Research Article

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Evaluating the Impact of High-Dose Corticosteroid Therapy in COVID-19 Hospitalizations

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Abstract

Coronavirus disease 2019 (COVID-19) is characterized by an abnormal immune and respiratory response, and therapeutic corticosteroids are among the few treatments consistently used since the initial outbreak in March 2020 [1]. However, the efficacy of high dose steroids, specifically in the first 48 hours of hospital admission, has been debated. This was a retrospective observation of COVID-19 admissions between September 2, 2020 and June 14, 2021, among patients whose maximum oxygen requirement resulted in intubation and/or tracheostomy. The systemic consistency of steroid prescriptions was assessed to ensure the probability of prescription did not independently infer variables associated with less improved outcomes. We compared outcomes (mortality, length of stay, major events [AFIB, AKI, AMI, ARDS, stroke, bleed]) in patients provided with varying doses (high dose = 40mg daily of methylprednisolone, standard dose = 4-40mg daily of dexamethasone, no dose) and time (since symptom onset and admission) of steroids. Of the 141 days of stay meeting study criteria, 83 days a patient received a high dose of steroids (median dose = 285mg), 49 a standard dose (median dose = 6mg), and of 9 days a patient received no dose during the first 48 hours of admission. According to laboratory results and oxygen requirements, the consistency of steroid prescriptions was widely inconsistent, leading to a lack of correlation between risk factors and likelihood of receiving steroids. Therefore, the unadjusted data which associated high dose steroids with lower risk of death (51.8% vs 67.9%, p<.001), length of stay (39.7 vs 49.6 days, p<.01), and major events (-0.23 correlation), among hospitalized COVID-19 patients, was sufficient.

Keywords

COVID-19, Corticosteroid Therapy, High-Dose, Mortality, Intubation

Introduction

During late 2020, the Society of Critical Care Medicine made a strong recommendation regarding use of corticosteroids during a short period. This was prompted by a metanalysis which revealed a significant decrease in mortality rates for patients receiving steroids, specifically dexamethasone [2]. At the time of the study's conception, steroids have been shown to be useful in mitigating probability of death and complications in patients battling moderate to severe coronavirus disease 2019 (COVID-19)–referring to those requiring high flow oxygen or mechanical ventilation. Despite anecdotal reporting, the efficacy of varying doses, at varying times during a patient's course of disease, has not been well understood.

The purpose of this retrospective study was to reveal whether a significantly higher dose of corticosteroids (>40mg daily) within the early stages of a patient's admission was associated with more improved outcomes in hospitalized COVID-19 patients. In addition to statistical significance testing, inverse probability weight regression adjustment (IPWRA) was used to minimize bias among systemic propensity during prescriptions of steroids [3].

To assess the efficacy of high dose corticosteroids in a statistically reliable manner, the remaining variables which could impact a patient's outcome required control. The initial question was whether high dose corticosteroids were more likely to be prescribed to the patients at a higher risk for death and/or major events-higher risk is determined by factors such as age, BMI, PMHx, oxygen requirement. More specifically, did the criteria for determining high-dose corticosteroids assume variables for high risk in itself. The answer required an evaluation of the consistency of prescription of high dose corticosteroids as seen through notes transcribed by physicians. According to infectious disease physicians who led such practices at Mount Sinai Hospital during the pandemic (Dr. Eric Neibart, MD and Dr. Glenn Hammer, MD), dosing of corticosteroids was determined by a patient's oxygen requirement as that was the most readily way of measuring a patient's respiratory status and degree of sickness compared to laboratory results which could take hours to be collected and assessed.

Methods

Study Design and Data Source

We performed an analysis of 396 adult COVID-19 patients admitted to Mount Sinai Hospital, a large urban hospital on the Upper East Side of Manhattan in New York City, NY, between September 2, 2020 and June 14, 2021. These patients were of common interest given the care provided by Dr. Jeffrey Bander, MD, FACC (Medical Director for the Mount Sinai Health Network and Chief of Cardiology at Mount Sinai West). A de-identified MSHS COVID-19 patient database was generated beginning in early 2021 from EPIC EMR as part of a larger study regarding hospitalized patients diagnosed with COVID-19.

