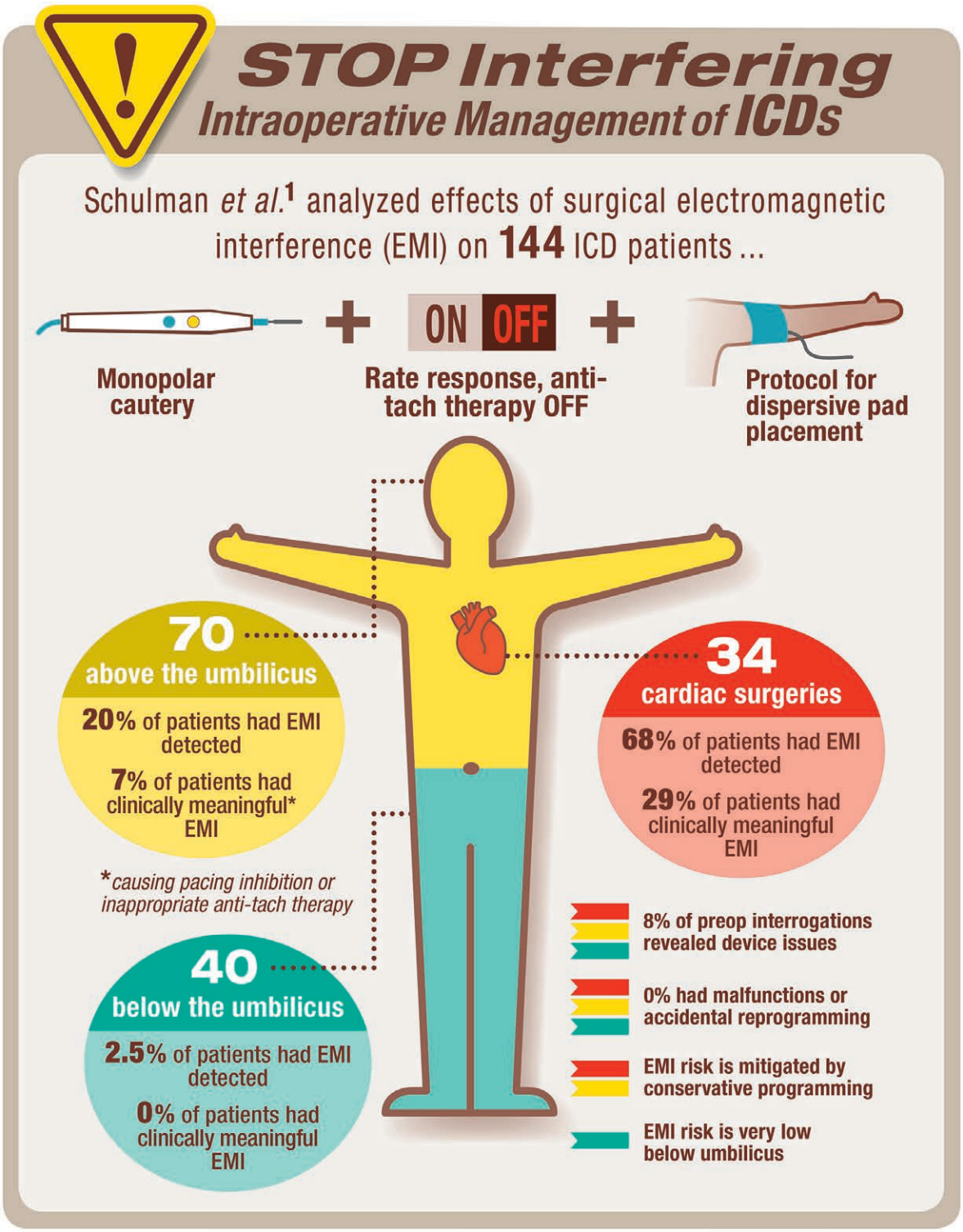

ICD, implantable cardioverter defibrillator.

Infographic created by Jonathan P. Wanderer, Vanderbilt University Medical Center, and James P. Rathmell, Brigham and Women's Health Care/Harvard Medical School. Illustration by Annemarie Johnson, Vivo Visuals. Address correspondence to Dr. Wanderer: jonathan.p.wanderer@vanderbilt.edu.

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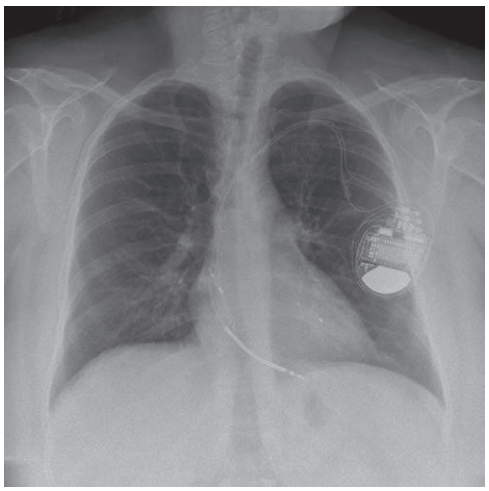
Intraoperative Electrosurgical Electromagnetic Interference in Patients with Implantable Cardioverter Defibrillators

Is It Safe?

G. Alec Rooke, M.D., Ph.D.

Most anesthesiologists understand that electromagnetic interference from monopolar electrosurgery may adversely impact the normal functioning of cardiovascular implantable electrical devices, including pacemakers and implantable cardioverter defibrillators. The most common consequences of electromagnetic interference are (1) pacing inhibition that could cause bradycardia and hypotension, and (2) inappropriate delivery of antitachycardia therapy, which can cause myocardial injury and might even increase mortality. Although previous studies have attempted to quantify how often intraoperative electromagnetic interference is detected by cardiovascular implantable electrical devices, the current study by Schulman *et al.*[1] examines this question prospectively and more thoroughly by defining three categories of electromagnetic interference: (1) any detectable electromagnetic interference; (2) electromagnetic interference that would have triggered antitachycardia therapy based on the implantable cardioverter defibrillator's actual programming ("clinically meaningful"); and (3) electromagnetic interference that would have triggered antitachycardia therapy if conservative programming strategies intended to reduce the risk of inappropriate antitachycardia therapy had been employed. Implantable cardioverter defibrillators record all tachyarrhythmia events, and that information can be downloaded. Implantable cardioverter defibrillators manufactured by Medtronic (USA) and Boston Scientific (USA) can be programed to a "monitor only" mode. This feature preserves the detection of arrhythmias, but prevents any therapies from being delivered, allowing safe use for surgery above the umbilicus. However, implantable cardioverter defibrillators by St Jude Medical (USA) and Biotronik (USA) do not have this capability, and therefore those devices could only be used for surgeries below the umbilicus.



"There are two options to disable therapy [internal cardioverter defibrillators]: place a magnet or reprogram the device. Both have their drawbacks."

Understanding how cardiovascular implantable electrical devices sense events is essential. Cardiovascular implantable electrical devices define a sensed event (*i.e.*, depolarization) whenever the voltage difference between the lead electrodes exceeds a predetermined threshold. Monopolar electrosurgery creates electromagnetic interference that produces high frequency, nonphysiologic signals (fig. 1), not all of which can be filtered out. Implantable cardioverter defibrillators are particularly prone to "oversensing" nonphysiologic signals because they must be sensitive enough to appropriately detect events of genuine ventricular arrhythmias. implantable cardioverter defibrillators categorize high-rate events as ventricular tachycardia or fibrillation based on rate and other proprietary criteria. If criteria for a ventricular arrhythmia are met, the implantable cardioverter defibrillator then delivers overdrive pacing or shocks.

