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Risk of Heart Failure Exacerbation with COVID-19

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CHART REVIEW PROTOCOL

Date: 12-4-21

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Project Title: Risk of Heart Failure Exacerbation with COVID-19

Site(s) where study will be performed: HCA Brandon Regional Hospital

1. Introduction - Background and Rationale

Heart failure (HF) is usually a chronic disease which increases the risk for mortality even with more benign diseases as the heart is a vital organ in our body's ecosystem. With COVID-19 causing a profound inflammatory response with the risk for Acute Respiratory Distress Syndrome (ARDS), septic shock, and multiorgan failure; it can be inferred that there might be a correlation in exacerbations with the severity of heart failure [1]. An article published by the European Society of Cardiology investigated the mortality of patients (n=134) with HF and COVID-19 vs HF without COVID-19 and found a 50% vs 10% risk in mortality, respectively ($P < .001$) [2]. One major limitation of this study was the early timeline (March to May 2020) as treatment has changed drastically since the beginning of the pandemic.

Due to the novel discovery of this virus and evolving treatment ideologies, there is limited research investigating the comorbidity of HF and COVID-19. Early literature indicates that HF exacerbation is one of the main complications seen with COVID-19 [1]. Therefore, further studies investigating this relationship are warranted. The aim of our study is to stratify risk of acute **on** chronic HF depending on New York Heart Association (NYHA) classification as well as assessing overall mortality.

References

1. Chen T, Wu D, Chen H, et al. Clinical characteristics of 113 deceased patients with coronavirus disease 2019: retrospective study. *BMJ*. 2020;368:m1091.
2. Chatrath N, Kaza N, Pabari PA, et al. The effect of concomitant COVID-19 infection on outcomes in patients hospitalized with heart failure. *ESC Heart Fail*. Published online October 11, 2020. doi:10.1002/ehf2.13059

2. Research Questions or Aims

The aim of this study is to assess the risk of HF exacerbations in COVID-19 patients depending on NYHA classification. It is hypothesized that there will be a direct correlation in the number of exacerbations and NYHA classification during the COVID infection. Therefore, among COVID-19 positive patients with previous diagnosis of HF, the higher the NYHA classification, the higher the risk for HF exacerbation during their infection.

2.1. Study Outcomes

1. HF exacerbation (ICD-10 Code: I50.21, I50.23, I50.31, I50.33, I50.41, I50.43)

- 2. In House mortality (survived/died)

3. Total Length of Stay (admission to discharge)

4. Requiring Mechanical Ventilation (Yes/No)

3. **Objectives**

1. Primary objective of this study is to determine the risk of HF exacerbation depending on NYHA classification among COVID positive patients with known HF.

2. Determine mortality risk among individuals with co-occurring heart failure exacerbations and COVID-19

3. Determine the need for mechanical ventilation among individuals with HF and COVID-19 infections


4. **Selection of Patients**

4.1. **Inclusion Criteria:** Heart Failure (ICD-10 I50.1, I50.2, I50.3, I50.4, I50.82), Age 40-75, COVID-19+

4.2. **Exclusion Criteria:** End Stage Renal Failure, Liver cirrhosis, , Age>75, Age<40, A1C>9, End Stage Heart Failure (NYHA IV; ICD-10 I50.84)

4.3. **Age Range:** 40-75 years old

5. **Indicate if this is a retrospective and/or prospective chart review**

5.1.  **Retrospective Chart Review** (Retrospective means the data is already in existence when the project is submitted to the IRB for initial review)

5.2. _____ **Prospective Chart Review** (Prospective means the data is not in existence when the project is submitted to the IRB for initial review)

5.3 **Provide the date range of the chart review:** 08-1-2020 to Present

6 **Study Design/Methods**

1. **Source (location) of records to be reviewed:** ALL of HCA (national)
2. **Describe how the charts to be reviewed will be identified:** The charts to be reviewed will be identified based on the inclusion & exclusion criteria (stated above in 4.1 and 4.2)
3. **Describe who will identify charts to be reviewed:** Data extractor and statisticians
4. **Estimated number of records:** minimum 400

7.0 **Confidentiality of data**

- 7.1 Describe how data (both paper and electronic) will be stored to safeguard confidentiality (e.g. in a locked cabinet, password protected computer):** Password protected computer and program.
 - 7.2 Specify who will have access to harvested patient data:** All investigators on the study, me/research director, and statistician
 - 7.3 Clarify how long harvested patient data will be stored and how it will be destroyed when no longer needed:** It will be stored in a password protected computer and password protected access manner on Citrix. I will delete per HCA guidelines upon completion of study.
- 8 Consent:** Retrospective study with de-identified data; will likely be IRB exempt and not require consent.
- 9. Risks and Benefits:**
- 9.1.Risks:** Confidentiality breach is a risk associated with reviewing charts, however, the research team is ensuring this does not happen by accessing de-identified data.
 - 9.2.Benefits:** The benefits of this study include furthering the knowledge base on the proposed research topic leading to potential improvements and benefits to society and biomedical community, but will not have direct benefits to the patients whose records were reviewed in this study.
- 10. Statistical Considerations**
- 10.1.Proposed sample size (number of records to be reviewed):** All records that satisfy inclusion criteria 4.1 and 4.2.
 - 10.2.Proposed time period to be evaluated:**08/01/2020 to 12/31/2020
 - 10.3.Specify how data will be analyzed and by whom:** HQ Statisticians
 - 10.4.Data analysis Plan:**

Descriptive Analysis:

Perform univariate analysis for all outcomes and predictor variables listed.
Descriptive analysis of the relevant variables (age, race, sex, tobacco and alcohol use history, LOS, mechanical ventilation usage). Mean and standard deviation or median and range for continuous variables can be reported.

Bivariate:

Evaluate rates of heart failure exacerbation and mortality among individuals positive for COVID-19 and diagnosed with HF prior to infection.

Proportion of COVID positive patients among different NYHA classifications for HF (Ranges from Level I – Level III)

Perform a regression analysis to identify how HF (based on NYHA classification) is associated with HF exacerbation among COVID positive patients ages 40-75. Control for covariates.

Perform a regression analysis to identify how HF (based NYHA classification) is associated with

mortality among COVID positive patients age 40-75. Control for covariates.

- 11. Appendices: Appendices must be attached to the protocol in the following manner**
 - 11.1.**

APPENDIX A: DATA COLLECTION FORM

1. Unique Subject Code

- Covid-19 Positive
- HF Diagnosis (ICD-10 I50.1, I50.2, I50.3, I50.4, I50.82)
- Heart Failure Exacerbation broken into NYHA classification (based on at home medications)
 - I. No symptoms and Limitations in activity (patients not on any of the meds below)
 - II. Symptoms and mild limitation with ordinary activity (Lasix or Furosemide; Bumex or Bumetanide)
 - III. Significant symptoms with activity and only rest resolves it (Spironolactone or eplerenone, and /or Isosorbide denitrate and Hydralazine(combo pill or 2 separate pills)
 - IV.** Symptoms at rest (excluded)

2. List all elements to be collected during the chart review

- a. Age
- b. Sex
- c. Race
- d. COVID-19 Positive
- e. Current home medications (this will determine NYHA classification)
- f. Mechanical Ventilation usage
- g. Tobacco use history
- h. Alcohol use History
- i. Length of stay