Original Article

Analyzing the Impact of Preoperative Interrogation of Cardiac Implantable Electronic Devices

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ABSTRACT

Background: Cardiac implantable electronic devices (CIED) are becoming more common for the management of underlying of cardiac dysrhythmias, and more patients with these devices are presenting for cardiac and noncardiac procedures.

Methods: We performed a retrospective, cohort, single-center study at a tertiary teaching medical center, gathering 151 patients with CIED undergoing elective and emergent surgeries for the time period between November 2013 and December 2016. We aimed to determine whether patients with CIED had the device interrogated before surgery as recommended by the Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) consensus, whether this lack of compliance led to delay in the holding area before surgery and determine the presence of intra- or postoperative cardiac events in these patients.

Results: A total of 76% of patients had interrogation of the device before surgery. *Emergent* cases were not interrogated as much as *elective* cases preoperatively (43% vs. 18%, respectively; $P < 0.05$). In total, 6% of cases had a CIED-related average holding area delay time of 54 minutes. Patients without preoperative device interrogation had more perioperative cardiac events than those who had the device checked (25% vs. 8%, respectively; odds ratio [OR] 0.26; 95% CI, 0.09–0.7, $P < 0.013$).

Conclusions: Our findings suggest that preoperative interrogation of the device plays a significant role to minimize the incidence of perioperative cardiac adverse events. Institutional providers show a lack of compliance with HRS/ASA recommendations for preoperative CIED management. Further research is required to determine if improved compliance to recommendations will lead to enhanced outcomes.

Keywords: American Society of Anesthesiologists, cardiac implantable electronic devices, Heart Rhythm Society, perioperative cardiac events

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INTRODUCTION

Cardiac implantable electronic devices (CIED) encompass several types of technologies for the treatment of cardiac dysrhythmias, including permanent pacemakers (PPM), automatic implantable cardioverter-defibrillator (AICD), cardiac resynchronization therapy pacemaker (CRT-P) or defibrillator (CRT-D).[1,2] Presently, more than 3 million patients in the United States have a PPM and more than 300,000 have an AICD in place.[3,4] Therefore, irrespective of their scope of practice, anesthesiologists ought to anticipate managing patients with such devices undergoing cardiac and noncardiac surgical procedures, in fact some authors have advocated for an *"anesthesiology device service"* for the perioperative care of patients with CIED.[3-10]

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Due to the increase in the incidence of CIED use, rapid evolution of this technology, the widespread use of electromagnetic interference sources during surgery, and the striking challenge they pose during intraoperative use, an expert consensus statement was developed in 2011 between the Heart Rhythm Society (HRS) and the American Society of Anesthesiologists (ASA), in collaboration with the American Heart Association and the Society of Thoracic Surgeons.[1,7,11,12]

The purpose of this consensus was to provide guidance for the perioperative care of patients with CIED. *Prior* to surgery, device interrogation is recommended for 12 months for patients with PPM and a minimum of 6 months for patients with AICD or any CRT device. These interrogations are usually performed by a provider such as a cardiologist, electrophysiologist, or representative from the CIED manufacturer.[7,8,11,13,14]

The HRS/ASA consensus also seeks to minimize adverse outcomes associated with these devices, including damage of the device, inability to deliver pacing or shocks, changes in pacing behavior, inappropriate CIED therapies, hypotension, tachyarrhythmia or bradyarrhythmia, myocardial tissue damage, delay or cancellation of surgery, and additional hospital resource utilization.[1,13,15,16]

The present study seeks to determine the degree of compliance to the current recommendations from the HRS/ASA for patients with CIED before surgery. The authors hypothesize that improper preoperative evaluation of patients with CIED may lead to delayed room starts on the day of surgery and increased perioperative adverse cardiac events.

METHODS

Study design

We conducted a retrospective analysis using data from our hospital's electronic medical record system (identified through International Classification of Disease Code, ICD-10 Code) to identify patients with CIED who underwent cardiac and noncardiac surgeries from November 2013 to December 2016. Institutional review board approval was obtained prior to patient record review.

