

Three subjects (one with a pacemaker, two with ICDs) died before outpatient device interrogation for reasons unrelated to their device. They had no programming changes and no magnet application during their procedures. Telemetry data from the postoperative hospital stay were reviewed for all three subjects, showing appropriate dual-chamber or biventricular pacing. A total of 331 subjects' data were analyzed: 174 pacemakers and 157 ICDs.

Participant mean age was 73 ± 10 years with 65% male. Left ventricular ejection fraction (EF), indications for CIED, and percent pacemaker dependent are displayed in Table II. Monopolar electrosurgery was used in 93% of subjects, with bipolar used in only 7%. Device generator manufacturers were Medtronic (n = 149, 45%), St. Jude (n = 92, 28%), and Boston Scientific (n = 90, 27%). Supine positioning (n = 287, 87%), prone positioning (n = 24, 7%), and lateral positioning (n = 20, 6%) were used in this study.

In the reprogramming group (n = 52, 16%), there were 18 pacemakers and 34 ICDs. The no change group (n = 228, 69%) included 153 pacemakers and 75 ICDs. In the magnet group (n = 51, 15%), there were three pacemakers and 48 ICDs (Fig. 1). The three pacemaker subjects had magnet use at the preference of the anesthesiologist, which was a deviation from the ICD-ON protocol.

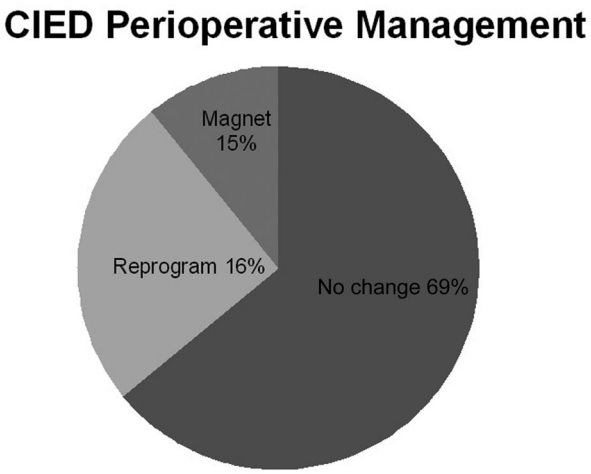

Figure 1. *CIED group assignments: no change (n = 228) included 153 pacemakers and 75 ICDs, reprogramming (n = 52) included 18 pacemakers and 34 ICDs, and magnet (n = 51) included three pacemakers and 48 ICDs. ICD = implantable cardioverter defibrillator.*

EMI

EMI was evaluated in 306 subjects. There were 25 subjects excluded from EMI analysis for the following reasons: 17 subjects were pacemaker dependent within surgical procedure within 6 inches (reprogrammed asynchronous) and thus, no EMI detection available in their specific device. One Medtronic ICD subject in the magnet group did not have SIC analysis available. Four subjects had limited device diagnostics available. Three subjects were reprogrammed with ICD therapies off but did not have monitoring programmed on.

Evaluable data from the CIEDs during electrosurgery demonstrated a total of 34 episodes (11%) of nonphysiologic oversensing suggesting EMI in 15 pacemakers and 19 ICDs. The incidence of EMI based on surgical location is displayed in (Fig. 2). Given close proximity to CIED, EMI was seen in 45% of thoracic surgeries. For nonthoracic surgery, there was EMI in 16 subjects (6%); of these, 10 were head/neck procedures, four upper extremity procedures, and two subjects with abdominal incisions. There were no episodes to suggest EMI in any procedures below the iliac crest (n = 143). There were no inappropriate shock therapies or device reset in any subjects.

Pacemaker-Dependent Patients

There were 82 subjects who were pacemaker dependent, 15% of ICD subjects and 34% of