Patient and Public Involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research. The study was a retrospective analysis of de-identified hospital records; therefore, no recruitment or consultation took place. Outcomes were selected based on clinical relevance during the COVID-19 pandemic.

Definitions

We Collected Clinical and Demographic Data: co-morbidities (age, sex, BMI, gender, PMHx [specific of: cancer, cardiology and endocrinology], symptom onset date, admit and discharge date, daily oxygen requirement [room air, nasal canal, high-flow nasal canal, non-rebreather mask, BiPap, intubation and tracheostomy]), laboratory values results (White blood count, Neutrophil, Lymphocyte, Immature Granulocyte, Hemoglobin, Platelet, D-dimer, Urea nitrogen, Creatinine, ALT, AST, LDH, Ferritin, C-reactive protein, Lactate, Procalcitonin, Troponin, Brain natriuretic peptide, Pro-brain natriuretic peptide, Albumin, Inteleukin-6, 8, Il1b and Tumor necrosis factor) and treatments provided for COVID-19 infection such as anticoagulants (mostly Aspirin, Heparin, Eliquis, Lovenox), corticosteroids (Decadron, Prednisone, Solumedrol), convalescent plasma and Remdesivir. We collected data for hospital-acquired events, including atrial fibrillation (AFIB), acute kidney injury (AKI), acute myocardial infarction (AMI), acute respiratory distress syndrome (ARDS), bleeds (gastrointestinal, hematoma, unclear), c. candidiasis infection, pulmonary embolism, staph. infection, septic shock, and stroke (hemorrhagic, ischemic).

We used methylprednisolone equivalent dosing (MED) for comparison. 1 mg of dexamethasone was equivalent to 5.3 mg of methylprednisolone [4]. An average daily dose of steroids was determined by dividing the total dose received during the course of steroid treatment by total number of days of the course. By examining the systemic prescription practices, a low (standard) dose was considered 40 mg of methylprednisolone or 8 mg of dexamethasone, and a high dose was any amount greater.

Our primary dependent variable was risk of in-hospital mortality, length of stay, and in-hospital acquired events most significantly AKI and ARDS.

Inflammatory Markers

In addition, we compared the initial inflammatory markers (Ferritin, CRP, LDH and D-dimer) prior to treatment of corticosteroids and one week subsequent of treatment course. Given a high population of patients studied had a deceased outcome, this portion of the study evaluated the impact of low vs. high steroid doses within patients who survived and were deceased within separate groups.

Statistics

To compare the two regimens of corticosteroids (low vs. high dose), inverse probability weight regression adjustment (IPWRA) was applied to undo the probable bias of prescription practices–higher doses were provided to sicker patients.

The probability of receiving high dose steroids (propensity score model) was calculated using a logistic regression model, with the dose of steroids as the dependent variable, and hospital measures to determine level of sickness, such as inflammatory markers, oxygen requirement and time from symptom onset to admission. Severity of one's oxygen requirement was evaluated through two ways: device (RA, NC, NRB, HFNC, BiPAP, Intubation, Tracheostomy) in conjunction with number of liters or FiO2% and calculating one's PaO2% (a derivation from SpO2%) divided by FiO2% [5].

We described the categorical data using frequency count and percentages. We reported means and standard deviation and determined p-value using chi-squared tests and interquartile ranges (IQRs). For all analyses, we deemed statistical significance a p-value less than 0.05. All statistical analysis was performed by GraphPad Prism software and Google Sheets.

Results

There were 396 COVID-19 admissions (4627 days of stay) during the study period. Of those, 47 patients (1894 days of stay) met inclusion criteria given their maximum oxygen requirement of intubation or tracheostomy. 78.8% (n=37) patients received a low dose (median=6 mg daily) of dexamethasone within 48 hours of admission.

Characteristics of Patients Receiving Corticosteroids

In a one-dimensional assessment of all 396 COVID-19 admissions, patients who received a high dose of corticosteroids had an 18.2% risk of requiring intubation compared to 3.8% for those who received low dose steroids. And those who required intubation had a 46.8% survival rate compared to 95.9% for those who did not.

