Perioperative Outcomes of Patients with Cardiac Implantable Electronic Devices

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Abstract

A large and increasing proportion of patients undergoing non-cardiac surgery have a permanent pacemaker (PM) or implantable cardioverter-defibrillator (ICD). These patients usually are considered to be at higher perioperative risk, but whether the presence of one of these cardiac implantable electronic devices (CIED) serves as a marker for increased perioperative morbidity or mortality remains unknown at this time. This retrospective propensity-matched retrospective cohort study will utilize the Multicenter Perioperative Outcomes Group (MPOG) database and the social security administration's death master file to determine if there is an increased risk of perioperative major adverse cardiac events among non-cardiac surgery patient with CIEDs compared to patients without CIEDs.

Introduction

In the United States, approximately 40 million patients undergo non-cardiac, non-obstetric surgery each year[1]. The occurrence of an adverse perioperative event appears to substantially increase the chance of significant morbidity or mortality.[2] Specifically, with regard to adverse perioperative cardiac events, patients who sustain a nonfatal perioperative myocardial infarction (MI) have a 15-20% in-hospital mortality rate and an increased risk of cardiovascular death and nonfatal myocardial infarction (MI) for six months following surgery.[2] Furthermore, the in-hospital mortality for patients experiencing a cardiac arrest following non-cardiac surgery is even higher, with one estimate being 65%.[2]

Because the majority of non-cardiac surgery is elective, accurate assessment of perioperative risk can offer important guidance for patient and clinician decision-making. Recent studies have demonstrated the overall incidence of perioperative adverse cardiac events in non-cardiac surgery to be 1 - 2%.[3] In patients who underwent non-cardiac surgery and either had or were at risk for cardiac disease, pooled results from multiple studies demonstrated the incidence of major adverse cardiac events (including nonfatal MI, nonfatal cardiac arrest and cardiac death) to be 3.9%.[2]

Although much effort has been made to identify specific independent factors that increase perioperative risk and to develop accurate preoperative risk assessment algorithms, significant uncertainty remains.[2] Studies have identified several factors independently associated with increased perioperative risk, including emergent or high risk surgery, advanced age, active congestive heart failure, cerebrovascular disease, hypertension, peripheral vascular occlusive disease, insulin dependent diabetes, serum creatinine > 2.0 mg/dl, and previous cardiac intervention defined as either percutaneous coronary intervention or cardiac surgery.[2,3]

Although not well studied, another factor that may be independently associated with increased perioperative risk is the presence of a cardiac implantable electronic

device (CIED) -- either a permanent pacemaker (PM) or an implanted cardioverter-defibrillator (ICD). Between 1993 and 2009, 2.9 million patients underwent PM implantation in the United States. During this time, PM use increased 55.6%, and the population of patients receiving PMs became older with more comorbidities.[4] In North America today, at least 3 million patients have a CIED, and more than 400,000 PMs and 120,000 ICDs are being implanted annually in the U.S. alone.[5,6]

Many of these CIED patients require non-cardiac surgery each year. While it is often assumed that these patients are at an increased perioperative risk from non-cardiac surgery compared to patients without one of these devices, limited data exists to support this hypothesis. Two single-center observational studies have shown evidence of an increased risk of mortality among PM patients undergoing non-cardiac surgery. A nine year retrospective review of 14,787 ophthalmologic surgeries at a center in India found that the presence of a PM was associated with increased mortality within 6 weeks postoperatively, regardless of anesthetic type.[7] However, this study included only patients who underwent ophthalmologic procedures, making it difficult to generalize the results to a larger surgical population. The second study followed a cohort of French PM patients undergoing on-cardiac surgery. Of the 65 patients enrolled, 11 (16%) had a cardiac event and two (3.5%) died from cardiac causes within 30 months of the initial surgery.[8] This study did not contain a control group without PMs to determine whether this risk was related entirely to the PM or to other population factors.

While these focused, single-center studies suggest that CIED patients may have an increased perioperative risk, no large, multi-center studies have investigated a possible association between the presence of a CIED and increased perioperative morbidity or mortality in patients undergoing non-cardiac surgery. Quantifying the perioperative risk in this patient population would lead to more accurate risk stratification and aid patients and clinicians in the process of informed decision-making. We hypothesize that patients with a CIED are at an elevated risk of postoperative mortality or cardiac ischemia, independent of the underlying cardiac morbidities associated with the CIED population.

Methods

This is a propensity-matched retrospective cohort study utilizing the Multicenter Perioperative Outcomes Group (MPOG) database. MPOG is a consortium of 30 anesthesiology and surgical departments with detailed risk adjustment, process of care, and outcome data from over 1.2 million perioperative episodes from 10 centers has been compiled from the perioperative electronic health record (EHR) employed by these institutions. Each contributing institution has a performance site institutional review board (IRB) approval to contribute a limited dataset to this database. IRB approval was also obtained at the coordinating center, the University of Michigan, for conduct of studies using the aggregated dataset. Seven centers contributing preoperative history and physical data and postoperative laboratory result data were included for analysis (University of Michigan, Oregon Health and Science University, University of Colorado, University of Tennessee, University of Oklahoma, University of Vermont, and Vanderbilt University).