The study's overall incidence (20%) of any electromagnetic interference in surgeries above the umbilicus during noncardiac surgery was lower than I expected. At least two possible explanations exist. This study consistently placed the dispersive ("ground") pad at the guideline-recommended location to direct the electrosurgery current return path away from the cardiovascular implantable electrical

Image: J. P. Rathmell.

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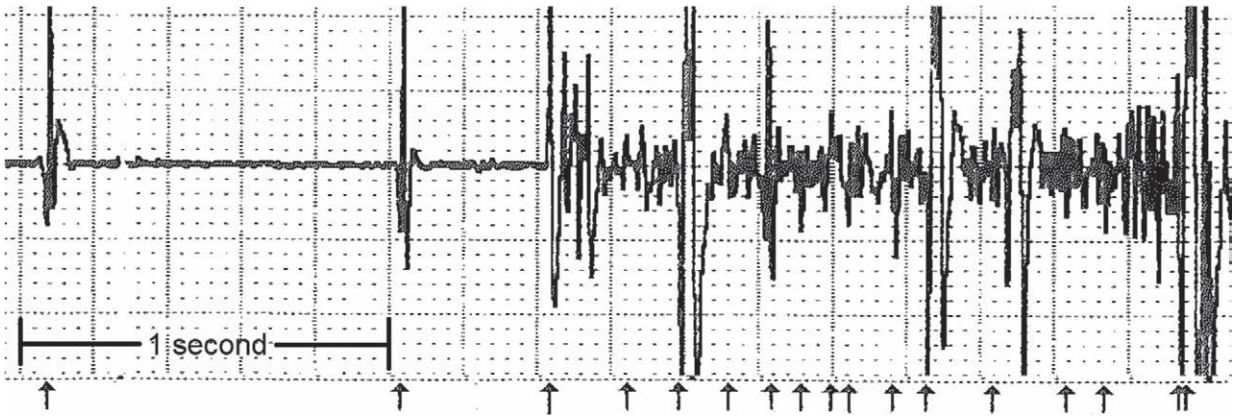

Fig. 1. An electrogram from a bipolar lead demonstrates what is observed by the lead. Two sinus rhythm beats are followed by electrosurgery electromagnetic interference. Each upward pointing *arrow* indicates where the device considers a sensed beat to have occurred. The criteria for delivering overdrive pacing or a shock can be complicated, but the criteria include the presence of rapid sensing.

devices.[2,3] In theory, this strategy should reduce detection of electromagnetic interference, but when the authors compared their results for specific surgical locations (*e.g.*, head/neck), they observed rates of electromagnetic interference that were similar to the prior literature. This failure to reduce electromagnetic interference detection questions the utility of the pad placement guidelines, but until more is known about the influence of pad location, the prudent strategy is to continue to position the dispersive pad to direct cautery current away from the device and leads. The more likely explanation for the low electromagnetic interference rate was that higher risk surgeries (thoracic, head/neck) were underrepresented and lower risk locations (abdomen) overrepresented in comparison to previous studies. In contrast, electromagnetic interference was very common using the underbody dispersive pad. The explanation may be as simple as the fact that cardiac surgery creates a very high risk of electromagnetic interference detection. But it could also be that the underbody pad disperses current too widely, providing sufficient current near the electrodes to generate detectable electromagnetic interference. Only additional studies will be able to determine if the underbody pad is less safe than the standard dispersive pad.

The most important issue, however, is whether or not the observed electromagnetic interference was sufficient to trigger antitachycardia therapy. Even with the stringent criteria, antitachycardia therapy would have been delivered to 3% of patients having noncardiac surgery above the umbilicus, a value that is still unacceptably high. Steps must be taken to mitigate that risk. Mitigation may also be necessary for surgeries below the umbilicus, given the current study's finding of one patient who demonstrated electromagnetic interference detection below the umbilicus and a recent case report of implantable cardioverter defibrillator discharge during knee surgery.[4] There are two options to disable therapy: place a magnet or reprogram the device. Both have their drawbacks. Correct magnet placement is not always the center of the device. Only some implantable cardioverter defibrillators provide audible feedback that the device has sensed the magnet. Magnets may slip during surgery, or may be difficult to place (*e.g.*, prone patient, near the surgical field). Some companies allow the implantable cardioverter defibrillator to be programed to ignore the magnet, though at present this is a highly unlikely scenario. Programming a device for surgery requires qualified personnel. Coordinating care for the consultation may cause case delays, and sometimes those specialists are unavailable. Programming also poses the risk of failing to restore implantable cardioverter defibrillator function postoperatively, leaving the patient unprotected. To circumvent these barriers, a few centers have trained anesthesiologists to accomplish this task.[5]

It is less clear what this study tells us about how electrosurgical electromagnetic interference will affect the pacing function of pacemakers and implantable cardioverter defibrillators. Any electromagnetic interference could inhibit demand pacing, but whether that causes bradycardia to the point of hypotension depends on many factors, including how close the surgical site is to the lead electrodes, and the frequency and duration of cautery. One factor that decreases the risk of pacing inhibition in pacemakers is that pacemaker leads are always the true bipolar model as opposed to the integrative bipolar leads that may be used with implantable cardioverter defibrillators. This study nicely documented that integrated bipolar leads are considerably more prone to detect electromagnetic interference than true bipolar leads. The electrodes of true bipolar leads are typically only about 1 cm apart, so it is more difficult for electromagnetic interference to generate different voltages at the two electrodes. For surgeries above the umbilicus,

electromagnetic interference inhibition of pacing cannot be reliably eliminated, so management during surgery for a patient with true pacing dependency at high risk of electromagnetic interference exposure requires either magnet placement (if the cardiovascular implantable electrical device is a pacemaker) or reprogramming (sole choice with an implantable cardioverter defibrillator, optional choice with a pacemaker). If a magnet is placed on a pacemaker, then the caregiver must be comfortable with a pacing rate that could be as high as 100 beats/min.

Another interesting observation from the study was that 8% of the devices had issues that were discovered during the interrogation just before surgery. At least half of those problems could have been corrected in advance of surgery, and some problems could have caused device malfunction in the operating room. This deficiency speaks to the need for systematic evaluation of cardiovascular implantable electrical devices prior to surgery as recommended by the guidelines.[2,3] Device evaluation is not an easy task to accomplish on a consistent basis, and many institutions struggle to achieve this goal.

In summary, the study by Schulman *et al.*[1] suggests that the likelihood of clinically dangerous electromagnetic interference from electrosurgery is relatively low for noncardiac cases above the umbilicus, but not low enough to ignore the need to inactivate the antitachycardia therapies of an implantable cardioverter defibrillator. The study also raises questions about whether the position of the dispersive pad affects the likelihood of detecting electromagnetic interference and suggests that the underbody pad may actually increase detection. The only solution to eliminate the risk of inappropriate therapy is if technological advances would entirely filter out electromagnetic interference and leave the true electrical signal of the myocardium undisturbed.

Competing Interests

The author is not supported by, nor maintains any financial interest in, any commercial activity that may be associated with the topic of this article.