However, when we assessed only the patients whose maximum oxygen requirement resulted in intubation, the consistency of steroid prescriptions dwindled, specifically within 48 hours of admission.

The most prominent criteria were oxygen requirement as COVID-19 attacks the lungs causing swelling and hypoxia and the most accessible, especially during a patient's triage early on in their admission, as other gauges such as IgG titer levels (antibody concentration) and blood tests required time (from hours to days) to be collected and measured. Ideally, on the recommendation of an infectious disease consult, the higher a patient's oxygen requirement, the more likely they were to be prescribed a higher dose of corticosteroids. However, there did not seem to be a significant trend, or at least a constant trend. Patients were denoted one of the following oxygen requirements (ascending order of required oxygen): room air (RA), nasal canal (NC), high-flow nasal canal (HFNC), BiPap, or intubation.

In a one-dimensional assessment of decision to prescribe based on oxygen device (Figure 1 and 2) the sicklier patients were more likely to be denied treatment; intubated patients (17 of 18) and those receiving BiPap (12 of 17), Figure 1.

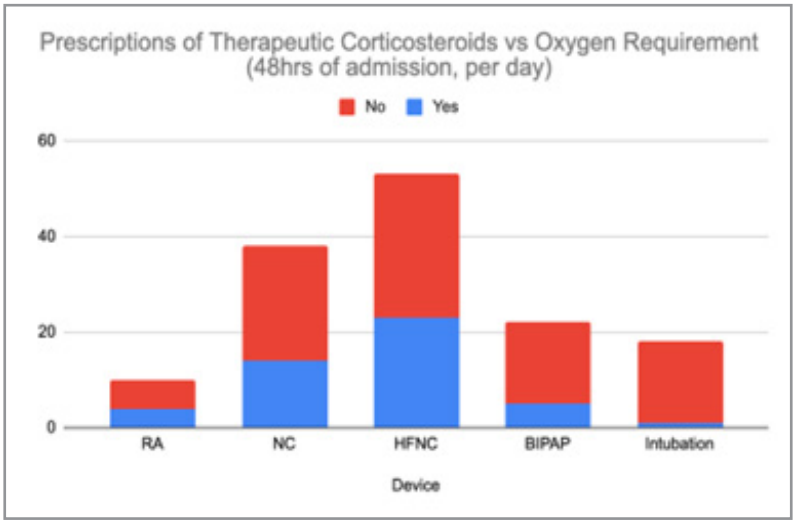

Figure 1: However, within the lesser vulnerable (only including those receiving RA, NC and HFNC), there seemed to be a correlation between an increase in required oxygen and likelihood of high dose steroids; patients receiving no oxygen (16.7%), NC (20%), and HFNC (66.7%) as seen in Figure 2.

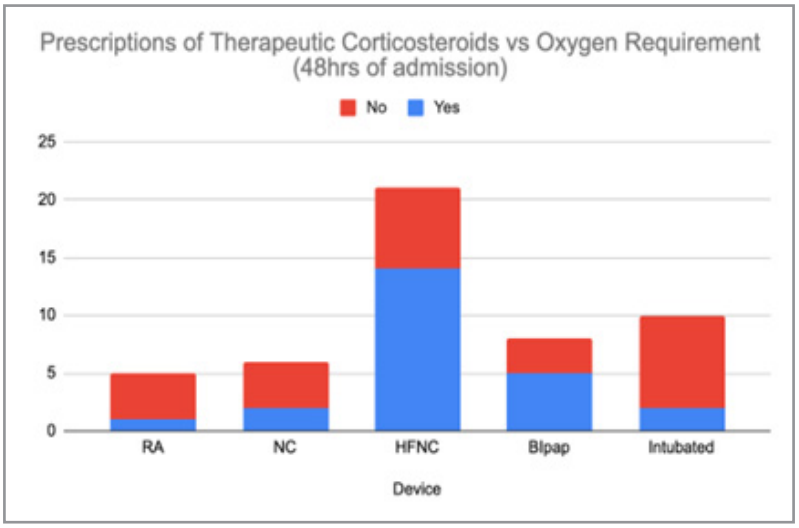

Figure 2: The discrepancy of Figure 1 and 2, is the former assesses oxygen requirement and steroid prescription per each day within 48 hours of admission, as opposed to the latter which only includes a patient's maximum oxygen requirement and steroid dose within 48 hours of admission.

