A retrospective study analyzing the risk factors for post-operative gastrointestinal complications after coronary artery bypass graft (CABG)

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North Florida Division Research Protocol

Do you plan to publish/present externally? ☒ Yes ☐ No

- Please remember that the publications (poster, talk, any type of presentation, manuscript…) require **PubCLEAR approval**. Manuscripts must be approved by the ***Program Director*** and ***Division Research Director*** prior to submitting to PubCLEAR.
- This protocol ***cannot be submitted to HCA IRB or DataCLEAR*** without the signature of the **Division Research Director**.

Date/ Version: 11/24/2020 (version 2)

Title of the Study:	A retrospective study analyzing the risk factors for post-operative gastrointestinal complications after coronary artery bypass graft
Principal Investigator:	Dr. Charles, Aidan
Research Team Members (Name, Role, ¾ ID)	Dr. Charles, Aidan, PI, oxc6734
Hospital/ Program	Ocala Regional Medical Center Surgery Program
Faculty Advisor	Dr. Darwin Ang
Program Director	Darwin Ang
Research Director	Katy Robinson Approved by Katy Robinson, Ph. D; via email; 3/12/2021
Research coordinator	☒ Cristobal Cintron ☐ David Xu
Statistician Request	No
Request for additional data	Yes
If using pre-existing data	Previous Project ID: Previous Research Analyst: Previous Biostatistician:

Section A: Background/Significance (Explain your project in one paragraph with up to 5 references)

Coronary artery bypass grafting(CABG) is a commonly performed open heart cardiac operation with approximately 515000 isolated CABG procedures performed annually[1]. Multiple single center and multi-center studies have demonstrated incidence rates of 0.6 to 4.8% for gastrointestinal complications and mortality rates of 14% to 63%.[2] One study estimates a fivefold increase in mortality rates in patients with GI complications and a doubling of hospital charges. Although relatively rare, GI complications can represent a significant setback in a cardiac patient's post-operative care. Prior studies have analyzed multiple risk factors such as age, gender and pre-operative co-morbidities but have not looked at intra-operative factors such as blood loss or clamp time. This case control study will analyze the correlation of these factors to the risk of developing GI complications, the severity of the complication and the effect on mortality.

References:

1. Rodriguez, F., et al., *Gastrointestinal complications after coronary artery bypass grafting: a national study of morbidity and mortality predictors.* J Am Coll Surg, 2007. **205**(6): p. 741-7.
2. Chaudhry, R., et al., *Gastrointestinal Complications After Cardiac Surgery: A Nationwide Population-Based Analysis of Morbidity and Mortality Predictors.* J Cardiothorac Vasc Anesth, 2017. **31**(4): p. 1268-1274.

Section B: Study Objectives.

The objective is to be able to predict patients who are most likely to develop post-operative complications and produce treatment strategies.

Section C: Hypothesis and Questions

Hypothesis: PICO

P- In adult patients (age 45+) who undergo CABG,
I - Does decreased blood loss, clamp time or length of hypotensive episodes
C- Compared to patients with higher values
O- lead to a decrease in the severity and incidence of GI complications after surgery.

Section D: Type of the study:

1. Type of Study: ☒ **Retrospective** ☐ **Prospective** ☐ **Other**
2. Which IRB will be used? (After submitting to the HCA IRB Manager system)
   ☒ **HCA IRB Manager** ☐ **UCF IRB** ☐ **Other** (specify)

Section E: Source of the data, Collection, Storage

1. **Source of data**: HCA North Florida Enterprise (All HCA hospitals, USA)
2. **How is the data going to be obtained?** HCA Enterprise data warehouse (EDW) data request via Dataclear after the Division Research Director's approval
3. **Who is extracting the data? Access to PHI?** The data will be extracted and de-identified by the HCA research analysts at the corporate.
4. **Where is the data stored?** The research team will be able to access to data in a password protected folder on the VDI on the HCA network.