Correspondence

Address correspondence to Dr. Rooke: rooke@uw.edu

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ANESTHESIOLOGY

Electromagnetic Interference with Protocolized Electrosurgery Dispersive Electrode Positioning in Patients with Implantable Cardioverter Defibrillators

Peter M. Schulman, M.D., Miriam M. Treggiari, M.D., Ph.D., M.P.H., N. David Yanez, Ph.D., Charles A. Henrikson, M.D., Peter M. Jessel, M.D., Thomas A. Dewland, M.D., Matthias J. Merkel, M.D., Ph.D., Valerie Sera, M.D., Izumi Harukuni, M.D., Ryan B. Anderson, M.D., Ph.D., Ed Kahl, M.D., Ann Bingham, M.D., Nabil Alkayed, M.D., Ph.D., Eric C. Stecker, M.D., M.P.H.

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During a surgical procedure, the function of an implantable cardioverter defibrillator may be disrupted by electromagnetic interference, most frequently resulting from monopolar electrosurgery (often called "cautery").[1–4] The potential for electromagnetic interference from electrosurgery depends on the power settings and set mode (*i.e.*, monopolar or bipolar) of the electrosurgical unit, and the distance between the current pathway and the implantable cardioverter defibrillator.[4] While bipolar electrosurgery is highly unlikely to cause electromagnetic interference,[3] the more frequently used monopolar electrosurgery requires a dispersive electrode applied to the patient's skin to complete the electrical circuit, frequently referred to as "return pad." A new option uses an underbody electrode that is incorporated into a pad and placed directly on the operating table. Consequences of electromagnetic interference in patients with implantable cardioverter defibrillators include hemodynamically significant bradycardia or asystole in the pacing-dependent patient, inappropriate shocks or antitachycardia pacing in the patient with an implantable cardioverter defibrillator ("antitachycardia therapies"),[5] direct damage to the implantable cardioverter defibrillator, and other, less common sequelae.[1,2,6,7] Failure to prevent or mitigate the effects of electromagnetic interference might lead to patient injury and even increase mortality.[5,8–12]

ABSTRACT

Background: The goal of this study was to determine the occurrence of intraoperative electromagnetic interference from monopolar electrosurgery in patients with an implantable cardioverter defibrillator undergoing surgery. A protocolized approach was used to position the dispersive electrode.

Methods: This was a prospective cohort study including 144 patients with implantable cardioverter defibrillators undergoing surgery between May 2012 and September 2016 at an academic medical center. The primary objectives were to determine the occurrences of electromagnetic interference and clinically meaningful electromagnetic interference (interference that would have resulted in delivery of inappropriate antitachycardia therapy had the antitachycardia therapy not been programmed off) in noncardiac surgeries above the umbilicus, noncardiac surgeries at or below the umbilicus, and cardiac surgeries with the use of an underbody dispersive electrode.

Results: The risks of electromagnetic interference and clinically meaningful electromagnetic interference were 14 of 70 (20%) and 5 of 70 (7%) in above-the-umbilicus surgery, 1 of 40 (2.5%) and 0 of 40 (0%) in below-the-umbilicus surgery, and 23 of 34 (68%) and 10 of 34 (29%) in cardiac surgery. Had conservative programming strategies intended to reduce the risk of inappropriate antitachycardia therapy been employed, the occurrence of clinically meaningful electromagnetic interference would have been 2 of 70 (2.9%) in above-the-umbilicus surgery and 3 of 34 (8.8%) in cardiac surgery.

Conclusions: Despite protocolized dispersive electrode positioning, the risks of electromagnetic interference and clinically meaningful electromagnetic interference with surgery above the umbilicus were high, supporting published recommendations to suspend antitachycardia therapy whenever monopolar electrosurgery is used above the umbilicus. For surgery below the umbilicus, these risks were negligible, implying that suspending antitachycardia therapy is likely unnecessary in these patients. For cardiac surgery, the risks of electromagnetic interference and clinically meaningful electromagnetic interference with an underbody dispersive electrode were high. Conservative programming strategies would not have eliminated the risk of clinically meaningful electromagnetic interference in either noncardiac surgery above the umbilicus or cardiac surgery.

(ANESTHESIOLOGY 2019; 130:00–00)

EDITOR'S PERSPECTIVE

What We Already Know about This Topic

- Electromagnetic interference from monopolar electrosurgery may disrupt implantable cardioverter defibrillators.
- Current management recommendations by the American Society of Anesthesiologists and Heart Rhythm Society are based on expert clinical opinion since there is a paucity of data regarding the risk of electromagnetic interference to implantable cardioverter defibrillators during surgery.

What This Article Tells Us That Is New

- With protocolized electrosurgery dispersive electrode positioning in patients with implantable cardioverter defibrillators, the risk of clinically meaningful electromagnetic interference was 7% in above-the-umbilicus noncardiac surgery and 0% in below-the-umbilicus surgery. In cardiac surgery, clinically meaningful electromagnetic interference with use of an underbody dispersive electrode was 29%.

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- Despite protocolized dispersive electrode positioning, the risk of electromagnetic interference in above-the-umbilicus surgery is high, supporting recommendations to suspend antitachycardia therapy when monopolar electrosurgery is used above the umbilicus.
- With protocolized dispersive electrode positioning, the risk of electromagnetic interference in below-the-umbilicus surgery is negligible, implying that suspending antitachycardia therapy might be unnecessary in these cases.
- With an underbody dispersive electrode, the risk of electromagnetic interference in cardiac surgery is high.

Thus, for patients with implantable cardioverter defibrillators undergoing surgery, key recommendations from the American Society of Anesthesiologists (ASA),[1] Heart Rhythm Society,[2] and others[13] include verifying whether the patient is pacing-dependent, ensuring the device is functioning properly, determining the likelihood of electromagnetic interference, and employing preventive strategies such as disabling antitachycardia therapy (*i.e.*, so that the implantable cardioverter defibrillator cannot deliver shocks or antitachycardia pacing) and reprogramming the device to an asynchronous pacing mode (*i.e.*, to prevent pacing inhibition) when necessary.

However, these recommendations are mainly based on expert opinion, case reports, and anecdotal experience since systematically collected data are lacking. The paucity of prospective data regarding the risk of electromagnetic interference has resulted in inconsistent or even contradictory practice recommendations. For example, although electrosurgery unit dispersive electrode positioning to direct the electrosurgery unit return current away from the pulse generator and leads is a key recommendation of both the ASA and Heart Rhythm Society, the ASA Practice Advisory states the literature is insufficient to determine the risk of electromagnetic interference using this approach.[1] Furthermore, the Heart Rhythm Society Expert Consensus Statement states that implantable cardioverter defibrillator reprogramming might be unnecessary when monopolar electrosurgery is employed inferior to the umbilicus,[2] whereas the ASA Practice Advisory recommends suspending antitachycardia therapy whenever monopolar electrosurgery is used, regardless of the surgical site.[1] Additionally, neither practice recommendation offers guidance regarding the use of an underbody dispersive electrode.

Given conflicting expert consensus guidance and limited data, we performed a single center, prospective cohort study to rigorously estimate the occurrence of intraoperative electromagnetic interference from monopolar electrosurgery with protocolized positioning of a conventional electrosurgery unit dispersive electrode, and with use of an underbody dispersive electrode.