The severity of a patient's COVID-19 illness in the context of oxygen requirements, or more specifically acute respiratory distress syndrome, defined by degree of hypoxemia, is calculated as the ratio of arterial oxygen tension to fraction of inspired oxygen (PaO2/FiO2). To calculate the PaO2/FiO2 ratio, the PaO2 is measured in mmHg using the alveolar gas equation (Figure

3) and the FiO2 is expressed as a decimal between 0.21 (value of room air) and 1. The values range from 0-455 mmHg and the severity of hypoxemia are defined as follows: Mild (200-455), Moderate (100-199), Severe (<100).

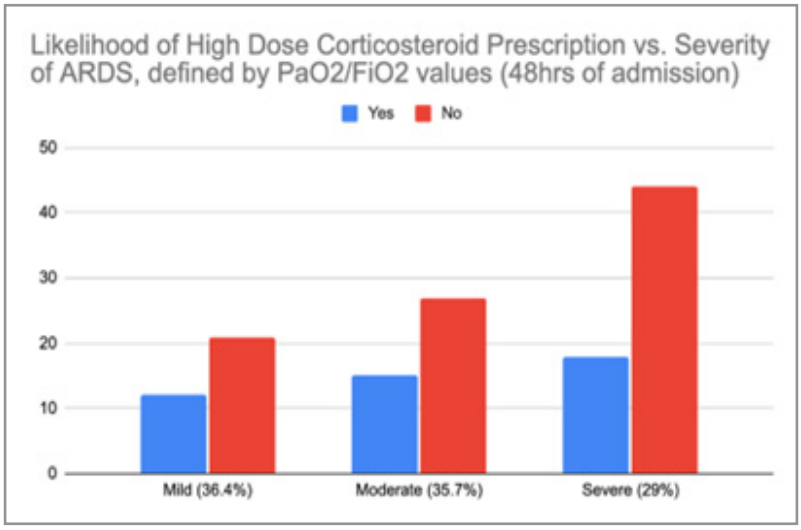

Figure 3: At first glance, the more vulnerable patients were least likely to be prescribed high dose steroids (29%) compared to the less vulnerable as defined by a mild and moderate (36.4% and 35.7%, respectively) PaO2/FiO2 value (Figure 3). The average PaO2/FiO2 value for patients prescribed high dose, low dose and no steroids are 150.4, 142.5 and 184.6, respectively (Table 1). However, when assessing the specific dosage compared to PaO2/FiO2 values, there was an insignificant correlation of -0.05.

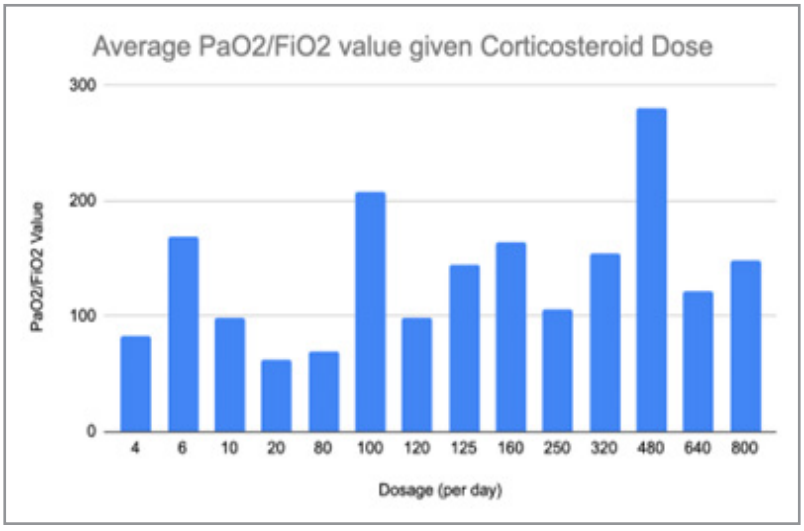

Figure 4: A large majority of high dose corticosteroids treatment courses began within 48 hours of admission (87.8%). The triage and treatments provided within the first two days of admission are critical as the disease is more likely to be controlled early in its progression. The most significant difference between varying doses is the in-hospital mortality which increases 35.1% for those who received no steroids compared to a high dose. For patients who survived, the length of stay also increased 24.9% for those prescribed no steroids compared to a high dose (Table 1).