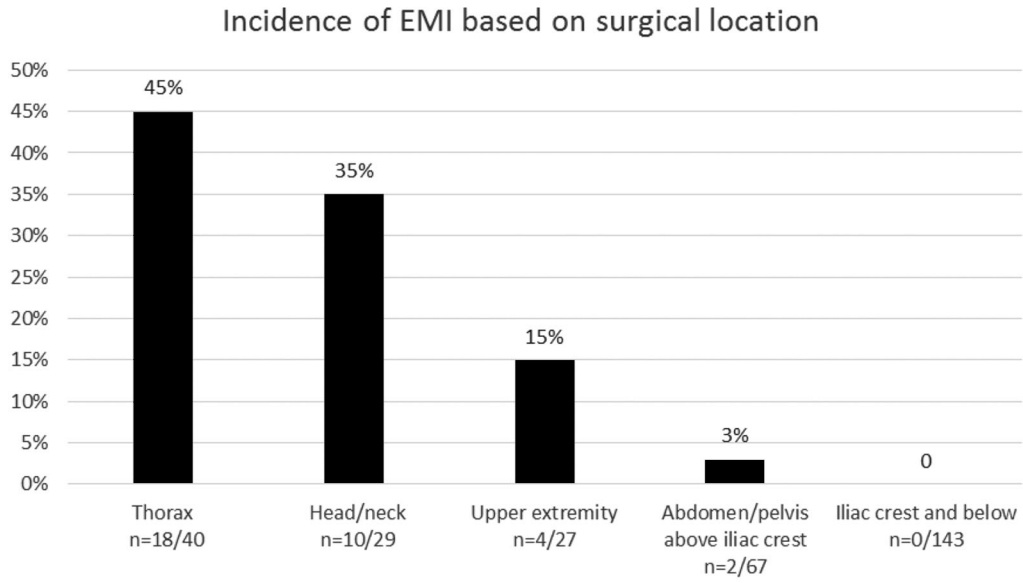

Figure 2. *Incidence of EMI Based on Surgical Location. EMI = electromagnetic interference.*

pacemaker subjects. All pacemaker-dependent subjects with a CIED that had a surgical procedure within 6 inches of the generator were programmed asynchronous and if an ICD, therapies off. There was one pacemaker subject having parathyroidectomy who had brief pacing inhibition noted intraoperatively. During preoperative review, the subject did not meet criteria for pacemaker dependence so no reprogramming was done. A magnet was used by the anesthesiologist to change to asynchronous pacing without further inhibition. There were no changes to pacing parameters or thresholds on postoperative interrogation.

Prone Positioning

There were 24 subjects with surgical procedures requiring prone position, 11 with ICDs and 13 with pacemakers. Of the 11 ICD subjects, none were pacemaker dependent, and only one (a left neck lesion removal) was in close enough proximity to require reprogramming. The remaining 10 subjects were lower lumbar spine or rectal surgeries (below iliac crest) and required no change. Of the 13 pacemaker subjects, six were pacemaker dependent. These included five lumbar spine surgeries and one mid-back lipoma removal. All surgical locations were >6 inches from the device, and in keeping with the ICD-ON protocol, no pacemaker reprogramming was required.

Reprogramming Needs for Device Reset

There were no unexpected programming needs for device reset.

Discussion

CIED Management

In order to best manage patients with CIEDs in the perioperative environment, it is important to understand the risk of EMI and determine best practices in their management. Risk of EMI may result in oversensing, potential for inappropriate ICD therapies (i.e., shocks), pacing inhibition, and rarely device reset. Our research supports prior EMI studies that show no surgical EMI below the iliac crest.[3–6,10] This simplifies perioperative management of CIEDs as nearly half (44%) of all the surgical procedures in our study were below iliac crest. Any ICD reprogramming has the potential for inadvertent discharge home with therapies off or worse: delay to defibrillation. In the case of procedures where electrosurgery occurs below the iliac crest, we recommend no change to the CIED.

For patients with ICDs having procedures with monopolar electrosurgery above the iliac crest and >6 inches from the CIED generator, our findings support the use of magnet application to disable ICD therapies.

An observation we made potentially impacting risk is perioperative patient positioning. Prone positioning can make magnet application challenging, depending on the specific position required and body habitus of the patient. The prone patient is uniquely vulnerable to the ability of the team to provide quick and efficient resuscitation interventions should they be required emergently during surgery. We believe that as with all patients, ICDs should be left with therapies

"on" if at all possible. In our study, of the 24 subjects requiring prone positioning, only one required reprogramming, all other devices had no change.