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From the Department of Anesthesiology and Perioperative Medicine (P.M.S., M.M.T., M.J.M., V.S., I.H., R.B.A., A.B., N.A.) and the Knight Cardiovascular Institute (C.A.H., P.M.J., T.A.D., E.C.S.), Oregon Health and Science University, Portland, Oregon; the School of Public Health, Oregon Health and Science University and Portland State University, Portland, Oregon (N.D.Y.); and Department of Anesthesiology, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin (E.K.).

Materials and Methods

Study Design

Consecutive individuals 18 yr of age and older with an implantable cardioverter defibrillator, undergoing elective surgery, were invited to participate if the use of intraoperative monopolar electrosurgery was planned. Individuals with an implantable cardioverter defibrillator manufactured by Medtronic (USA) or Boston Scientific (USA) were eligible for inclusion, regardless of the location of surgery. Because St. Jude Medical (USA) and Biotronik (USA) implantable cardioverter defibrillators cannot be programmed to a "monitor only" mode, individuals with a device by these manufactures were excluded if the location of surgery was above the umbilicus. Subjects undergoing surgery above the umbilicus were also excluded if they were pacing dependent because asynchronous pacing was necessary and precluded use of a ventricular tachycardia monitor zone. Individuals were also excluded if monopolar electrosurgery was not used, or surgery involving the implantable cardioverter defibrillator pulse generator pocket was planned.

The Institutional Review Board of Oregon Health and Science University (Portland, Oregon) reviewed and approved this study. Written informed consent was obtained from each participant. Between May 2012 and September 2016, 167 subjects were consented and enrolled. Once enrolled, subjects were classified into one of three groups based on surgery type and location; group surgery above the umbilicus were subjects undergoing noncardiac surgery superior to the umbilicus, group surgery below the umbilicus were subjects undergoing noncardiac surgery at the level of or inferior to the umbilicus, and group cardiac surgery were subjects undergoing cardiac surgery.

Preoperative Implantable Cardioverter Defibrillator Interrogation and Programming

Implantable cardioverter defibrillators were interrogated by specially trained and credentialed anesthesiologists or members of the electrophysiology service. Battery status, lead parameters, and arrhythmia log were recorded. Antitachycardia therapy was programmed off for participants in the surgery above the umbilicus and cardiac surgery groups. However, antitachycardia detection was kept on, in "monitor-only mode," so that sensed events could still be recorded. Antitachycardia settings were not

changed for participants in the surgery below the umbilicus group. Pacing parameters (*i.e.*, lower rate limit, pacing mode) were only changed if clinically indicated. If an asynchronous pacing mode was deemed clinically indicated, the patient was considered no longer eligible for study participation.

Intraoperative Management

The dispersive electrode was placed by the operating room nurse. A specific protocol (table 1 and fig. 1) was used to determine the dispersive electrode position and type. A conventional dispersive electrode was used for patients undergoing noncardiac surgery. The conventional dispersive electrode position was determined by the site of surgery and location of the patient's pulse generator, with the intention of diverting the current return pathway away from the implantable cardioverter defibrillator. The Megadyne (Mega Soft, USA) under body dispersive electrode was used for patients undergoing cardiac surgery. In all cases, the electrosurgery unit was utilized as clinically indicated with settings and duration of use left at the surgeon's discretion.

Postoperative Implantable Cardioverter Defibrillator Interrogation and Programming

Implantable cardioverter defibrillators were reinterrogated and data were collected as previously described. All preoperative settings were restored (antitachycardia therapy was programmed back on) unless programming changes (*i.e.*, lower rate limit, pacing output) were deemed clinically necessary.

Study Endpoints

The primary endpoints were (1) the occurrence of right ventricular lead electromagnetic interference from monopolar electrosurgery with protocolized electrosurgery unit dispersive electrode positioning for patients undergoing noncardiac surgery superior to the umbilicus (above the umbilicus group) and at or inferior to the umbilicus (below the umbilicus group); and (2) the occurrence of right ventricular lead electromagnetic interference from monopolar electrosurgery for patients undergoing cardiac surgery (group cardiac) when an underbody dispersive electrode was used. Secondary endpoints were the occurrence of clinically meaningful electromagnetic interference, defined as electromagnetic interference that would have resulted in the delivery of inappropriate antitachycardia therapy if the antitachycardia therapy had not been programmed off for patients in the surgery above the umbilicus or cardiac surgery groups, or electromagnetic interference that resulted in the delivery of inappropriate antitachycardia therapy for patients with surgery below the umbilicus.

Table 1. Electrosurgery Unit Dispersive Electrode Positioning

Surgery Type	Electrosurgery Unit Dispersive Electrode Position*	Figure Reference††
Surgery superior to clavicles	Posterior-superior shoulder contralateral to pulse generator	1
Breast, axilla, or upper extremity on same side as pulse generator	Posterior-superior shoulder ipsilateral to pulse generator	2
Breast, axilla, or upper extremity on opposite side from pulse generator	Posterior-superior shoulder contralateral to pulse generator	3
Thoracotomy	Flank at inferior margin of surgical sterile field	4
Mediastinoscopy	Back at the level of surgery, contralateral to pulse generator	5
Abdominal surgery	Either thigh as close as possible to the inferior margin of surgical sterile field	6
Pelvic/hip surgery	Thigh or buttock contralateral to the side of surgery	7
Lower extremity surgery	Thigh contralateral to the side of surgery, or buttock ipsilateral to the side of surgery	8
Spine surgery	Midaxillary flank contralateral to pulse generator as close as possible to the inferior margin of the surgical sterile field	9
Median sternotomy	Under body dispersive electrode	Not applicable

*Assumes pectoral implant of generator.

†Refer to figure 1 for electrosurgery unit dispersive electrode positioning relative to surgery locations described in this table.

Modified with permission from Marc A. Rozner.

Inappropriate antitachycardia therapy (*i.e.*, due to a non–life-threatening arrhythmia, or physiologic or nonphysiologic oversensing) can have adverse consequences and might even increase mortality. Modern ("conservative") programming strategies attempt to reduce the risk of inappropriate and avoidable antitachycardia therapy by utilizing higher detection rates, longer detection durations, antitachycardia pacing, and algorithms that discriminate supraventricular tachycardia from ventricular tachycardia. Thus, we determined whether the occurrence of electromagnetic interference and clinically meaningful electromagnetic interference would have been further decreased if all implantable cardioverter defibrillators had been programmed to a conservative strategy (*i.e.*, Multicenter Automatic Defibrillator Implantation Trial–Reduce Inappropriate Therapy[8] or PainFree SmartShock Technology study[14]). Finally, we investigated the occurrence and the nature of implantable cardioverter defibrillator–related problems identified during preoperative implantable cardioverter defibrillator interrogation.