Table 1: Demographical, clinical characteristics and outcomes of intubated COVID-19 patients according to dosage of corticosteroids within the first 48 hours of admission.

	High Dose (>40mg)	Low Dose (5-40mg)	None	p value
Count (%)	83 (58.9)	48 (34.0)	10 (7.1)	
M/F (%)	78.3/21.6	55.3/44.7	40/60	0.17
Age	66.38 (14.1)	68.3 (14.5)	69.5 (14.4)	0.001

BMI	30.9 (7.5)	32.9 (12.7)	36.2 (5.8)	0.5
In-hospital mortality (%)	51.8	59.6	70	<0.001
SOT upon Admission	7.4 (8.8)	4.4 (3.4)	8.9 (10.3)	0.001
Length of Stay, survived	39.7 (23.1)	42.1 (25.3)	49.6 (31.6)	0.13
WBC (4.5 to 11)	9.9 (4.7)	10.0 (5.8)	8.23 (5.1)	
Neutrophil % (40-60)	85.6 (14.5)	83.7 (7.7)	82.8 (8.6)	
Lymphocyte % (20-40)	8.6 (13)	8.9 (5.8)	8.5 (5.8)	
Immature Gran # (0-0.5)	0.09 (0.1)	0.14 (0.15)	0.1 (0.09)	
Hgb (11.6-16.6)	12.6 (2.1)	11.9 (2.5)	11 (2.7)	
Plt (150-450)	216.6 (125.4)	208.6 (95.6)	244 (214.8)	
D-dimer (<0.5)	1.99 (3.8)	2.1 (2.7)	0.76 (0.38)	
Creatinine (0.59-1.35)	1.2 (0.9)	1.6 (1.4)	2.2 (2.1)	
BUN (6-24)	30.3 (18.8)	36 (21.3)	36.9 (23.1)	
ALT (19-33)	34.5 (25.2)	61.8 (123.4)	26.9 (14.6)	
AST (10-40)	48 (28.7)	87.9 (223.1)	40.6 (31)	
LDH (140-280)	506 (171.3)	665.5 (911.4)	552.4 (373.6)	
Ferritin (11-307)	1141.8 (858.6)	1545.9 (1992.4)	1382.5 (1659.5)	
CRP (<350)	138.54 (82.7)	119 (70.2)	81.7 (41.8)	
PaO2	74 (12.2)	76.15 (13.3)	69.5 (10.6)	0.06
PaO2/FiO2	150.4 (100.5)	142.5 (87.3)	184.6 (129.9)	0.06
Average Number of Events	2.7	2.78	3.1	0.03
Risk of AKI				

SOT is Defined as Symptom Onset Time

- Laboratory test names include (normal range) according to Merck Manual (reference)
- Non percentage values include mean (STD)

Of the remaining patients (41.1%) who did not receive high-dose steroids during the initial 48 hours of admission, 45.5% eventually received a high dose of corticosteroids Solumedrol (Methylprednisolone) or Prednisone. 36.3% patients received a low dose form, and 18.2% received no steroids during their hospital stay. The statistics of steroid impact for days of stay beyond 48 hours are shown in Table 2.

Table 2: Demographical, clinical characteristics and outcomes of intubated COVID-19 patients who did not receive high-dose corticosteroids in first 48 hours of admission