A barrier to magnet use with ICDs has been the concern for potential ICD reprogramming with magnet and potential to ignore magnet. All ICD subjects with Boston Scientific or St. Jude were evaluated for programmed magnet response. There were none programmed to ignore magnet in either this cohort or our prior study.[6] Earlier generation Boston Scientific (formally Guidant) ICDs had a "change tachy mode with magnet" programmable option. The existing Vitality ICDs with this programming option were approved in 2003 and distributed until 2007 with estimated battery longevity of 5.5–6.5 years.[11] As some of these Vitality ICDs were implanted for primary prevention, the battery longevity may be longer. Our protocol evaluates magnet response preoperatively, so these subjects will be identified in the chance that this rare programming option exists. In our study, we reviewed magnet response remotely through review of electronic records.

Pacemaker-Dependent Patients

We were able to direct special focus on pacemaker-dependent patients. The low rate of EMI supports that it may not be necessary to reprogram all pacemaker-dependent subjects unless their surgery is within 6 inches of the CIED. It should be reemphasized that magnet placement over Medtronic, Boston Scientific, and St. Jude ICDs will not change to asynchronous pacing. These pacemaker-dependent patients will require reprogramming to asynchronous pacing for procedures within 6 inches. As recommended by the HRS/ASA consensus statement, short bursts of electrosurgery may be a safer approach than reprogramming in most pacemaker-dependent patients

Device Reset

Potential device reset is the rationale for HRS/ASA-recommended 1-month postoperative device interrogation. Our data do not support this recommendation as there was no EMI in 89% of subjects and no device reset.

It will be important in future studies to take the approach in recently published study by von Olshausen et al.[12] In their analysis of clinic records they found EMI rare (0.23%) in 2,940 subjects. They classified EMI as clinically significant, potentially significant, and of minor significance. Further study of surgical and endoscopy patients would be helpful utilizing these criteria. Many brief episodes of EMI from electrosurgery in ICD subjects are well below the programmed detection duration. This classification may help minimize reprogramming in CIED subjects as many EMI episodes may be of minor significance.

Limitations

Although EMI has been documented in endoscopic procedures such as esophagastroduodenoscopy (EGD) or colonoscopy, we had only three subjects enrolled undergoing endoscopic procedures. Since the inclusion criteria specified "procedures with anticipated electrosurgery," most endoscopic gastrointestinal procedures were excluded due to the uncertain need for electrosurgery during the case. In earlier work, we evaluated 218 ICD subjects having EGD or colonoscopy and found that only 18% required monopolar electrosurgery, most for polypectomy. Polypectomy typically involves only 1–2 seconds of electrosurgery.[13] This is far below programmed detection intervals and should be considered before ICD deactivation. We recommend magnet application only for gastrointestinal endoscopic procedures requiring monopolar electrosurgery.

Another limitation is that there is a possibility that very short episode(s) of oversensing were not stored in the device and therefore not able to be characterized as EMI. However, if the EMI was not stored, then the episodes have no clinical significance.

Study design also posed a limitation as this was not a randomized-controlled trial, the standard for assessing efficacy of an intervention. While an observational design, the study proves a valuable and effective approach to perioperative management of CIEDs. Findings also cannot be generalized to Sorin/ELA or Biotronik CIEDs as we did not include those devices in our study.

Conclusions

The ICD-ON protocol was developed to provide safe and efficient perioperative management of CIEDs. The protocol is based on surgical location, with consideration of type of electrosurgery, pacemaker dependence, and programmed magnet response. Risk of EMI is highest with monopolar electrosurgery in thoracic, head/neck, and upper extremity procedures. For abdominal procedures, the risk of EMI is potential, but small. In this group of patients, magnet application over ICD seems most appropriate. For procedures below the iliac crest, we have not found EMI in this or prior studies and feel that no change approach for CIEDs should be considered. Routine outpatient postoperative interrogations appear sufficient for those not requiring reprogramming.

This accounted for 84% of subjects in our study.

There were no inappropriate therapies or device reset using the ICD-ON protocol. Our goal is to minimize risk of surgical EMI without increasing risk of reprogramming lifesaving therapies off patients with procedures distant from the ICD. Systematic approaches of communication with CIED team and surgical team are essential for safe and efficient perioperative management.

Our findings support that perioperative CIED management should be individualized based on surgical location. If surgical location is within 6 inches of the CIED, reprogram ICD therapies off and if pacemaker dependent change to asynchronous pacing. For ICD patients with surgical location above the iliac crest yet greater than 6 inches from the ICD, use a magnet. And finally, no change for any pacemaker greater than 6 inches from the surgical site, and no change for any ICD with surgeries that occur below the iliac crest.

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