Section F: Data extraction specifics

1. **Years** Data from January 20 16 - 2020
2. **Facilities:** ☐Hospital ☐Division ☒ Enterprise
3. **ICD-9 codes:** none
4. **ICD-10 codes:** see appendix
5. **Procedure codes:** see appendix
6. **Other:** none
7. **Add COHORT diagram (if possible)**
8. **Study Subjects**
    a. Inclusion criteria
    Age 45+ adults who underwent CABG during their admission.

    b. Exclusion criteria
    History of inflammatory bowel disease

Section G: Data Points/Parameters/Outcome Measures/Quality metrics

Facility, state, gender, age,

Number of vessels bypassed during the coronary artery bypass graft according to the CPT code

for the graft.

Diagnosis of K55.059, K63.1, K56.0, K59.69 during admission

Diagnosis of K55.059, K63.1, K56.0, K59.69 before admission

Total minutes of aortic clamp time obtained from operative report

Total minutes of bypass time obtained from operative report

Total CC's of blood loss obtained from operative report

Prior history of K50-K52 ICD -10 codes indicating Crohn's/ Ulcerative Colitis.

Demographics

Gender
Age
State
Facility

Labs

Pre-operative hemoglobin
Post-operative hemoglobin

Vitals

Record of heart rate during admission
Record of blood pressure during admission

Medication list prior to admission

N/A

Medications in hospital

N/A

Outcome Measures

Section H: Other information

1. **Sampling and Sample Size**
   Assuming intra-operative complications increased risk of GI complications by 2; 10% of pt. had intra-op complications, a control/case ratio of approximately 20 and power of 80, approximately 2793 pts. Are needed.

2. **Statistical Considerations**
   Linear regression analysis

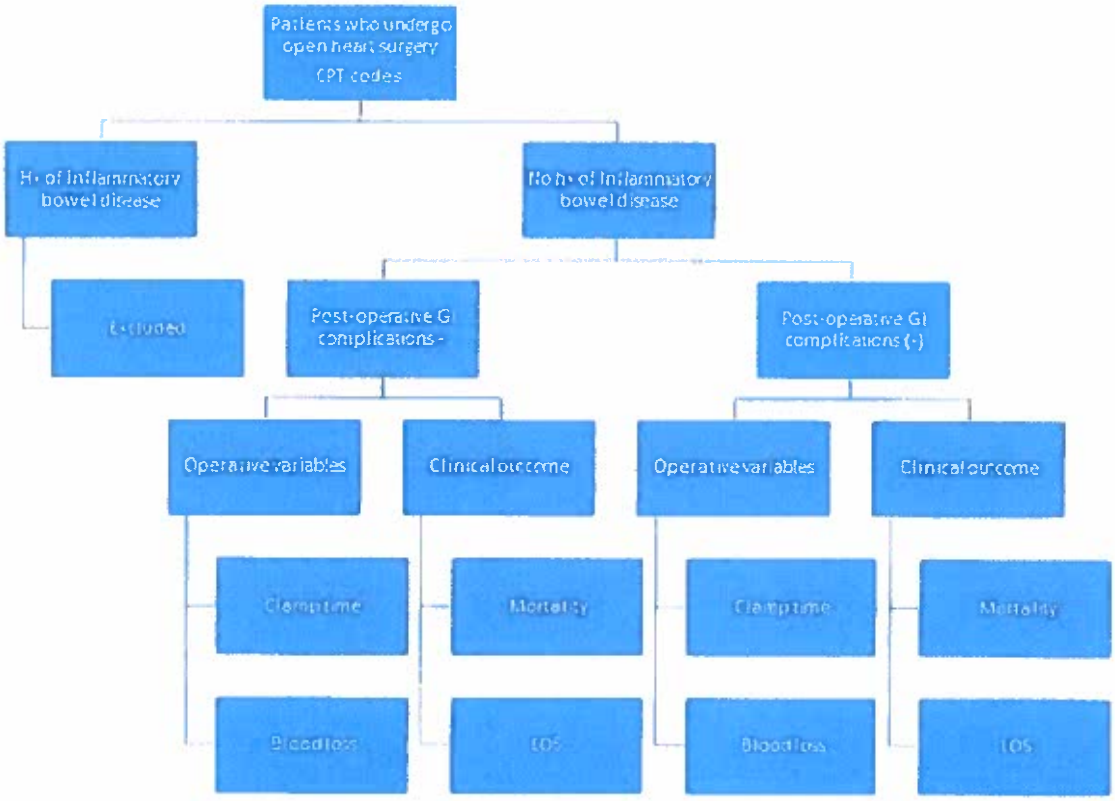
3. **Feasibility and Time Frame**
   a. This project will require an estimated 4 months to complete.
4. **Strengths**
   Analysis of intra-operative variables
5. **Limitation**
   Does not determine preventative strategies
6. **Benefits**
7. **Potential Risk**
   a. None
8. **Protection against risks:**

