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Acute pancreatitis patients that are older with elevated LDH, HCT on admission require longer hospital stay and have higher mortality rate

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RETROSPECTIVE CHART REVIEW PROTOCOL IRB protocol # (for IRB use only):

Title: Acute pancreatitis patients that are older with elevated LDH, HCT on admission require longer hospital stay and have higher mortality rate

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1.0 Description of Study:

Acute pancreatitis is one of the most common gastrointestinal presentations to the Emergency department in the United States (1). It has been showing a reported incidence of up to 35 per 100,000 with a mortality rate of apx 5% (2). A combination of aggressive IV fluid, pain management, and NPO has been the standard treatment for patients with acute pancreatitis. Studies in the past have presented the concept that patients with acute pancreatitis can present with independent factors as age, certain past medical history, certain labs, and imaging findings that can ultimately correlate with patients developing a worsening acute pancreatitis with multiple complications. In addition, monitoring patients labs during hospitalization can also demonstrate patients developing worsening acute pancreatitis. Our aim is to perform a retrospective study on patients presenting with acute pancreatitis and to evaluate whether certain presentations are associated with longer hospital stay, longer ICU stay and higher mortality rate. We want to compare patients presenting with age >50, HCT >40, LDH >600 and have comorbidities as CAD and/or Cerebrovascular disease vs. patients who don't meet these criteria on admission. We believe that patients presenting with this history and labs require longer hospital stay, longer ICU stay and have a higher mortality rate compared to patients who don't.

2.0 Study Objectives/Hypothesis

Primary objective: To determine whether patients older than 50 years old, with comorbidities as CAD and/or Cerebrovascular disease presenting with acute pancreatitis with labs significant for

HCT >40, and LDH >600 would require longer hospital stay, more time in intensive care unit and have a higher mortality rate compared to other acute pancreatitis patients.

Hypothesis: We believe that patients older than 50 years old, with comorbidities as CAD and/or Cerebrovascular disease presenting with acute pancreatitis with labs significant for HCT >40, and LDH >600 do require longer hospital stay, more time in intensive care unit and have a higher mortality rate compared to other acute pancreatitis patients.

3.0 Rationale/Background

Acute pancreatitis is uncommon as one would assume but it can be associated with serious complications, longer hospital stay, life threatening infection and definitely high mortality rate. Acute pancreatitis is one of the leads most common gastrointestinal presentation presentation to the emergency department (3, 4). Incidence of acute pancreatitis is appx 5-35 per 100,000 population in the United States (5). The overall mortality rate from acute pancreatitis is appx 5% and mainly from the complications that are associated with it. (5). Acute pancreatitis is defined when at least two the following criteria are met: 1. Upper abdominal pain. 2. Serum amylase or lipase (or both) >3 times the upper limit of normal and 3. Typical finding on imaging. Acute pancreatitis can then be classified as mild, moderate or severe based on the received Atlanta calcification (6).

Patients that present with acute pancreatitis usually require 2-3 days of hospital stay with treatment of IV fluid, and pain management. Multiple studies have demonstrated that patients presenting with hematocrit > 47% are at higher risk of developing worsening pancreatitis and complications such necrotizing pancreatitis. (4,7). In addition, elevated LDH level has been associated with a higher risk of Infected necrotizing pancreatitis in patients presenting with severe acute pancreatitis (8). A small study of 42 patients found that patients with severe acute pancreatitis had a higher LDH (9) The presence of comorbidities in patient history particularly cardiovascular as coronary artery disease and cerebrovascular disease can increase the risk of developing worsening acute pancreatitis as well lead to complications (10).

The aim of this study is to investigate whether patients older than 50 years old, with comorbidities as CAD and/or Cerebrovascular disease presenting with acute pancreatitis with labs significant for HCT >40, and LDH >600 would require longer hospital stay, more time in intensive care unit and have a higher mortality rate than patients with no such presentation. We believe that we would have a better idea by doing a retrospective study on patients who have presented to HCA facilities with acute pancreatitis. By being able to anticipate patients who are going to require longer hospital stay, longer ICU stay or have a higher mortality rate, we can possibly alternate our approach in terms of treatment and be able to better manage the complications that can be associated with their diagnosis.

4.0 Selection of Participants

- 4.1 Inclusion Criteria:
 - Patients >18 years old presenting with acute pancreatitis

- ICD 10 code: K85, K85.9

4.2 Exclusion Criteria: None

4.3 Age Range: >18 years old

5.0 Data Collection

- 5.1 Source (location) of the records to be reviewed: HCA databank of all patients in the HCA system in the past 10 years.
- 5.2 Describe how the charts to be reviewed will be determined: Data analysts will evaluate the data based on pre-specified search criteria
- 5.3 Describe the type of data to be collected and timeframe: Age, sex, BMI, Hx of Cornary artery disease, Myocardial infraction, Angina, unstable angina, Hx of cerebrovascular disease, stroke, labs on admission: serum amylase, serum lipase, Hematocrit, Lactate dehydrogenase (LDH), Length of stay, Time in intensive care unit, Death.

