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Hypoproteinemia and Hypoalbumenaemia as Predictor Factors for Severity of Infection and Mortality in COVID – 19 patients

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Abstract
Coronaviruses are significant diseases in both humans and animal's acute respiratory distress syndrome (ARDS), a life-threatening acute, diffuse, inflammatory form of lung injury, is characterized by pulmonary infiltrates, poor oxygenation, and sharpness of onset in critically sick patients. Assessment of the correlation between total serum protein and serum albumin with severity of respiratory involvement in hospitalized Coronaviruses patients. A prospective cohort study that involved 100 newly diagnosed Coronaviruses patients (confirmed by positive polymerase chain reaction (PCR) test for coronavirus infection from nasopharyngeal swabs) The patients sent for total serum protein and serum albumin (at day of admission, three days after admission and ten days after admission). The diagnosis and assessment of severity according to the WHO classification of COVID-19. The study was carried out in Al Diwaniyah teaching hospital, it started from October 2021 till the end of March 2022. Both hypoalbuminemia and hypoproteinemia significantly associated with severity of infection of COVID-19(30.0%) $P<0.001$ of moderate cases and (98.0%) $P<0.001$ of severe cases of Coronaviruses infection have hypoproteinemia during the 10 days follow up , in severe Coronaviruses cases the magnitude of reduction in serum protein and albumin increased with time, this indicates that possibly with time severe case associated with lower values of both markers, Our study reported that hypoalbuminemia observed at admission (34.0%) $P<0.001$, and after 3 days of admission (50.0%) $P<0.001$, and after 10 days of admission (54.0%) $P<0.001$ in moderate cases and in severe cases hypoalbuminemia at admission (80.0%) $P<0.001$, after 3 days of admission (86.0%) $P<0.001$, and after 10 days of admission (84.0%) $P<0.001$ of patients. In conclusion the current thesis validated that the COVID-19 is a picture of ARDS, morbidity and mortality increase with low serum protein and serum albumin.

Keywords: Hypoproteinemia, hypoalbumenaemia, COVID-19, Iraq

Introduction
Coronaviruses are significant infections that affect both humans and animals. A cluster of pneumonia cases in Wuhan, a city in China's Hubei Province, at the end of 2019 were linked to a new coronavirus. As a result of its quick spread, China experienced an epidemic, and more instances were reported in other nations worldwide. The World Health Organization classified the illness as COVID-19, or coronavirus disease 2019, in February 2020. Previously known as 2019-nCoV, the virus that causes COVID-19 is now known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (WHO, 2020). Positive-stranded RNA viruses that are enclosed are known as coronaviruses. The coronavirus that causes COVID-19 is a beta-coronavirus that belongs to a distinct clade but shares a subgenus with the severe acute respiratory syndrome (SARS) virus and a number of bat coronaviruses, according to full-genome sequencing and phylogenic analysis. The International Committee on Taxonomy of Viruses' Coronavirus Study Group has suggested that this virus be known as SARS-CoV-2 (Gorbalenya *et al.*, 2020) [2]. A further beta-coronavirus that seems to be more distantly related is the Middle East respiratory sickness (MERS) virus (Zhu *et al.* 2020) [3]. It is unclear whether the COVID-19 virus is spread directly from bats or by another method (such as an intermediary host), although the closest RNA sequence similarity is to two bat coronaviruses, suggesting that bats are the main source (Perlman, 2020) [4].
The primary way that SARS-CoV-2 spreads is from person to person. The main way that the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spreads is through direct