Section I: Appendix for Variables and Definitions

1. **ICD and CPT Codes**
    - K55.059 development of mesenteric ischemia,
    - K63.1 bowel perforation,
    - K56.0 paralytic ileus,
    - K56.69 small bowel obstruction
    - 33510 – 33536 – Coronary artery bypass grafts codes.
    - K50-52 – Crohn's Disease and Ulcerative colitis
2. **Therapeutic regimens**

3. **Tables**

4. COHORT Diagram



Do not need to provide data for excluded group.

Darwin Ang M.D, PhD, Program Director

ICD10 codes for Gastrointestinal Symptoms

K55.059 development of mesenteric ischemia,
K63.1 bowel perforation,
K56.0 paralytic ileus,
K56.69 small bowel obstruction,

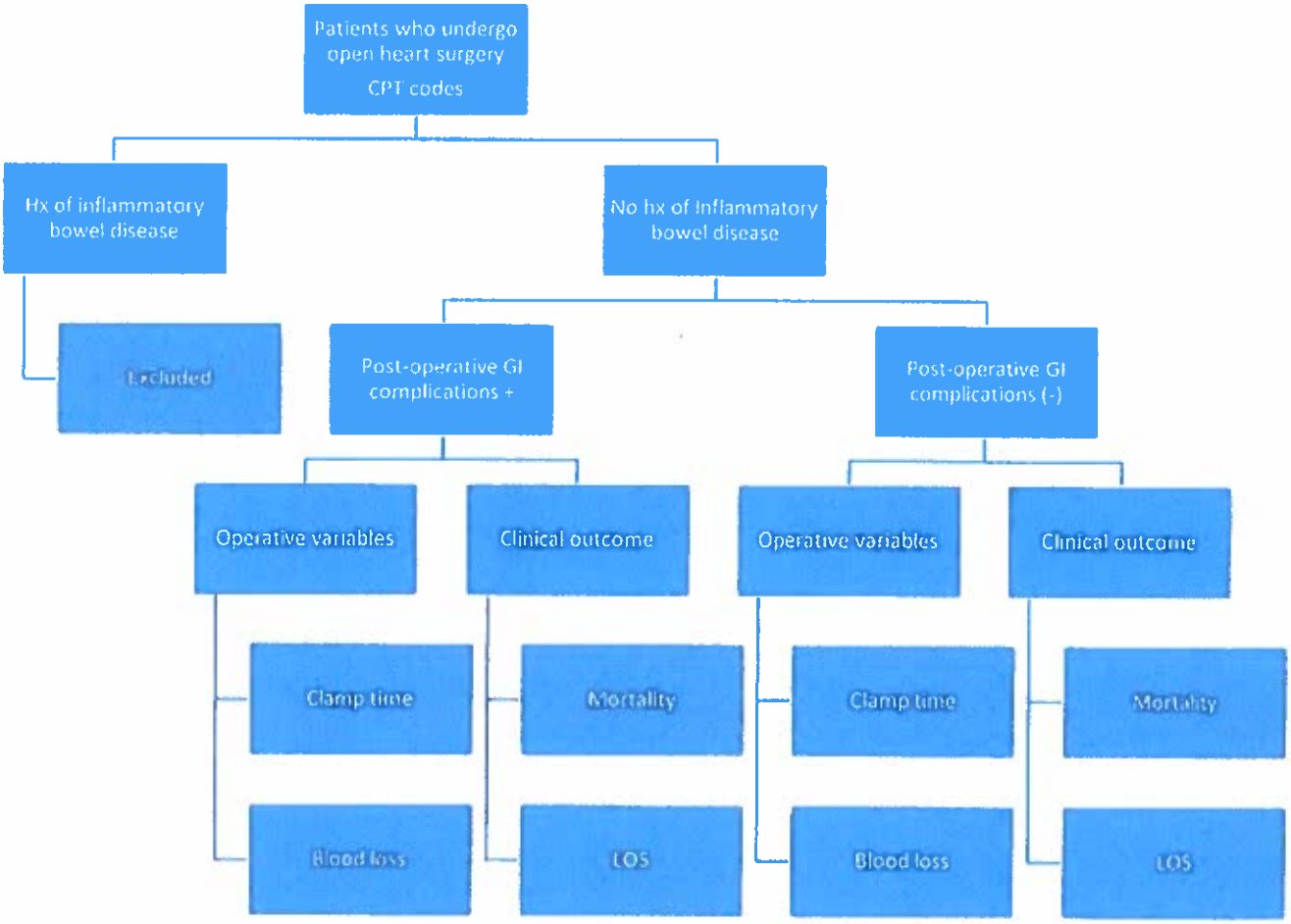
CPT codes for open heart surgeries.

