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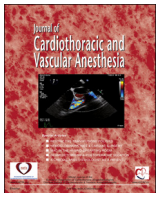

Inappropriate Implantable Cardioverter-Defibrillator Therapy During Surgery: An Important and Preventable Complication

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MOUNTING EVIDENCE suggests that inappropriate high-energy therapy from an implantable cardioverter-defibrillator (ICD), whether antitachycardia pacing (ATP)[1] or shock,[2-4] causes myocardial injury (eg, troponin release or ST-segment changes consistent with injury currents) and increases mortality. In the hospital environment, electromagnetic interference (EMI), which most commonly results from intraoperative monopolar electrosurgery, can precipitate inappropriate ICD therapy, suggesting that failure to prevent or mitigate EMI could increase the risk of patient injury.

This report presents 3 cases from different institutions in which failure to adhere to all recommended precautions from the American Society of Anesthesiologists (ASA)[5] or Heart Rhythm Society (HRS)[6] regarding the perioperative management of ICDs resulted in inappropriate ICD therapy during surgery.

To the authors' knowledge, the frequency of inappropriate high-energy therapy from an ICD during surgery remains unknown, and this problem rarely has been reported in the literature. Because the use of cardiovascular implantable electronic devices (CIEDs) continues to increase and these patients are presenting for surgery and other interventional procedures with increasing frequency, routine postoperative ICD checks are not always performed, and no rule from the Joint Commission or other regulatory agency mandates reporting such events. It is conceivable that inappropriate ICD therapy during surgery constitutes an important and largely preventable patient safety issue that is underrecognized and underreported.[7]

Because these cases were single events, retrospectively reviewed, and without aggregated data, the authors' institutional review board determined that specific written approval for publication was not required.

Case Presentations

Case 1

An 84-year-old man with nasopharyngeal carcinoma, ischemic cardiomyopathy (ejection fraction $< 20\%$), and a Boston Scientific (Natick, MA) E110 dual-chamber ICD, presented for preradiation assessment. His ICD examination revealed the following programmed parameters; mode: VVE-DDDR; lower pacing rate limit: 60 beats/min; upper pacing tracking rate: 130 beats/min; upper pacing sensor rate: 130 beats/min; and ATP or shock rate: > 160 beats/min.

The event log and stored electrogram (Fig 1) demonstrated delivery of inappropriate ATP resulting from EMI during endoscopic sinus surgery at a community hospital. Although preoperative notes from both the surgeon and anesthesiologist acknowledged the ICD, the hospital record contained no discussion of device parameters, plans to mitigate EMI, or recognition that EMI occurred. There was no mention of device reprogramming or magnet application. Operating room

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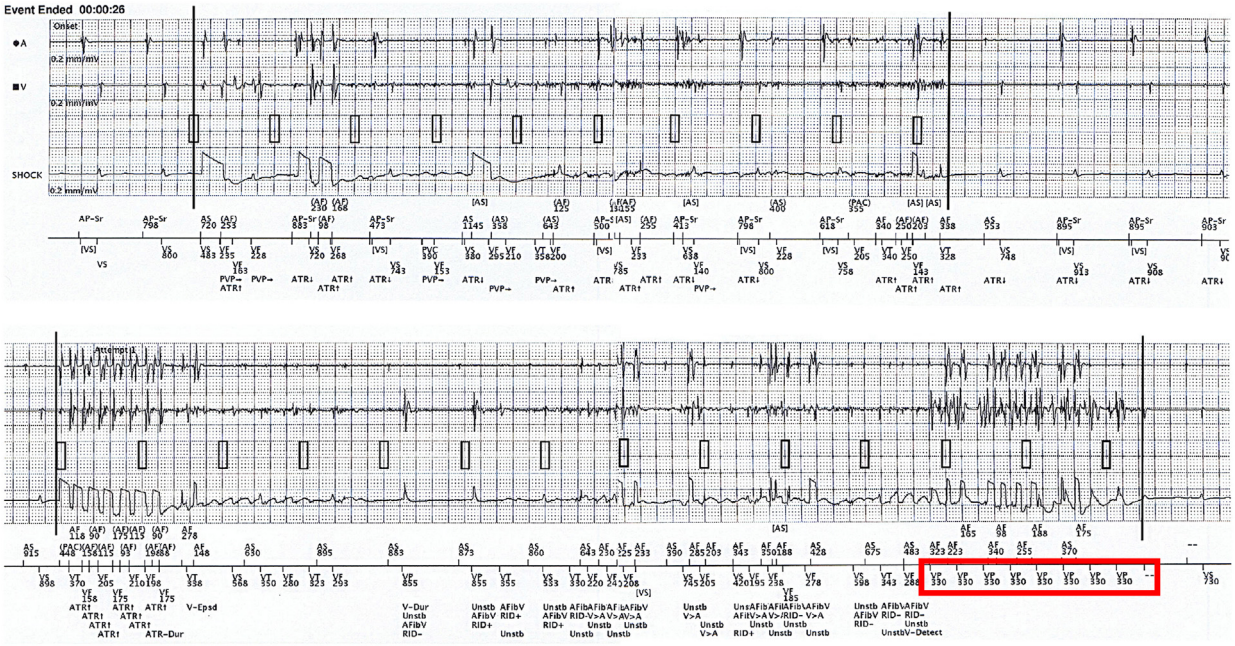