respiratory contact between individuals (Zhou *et al.*, 2020; Hoffmann *et al.*, 2020) [5, 11, 6]. The virus released in respiratory secretions when an infected person coughs, sneezes, or talks can infect another person if it is inhaled or comes into direct contact with mucous membranes. It is believed to primarily occur through close-range contact (i.e., within about six feet or two meters) via respiratory particles. Although contaminated surfaces are not believed to be a primary channel of transmission, infection may also occur if a person's hands become contaminated by these secretions or if they touch contaminated surfaces and subsequently touch their mouth, nose, or eyes (Meyerowitz *et al.*, 2021) [7]. Although people of any age who are otherwise healthy might develop severe sickness, adults who are older or have specific underlying medical conditions are more likely to experience it. Severe illness has also been linked to certain test abnormalities and demographic characteristics. Based on epidemiologic, clinical, and laboratory characteristics, a number of prediction tools have been developed to identify patients who are more likely to have severe illness; however, the majority of studies assessing these tools are constrained by the risk of bias, and they have not received sufficient validation for clinical management (Wynants *et al.*, 2020; Lombardi *et al.*, 2021) [8, 9]. The cytokine storm, advanced age, male sex, hospitalization, and concomitant diabetes mellitus are all associated with low albumin and related mortality (Huang *et al.*, 2020; Zhou *et al.*, 2020) [10, 18, 5, 11]. 67.0% of patients in a prior study that included 663 COVID-19 patients had decreased albumin levels, and lower albumin was linked to COVID-19 aggravation compared to patients who do not die in the hospital, those who do have lower albumin levels (Zhao *et al.*, 2020) [12]. Hypoproteinemia in COVID-19 patients has been documented in an increasing number of investigations. A biochemical indicator that is frequently measured in hospitalized patients, serum albumin indicates the nutritional condition of the patient and is correlated with liver function, illness morbidity, and mortality. It is crucial for regulating vascular permeability, plasma osmotic pressure, and the movement of different substances (including metals, nitric oxide, cholesterol, bile pigments, and other chemicals) (Chen *et al.*, 2021) [13]. The purpose of study was assessment of the correlation between total serum protein and serum albumin with severity of respiratory involvement in hospitalized Coronaviruses patients.

Materials and Methods

Study design and sampling

In this study, the patients' eligibility were examined for the study, and those deemed fulfilling the study inclusion and exclusion criteria were entered it. The patients' demographic (including age, gender, BMI, and smoking), past medical history, and severity of COVID-19 were registered for each patient. Each patient was followed-up three times, first at baseline (at admission), for their total serum protein, and serum albumin, second after three days of admission and then after ten days of admission, fate registered whether recovered or died .After admission, COVID-19 patients were classified according to radiological and clinical evaluation to mild cases (with or without cough ,no dyspnea and no pneumonia on a CT scan), moderate cases (fever , respiratory symptoms and pneumonia on a CT scan), severe cases (respiratory rate ≥ 30 breaths /min, oxygen saturation ≤ 93% or patients with pneumonia on a CT scan) and critical cases (respiratory failure/need mechanical ventilation). All patients were treated according to the MOH treatment protocol which relies on patient severity status (Abbas *et al.*, 2021) [14].

A prospective cohort study that involved 100 new diagnosed COVID-19 patients (confirmed by positive polymerase chain reaction (PCR) test for COVID-19 from nasopharyngeal swabs). The diagnosis according to WHO classification of COVID-19 (table 1).

Table 1: WHO classification of COVID-19

Types	Findings
Mild	Mild clinical symptoms [fever < 38ºC (quelled without treatment) , with or without cough , no dyspnea , no chronic disease, No imaging findings of pneumonia
Moderate	Fever, respiratory symptoms, imaging findings of pneumonia.
Severe	Meet any of the followings : a) Respiratory distress, RR ≥ 30 times/min b) SpO2 < 93% at rest c) PaO2/FiO2 ≤ 300 mmHg *patients showing a rapid progression (> 50%) on CT imaging within 24-48 hours should be managed as severe (added in the trial sixth edition)
Critical	Meet any of the followings : a) Respiratory failure, need mechanical assistance b) Shock c) Extra pulmonary organ failure , intensive care unit is needed

The study was carried out in Al Diwaniyah teaching hospital, the started from October 2021 till the end of March 2022, for ethical considerations**,** participants were informed of the study's purpose and all related procedures and tests, and then given the option to participate after receiving approval, the scientific council of the anesthesia specialization of the Iraqi Board of Medical Specializations. All participants signed a consent form before taking part in the research.

Inclusion Criteria

1. Patients classified as moderate, severe, or critically ill cases of COVID-19 and admitted to the Respiratory Care Unit (RCU).
2. Patients aged above 14 years, in accordance with the World Health Organization (WHO) criteria for adults.

