Risk Stratification for Heart Failure Patients Undergoing Noncardiac Surgery: A Prospective Analysis

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A. Study Purpose and Rationale

Heart Failure (HF) is a major medical problem throughout the United States that will only increase with the aging of the general population. Over five million Americans are affected with HF and 80% of all cases of heart failure in the US occur in individuals who are 65 years and older.[1] HF accounts for over 1.5 % of the total health care spending and is the most common hospital discharge diagnosis for those over age 65.[2] With the rising prevalence and incidence of HF, it is anticipated that a growing number of patients with heart failure will undergo noncardiac surgical intervention. While it is well known that a history of hypertension, coronary artery disease, underlying valvular heart disease, diabetes and cardiomyopathy are risk factors for the development of CHF and that coronary artery disease is the underlying cause of heart failure in 68% of these patients[3,] the risk of peri-operative complications in patients who suffer from HF has not been well defined nor has the risk factors for such outcomes and the therapies employed to modify risk.

Patients with clinical HF or a history of HF are at significant risk for perioperative complications. Several well known and widely used indices of cardiac risk are routinely used when assessing the preoperative patient, and a presence of or a history of HF remains a significant risk factor in both the original and the revised cardiac risk indices. In the original Goldman study published in 1977, an S3 gallop or JVD was named one of the nine risk factors to be associated with life threatening cardiac complications and perioperative cardiac death. In addition, it was found that the rates of perioperative HF were 2% among patients with no history of CHF, 6% among those with a prior history of HF and 16-35% among those with HF based on clinical or radiological evidence prior to surgery.[4] In the ACC/AHA guidelines for perioperative cardiovascular evaluation, "decompensated heart failure" is a major clinical predictor of increased perioperative risk and "compensated" or prior congestive heart failure is an intermediate predictor of risk.[5] Recently, Lee et al developed the Revised Cardiac Risk Index that lists HF as 1 of 6 important risk factors. Other risk factors included ischemic heart disease, high risk surgery, diabetes mellitus-especially insulin dependence, renal insufficiency with a creatinine > 2mg/dl, history of CVA and poor functional status. In these revised Goldman criteria the rates of major cardiac complications increased significantly in patients with two or more risk factors; those with two factors had a moderate risk (7%) and 3 or more factors conferring high risk (11%).[6]

Unfortunately, there is limited information on the assessment of the risk and prevention of perioperative complications in patients with predominately HF. Recently, Hernandez et al showed that in patients 65 and older, HF patients undergoing major non-cardiac surgery suffer substantial morbidity and mortality whereas patients with coronary artery disease without HF have similar mortality compared to a more general population.[7] Preliminary unpublished retrospective data from a recent study performed at our institution shows that out of 134 patients with heart failure undergoing non-cardiac surgery 36 patients (27%) had at least one perioperative event including 10 (7.5%) deaths, 19 (14.2%) non q-wave myocardial infarctions, 2 (1.2%) ST elevation myocardial infarctions and 28 (21%) HF exacerbations. Therefore, since these patients represent a rising subgroup of the subjects undergoing noncardiac surgery and because of advances in treatment for such patients including vasodilator therapy, beta adrenergic antagonists and additional neurohormonal blockade, I propose to prospectively evaluate in a systemic manner the clinical and demographic characteristics of a consecutive series of patients with HF undergoing noncardiac surgery and to describe the treatments employed, hospital course and clinical outcomes.

The purpose of this investigation is two-fold. First, to identify risk factors that are associated with peri-operative complications in patients with HF undergoing noncardiac surgery. Second, to evaluate the pharmacological interventions used during the peri-operative period and their relation to outcomes in patients with HF undergoing non-cardiac surgery.

B. Study Design and Statistical Analysis

This study is a prospective observational study of patients at Columbia Presbyterian Medical Center who are diagnosed with HF and are undergoing a specific surgical procedure. Subjects will be identified by a review of the surgical cases for the specific week. All subjects who had a physician visit or hospitalization for HF (ICD – 9 428.0) in the two year period prior to the surgical procedure and are scheduled for one of the following surgical procedures (1) peripheral vascular surgery (high risk) (2) aortic repair – including aneurysm and dissection (high risk) (3) major intrabdominal surgery (intermediate risk) (4) radical prostatectomy or radical hysterectomy (intermediate risk) (5) orthopedic surgery – including hip and knee replacements (intermediate risk) (6) carotid endarterectomy (intermediate risk) and (7) head and neck (intermediate risk) will be eligible. The hospital chart of each patient for the hospitalization related to the surgical procedure will be obtained and reviewed and the patient may be asked directly pertinent questions. Consent will be obtained from the patient to be included in the study. The following will be assessed for each patient :

a. Pre-operative:

i. Clinical/Demographic characteristics

Age, race, gender, NYHA Class of HF, history of an MI (defined by patient history or notes in chart/webcis), prior coronary artery bypass surgery, valvular disease, history of HTN (defined the use of antihypertensive medications at home), diabetes mellitus (defined by the use of oral agents or insulin, HbAIc > 7.0, or random sugar > 200 mg/dl) or PVD (defined by the history or evidence of an angiogram done preoperatively, claudication, previous amputation, or history of NIFS study suggestive of PVD) will be extracted from the chart or obtained from discussion with the patient.

ii. Physical Exam:

Blood Pressure, Heart Rate, Respiratory Rate, Height and Weight, JVP, rales or not, S3, LE edema from the day prior to the surgical procedure will be recorded .

iii. Pre-operative Laboratory Tests

Preop lab values to be recorded will be Hct, BUN and creatinine, and blood sugar (Preop labs on day prior to surgery)

iv. Medications

The dose, route, frequency and duration of the following meds in the pre-operative period will be recorded: ACE, ARB, B-blocker, Diuretic, Digoxin, Statin,

b. Intra-operative:

i. Anesthesia. The specific type of anesthesia used in the surgery.

ii. Type of Surgery

iii. Timing of Surgery (Urgent/Emergent/Elective)

c. Post-operative

i. Clinical/Demographic characteristics:

Symptoms of fatigue (present or not by clinical history), dyspnea (present of not by clinical history), angina (present or not by clinical history), perioperative MI (defined by elevated troponins +/- EKG changes), and induction of arrhythmias (VT/SVT/VF) will be recorded. The need for an ICU stay (and number of days) will be recorded. The need for transfusion (and number of units) will be documented. In addition I will note any post op complications resulting in death or other morbid events.

ii. Physical Exam

Blood Pressure, Heart Rate, Respiratory Rate, JVP, rales or not, S3, LE edema from the day after the surgical procedure will be recorded

iii. Post-operative Laboratory Tests

Post-op lab values to be recorded will be Hct, BUN and creatinine, blood sugar, and troponin.

iv. Medications

The dose, route, frequency and duration of the following meds in the post-operative period will be recorded: ACE, ARB, B-blocker, Diuretic, Digoxin, Statin.

d. Other

The length of stay will be recorded.

e. Analysis

Approximately 600 patients will be needed for categorical variables to have a power of 80%. This was based on preliminary retrospective data that showed approximately a 30 % rate of primary complications in HF undergoing noncardiac surgery. A chi square was performed to calculate this power. Morbid events postoperatively will include any of the following during the hospital stay: death, MI (elevated troponins post op), decompensated HF (defined by increasing or new rales on exam or new/worsening pulmonary vascular congestion on chest x-ray, a decrease in blood pressure by 25% from baseline, worsening of renal function by 50% based on calculated GFR, or the need for ionotropic therapy) A composite endpoint for adverse outcomes will include any of the following: death, MI, decompensated HF. In order to determine which factors are associated with adverse outcomes, a univariate analysis will be performed to determine associations of pre-operative, intra-operative and post-operative variables with the composite endpoint. For dichotomous variables a chi-square will be employed. For continuous variables a student's t-test for unpaired comparisons will be employed. In order to determine which factors contribute to risk stratification, a logistical regression will be performed and any factor that is significant in the univariate analysis at the $p<0.05$ level will be entered into the model.

C. Study Procedure

The duration of the study is difficult to predict. It will most take about two years to get enough patients to have a power of 80%.

D. Study Drugs

Not Applicable

E. Medical Devices

Not Applicable

F. Study Questionaire

Not Applicable

G. Study Subjects

As stated above the subjects will be identified by a review of the surgical cases for the specific week. All subjects who had a physician visit or hospitalization for HF (ICD – 9 428.0) in the two year period prior to the surgical procedure and are scheduled for one of the following surgical procedures (1) peripheral vascular surgery (high risk) (2) aortic repair – including aneurysm and dissection (high risk) (3) major intrabdominal surgery (intermediate risk) (4) radical prostatectomy or radical hysterectomy (intermediate risk), (5) head and neck surgery (6) carotid endarterectomy (intermediate risk) and (7) orthopedic surgery – including hip and knee replacements (intermediate risk) will be eligible. Patients who met the initial screening will then have their diagnosis of HF further investigated. To be included in the study the diagnosis of HF has to be given prior to the hospital admission for the surgery by the PMD.

If the diagnosis of HF is not assigned by PMD then the patient has to meet the Framingham Criteria for HF on a past admission. Subjects will be excluded from the study if they have had a prior transplant of any organ in the past, their current hospitalization was not specifically for the surgical procedure, or a history of HF could not be found, or if HF was diagnosed during the hospital admission for the surgery. Once the subjects are identified they will be approached on the day prior to the surgical procedure or on the day of the surgical procedure to explain the study and obtain consent.

H. Recruitment of Subjects

As stated above subjects will be identified by a review of the surgical cases for the specific week. If they have an ICD – 9 code of 428 and are undergoing the appropriate surgical procedures they will be screened to see if the inclusion criteria are met. If the criteria are met then the study will be explained to them and if they consent they will be included in the study.

I. Confidentiality of Study Data

A unique code number will be given to each subject for identity to obtain confidentiality. The data collected will be stored in a secure location that is yet to be determined.

J. Potential Conflict of Interest

There is no conflict of interest for this study.

K. Location of Study

This study will be conducted at Columbia Presbyterian Hospital in New York, NY.

L. Potential Risks

There are no potential risks to the subjects as this is an observational study and no intervention will be implemented.

M. Potential Benefits

One potential benefit may be that the subjects in the study may be more closely observed than subjects not in the study.

N. Alternative Therapies

Not Applicable

O. Compensation to Subjects

There will be no compensation to the subjects enrolled in the study.

P. Costs to Subjects

There will be no additional cost to subjects

Q. Minors as Research Subjects

Not Applicable

R. Radiation or Radioactive Substances

Not Applicable

S. References

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