Fig 1. Electromagnetic interference (EMI) sensed by the implantable cardioverter-defibrillator (ICD) as atrial fibrillation, ventricular tachycardia, and ventricular fibrillation led to antitachycardia pacing during sinus surgery. The ICD treatment record showed about 9 seconds of EMI, followed by about 4 seconds of no EMI, then just over 1 second of EMI, leading to the episode onset (V-Epsd). The ATP was delayed because of the "unstable" nature of the V-V intervals (an unstable V-V interval is interpreted by the device as atrial fibrillation). Ultimately, antitachycardia pacing (ATP) (*highlighted in the red box*) was delivered because the ventricular rate was greater than the atrial rate and because of the failure of the QRS morphologic match (RID-). Recordings (top to bottom) are atrial lead electrogram, ventricular lead electrogram, shock lead electrogram (approximates a surface electrocardiographic signal), and markers reflecting the ICD decision tree. The *tall rectangles* (added to figure) indicate 1 second intervals (paper at 25 mm/sec). –, uncategorized and ignored event (usually due to blanking issues); AF, atrial fibrillation event; AFibV, indication that the ICD is counting ventricular tachycardia or ventricular fibrillation events even though its mode has been switched for atrial tachyarrhythmia; AP, atrial pace (-SR indicates that the rate sensor was active); AS, atrial sense—(AS) indicates that the AS event was ignored for ventricular pacing purposes; ATR, a counter that determines a pacing mode switch from DDD (atrial tracking) to DDI because of atrial tachyarrhythmia (eg, atrial fibrillation; arrow direction indicates increment [up] or decrement [down]. At ATR-DUR, the ICD began counting a second set of atrial tachyarrhythmia events that would have led to a mode switch with 8 additional counts or a de-arming of the atrial tachyarrhythmia event with 8 normal A-A sequences); PAC, premature atrial electrical event; PVC, ventricular event not preceded by an atrial event during DDD pacing mode; PVP - > , identifies the postventricular atrial refractory period that indicates that the ICD will not track an atrial sensed event; RID-, QRS morphology that does not match the stored QRS image and will lead to high voltage therapy; RID+, QRS morphology that matches the stored QRS pattern and will lead to a delay in high voltage therapy; Unstb, V-V interval variability that exceeds stability criteria used to identify AF with rapid ventricular response, which delays high-energy therapy while the V rate is lower than the VF rate but higher than the minimum treatment rate; V > A, indication that the ventricular rate is greater than the atrial rate—V > A overrides nearly every other parameter that might delay high-energy therapy; V-Epsd, start/end of a ventricular tachydysrhythmic event; VF, ventricular event sensed in the ventricular fibrillation window; VP, ventricular pace; VS, ventricular sense; [VS], ventricular noise event; VT, ventricular event sensed in the ventricular tachycardia window.

records showed use of monopolar electrosurgery during the case and placement of the electrosurgery unit dispersive electrode on the thigh. The data of the prior interrogation stored in the ICD memory demonstrated the lack of preoperative or postoperative examination of the ICD. Neither the patient nor any of his medical providers had any knowledge of this event.