Exclusion Criteria

1. Patients with mild cases of COVID-1
2. Patients receiving active immunosuppressive therapy.
3. Pregnant women.
4. Patients with pre-existing medical conditions known to cause decreased serum albumin levels (e.g., chronic liver disease, nephrotic syndrome).

Statistical analysis

Normality test was done using Anderson Darling test and all variables adhere to normal distribution. The paired t-test for continuous variables and the chi square test for categorical variables were used to compare groups M and S. The results were presented using the odd ratio (OR) and its 95% confidence interval (CI), where a value above 1.0 indicates increased risk. Logistic regression analysis was utilized for risk assessment, and SPSS version 25 was employed for the formal analysis. P-values less than 0.05 were regarded as significantly different. Hypoproteinemia is defined as a total serum protein level less than 6 g/dl. Hypoalbumenemia is defined as a serum albumin level of less than 3.5 g/dl.

Results and Discussion

The study included 100 patients, they were divided into two groups according to WHO classification of COVID-19, moderate COVID-19 infection included 50 patients (group M), while 50 patients had severe COVID-19 infection (group S). In terms of demographic data, there was no significant difference between both groups in their age, gender, BMI, and smoking status, as illustrated by table 2.

Table 2: Assessment of demographical data according to severity

Variables	Group M	Group S	p-value
Number	50	50	-
Age, mean ± SD	46.0 ± 12.8	49.1 ± 10.8	0.198
Gender, n (%)			
Female	19 (38%)	15 (30%)	0.398
Male	31 (62%)	35 (70%)	
BMI, mean ± SD	28.9 ± 4.3	29.1 ± 4.0	0.754
Group M: moderate COVID, Group S: severe COVID			

In terms of past medical history, there was no significant difference between both groups in their hypertension, Diabetes mellitus (DM), respiratory diseases, and smoking status as illustrated by table 3.

Table 3: Assessment of risk factors

Variables	Group M	Group S	p-value
Number	50	50	-
Hypertension, n (%)	8 (16%)	14 (28%)	0.148
DM, n (%)	16 (32%)	21 (42%)	0.300
Respiratory diseases[a], n (%)	6 (12%)	10 (20%)	0.275
Smoking, n (%)	12 (24%)	9 (18%)	0.461
[a] Asthma, and COPD; a: number; Group M: moderate COVID; Group S: severe COVID			

Mean total serum protein was significantly lower in group S compared to group M at baseline, after 3 days, and after 10 days, as illustrated by table 4 and figure 1.

Table 4: Assessment of total serum protein in g/dl by the study groups

Variables	Group M	Group S	p-value
Number	50	50	-
At admission	6.25 ± 0.94	5.11 ± 1.15	<0.001
After 3 days	6.21 ± 0.98	4.48 ± 1.00	<0.001
After 10 days	6.41 ± 1.10	4.18 ± 0.99	<0.001
Data presented as mean ± standard deviation; Group M:moderate COVID; Group S: severe COVID			