All intraoperative events recorded by the implantable cardioverter defibrillator were independently reviewed by two electrophysiologists blinded to surgery type. Each event was

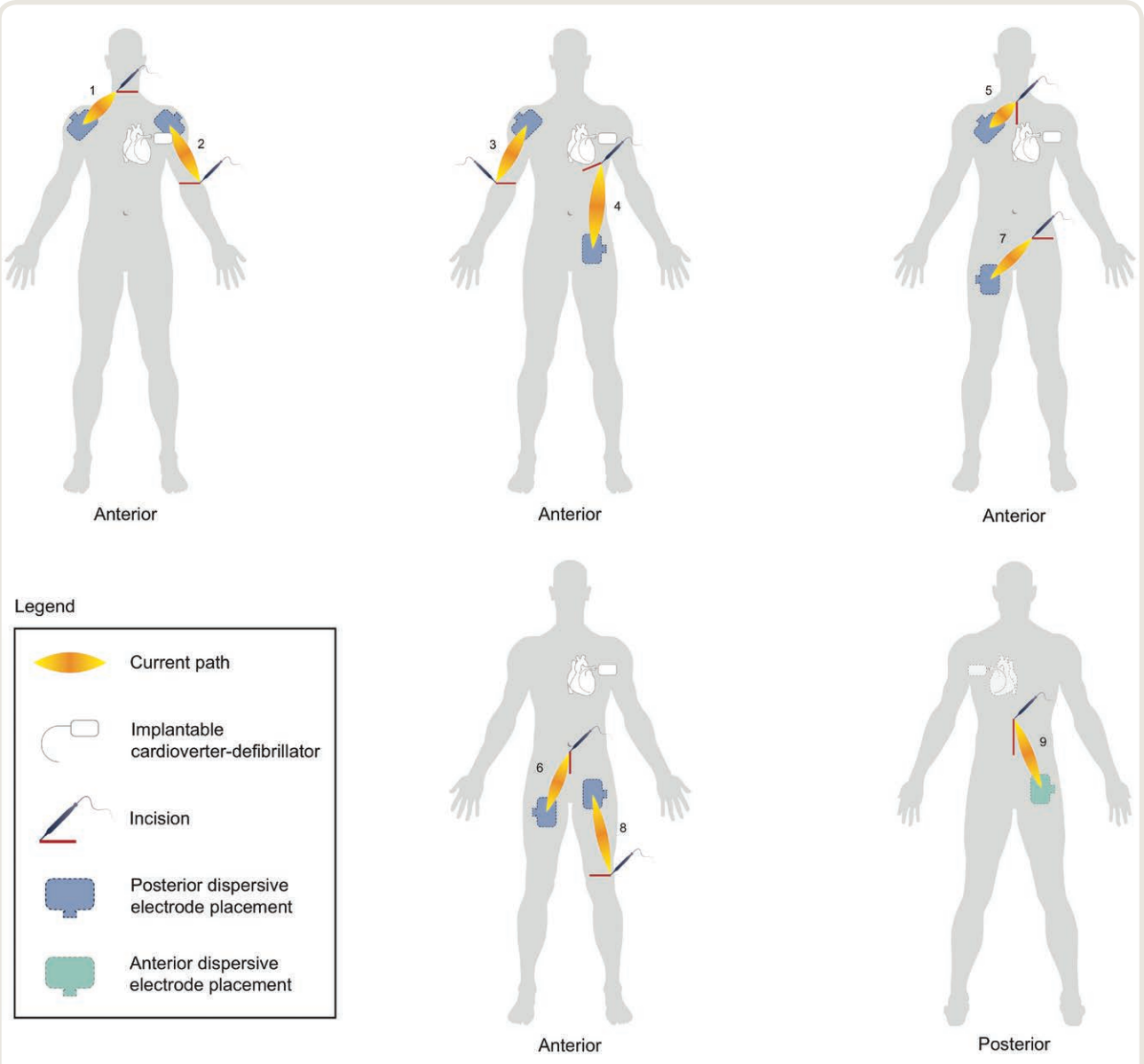

Fig. 1. Illustration of the protocolized position of electrosurgery unit dispersive electrode positioning. See also table 1.

categorized as either a true arrhythmia or an electromagnetic interference. A third electrophysiologist adjudicated any discordant interpretations. Electromagnetic interference was further categorized as (1) not clinically meaningful (*i.e.*, not sufficiently severe enough to trigger inappropriate antitachycardia therapy); (2) clinically meaningful (*i.e.*, severe enough to trigger inappropriate antitachycardia therapy based on how the implantable cardioverter defibrillator was actually programmed preoperatively); or (3) clinically meaningful with conservative programming (*i.e.*, severe enough to trigger inappropriate antitachycardia therapy if a programming strategy known to reduce the risk of inappropriate antitachycardia therapy had been employed).

Statistical Analysis

Summary statistics were determined for all key characteristics evaluated for this study. Means ± SD are provided for quantitative characteristics, and frequencies (%) are provided for categorical characteristics. All summaries were stratified by study group (above the umbilicus, below the umbilicus, and cardiac). Estimates of dispersion were expressed as 95% CIs for each outcome. CIs were calculated using the Agresti–Coull method.[15] Standard CIs and "exact" intervals[16] are known to perform poorly when outcome probabilities are rare (small), even for moderate sample sizes.[17] The Agresti–Coull CIs employ corrections to standard

intervals and have superior coverage and precision.[15] All CIs are two-sided. For sample size considerations, we planned to collect the maximal number of eligible patients between May 2012 and September 2016. Our objective was to estimate the occurrences with maximal precision.

Finally, it is plausible that a more closely spaced sensing and pacing electrode configuration might reduce the risk of electromagnetic interference.[18] Thus, in exploratory analyses, we investigated whether implantable cardioverter defibrillators with a true bipolar lead configuration or implantable cardioverter defibrillators with an integrated bipolar lead configuration were associated with different risks of electromagnetic interference for each of the three groups. A true bipolar configuration uses two closely spaced electrodes near the distal end of the lead tip for pacing and sensing, whereas with an integrated bipolar configuration, the electrodes for pacing and sensing are more widely spaced, since the distal shocking coil is used in lieu of one of the dedicated lead tip electrodes.

We evaluated the dataset for missing data and determined the possible impacts (biases) were minimal given that we had complete data on 21 of 24 characteristics evaluated in this manuscript. Furthermore, of the three characteristics with missing data (*i.e.*, anesthesia duration, lead type, shock), percentages missing were less than 5%, 4.2%, and 4.9%, respectively. Statistical analyses were performed using Stata version 15.1 (StataCorp LLC, USA).

Results

During the study period, 167 patients were screened, of whom 144 (86%) met eligibility criteria. Figure 2 shows the flow of study participants from screening to assessment of the primary outcomes. Patient demographic characteristics are presented in table 2.