Case 2

A man older than 89 years with recurrent tongue cancer, chronic atrial fibrillation, nonischemic dilated cardiomyopathy (ejection fraction $< 30\%$), and a St. Jude Medical (Sylmar, CA) model 2211-36 dual-chamber defibrillator implanted in the left pectoral position presented for evaluation and treatment planning. His ICD examination revealed the following programmed parameters (mode: VVE-VVIR): Lower pacing rate limit: 75 beats/min; upper pacing sensor rate: 120 beats/min; and ATP or shock rate: > 171 beats/min.

The event log and stored electrogram (Fig 2) demonstrated delivery of an inappropriate shock resulting from EMI during his surgical biopsy at a community hospital. Several of the medical notes incorrectly refer to this device as a pacemaker. The anesthesia record showed "magnet on ICD," but there was no documentation of device parameters or plans to mitigate EMI (this ICD has no method to confirm appropriate magnet placement). The electrosurgery unit dispersive electrode was placed on his right thigh, forcing the path of the electrosurgical unit current to cross the chest and ICD system, likely increasing the development of EMI during the procedure.[8] The ICD discharge during the procedure was not documented. Even though data stored in the ICD showed that the discharge had been reviewed during a previous examination, the patient was unaware that this event had occurred.

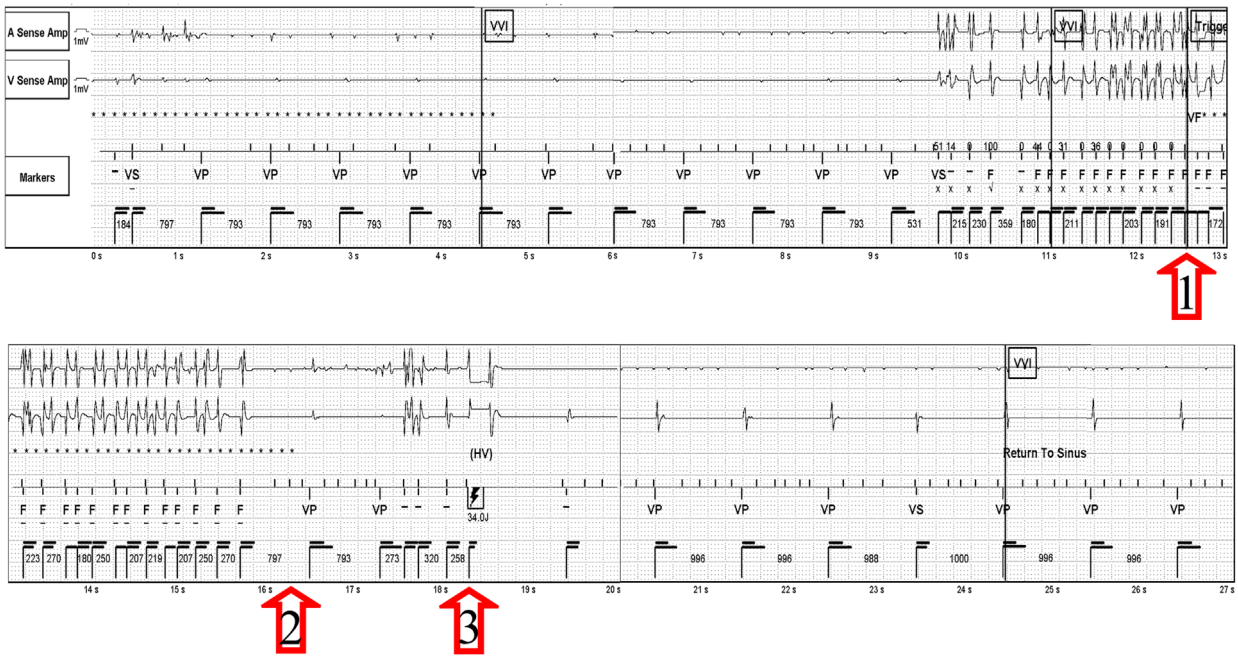

Fig 2. Electromagnetic interference (EMI), sensed by the implantable cardioverter-defibrillator (ICD) as ventricular fibrillation, instigating a 34-joule shock. The ICD treatment record shows an aborted charge followed by another round of EMI leading to a shock. Recordings (top to bottom) are atrial electrogram, ventricular electrogram, markers (reflecting the ICD decision tree), ventricular timing data (milliseconds), and elapsed time (in seconds). Above the marker line are *vertical hash marks* identifying the atrial signal (atrial fibrillation), and the small numbers represent the percent match to normal QRS morphology. The symbols immediately below the marker line show the ventricular classification (see the following). The paper speed was 25 mm/sec. *** from time 0 to 4.6 seconds reflects ICD charging due to a ventricular fibrillation (VF) detection with ICD activation that did not deliver a shock because the EMI transiently stopped. Resumption of the EMI at 9.6 seconds led to a second charge at 12.5 seconds (*red arrow 1*). The charge cycle finished at 16.5 seconds (*red arrow 2*). The EMI again ended, but a short burst at 17.6 seconds during the rhythm reconfirm period caused the ICD to deliver a shock (*red arrow 3*). -, ventricular event that could not be characterized because of discrepancy between the average calculated rate over the last 4 events and the short interval from the previous V sense (however, the measured V-V interval is used in the calculation of average V rate); F, a ventricular event falling into the VF zone by timing; (HV), delivery of a shock; "Return To Sinus," the end of the episode; VS, ventricular sense; VP, ventricular pace.