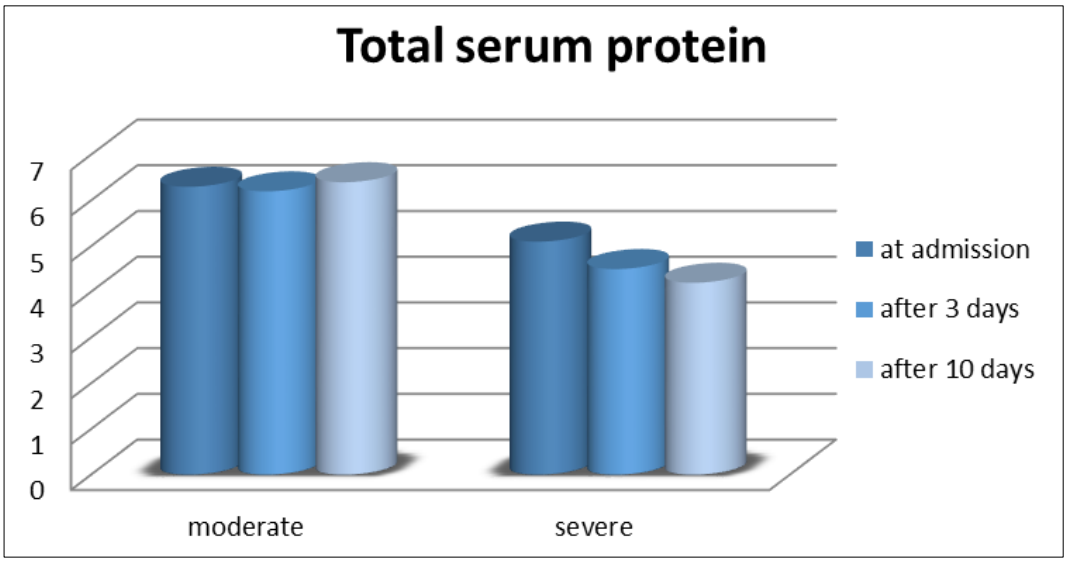

Fig 1: Nested histogram of total serum protein

The proportion of patients with hypoproteinemia was higher in group S compared to group M, during all the follow-up periods, as illustrated by table 5

Table 5: Assessment of hypoproteinemia by the study groups

Variables	Group M	Group S	p-value
Number	50	50	
At admission, n (%)	15 (30%)	36 (72%)	<0.001
After 3 days, n (%)	18 (36.7%)	46 (92.0%)	<0.001
After 10 days, n (%)	15 (30%)	49 (98.0%)	<0.001
N: number; Group M: moderate COVID; Group S: severe COVID			

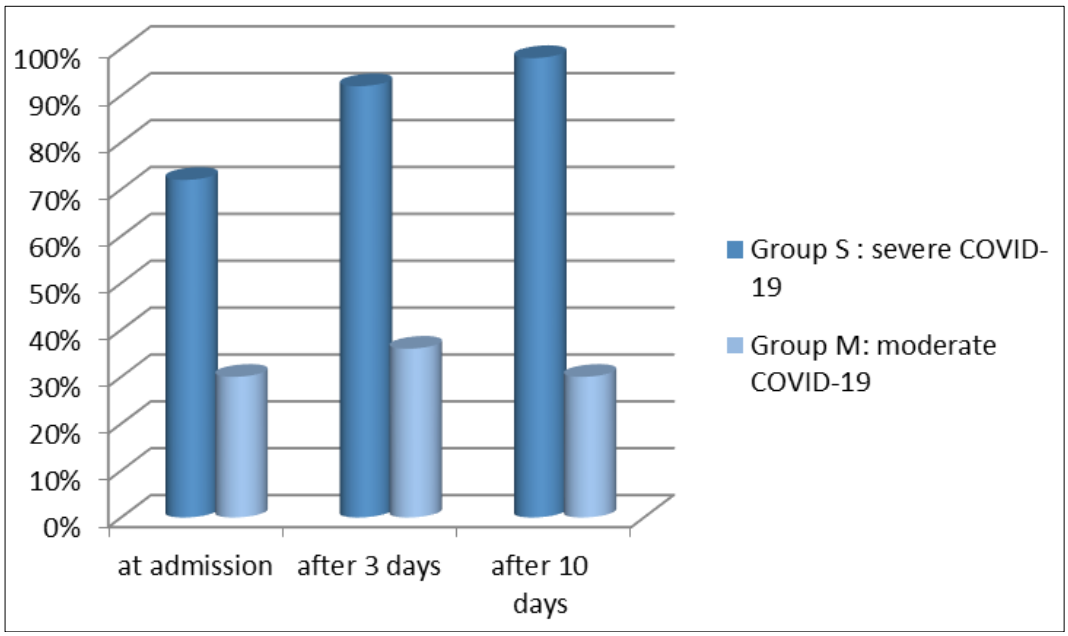

Fig 2: Assessment of hypoproteinemia by the study groups

Mean serum albumin was significantly lower in group S compared to group M at baseline, after 3 days, and after 10 days, as illustrated by table 6 and figure 2.