Device Characteristics

There were 79 Medtronic, 51 Boston Scientific, 9 St. Jude Medical, and 5 Biotronik implantable cardioverter defibrillators (table 3). There were 101 (70%) conventional implantable cardioverter defibrillators and 43 (30%) biventricular implantable cardioverter defibrillators. The implant duration

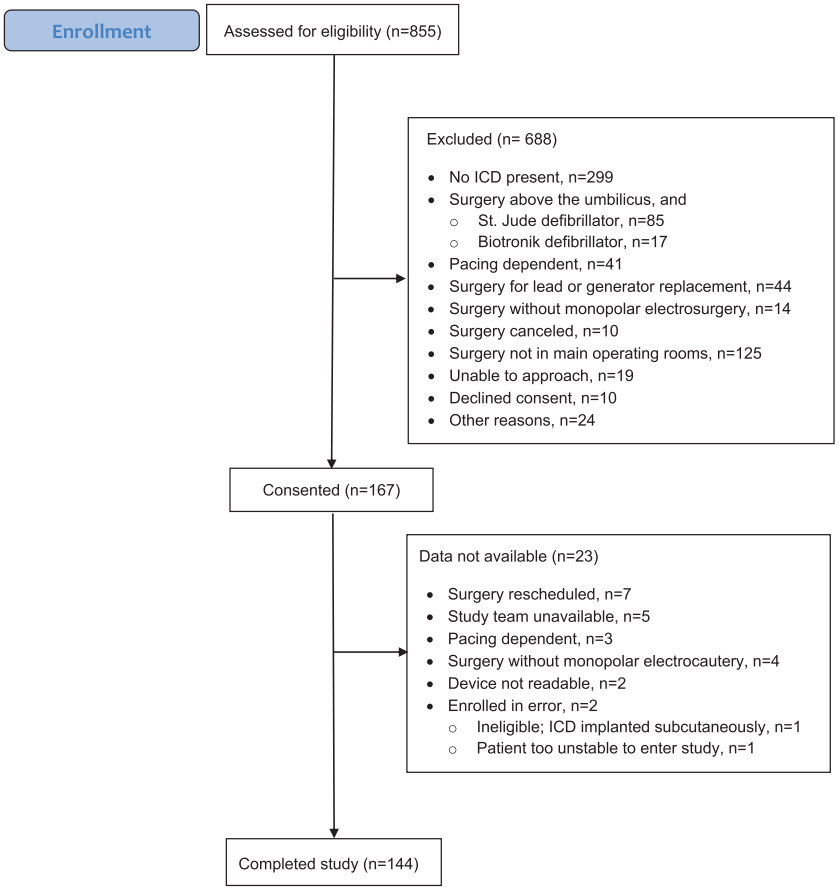

Fig. 2. Study flowchart displaying characteristics of cohort selection. ICD, implantable cardioverter defibrillator.

Table 2. Demographic Characteristics of Study Population

	Surgery above the Umbilicus N = 70	Surgery below the Umbilicus N = 40	Cardiac Surgery* N = 34
Gender, male, No. (%)	42 (60)	29 (73)	28 (82)
Age, yr, mean ± SD	62 ± 14	65 ± 11	50 ± 15
Weight, kg, mean ± SD	94 ± 34	97 ± 34	96 ± 39
Height, cm, mean ± SD	172 ± 11	173 ± 8	175 ± 8
Left ventricular assist device, No. (%)	5 (7)	4 (10)	4 (12)
Heart failure, No. (%)	35 (50)	19 (48)	26 (76)
Coronary artery disease, No. (%)	38 (54)	23 (58)	11 (32)
Surgery type, No. (%)			
Orthopedic surgery	10 (14)	25 (62.5)	0 (0)
General surgery	30 (43)	10 (25)	0 (0)
Otolaryngology/ maxillofacial	10 (14)	0 (0)	0 (0)
Neurosurgery	0 (0)	0 (0)	0 (0)
Vascular surgery	11 (16)	1 (2.5)	0 (0)
Cardiothoracic surgery	3 (4)	0 (0)	34 (100)
Urology/gynecology	6 (9)	4 (10)	0 (0)
Anesthesia type, No. (%)			
General	65 (93)	26 (65)	34 (100)
Monitored anesthesia care	5 (7)	7 (17.5)	0 (0)
Neuraxial block (*i.e.*, spinal or epidural)	0 (0)	7 (17.5)	0 (0)
Anesthesia duration, min, mean ± SD	252 ± 145	185 ± 116	399 ± 121
Surgical position, No. (%)			
Supine	55 (79)	27 (67.5)	33 (97)
Prone	4 (6)	1 (2.5)	0 (0)
Lithotomy	2 (3)	3 (7.5)	0 (0)
Lateral decubitus	4 (6)	9 (22.5)	1 (3)†
Beach chair	5 (7)	0 (0)	0 (0)

*One patient had sternotomy without cardiac surgery.

†Open thoracic abdominal aortic aneurysm repair with cardiopulmonary bypass.

of the generator and leads varied with a mean ± SD time of 32 ± 25 months (n = 141) and 51 (44) months (n = 138), respectively. Other than suspending antitachycardia therapy, no preoperative programming changes were deemed necessary in 126 of 144 (88%), thus these implantable cardioverter defibrillators were considered optimally programmed. Reprogramming was performed in 18 of 144 implantable cardioverter defibrillators (12%) to change the pacing mode (predominantly to turn off rate response), rate, output, or in one case the type of antitachycardia pacing (because of recent ventricular tachycardia). A preoperative problem was found in 8% (12 of 144), as follows: battery at elective replacement indicated (n = 3); inadequate safety margin for pacing on ventricular (n = 5) or atrial channel (n = 1); high right ventricular pacing threshold and failure of the atrial lead to capture (n = 1); high right ventricular pacing threshold (n = 1); and high right ventricular lead impedance (n = 1). Preoperative interrogation data were not available in 3.5% (5 of 144) of cases. In one case, an intraoperative device–related problem occurred (T wave oversensing).

Primary and Secondary Endpoints

Outcome probabilities are presented in table 4 and in figure 3. The occurrence of intraoperative electromagnetic interference of any detected rate or duration was 20% (95% CI, 12.1 to 31.2) in noncardiac surgery above the umbilicus, 2.5% (95% CI, 0.0 to 14.4) in surgery below the umbilicus, and 68% (95% CI, 50.3 to 81.2) in cardiac surgery. When restricted to intraoperative electromagnetic interference that would only have been clinically meaningful based on actual preoperative programming, the occurrence of electromagnetic interference was 7% (95% CI, 2.7 to 16.2) in noncardiac surgery above the umbilicus, 0% (95% CI, 0.0 to 10.8) in surgery below the umbilicus, and 29% (95% CI, 16.5 to 46.7) in cardiac surgery. When restricted to intraoperative electromagnetic interference that would only have been clinically meaningful based on programming strategies known to reduce inappropriate therapies (*i.e.*, if all implantable cardioverter defibrillators had been programmed to utilize high detection rates or long detection durations), the occurrence of electromagnetic interference would have been 2.9% (95% CI, 0.15 to 10.7) in noncardiac surgery above the umbilicus, 0% (95% CI, 0.0 to 10.8) in surgery below the umbilicus, and 8.8% (95% CI, 2.2 to 24.1) in cardiac surgery.

Postoperative Characteristics

Postoperative interrogation demonstrated that all implantable cardioverter defibrillators withstood intraoperative electromagnetic interference without malfunction or occurrence of unanticipated programming changes.

Exploratory Endpoints

A true bipolar lead, as compared to an integrated bipolar right ventricular lead, was associated with a significantly lower occurrence of intraoperative electromagnetic interference in the noncardiac surgery above the umbilicus group (1 of 34 [3%] true bipolar *vs.* 11 of 33 [33%] integrated bipolar; $P = 0.001$); however, there were no differences for patients with surgery below the umbilicus (1 of 27 [4%] *vs.* 0 of 10 [0%]; $P = 0.781$) or in cardiac surgery (11 of 20 [55%] *vs.* 12 of 14 [86%]; $P = 0.060$). The occurrence of clinically meaningful electromagnetic interference or electromagnetic interference assuming conservative programming was not different for implantable cardioverter defibrillators with a true *versus* integrated bipolar lead for any of the study groups.