	High Dose (>40mg)	**Low Dose (5-40mg)**	**None**
M/F %	40/60	50/50	50/50
Age	64.4 (14.8)	70.5 (18.9)	80.5 (6.4)
BMI	33.2 (10.9)	33.1 (23.7)	34.3 (1.8)
In hospital mortality %	40	50	100
Day of Stay (first dose)	8.2 (3.1)	4 (0)	N/A
SOT upon Admission	12.2 (4.8)	9.8 (1.9)	N/A
Length of Stay (survived)	32 (13.1)	63.5 (34.6)	N/A
WBC	12.78 (9.4)	13.4 (7.3)	11.6 (1.8)
Neutrophil %	81.2 (10.5)	87.4 (8.1)	82.3 (0.5)
Lymphocyte %	8.8 (5.2)	7.2 (7.8)	7.2 (0.9)
Immature Gran #	0.47 (.72)	0.28 (.25)	0.2 (0.07)
Hgb	10.7 (1.0)	9.8 (1.2)	8.4 (1.7)
Plt	314.8 (151.3)	151 (87.4)	210.5 (51.6)
D-dimer	1.7 (1.4)	5.9 (3.6)	0.58
Creatinine	1.0 (0.5)	1.9 (1.8)	3.5 (2.4)
BUN	39.3 (17.9)	60.5 (30.6)	46.5 (7.8)
ALT	25.8 (7.2)	46.7 (8.6)	22

AST	34.8 (6.8)	49.3 (29.9)	46
LDH	524.5 (180.3)	600.5 (103.9)	354
Ferritin	1361.3 (938.7)	678.3 (296.9)	1258
CRP	84.6 (61.9)	121.2 (68.6)	25.9
PaO2%	72.0 (13.4)	79.5 (12)	71.5 (11.1)
PaO2/FiO2	152.4 (101.5)	146.5 (78.1)	183.2 (125.5)

As Table 1 demonstrates, there is a significant difference in outcome for patients who received high dose as opposed to low dose, or no corticosteroids in the first 48 hours of admission. However, what is the impact of a changed dose; specifically high dose throughout admission, low dose switched to high dose after 48 hours and only a low dose throughout one's hospital stay (Table 3)? Despite a lack of consistency for treating patients with varying doses of steroids in the first 48 hours of admission, the likelihood to prescribe a higher dose after 48 hours was associated with risk of death (62.5% vs 50%) and length of stay for patients who survived (24 days vs 19 days). There were no patients who received no dose of corticosteroids during their stay.

Table 3: Risk factors associated with varying doses of corticosteroids during and after 48 hours of admission

	High Dose (48hrs)	Low Dose (48hrs) > High Dose (after 48hrs)	No dose (48hrs) > High Dose (after 48hrs)	Only Low Dose (48hrs)	p-value
Count (%)	48.3	27.9	4.7	19.2	
Length of Stay, Patients survived (days)	15.5	24	22	19	0.01
Number of Events	2.7	2.5	3.1	2.9	0.06
Risk of AKI					
Mortality Rate (%)	47.2	62.5	55.6	50	0.001

Discussion

Limitations

Given that a large majority (87.8%) of patients who were prescribed high-dose steroids were prescribed within 48 hours of admission, the breakdown of remaining patients (Table 2) is of a small number (n=11) and therefore the dexterity of the data (specifically the risk of mortality, and gender assessment) is limited. Also, within table 3, although the correlation of high dose steroid prescription after 48 hours and higher risk of death, length of stay is demonstrated clearly when comparing column 2, 3 and 5, the lack of patients who are represented in column 4–patients who were prescribed no dose in the first 48 hours and then switched to high dose–(4.7%), leaves such values with limited significance.

Conclusion

This study provides a conclusive correlation between an increase of high-dose corticosteroids and decrease in mortality rates and major events (mostly AKI). The systemic practices among steroid prescriptions were not trustworthy, which led to a more reliable data set. Despite a general understanding among physicians to prescribe higher doses of steroids to more sickly patients, specifically based on oxygen requirements, during the height of the pandemic, ideal hospital practices became less relevant. According to individual notes assessed, patients who were admitted in the evening were referred to an "infectious disease consult" which was likely not to be addressed until the following day or even later, especially if the patient was in the emergency room and not on a floor in a specific unit which met their needs (such as the intensive care unit). The lack of a "hardened" protocol for patients admitted with COVID-19, in addition to overwhelmed hospitals, led to prolonged time until the patient was adequately assessed and provided a treatment plan. The only resemblance of a consistent treatment plan was an automatic prescription of low dose steroids (6mg of Dexamethasone) to most patients upon admission (78.8%).

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