Table 6: Assessment of serum albumin in g/dl by the study groups

Variables	Group M	Group S	p-value
Number	50	50	-
At admission	3.82 ± 0.91	3.07 ± 0.62	<0.001
After 3 days	3.45 ± 0.69	2.94 ± 0.50	<0.001
After 10 days	3.35 ± 0.63	2.89 ± 0.53	<0.001
Data presented as mean ± standard deviation ; Group M: moderate COVID; Group S: severe COVID			

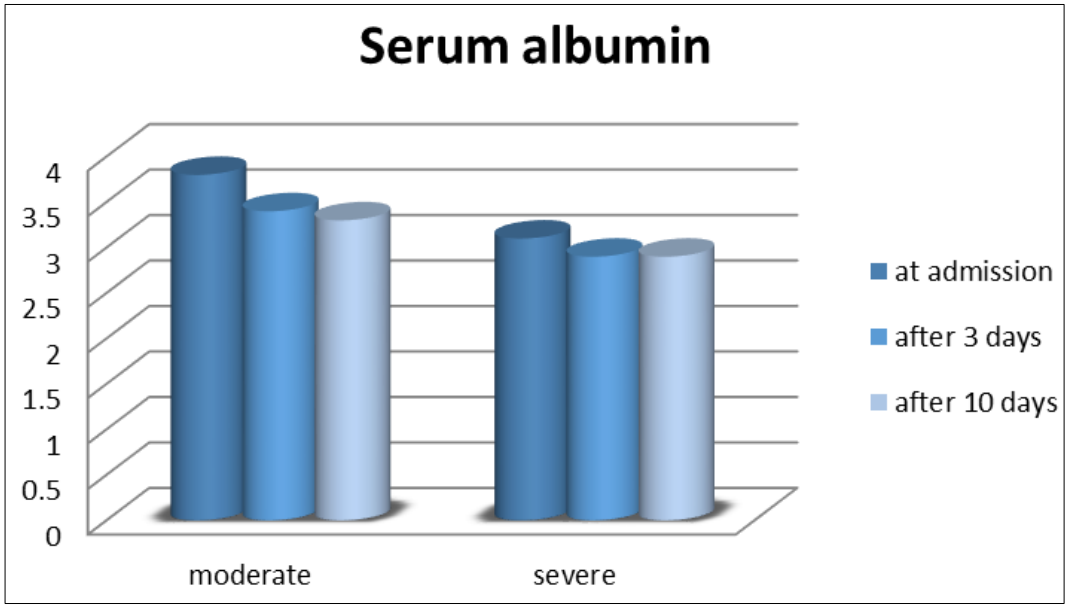

Fig 3: Nested histogram of serum albumin

The proportion of patients with hypoalbuminemia was higher in group S compared to group M, during all the follow-up periods, as illustrated by table 7.

Table 7: Assessment of hypoalbuminemia by the study groups

Variables	Group M	Group S	p-value
Number	50	50	
At admission, n (%)	17 (34.0%)	40 (80.0%)	<0.001
After 3 days, n (%)	25 (50.0%)	43 (86.0%)	<0.001
After 10 days, n (%)	27 (54.0%)	42 (84.0%)	<0.001
N: number; Group M: moderate COVID; Group S: severe COVID			