Discussion

We conducted a large cohort study in a population of patients with implantable cardioverter defibrillators to evaluate the risk of intraoperative electromagnetic interference from monopolar electrosurgery. Our study was the first to determine the risk

Table 3. Implantable Cardioverter Defibrillator Characteristics

	Surgery above the Umbilicus (N = 70)	Surgery below the Umbilicus (N = 40)	Cardiac Surgery (N = 34)
Manufacturer, pulse generator, No. (%)			
Medtronic	44 (63)	16 (40)	19 (56)
Boston Scientific	26 (37)	10 (25)	15 (44)
St. Jude	0 (0)	9 (22.5)	0 (0)
Biotronik	0 (0)	5 (12.5)	0 (0)
Indication for implant, No. (%)			
Primary prevention	44 (63)	21 (52.5)	28 (82)
Secondary prevention	26 (37)	19 (47.5)	6 (18)
Pacing-dependent, No. (%)	0 (0)	5 (13)	0 (0)
Implantation site, No. (%)			
Left	67 (96)	39 (97.5)	34 (100)
Right	3 (4)	1 (2.5)	0 (0)
Biventricular implantable cardioverter defibrillator, No. (%)	13 (9)	15 (38)	15 (45)
Lead type, No. (%)			
Bipolar	34 (49)	27 (67.5)	20 (59)
Integrated bipolar	33 (47)	10 (25)	14 (41)
Unknown	3 (4)	3 (7.5)	0 (0)
Interrogation within prior 6 months, No. (%)	49 (70)	20 (50)	20 (59)
Preoperative programming problem identified			
Battery at elective replacement indicator	2 (3)	0 (0)	1 (3)
Inadequate safety margin for pacing	2 (3)	2 (5)	2 (6)
Other	2 (3)	0 (0)	1 (3)
Electrosurgery dispersive electrode location, No. (%)			
Shoulder	36 (51)	0 (0)	0 (0)
Thigh/buttock	32 (46)	39 (98)	0 (0)
Back	0 (0)	1 (3)	0 (0)
Underbody (*i.e.*, Megadyne)	0 (0)	0 (0)	34 (100)

Table 4. Primary and Secondary Study Outcomes by Surgical Procedure Location Group*

EMI, No. (%)	Surgery above the Umbilicus (N = 70)	95% CI	Surgery below the Umbilicus (N = 40)	95% CI	Cardiac Surgery (N = 34)	95% CI
Any intraoperative	14 (20)	2.1–31.2	1 (2.5)	0.0–14.4	23 (68)	50.3–81.2
Clinically meaningful†	5 (7.0)	2.7–16.2	0 (0.0)	0.0–10.8	10 (29)	16.5–46.7
Antitachycardia pacing	3 (4.3)		0 (0.0)		5 (14.7)	
Shock	2 (2.9)		0 (0.0)		5 (17.2)	
Intraoperative VA	0 (0.0)		0 (0.0)		6 (17.7)	
Conservative programming‡	2 (2.9)	0.15–10.7	0 (0.0)	0.0–10.8	3 (8.8)	2.2–24.1

EMI, electromagnetic interference; VA, ventricular arrhythmia.

*Percentages may vary slightly due to missing values.

†Clinically meaningful intraoperative EMI refers to EMI with the potential delivery of antitachycardia therapy.

‡Conservative programming strategies refers to Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy or PainFree SmartShock Technology study[14] programming.

of electromagnetic interference with protocolized electrosurgery unit dispersive electrode positioning and the occurrence of clinically meaningful electromagnetic interference. Despite protocolized electrosurgery dispersive electrode positioning as recommended by the ASA and Heart Rhythm Society, we found an overall high risk of electromagnetic interference among patients who underwent noncardiac surgery above the umbilicus. The risk of electromagnetic interference among patients who underwent surgery below the umbilicus was negligible. The occurrence of electromagnetic interference was exceedingly high among patients who underwent cardiac surgery with an underbody dispersive electrode. The occurrence of clinically meaningful electromagnetic interference, which, although substantially lower than the overall occurrence of electromagnetic interference, was still as high as 7% for surgeries above the umbilicus, and 30% for cardiac surgery. Interestingly, we found that clinically meaningful electromagnetic interference would not have occurred for noncardiac surgeries below the umbilicus if all implantable cardioverter defibrillators had been programmed according

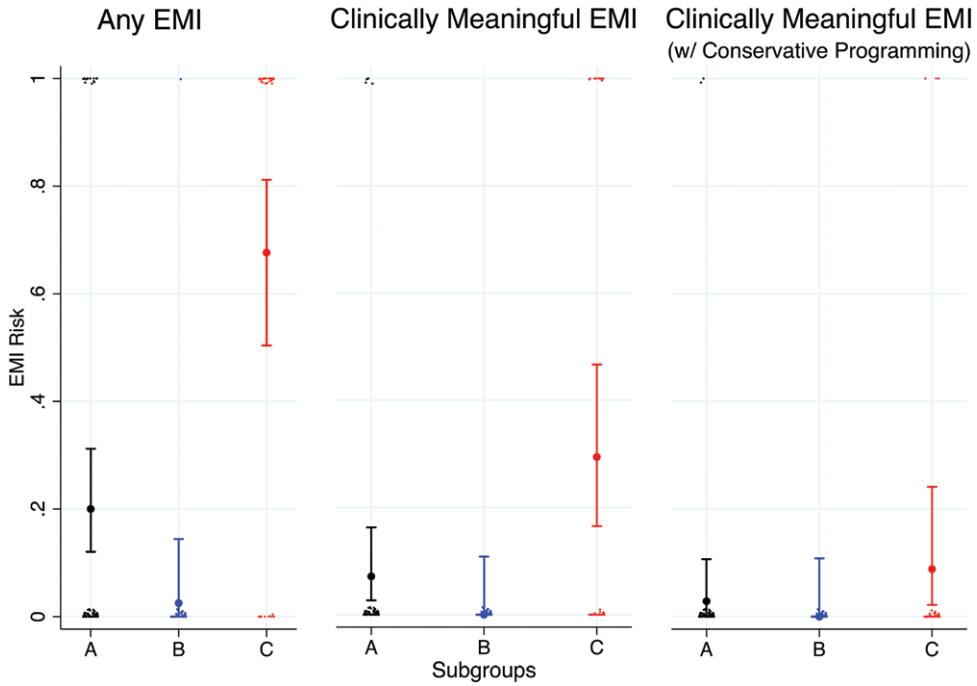

Fig. 3. Distribution and summary statistics (mean, standard error) of electromagnetic interference (EMI) in patients undergoing surgery above the umbilicus (*A*), surgery below the umbilicus (*B*), and cardiac surgery (*C*) groups. The *left* displays the occurrence of any intraoperative EMI, the *center* displays the occurrence of clinically meaningful intraoperative EMI (EMI that would have or did result in delivery of inappropriate antitachycardia therapy), and the *right* displays the occurrence of EMI had all implantable cardioverter defibrillators been programmed to a conservative strategy (Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy or PainFree SmartShock Technology study[14]).

to the conservative strategies of the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy or PainFree SmartShock Technology study.[14] These programming strategies are now considered standard for all new implantable cardioverter defibrillators implanted for primary prevention based on multiple trials showing a lower risk of inappropriate shocks and improved outcomes.