Inclusion criteria encompassed patients over 18 years old, undergoing all types of procedures whether elective or emergent, with a permanent CIED (PPM, AICD, CRT-P, and CRT-D) in place. *Exclusion criteria* included patients with temporary cardiac electronic devices (such as transcutaneous, epicardial pacemakers, etc.), incomplete medical records, patients who died intraoperatively or within 30 days of the procedure, patients undergoing implantation or removal of the CIED, and consecutive interventions on the same patient during same admission (as these patients are no longer candidates to follow the HRS/ASA recommendations due to successive interventions).

Outcomes

The primary endpoint of this study was to determine the degree of compliance to the current recommendations from the HRS/ASA for preoperative CIED interrogation. Secondary outcomes included analysis of unnecessary delays from interrogation of the device in the holding area prior to surgery. The authors reported delay in holding area as the minutes beyond the scheduled time for the surgery. Average delay in holding area time was reported as CIED and non-CIED related, as well as patients that did not experience any delay. We also compared the incidence of perioperative cardiac events (intra- and postoperative) to preoperative CIED interrogation and nature of the procedures whether as elective or emergent.

Sample size considerations

After statistical analysis, the authors estimated that for a two-sample chi-square test with alpha set at 0.05, a total sample size of 151 patients ($n = 151$) would provide 80% power to detect a change in the rate of events for the target population to be analyzed.

Analyses

The authors used the Fisher's exact test, two-sample *t*-test and chi-square to determine mean differences between groups. Associations between categorical variables were tested with either chi-square or Fisher's exact tests; $P < 0.05$ denoted statistical significance. R v3.3.3 software (R-Foundation, Vienna, Austria) was used for all analyses.

RESULTS

A total of 151 patients ($n = 151$) were analyzed based on our *inclusion* and *exclusion* criteria as described earlier. Study demographics, procedures, events, and devices are displayed in Tables 1 and 2.

OUTCOMES

Device interrogation

A total of 76% of patients had preoperative interrogation of the device before surgery. *Emergent* cases were not interrogated as much as *elective* cases before surgery (43% *vs.* 18%), respectively ($P < 0.05$) [Table 3].

Table 1: Population baseline characteristics and types of procedures performed

Factors	*n*, %
Total population analyzed	151
Age (years)	
Mean	66 +/- 12
Range	30-100
Gender	
Male	97 (64)
Female	54 (36)
Case Nature	
Elective	116 (76.8)
Emergent	35 (23.2)
Number of Perioperative	18 (11.9)
Cardiac Events in Study	
Procedure Type	
Vascular Surgery	28 (18.5)
Urology	24 (15.8)
General Surgery	22 (14.5)
Cardiothoracic Surgery	18 (11.9)
Orthopedic Surgery	16 (10.5)
Otolaryngology	12 (7.9)
Neurosurgery	8 (5.2)
Ophthalmology	7 (4.6)
Colorectal Surgery	6 (3.9)
Gynecology	6 (3.9)
Plastic Surgery	2 (1.3)
Oncologic Surgery	1 (0.6)
Transplant Surgery	1 (0.6)

Table 2: Prevalence of cardiac implantable electronic device in the population analyzed

Factors	*n*, %
Type of device	
Automatic implantable cardioverter-defibrillator	127 (84.1)
Cardiac resynchronization therapy-defibrillator	15 (9.9)
Permanent pacemaker	6 (4)
Cardiac resynchronization therapy-pacemaker	3 (2)
Manufacturer	
Medtronic[a]	73 (48.3)
Boston Scientific[b]	39 (25.8)
St Jude[c]	34 (22.5)
Biotronik[d]	4 (2.7)
LivaNora[e]	1 (0.66)

[a]Medtronic PLC (Fridley, MN, USA). [b]Boston Scientific (Marlborough, MA, USA). [c]St Jude Medical (Little Canada, MN, USA). [d]Biotronik SE & Co. (Berlin, Germany). [e]LivaNora (London, UK)

Table 3: Device interrogation

Preoperative Interrogation	Overall (*n*=151)	Elective (*n*=116)	Emergent (*n*=35)	*P**
Yes	115 (76.2)	95 (81.9)	20 (57.1)	<0.05
No	36 (23.8)	21 (18.1)	15 (42.8)	

**P*-values from Chi-square test. Values expressed as #, (%)

Holding area delays on day of surgery and perioperative cardiac events

Overall, 6% of the patients analyzed experienced a delay due to CIED assessment in the holding area. All delays occurred during elective procedures. The average CIED-related holding area time was 54 minutes, whereas the average holding area delay time was 30 minutes for non-CIED-related issues (e.g., nursing staff, surgical or anesthesia team). One-third of the patients who presented with CIED-related delay did not have the device checked prior day of surgery (P = 0.45). These patients experienced a longer average delay when compared to those patients who had the device checked prior day of surgery (54 minutes vs. 20 minutes, P = 0.33) [Table 4].