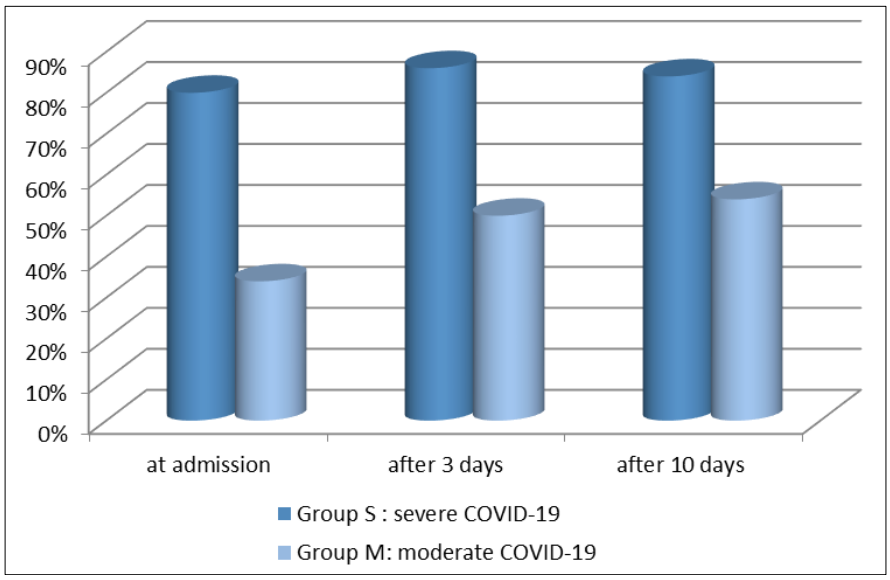

Fig 4: Assessment of hypoalbuminemia by the study groups

At all time periods (at admission, 3 days, and 10 days) there was significant association between hypoproteinemia and hypoalbuminemia with severe COVID-19 infection, as illustrated by table 8.

Table 8: Risk assessment of low serum protein and albumin at different periods with severe COVID-19 infection

Variable	OR	95%CI	p-value
Hypoproteinemia			
At admission	6.00	2.53 – 14.24	<0.001
After 3 days	20.44	6.32 – 66.11	<0.001
After 10 days	114.33	14.42 – 906.25	<0.001
Hypoalbuminemia			
At admission	7.57	3.14 – 19.23	<0.001
After 3 days	6.14	2.32 – 16.24	<0.001
After 10 days	4.47	1.75 – 11.43	0.002
OR: odd ratio, CI: confidence interval			

The proportion of death in group S compared to group M, patients with hypoproteinemia and patients with hypoalbuminemia during all the follow-up periods, as illustrated by table 9.

Table 9: COVID severity, protein and albumin and death

Number	Survived	Death	p-value
	92	8	
COVID severity			
Moderate	49 (53.3%)	1 (12.5%)	0.059
Severe	43 (46.7%)	7 (87.5%)	
Hypoproteinemia			
At admission	44 (47.8%)	7 (87.5%)	0.060
After 3 days	57 (62.0%)	7 (87.5%)	0.149
After 10 days	56 (60.9%)	8 (100.0%)	0.027
Hypoalbuminemia			
At admission	50 (54.3%)	7 (87.5%)	0.133
After 3 days	60 (65.2%)	8 (100.0%)	0.043
After 10 days	61 (66.3%)	8 (100.0%)	0.048