The strengths of the current prospective study are the following: we prospectively stratified patients based on location and type of surgery into three groups; we only included surgeries that involved the use of monopolar electrosurgery; and we excluded interventional and endoscopic procedures that would have been unlikely to result in electromagnetic interference. Our study design differs from previous reports in several ways; therefore, the interpretation of our findings in the context of previous studies needs to account for these differences. In all prior studies evaluating the occurrence of intraoperative electromagnetic interference, the electrosurgery unit dispersive electrode was placed on the thigh or in an undefined "standard" position, without regard for the surgical site or location of the patient's pulse generator.[19–24] Other complicating issues that make interpreting the risk of electromagnetic interference in these studies difficult include (1) lack of accounting for the use of bipolar rather than monopolar electrosurgery; (2) inconsistency in reporting the location of surgery (*i.e.*, superior or inferior to the umbilicus); and (3) failure to exclude interventional and endoscopic procedures that typically do not require monopolar electrosurgery. Moreover, none of these previous studies evaluated the risk of electromagnetic interference with an underbody dispersive electrode.[25]

Gifford *et al.* reported electromagnetic interference occurrence for noncardiac surgery superior to the umbilicus ranging from 22% (upper extremity) to 50% (thorax or head/neck).[22] In a subsequent study, Gifford *et al.* reported similar electromagnetic interference rates ranging from 15% (upper extremity) to 35% (head/neck) to 45% (thoracic).[23] Friedman *et al.*[24] reported similar electromagnetic interference rates (shoulder/upper extremity, 9%; head/neck, 43%; thoracic, 50%) to the two aforementioned studies by Gifford et al.[22,23] Using the same surgery location categories, our figures of overall electromagnetic interference risk would have been overall slightly higher (upper extremity, 25%; head/neck, 35%; thorax, 61%). For surgery inferior to the umbilicus, all three of the aforementioned studies found an overall electromagnetic interference rate of 0%, while this figure was 3% in our study.

For noncardiac surgery above the umbilicus, we found an overall occurrence of electromagnetic interference

of 20%. Thus, the average occurrence of electromagnetic interference in this group was lower than previously reported, a finding that might be attributable to our use of protocolized dispersive electrode positioning, or to the inclusion of cardiac surgery in previously reported thoracic surgery groups. Even though the occurrence of electromagnetic interference in surgeries above the umbilicus was lower than previously reported, it was still higher than we anticipated. It is conceivable that the true overall risk of intraoperative electromagnetic interference from monopolar electrosurgery is higher than may be inferred from previous reports due to the aforementioned limitations of these prior studies. Although very low, we were surprised to detect a nonzero frequency of electromagnetic interference in surgeries below the umbilicus, which may have occurred because, unlike some of the previous studies that excluded lower abdominal surgery in their "below the umbilicus" groups, we included lower abdominal surgery in this group.

For patients undergoing cardiac surgery with an underbody dispersive electrode, we found an electromagnetic interference occurrence of 68%. Since the surface area of this electrode is substantially larger than a conventional electrode, it is conceivable that this risk of electromagnetic interference might have been reduced by the use of a conventional electrosurgery dispersive electrode positioned according to a defined protocol.[25]

Interestingly, we determined that the risk of electromagnetic interference would have been substantially reduced in noncardiac surgery with programming strategies now frequently used to decrease the risk of inappropriate antitachycardia therapy among patients receiving implantable cardioverter defibrillators for primary prevention of sudden cardiac death. These findings suggest that the benefits of these conservative programming strategies might also extend to the perioperative setting.

Our study has limitations. The underbody dispersive electrode was only used in patients undergoing cardiac surgery. Therefore, we cannot draw conclusions about the risk of electromagnetic interference when this electrode is applied in other surgeries. We also did not randomize cardiac surgery patients to an underbody or conventional dispersive electrode. Furthermore, since monopolar electrosurgery was used at the discretion of the surgeon, the electrosurgical unit settings were not standardized.

In summary, our study demonstrated a substantial overall risk of intraoperative electromagnetic interference from monopolar electrosurgery for surgery above the umbilicus, despite protocolized placement of the dispersive electrode, and for cardiac surgery with the use of an underbody dispersive electrode. Understanding the true risk of intraoperative electromagnetic interference is important because evidence suggests that inappropriate antitachycardia therapy, whether antitachycardia pacing or shock, can cause adverse outcomes and even increase mortality.[5,8–12] Furthermore, inappropriate antitachycardia therapy occurring intraoperatively may be especially serious because of the hemodynamic perturbations and physiologic stress often associated with surgery and anesthesia, and because a shock might cause unexpected patient movement.

While the risk of clinically meaningful electromagnetic interference was substantially lower than the overall risk of electromagnetic interference, it was still high enough to warrant recommending suspending antitachycardia therapy anytime monopolar electrosurgery is used in procedures above the umbilicus. Since the rate of clinically meaningful electromagnetic interference in this group would have been further reduced had all implantable cardioverter defibrillators been programmed to minimize inappropriate antitachycardia therapy (*i.e.*, according to the Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy or PainFree SmartShock Technology study,[14] programming strategies that are often used in patients who have not yet experienced ventricular tachycardia or ventricular fibrillation), in the future as programming strategies continue to evolve, it may be worth reevaluating whether perioperative recommendations for implantable cardioverter defibrillator management can be modified accordingly. While it is hard to be confident that systems of care could be implemented to routinely ensure safe use of monopolar electrosurgery without implantable cardioverter defibrillator reprogramming for surgery above the umbilicus, it is possible that with promulgation of modern conservative programming strategies (and attention to patterns of electrosurgery use), the risk of electromagnetic interference could be substantially mitigated. Alternate strategies to mitigate the risk of electromagnetic interference are especially important for emergency situations when implantable cardioverter defibrillator or pacemaker reprogramming is often not possible, and magnet use is either impractical (*i.e.*, prone surgery or magnet in surgical field) or not effective (*i.e.*, pacing-dependent patients with an implantable cardioverter defibrillator). Our study also demonstrated that the risk of electromagnetic interference for surgery below the umbilicus was extremely low and without clinical relevance, which corroborates the findings of prior studies. This finding supports the recommendation of the Heart Rhythm Society that implantable cardioverter defibrillator reprogramming might be unnecessary when monopolar electrosurgery is employed inferior to the umbilicus, and may call for more nuance than the current recommendation from the ASA to suspend antitachycardia therapy whenever monopolar electrosurgery is used, regardless of surgical site. While the ASA recommendations may be appropriate for elective surgeries in centers with well-established protocols for implantable cardioverter defibrillator management, in the setting of urgent or emergent surgeries or when appropriate postoperative reprogramming cannot be guaranteed, the harms of preoperative implantable cardioverter defibrillator reprogramming for surgery inferior to the umbilicus could exceed the small potential benefits. Finally, we found the risk

of electromagnetic interference with an underbody dispersive electrode was alarmingly high, and believe future studies to evaluate its use in patients with implantable cardioverter defibrillators are needed. We believe the results of our study can be used to better inform perioperative decision making, and guide future recommendations and advisories on the perioperative management of patients with implantable cardioverter defibrillators.

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Competing Interests

The authors declare no competing interests.

Correspondence

Address correspondence to Dr. Schulman: Department of Anesthesiology and Perioperative Medicine, Oregon Health and Science University, 3181 SW Sam Jackson Park Road, Mail Code KPV12C, Portland, Oregon, 97239. schulman@ohsu.edu.

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