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OFFICIAL TITLE OF STUDY: Association of Type of Anesthetic and Outcomes in Transfemoral Aortic Valve Replacement

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Statistical Analysis Plan:

Sample: We will create an EMR-based cohort of adult patients age > 21 scheduled to receive a TAVR procedure surgery at Yale-New Haven Hospital under conscious sedation between December 2014 and June 2016. The Multicenter Perioperative Outcomes Group (MPOG) local data repository in conjunction with subsequent chart review will be used for cohort identification.

Data available: Data on patients will include: demographics, vital signs, medications, anesthesia notes, laboratory values, clinician and health care encounter information (including, provider type, location, date time), as well as diagnostic codes, procedure codes, clinic notes, and pharmacy records associated with that encounter.

Statistical Analysis Plan:

Measurement/Operationalization of Variables:

Outcomes: The primary outcome was the days to discharge following TAVR between dexmedetomidine dominant MAC versus other forms of MAC. Secondary outcomes included conversion to GA, presence of delirium, blood pressure, heart rate, permanent pacemaker insertion, surgical procedure length, and ICU length of stay with dexmedetomidine dominant MAC versus other forms of MAC.

Preoperative Variables:

Demographics: Age, sex, self-identified ethnicity/race – taken from the MPOG database
Perioperative Predictor Variables:

- Height and weight – taken from anesthesia record
- Body mass index – converted into the body-mass index as the weight in kilograms divided by the square of the height in meters
- ASA Physical Status Score – taken from anesthesia record
- NYHA CHF Classification – taken from chart
- LVEF – taken from chart
- Comorbid diagnoses: Dichotomous variables will be created for the preoperative presence of a diagnostic code for each of the following conditions: alcoholism, anxiety disorder, atrial fibrillation, cerebrovascular disease, congestive heart failure, coronary artery disease, diabetes, hypertension, depression, obstructive sleep apnea (OSA), peripheral vascular disease, psychosis, renal disease, and substance abuse.
    - If the diagnosis was mentioned in any of the patients charts prior to the TAVR, it was included
- Medications by class: Separate dichotomous variables will be created for the presence or absence of a prescription for anti-hypertensive medications by drug class and for psychiatric medications by drug class.
    - Drug classes: Beta-blocker, calcium channel blocker, ACE inhibitor/ARB, non-K-sparing diuretic, K-sparing diuretic, vasodilator, other anti-hypertensive, alpha-2 adrenergic agonist, antiarrhythmias, SSRI/SNRI, other antidepressant, antipsychotic, anticonvulsant, anti-anxiety, dementia drug
    - For the presence of a prescription drug, the most recent medical note prior to the TAVR was used

Perioperative Variables:

- Medications used for conscious sedation – taken from anesthesia record
- Blood pressure – taken from anesthesia record
- Heart rate – taken from anesthesia record
- Conversion of general anesthesia – taken from anesthesia record

- Procedure length – taken from anesthesia record

Postoperative Variables:

- Length of hospital stay – length of hospital stay was defined as the number of days from the day of surgery to the date of discharge, rounded to the nearest whole day
- Length of ICU stay – all patients were transferred to the ICU after surgery; length of ICU stay was defined as the number of days from the day of surgery to the date of transfer to the floor, rounded to the nearest whole day
- Permanent pacemaker placement – taken from the chart
- Presence of delirium – presence of delirium was determined when documented in the medical chart
- Mortality – death dates were taken from the MPOG database

Data Analysis: Formation of the Model

The first step in the analysis will be to delineate the basic descriptive characteristics of the cohort including the prevalence of each variable among surgical patients. Descriptive statistics (means, medians, frequencies) will be used to characterize variables of the study patients. Histograms and box plots will be constructed to evaluate variable distributions. Missingness will be examined for each variable. Missing values will be carefully investigated to identify the causes and mechanisms of missing data.

Secondly, we will test for the primary outcome by measuring the association between length of hospital stay and type of conscious sedation. The model will be determined by the distribution of the variables as determined above.

Sample size estimation and power analysis: The power analysis took into account the following assumptions: We assumed that the mean length of stay among the dexmedetomidine group was 3 days versus 4 days in the remaining subjects. We further assumed a standard deviation to be 1.8 days in both groups. Given these assumptions, we calculated that a group of 40 patients in the dexmedetomidine group and 80 patients in the comparator group would have 81% power to detect a difference in one day in length of stay with a 2-sided alpha of 0.05.

Third, we will examine secondary outcomes for associations between conversion to general anesthesia, incidence of delirium, and ICU length of stay among the different types of conscious sedation.