A total of 12% (18 of 151) perioperative cardiac events were observed. The various adverse cardiac events occurred in the population analyzed are displayed in Table 5. For all cases, patients without preoperative device interrogation had more perioperative cardiac events than those who had the device checked (25% *vs.* 7.8%, respectively (Odds Ratio [OR] 0.26; 95% CI 0.09-0.7, $P < 0.013$). *Elective* cases without preoperative device interrogation were found to have greater incidence of perioperative cardiac events than their counterparts who had device interrogation (19% *vs.* 4%, respectively [OR 0.19, 95% CI 0.05-0.81], $P < 0.035$). In *emergent* cases, there was no difference in the incidence of perioperative cardiac events whether the device was interrogated preoperatively or not (25% *vs.* 33%, respectively [OR 0.68, 95% CI, 0.16–2.84], $P = 0.87$) [Table 6].

DISCUSSION

The perioperative period represents unique challenges that anesthesiologists face in order to assure the best possible outcome for patients with CIED undergoing cardiac or noncardiac surgery.[7,10] The expert consensus provided by the HRS and the ASA was described by the authors as a *practice advisory* intended to guide the perioperative care for patients with CIED. The management of these patients perioperatively continues to be inconsistent, leaving the decision to the *"CIED Team"* (a multidisciplinary committee including a cardiologist, electrophysiologist, device manufacturer representative, surgeon, and anesthesiologist) to reach the most appropriate plan of care.[1,7–9,13,15,17] In theory and practice, this multidisciplinary committee could plan a system-wide initiative that facilitates a reliable standard of care in perioperative CIED management.

Degree of compliance with current guidelines

In our analysis, despite a considerable percentage of CIED patients presenting for surgery at our institution had a preoperative device interrogation, a significant amount of elective and emergent cases underwent surgery without this important requirement. Factors that play a role in the lack of preoperative device interrogation can be grouped into prehospital or inpatient. Prehospital factors include lack of routine device interrogation, lost on follow-up, and perioperative team unable to encourage or facilitate preoperative interrogation. Patients may not

be thoroughly explained the specific intervals of regular device check-up or may be unable to follow the necessary steps to get the device interrogated or have challenging access to electrophysiology technicians for either remote or direct device interrogation, among other factors. Inpatient factors that affect CIED interrogation in the holding area include urgency of the needed procedure, access to the electrophysiology service or a company representative.

Table 4: Holding area delays

	Time (min)¶	
Holding Area Delays		
CIED Related	54 (16-133)	
Non-CIED Related	30 (2-77)	
	# (%)	*P**
CIED-Related Delays		
Preoperative Interrogation	6 (66.7)	0.45
No Preoperative Interrogation	3 (33.3)	
	Time (min)¶	*P**
CIED-Related Holding Area Time		
Preoperative Interrogation	20 (16-46)	0.33
No Preoperative Interrogation	54 (48-133)	

¶Time expressed as: average (range). **P*-values from two-sample t-test and Fisher's exact test. % derived from total population analyzed (*n*=151)

Table 5: Documented perioperative cardiac events

Intraoperative and Postoperative Cardiac Events associated to CIED	Total (*n*=18)
Sustained Device Firing due to VT	3
Uncontrolled Intraoperative Atrial Fibrillation with Rapid Ventricular Response	3
Non-sustained VT	3
Symptomatic Sinus Bradycardia with multiple device firing	2
Loss of Biventricular Capture	1
Symptomatic Atrial Tachycardia	1
New onset LBBB	1
Symptomatic Bigeminy	1
Torsades des Pointes	1
Symptomatic Sinus Tachycardia	1
Symptomatic PVCs	1

CIED:Cardiac Implantable Electronic Device; VT:Ventricular Tachycardia; LBBB:Left-Bundle Branch Block; PVCs:Premature Ventricular Contractions

Ultimately, if these factors prevent the preoperative CIED interrogation, the final responsibility for the management of the device intraoperative lies with the staff anesthesiologist, which frequently occurs on the same day of surgery. In our institution, several mechanisms are implemented when a patient scheduled for a surgical procedure lacks a preoperative device check. The electrophysiology service on call or a company representative is contacted, but this is usually neither timely nor reliable.