Case 3

A 62-year-old man with a Medtronic (Minneapolis, MN) D224TRK biventricular ICD and suspected ICD pocket infection presented for pocket exploration, debridement, and repositioning of the ICD to a subpectoral location. The ICD was not examined or reprogrammed preoperatively. No magnet was placed. Instead, short bursts of monopolar electrosurgery were planned to mitigate the risk of EMI and prevent unwanted pacing inhibition and ICD firing. In the operating room, a "whole-body electrode" (Megadyne Mega Soft dual-cord patient return electrode system [Draper, UT]) was placed. Soon after the surgical incision, an ICD shock caused apparent patient movement. The patient remained hemodynamically stable in an A-V sequentially paced rhythm. The surgical care team then reprogrammed the ICD to disable its high-energy therapy. At the conclusion of the procedure, ICD high-energy therapy was restored, the patient's airway was extubated, and the patient was taken to the recovery room in stable condition. Postoperative examination revealed the following programmed parameters (mode: VVE-DDDRV): Lower pacing rate limit: 60 beats/min; upper pacing tracking rate: 120 beats/min; upper pacing sensor rate: 120 beats/min; and ATP or shock rate $>$ 182 beats/min.

The stored shock electrogram (Fig 3) shows a "ventricular fibrillation (VF)" event at the 6th short burst of EMI. The additional short bursts of EMI during capacitor charging and the VF reconfirm period led to the inappropriate shock.

Discussion

This article presents three cases, from different institutions, that involved ICDs from each of the 3 major US manufacturers in which failure to adhere to all precautions resulted in inappropriate intraoperative ICD therapy.

The failure to take all steps necessary to prevent inappropriate intraoperative ICD therapy likely was the result of several "systems" issues. These issues included the following: (1) the relative rarity of these cases, (2) the incorrect assumption that inappropriate ICD therapy is not of significant concern,[9] (3) failure to understand that location of the electrosurgical dispersive electrode is an important consideration when caring for a surgical patient with an ICD,[5,6,10] and (4) confusion that still exists surrounding the perioperative care of these patients.[11-13]

Some of the confusion surrounding the care of patients with these devices likely stems from published recommendations that might be construed as incongruent. For example, the HRS