Variables:

- -Demographic: Age >18, Gender (Male or Female)
- -Past medical history on admission: Hx of Coronary artery disease , Myocardial infarction, Angina, unstable angina

ICD: I20, I20.1 I20.2, I20.8, I20.9, I21, I21.1, I21.01, I21.02, I21.09, I21.1, I21.11, I21.19, I21.2, I21.21, I21.29, I21.3, I21.4, I21.9, I21.A, I21.A1, I21.A9, I22, I22.01, I22.1, I22.2, I22.8, I22.9, I24.8, I24.9, I25.2, I25.42, I25.5, I25.6, I25.7, I25.70,

Hx of cerebrovascular disease, stroke

ICD: I60, I60.0, I60.00, I60.01, I60.02, I60.1, I60.10, I60.11, I60.12, I60.2, I60.3, I60.30, I60.31, I60.32, I60.4, I60.5, I60.50, I60.51, I60.52, I60.6, I60.7, I60.8, I60.9, I61, I61.0, I61.1, I61.2, I61.3, I61.4, I61.5, I61.6, I61.7, I61.8, I61.9, I62, I62.0, I62.00, I62.01, I62.02, I62.03, I62.1, I62.9, I63, I63.0, I63.00, I63.01, I63.011, I63.012, I63.013, I63.019, I63.02, I63.03, I63.1, I63.13, I63.2, I63.21, I63.23, I63.3, I65.0, I65.01, I65.02, I65.03, I65.09, I65.1, I65.2, I65.21, I65.22, I65.23, I65.29, I65.8, I65.9, I66, I66.01, I66.02, I66.03, I66.09, I66.1, I66.11, I66.12, I66.13, I66.19, I66.2, I66.21, I66.22, I66.23, I66.29, I66.3, I66.8, I66.9, I67, I67.0, I67.1, I67.2, I67.3, I67.4, I67.5, I67.6, I67.7, I67.8, I67.81, I67.82, I67.83, I67.84, I67.841, I67.848,

- -Labs on admission: Lipase, amylase, HCT, LDH
- -Labs throughout admission: LDH

-Other data: Total length of stay, length of stay in the intensive care unit, death

6.0 Confidentiality of data

6.1 Describe how data (both paper and electronic) will be stored to safe-guard confidentiality:

Password protected computers, limited access to information except to the research data collection specialist, paper files will be in locked cabinets with ley access.

6.2 Specify who will have access to harvested patient data: The study team and the statistician

6.3 Clarify how long data will be stored and how it will be destroyed when no longer needed: Data collected will be stored pending ongoing research, with subsequent secure destruction upon completion after 2 years.

7.0 Study duration/timeline

Stage 0, ROC and IRB approval: 1 month

Stage 1, review of medical records: 1-2 months

Stage 2, data analysis: 2-4 months

Stage 3, presentation and publication: 2 month

Projected start date: 03/01/2021

Approximate end date of the study: 10/01/2021

8.0 Statistical Considerations

8.1 Proposed Sample size (number of records to be reviewed): 5000

8.2 Specify how data will be analyzed and by whom:

Used multivariable logistic regression to identify whether patients with acute pancreatitis presenting with certain past comorbidities, increasing age, and labs requiring more hospital stay, ICU stay, and higher mortality rate.

(* something Yui wants to add here)

9.0 Consent

Waiver of documented informed consent requested from the IRB.

10.0 Risks and benefits

10.1 Risks

Confidentiality breach is a minimal risk associated with chart review research. However, the study team will only have access to de-identified data, so the risk is minimized.

10.2 Benefits

The participant's whose charts are reviewed are not likely to receive any direct benefit from the proposed research. However, society and investigators will benefit from the knowledge gained.

Reference

- 1.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565044/
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- 3.. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565044/
- $\textbf{4.} \underline{\text{https://hcahealthcare.ovidds.com/discover/result?logSearchID=60096008\&pubid=solr_6057-medline} \\ \textbf{3A28746189}$
- **5.** https://www.uptodate.com/contents/etiology-of-acute-pancreatitis
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- **8**. https://pubmed.ncbi.nlm.nih.gov/24720587/#:~:text=Conclusion%3A%20Increased%20LDH%20%20high%20CTSI,infection%20in%20patients%20with%20SAP.
- 9.https://www.atsjournals.org/doi/full/10.1164/ajrccm.164.1.2008026
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