Preoperative delays in the holding area on the same day of surgery due to CIED-related issues were 6% overall, and all of these cases represented elective surgical procedures. The majority of these delays were for elective cardiothoracic cases, which raises the possibility of an observation bias, whereby increased concern for perioperative function of the device makes detection of improper CIED management more likely.

Furthermore, our results demonstrate a 34-minute difference, between CIED and non-CIED-related issues in the holding area, as well as a 24-minute difference for CIED-related delays with and without preoperative device check. Such delays are eventually translated to organizational flow issues, increased hospital costs, and patient concern.

Perioperative cardiac events and device interrogation

There was a significant association between preoperative interrogation of these devices and occurrence of perioperative adverse cardiac events. The authors defined these events as *inappropriate* delivery of CIED therapy (or lack thereof), new onset bradyarrhythmia or tachyarrhythmia different from the patient's current underlying rhythm or symptomatic cardiac dysrhythmia during the intraoperative period or within 30 days of the procedure.[7,8,13,15] Current guidelines have suggested that clinicians take prudent measures to avoid these events related to suboptimal CIED management.[7,12,14] There appears to be an assumption that the lack of preoperative interrogation or improper magnet use results in patient

Table 6: Association between preoperative CIED interrogation and perioperative cardiac events

Preoperative CIED interrogation and perioperative cardiac events for all cases						
Variable	**Response**	**Overall**	**No Interrogated**	**Interrogated**	***P*¶**	**Test & OR (95% CI)**
Cardiac events	No	133 (88.08%)	27 (75.00%)	106 (92.17%)	0.013	0.26 (0.09, 0.7)
	Yes	18 (11.92%)	9 (25.00%)	9 (7.83%)		
Preoperative CIED interrogation and perioperative cardiac events for elective cases						
Variable	**Response**	**Overall**	**No Interrogated**	**Interrogated**	***P****	**Test & OR (95% CI)**
Cardiac events	No	108 (93.10%)	17 (80.95%)	91 (95.79%)	0.035	0.19 (0.05, 0.81)
	Yes	8 (6.90%)	4 (19.05%)	4 (4.21%)		
Preoperative CIED interrogation and perioperative cardiac events for emergent cases						
Variable	**Response**	**Overall**	**No Interrogated**	**Interrogated**	***P*¶**	**Test & OR (95% CI)**
Cardiac events	Yes	25 (71.43%)	10 (66.67%)	15 (75.00%)	0.871	0.68 (0.16, 2.84)
	No	10 (28.57%)	5 (33.33%)	5 (25.00%)		

¶*P*-values from Chi-Square Test. **P*-values from Fisher's Exact Test

mortality and morbidity; however, there is a dearth of scholarly work demonstrating this association.[18] Patients who developed perioperative cardiac events as described in Table 5 were admitted to the intensive care unit for 24-hour cardiac telemetry observation. Additionally, reassessment of the device was made by either the electrophysiology team or a company representative remotely.

Our study represents one of the first analyses that have demonstrated the association between lack of device interrogation and increased incident of intraoperative cardiac events. This statistically significant relationship demonstrates that clinicians should stress the importance of proper preoperative interrogation of the CIED as a means of improving patient safety in the operating room.

Limitations

The authors acknowledge several limitations in this study starting by the fact of this being a single-center, retrospective analysis. The authors did not describe which patients were device dependent, which identifies patients more susceptible to perioperative cardiac events, besides the number of patients that followed the recommendations provided by the HRS/ASA was small; therefore, it is possible that the sample analyzed was underpowered to determine differences in this group.

CONCLUSION

In summary, preoperative interrogation of a CIED is crucial for patients undergoing any surgical procedure in order to minimize the risk of perioperative adverse cardiac events. We have demonstrated that preoperative interrogation seems to reduce the occurrence of these types of events. Our study suggests that strict adherence to the HRS/ASA guidelines may lead to decreased adverse perioperative cardiac events although clearly more research is required to substantiate these findings.

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Conflicts of interest

There are no conflicts of interest.

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