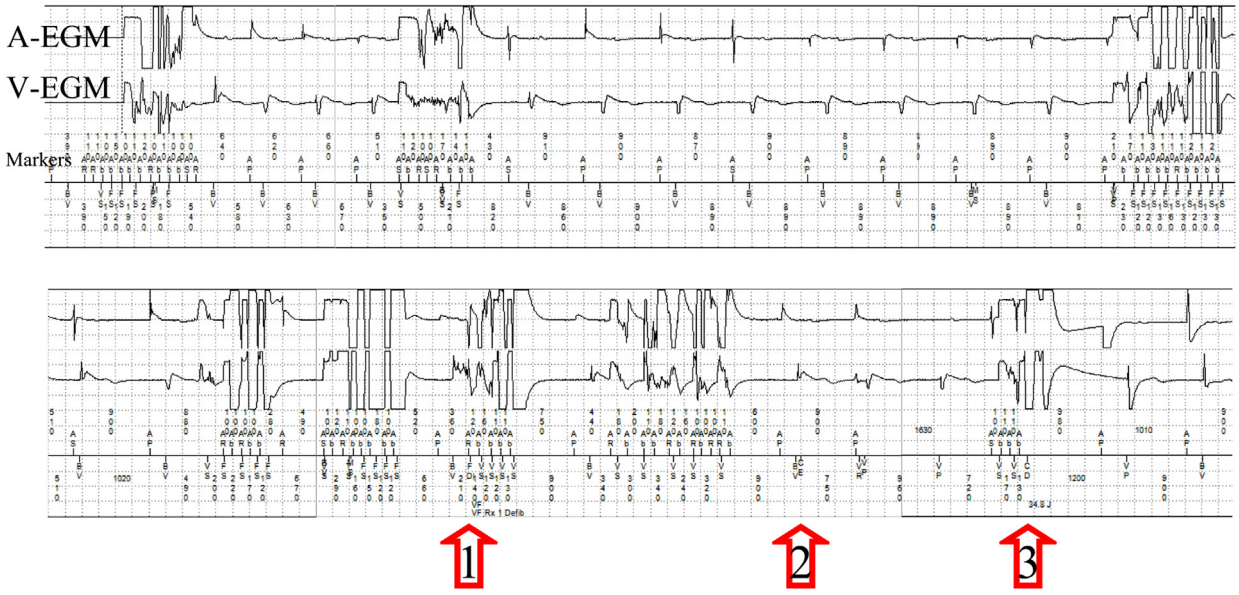

Fig 3. Short bursts of monopolar electrosurgery do not protect against implantable cardioverter-defibrillator (ICD) shocks. Short bursts of electromagnetic interference (EMI) during surgery resulting from monopolar electrosurgery were sensed by the ICD as atrial fibrillation, ventricular tachycardia, and ventricular fibrillation. At the sixth "burst" of EMI (*red arrow 1*), the ICD declared a "VF" event and began charging, likely due to the relative periods of EMI on and EMI off, which did not allow the VT/VF counters to completely clear. About 3.9 seconds later, the ICD completed the charge ("CE," *red arrow 2*) and began the "reconfirm period." The EMI during the charge cycle and again 2.3 seconds after CE led to the delivery of a 34.8-joule shock ("CD," *red arrow 3*). Recordings (top to bottom) are atrial electrogram, right ventricular electrogram, and markers (atrial markers above the line, ventricular markers below the line) reflecting the ICD decision tree. The numbers reflect the time between 2 adjacent events in milliseconds. The paper speed was 25 mm/sec. Ab, atrial event in the "blanking period" and thus completely ignored by the ICD; AP, atrial pace; AR, atrial event sensed during the postventricular refractory period and therefore not tracked into the ventricle or any atrial event occurring after an appropriately sensed atrial event but before any ventricular event (these events are counted for mode switch determination); AS, atrial sense; BV, biventricular (ie, both right and left ventricular) pace; CD, delivery of high-energy (shock) therapy; CE, end of the ICD charge cycle and beginning of the reconfirm period; FD, tachydysrhthymia episode declaration in the VF zone—initiation of an ICD charge cycle; FS, ventricular sensed event occurring in the VF timeframe; MS, entry into or out of the "mode switch" mode—during MS, the ICD acts as if the pacing mode is DDI rather than DDD; TS, ventricular sensed event occurring in the VT timeframe; VP, ventricular pace; VR, any ventricular event occurring in a nonphysiologic window and that does not inhibit the next expected ventricular pace; VR-VP, a ventricular-sensed event occurring in the safety or crosstalk window that results in a VP approximately 60 millseconds later; VS, ventricular sense.