33510 – 33536 – Coronary artery bypass grafts codes.

Co-morbidities

Number of comorbidities from the following list (see ICD) **E08 – Diabetes due to underlying condition** **E09: Drug or chemical induced diabetes mellitus.** **E11: Type 2 diabetes mellitus.** **E13: Other specified diabetes mellitus.**

Hypothesis 1: Patients with elevated intra-operative clamp time and blood loss are more likely to experience GI complications.



Data Dictionary		
Variable	**Type**	**Values**
Age	Numeric	Age in years. (mean, median, SD, SE) 45+
Sex	Binary	1: Male 0: Female
Race/ Ethnicity	Categorical	Black Hispanic White Other
Gastrointestinal disorder	Binary	1: Presence of at least one DX code for listed gastrointestinal Disorders: 0: No presence of one of these DX codes
Past history		**E08 – Diabetes due to underlying condition** **E09: Drug or chemical induced diabetes mellitus.** **E11: Type 2 diabetes mellitus.** **E13: Other specified diabetes mellitus.** **K50, crohn's disease [regional enteritis]** **K51, ulcerative colitis** **K52, other and unspecified noninfective gastroenteritis and colitis**
Mortality	Binary	0: Discharged Alive 1: Expired/Hospice
LOS	Numeric	Total Length of Stay (days) mean, median, SD, SE
hemoglobin	Numeric	Lowest Lab value
platelets	Numeric	Lowest Lab value
Ferritin	Numeric	Highest Lab value
Total blood loss	Numeric	Highest value from intra-operative charting
Clamp time	Numeric	Value
Operative time	Numeric	Value

Table 1: Demographics

		Total N (%)	GI Complications	No GI complication	p	Confidence interval
Age (yrs) Mean or median						
Sex	**Male Female**					
Race/ Ethnicity	Black Hispanic White Other					
Past history of GI disorders	**Yes No**					
Avg. Clamp Time						
Avg. Blood loss						
LOS median or mean days						
Mortality						

Table 3: Labs and vitals

		Total N (%)	GI complications	No GI complications	p	Confidence interval
hemoglobin						
platelets						

Linear Regression Section:

Dependent Variable: Operative clamp time, operative blood loss

Independent variable: Presence of post-operative GI complications.