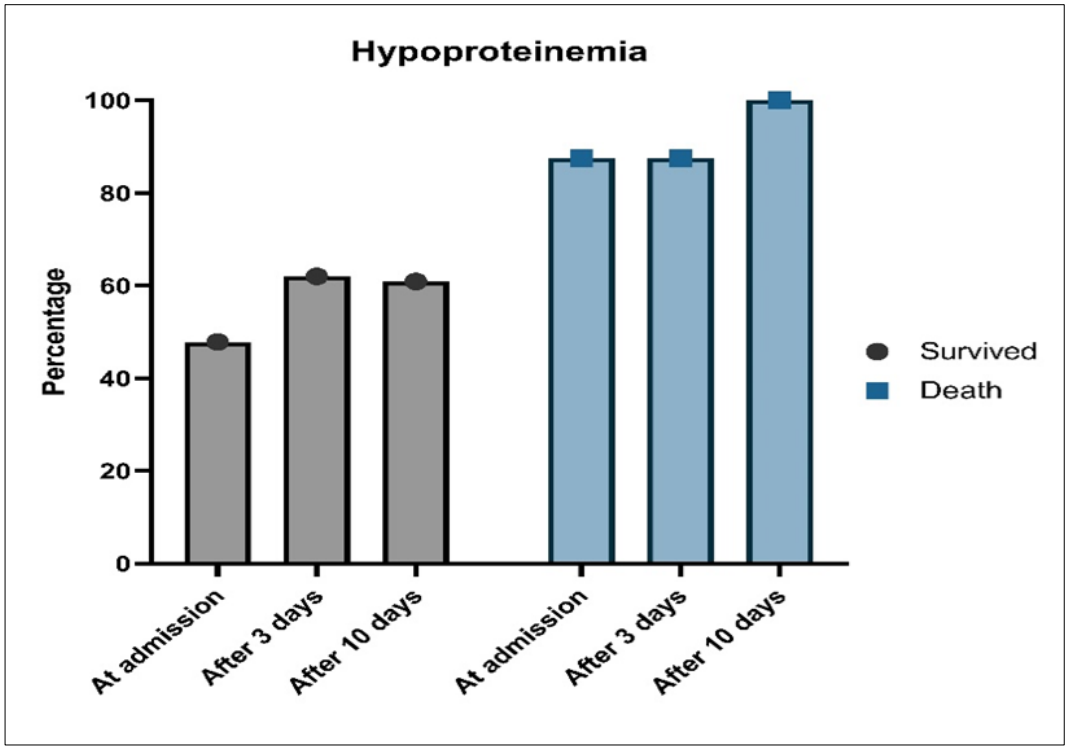

Fig 5: Probability plot of serum protein and its relation to death

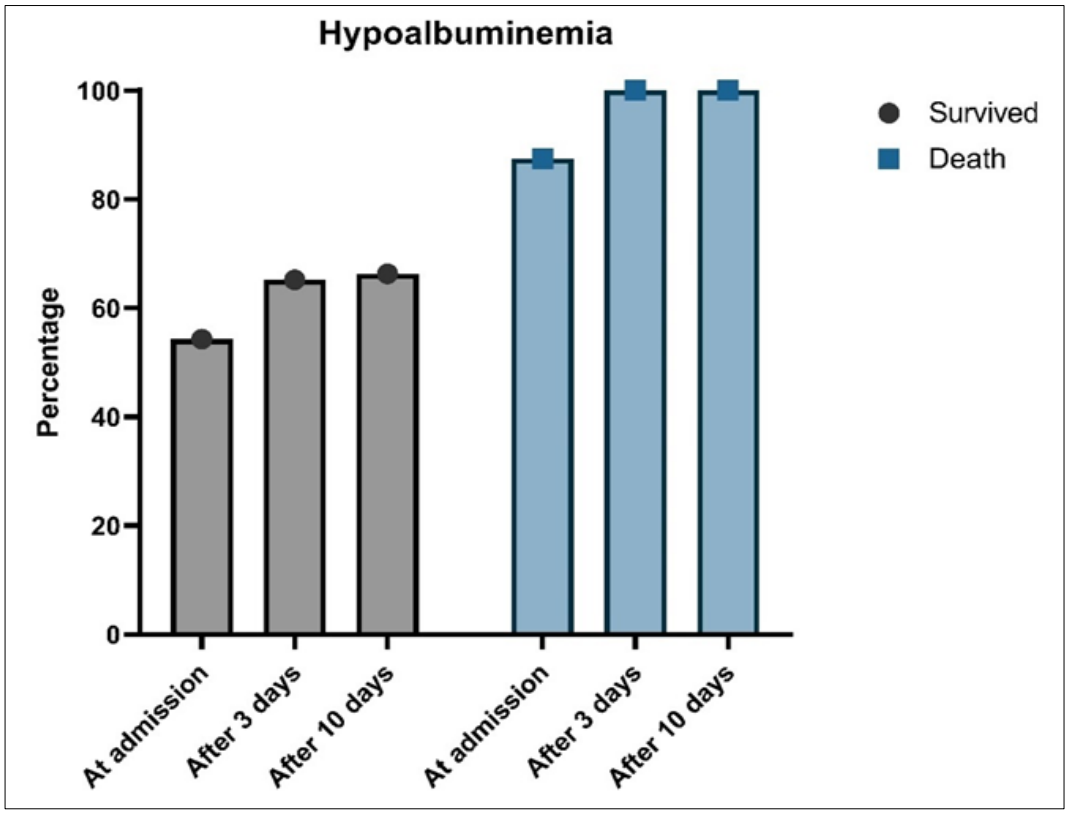

Fig 6: Probability plot of serum albumin and its relation to death

Both serum albumin and total serum protein were significantly associated with death (in which decreased serum levels of both associated with death), as illustrated by table 10 and figures 3 and 4.