Patient population

Adult patients (age >= 18 years) undergoing major non-cardiac surgery will be included in the analysis. Major surgery will be defined as procedures requiring admission that are performed in operating rooms or hybrid operating rooms. Minor procedures, interventional radiology procedures, and diagnostic procedures performed in offsite locations will be excluded. Patients with an existing ventricular assist device or ASA physical status 5 will also excluded. In addition, emergency procedures, procedures involving cardiopulmonary bypass, cardiac catheterization, dysrhythmia ablation and CIED implantation procedures will be excluded. This group will be divided into those with CIEDs and those without. To identify patients with a CIED, data will be extracted from the structured preoperative evaluation used at each center. In this evaluation providers select patient history details from predefined pick lists that include the presence of a CIED. In addition, a preoperative history and physical free text search will be conducted for the following key words: magnet, pacer, pacemaker, pacemaker-defibrillator, ICD, AICD, VVI, VVIR, DDD, DDDR, AAI, VOO, DOO.

Primary Outcome

The primary outcome will be major cardiac adverse events within seven postoperative days. The major adverse events included as primary outcomes will be mortality within seven post-operative days and myocardial infarction within seven post-operative days. Perioperative myocardial infarction will be defined per the American Heart Association guidelines, by a post-operative serum Troponin-I value that is equal to or greater than 10% above the coefficient of variation for the assay at each participating institution.[3] Mortality will be derived by identifying patients in the social security

administration's death master file (United States Department of Commerce, Springfield, Virginia), a publicly available database that lists all deaths by social security number. If the patient is found in the death master file, the date of death will be compared to the date of operation to establish a seven-day and 30-day all-cause mortality.

Secondary Outcomes

Secondary outcomes of this study will include 30 day mortality or myocardial infarction (as defined above) within 30 days.

Patient matching

Propensity scores estimating the probability of a patient having a CIED will be calculated for the entire included patient population using logistic regression. Based on previously published literature, baseline covariates to be included in the model are age, sex, body mass index (BMI) category, hypertension, previous cardiac surgery (excluding CIED placement or revision), chronic kidney disease (CKD)(creatinine >2mg/dL), ASA physical status score, history of congestive heart failure, history of arrhythmia, history of ischemic heart disease, history of cerebrovascular disease, history of insulin dependent diabetes mellitus, and history of cardiac valvular disease (CVD).[2,3,9-17] A computer based nearest-neighbor matching program with greedy 5 to 1 digit matching will be utilized to identify as many matches between the CIED and non-CIED group as possible using the propensity scores. Standardized differences will be calculated and used to compare means and prevalences of baseline characteristic between the two groups to ensure the matching process was successful. Additional interaction terms will be included as necessary to ensure balance between the matched cohorts.

Data analysis

Baseline characteristics between those with and without CIEDs in the propensity-matched cohort will be compared using a chi-square test for categorical variables and a student's t-test for continuous variables. Logistic regression will be used to assess the relationship between CIED and the primary and secondary outcomes of this study. Backward step-wise selection will be used to determine which covariates are retained in the model using a $p<0.10$ as the criterion for retention.

Impact

Given the presumed presence of pre-existing cardiac disease in CIED patients, as well as the introduction of the additional potential for mechanical failure and/or human error through the presence of a permanently implanted complex electronic medical device, perioperative morbidity and mortality is likely increased in these patients relative to the general non-cardiac surgery population. However, this association has not been adequately studied. Thus, defining the risk of major adverse perioperative

events in surgical patients with CIEDs could eventually lead to more reliable assessment of their perioperative risk and steps to mitigate it. The availability of comprehensive surgical quality improvement databases will allow us to analyze the incidence of these events retrospectively in order to begin to answer this question, and this investigation will also establish a foundation for future prospective research studies.

Questions for discussion

1. Should we use creatinine to default CRF or free text cleaning in H&P? already getting/restricting to site with lab values due to troponin outcome
2. Can we simplify the matching somehow?

Data Elements

Source	Data	Data type	MPOG concept ID
	Admission type	OP, IP, AP, Emergency	
	Sex		
Preoperative Evaluation	ASA status	Numeric, 1-4	MPOG concept ID 70233
	Permanent Pacemaker		MPOG concept ID 70035
	Implanted Defibrillator		MPOG concept ID 70032
	Dysrhythmia		MPOG concept ID 70024
	Pacer, pacemaker, ICD, AICD, device settings	Free text	Throughout H&P
	Body mass index		Anthropometrics. mpog_body_mass_index
	Hypertension		70031
	Past surgical history		70105
	Congestive heart failure		70026
	Ischemic cardiac disease		70027, 70033
	Cerebrovascular disease		70088
	Cardiac valvular disease		70042

	Cerebrovascular disease		70086
	Insulin dependent diabetes mellitus		70046
	Home medications (identify insulin)		MPOG_Preop_Concept ID in (70077, 70079, 71210)
Pre op labs	Peak creatinine within 60 preop days of anesthesia_start >= 2.0	Numeric, 0-500	MPOG concept 5002
Post op labs	Peak postoperative troponin (within 7 days)	Numeric, 0-500	Aims_labvalues, MPOG concept 5011
Master Death File	Death 1, 12 months		

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