Confounders: Prior episodes of SBO, Mesenteric ischemia. Hx of severe arteriosclerotic disease.

We will compare the average clamp times and operative blood loss between patients who have post-operative GI complications vs. pts who did not.

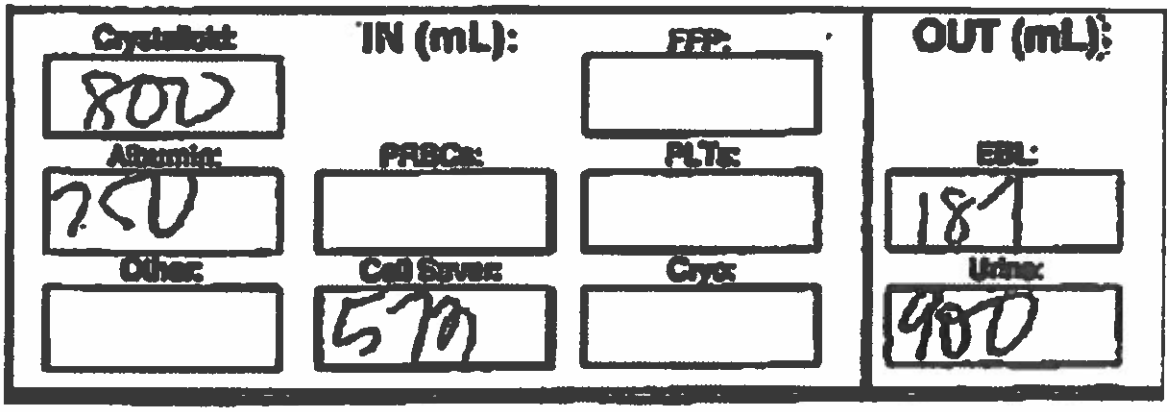
OPERATIVE REPORT Detail

DateTime 03/02/20 17:28 Status Signed

We then closed the atriotomy in a running fashion using 3-0 Prolene suture. Atriotomy was closed. We made two 4 4 mm aortic hole punch and 2 proximal vein graft anastomosis was performed to the end of vein side of aorta with the aid of a 5-0 Prolene suture. We removed total clamp time. We gave warm shot and removed clamp. Total clamp time was 102 minutes. The patient did receive additional dose of del Nido cardioplegia 45-50 minute interval delivered to vein grafts. EF was approximately 35%, had no evidence of mitral regurgitation. We de-aired, removed venous cannula LV vent. After weaning from bypass with a bypass time of 122 minutes. The aortic root vent line was removed. We then gave protamine. Following satisfactory protamine administration, removed the aortic cannula. All cannulation sites were secured. Evicel was used for additional hemostasis. We placed two 24 Blake drains within the pericardial space. We then closed the sternum using stainless steel wires. Soft tissue was closed in layers using 0 Vicryl, 2-0 Vicryl, 4-0 Vicryl in circular fashion. We applied Dermabond at the end. The patient tolerated this procedure well, was subsequently transferred to the ICU for continued postoperative monitoring. No complication with this case. All sponge and instrument counts were correct.

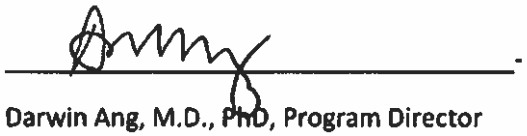
Omaral N Ozlan, MD

Clamp and bypass time can be obtained from operative reports.



ANESTHESIA RECORD

EBL can be obtained from anesthesia records.



Darwin Ang, M.D., PhD, Program Director