Table 10: Risk Assessment of death

Variables	OR (95%CI)	p-value
Total protein at admission	0.42 (0.21-0.84)	0.013
Total protein at 10 days	0.34 (0.16-0.72)	0.005
Albumin at admission	0.14 (0.02-0.99)	0.048
Albumin at 10 days	0.01 (0.001-0.15)	<0.001

In the present study we assessed prospectively the association between serum protein and albumin with both severity of respiratory infection in COVID-19 and death in hospitalized patients. Both hypoalbuminemia and hypoproteinemia significantly associated with severity of respiratory infection in COVID-19 infection during the 10 days follow up and for severe COVID-19 cases the magnitude of reduction in serum protein and albumin increased with time, this indicate that the respiratory involvement in COVID – 19 is ARDS as hypoproteinemia and hypoalbuminemia are seen in this disease and the cause is extravascular leakage of protein in the lung tissue and this is part of pathophysiology of ARDS . Our prospective cohort study of 100 patients with confirmed COVID-19 , 50 patients was moderate and 50 patients was severe , aged above 14 years , 66.0% were male , the mean ± SD BMI was 28.9 ± 4.3 for moderate cases and 29.1± 4.0 for severe cases , (74.0%) P=0.300 had DM. The patients were followed at three time points (at admission, after 3 days of admission, after 10 day of admission). Abnormal albumin was observed at admission (34.0%) *P*<0.001, and after 3 days of admission (50.0%) *P*<0.001, and after 10 days of admission (54.0%) *P*<0.001 and the low albumin level run in associated with severe cases.

The present investigation was consistent with several studies. For example, in Hundt *et al.,* (2020) [15], retrospective cohort study of 1,827 patients with confirmed COVID-19, the mean age was 65 years (range: 1-103), 53.0% of the patients were male, the mean BMI was 29.8 (42.5% obese), and 39.0% of the patients had diabetes mellitus. Preinfection baseline, admission, and peak hospitalization were the three time points at which the patients were monitored.They reported that abnormal albumin observed at prehospitalization (27%), and peak hospitalization (86.6%), median albumin was significantly lower in severe albumin 3.3 compared to non-severe cases 3.5 mg/dL. They found low albumin associated with ICU admission (OR: 2.95), mechanical ventilation (OR: 2.36), but they did not found association with death (OR: 1.0).

Zhang *et al.,* (2020) [16], carried out a retrospective, single-center research on 115 confirmed cases of COVID-19 in Wuhan, China. In terms of gender, there were 66 (57.40%) females and 49 (42.60%) males. The average age at diagnosis was 49.52 ± 17.06 years (IQR, 35-62; range, 20-86 years). Mild cases had significantly lower serum albumin levels than severe cases (40.4 vs. 34.4 mg/dL). Additionally, they discovered that during admission, serum albumin dropped dramatically from 33.7 to 29.0 mg/dL. Among COVID-19 patients, hypoalbuminemia (ALB <40 g/L) is found in more than half (63/115, 54.78%). The percentage for patients with severe COVID-19 is 90.32% (28/31). Additionally, individuals who have advanced to critical illness exhibit a persistent decline in serum albumin levels. . Poor clinical outcomes for hospitalized COVID-19 patients are associated with hypoalbuminemia. Overconsumption and inadequate nutrient intake may be the primary causes of hypoalbuminemia.

A retrospective cohort study that involved 207 patients, the patients were followed-up at admission after 3 and 7 days. Low serum albumin was found in 50.7% patients at hospital admission. A strong association was found between albumin levels and severity of COVID-19 (*P*< 0.001) and death (P = 0.003) (Levitt and Levitt. 2016) [17].

The average age of the 299 adult patients in a research by Huang *et al.,* (2020) [10, 18], was 53.4 ± 16.7 years, with 160 (53.5%) of them being male. Survivors and non-survivors had significantly different albumin levels (37.6 ± 6.2 vs. 30.5 ± 4.0, P <.001). Comorbidities (OR, 6.816; 95% CI, 1.361-34.133) and hypoalbuminemia (OR, 6.394; 95% CI, 1.315-31.092) were found to be independent predictors of death using multivariate analysis.

Conclusion

In conclusion the current thesis validated that COVID-19 respiratory involvement goes with of ARDS, morbidity and mortality increase with low serum protein and serum albumin.

Conflict of Interest

Not available.

Financial Support

Not available.

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