Consensus Statement[6] states that ICD reprogramming may be unnecessary when monopolar electrosurgery only will be used inferior to the umbilicus; however, the ASA Practice Advisory[5] recommends suspending antitachycardia therapy whenever EMI is "likely" but does not specify when EMI might be "likely" or "unlikely" to occur. Furthermore, even though the ASA Practice Advisory states that all patients ideally should undergo a comprehensive device evaluation before elective surgery, the HRS Consensus Statement states that a preoperative ICD check within 6 months before scheduled surgery generally is sufficient. No statement addresses the use of the "whole-body" dispersive electrode (which was used in case 3), and no testing of this device in a patient with a CIED has been published.

Because ICD therapy rarely causes immediate recognizable harm, practitioners may not appreciate fully the adverse consequences. ICD shocks can injure the myocardium,[1] cause troponin release,[2] induce ventricular tachycardia,[14] and shorten lives.[7,15,16] Moreover, even inappropriate ATP can injure myocardium[1] and increase mortality. Inappropriate ATP delivered during atrial fibrillation with rapid ventricular response has induced ventricular tachycardia (VT),[17] and delivery of ATP might alter ICD treatment algorithms, increasing the likelihood of an inappropriate shock with induction of VF.[18] Whether inappropriate ATP from EMI actually can induce VT remains unclear.

In-hospital EMI (principally from monopolar electrosurgery) appears to confer significant risks to patients with ICDs,[7] and the authors believe that the majority of events such as those described herein remain undetected and/or unreported. As demonstrated in patients 1 and 2, both shock and ATP might be missed in the operating room because of the following: (1) these therapies can occur very quickly; (2) the 8 beats of ATP at 180 beats/min (approximately 2.6 seconds' duration) in patient 1 occurred during the use of monopolar electrosurgery, which likely introduced significant electrocardiogram monitor artifact; and (3) many patients who undergo general anesthesia have been treated with muscle relaxants, preventing movement during shock.

These cases reinforce the need for adherence to all published perioperative management recommendations from the ASA and HRS for patients with these devices. In particular, attention should be paid to EMI mitigation. Despite the confusion that continues to exist surrounding the perioperative care of these patients, and the inconsistency of some of the published recommendations on this topic, there appears to be a wide consensus about the importance of protecting patients from inappropriate high-energy therapy during surgery.

Before any elective procedure, the perioperative care team should verify proper ICD function and obtain a prescription from a CIED expert for the perioperative management of the device because not all CIEDs operate correctly.[19] A plan should be developed and carried out for mitigating intraoperative EMI, which might include either ICD reprogramming or the application of a magnet (if appropriate). For some patients, selection of surgical instruments (eg, bipolar electrosurgery or ultrasonic devices) that will not create EMI might be appropriate. Furthermore, the electrosurgery dispersive electrode should be positioned appropriately to prevent the presumed electrosurgery unit current path from crossing the chest and ICD circuitry. Testing of newer equipment, such as the whole-body dispersive electrode, to determine whether it should be used during surgery in the patient with a CIED should take place. In addition, practitioners should not rely solely on the use of short bursts of monopolar electrosurgery; this strategy failed to protect the patient in case 3 from shock because the VT/VF counters were incremented quickly based on the high-frequency EMI but only slowly decremented based on the paced rate of 75 beats/min (800-millisecond cycles).

Finally, because many patients with an ICD transmit their ICD data to the manufacturers, perhaps the manufacturers should report noise-induced therapies to regulatory agencies such as the Food and Drug Administration, and any inappropriate therapy delivered in a medical care setting should be reported to the Joint Commission. Review of noise-induced therapies has resulted in lead recalls.[20] This strategy also might be used to enhance perioperative patient safety for patients with CIEDs.

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