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A PROSPECTIVE OBSERVATIONAL STUDY TO ASSESS THE OUTCOME OF ANTICOAGULANT THERAPY IN HOSPITALIZED COVID-19 PATIENTS WITH SPECIAL REFERENCE TO D-DIMER IN A TERTIARY CARE HOSPITAL IN NORTH INDIA

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ABSTRACT

Background: Coagulopathy is a potentially fatal complication of the newly discovered SARS-CoV-2 that significantly affects the hematological and hemostatic systems. SARS-CoV-2 promotes massive formation and deposition of fibrin, which showed very high D-dimer levels in these patients. Preliminary evidence suggests that administration of anticoagulants may reduce mortality in patients with moderate to severe COVID-19. In hospitalized patients with COVID-19, low molecular weight heparin, unfractionated heparin, is preferred over oral anticoagulants. **Materials and Methods:** A prospective observational study was conducted at Chest Disease Hospital, Government Medical College, Srinagar over one year to assess the outcome of anticoagulant therapy in hospitalized COVID-19 patients with a special focus on D-dimer. Data were collected using a pre-structured Proforma and then analyzed using appropriate statistical methods. **Results:** A total number of 225 patients were included in the study. In our study, 64% were male and 36% were female patients. Patients had higher D-dimer levels at admission (mean 1.81 ± 1.04 mcg/mL) than at follow-up on the fifth hospital day (mean 0.52 ± 0.44 mcg/mL), with a mean difference of 1.29 mcg/mL. **Conclusions:** Anticoagulation therapy has been recommended as a mitigating strategy in patients with COVID-19. The level of thrombotic markers decreased significantly.

KEYWORDS: COVID-19, SARS-CoV-2, Anticoagulants, D-Dimer, Coagulopathy.

INTRODUCTION

Since the early days of the COVID-19 pandemic, doctors have been reporting coagulation disorders, both thrombotic and bleeding, in hospitalized patients. Several mechanisms have been identified for the increased risk of thrombosis, but many hospitalized patients with COVID-19 appear to develop a cytokine storm that leads to hyper-inflammation, endothelial disruption, platelet activation, and coagulopathy, predisposing to hemostatic and thrombotic complications.[1] Lungs are the most affected organs, and critically ill patients often show thrombotic lesions in pulmonary microvasculature, which is twice as common as in non-critically ill patients with COVID-19.[2] Preliminary evidence suggests that administration of anticoagulants may reduce the mortality of patients with severe COVID-19.[3] Although some, but not all, laboratory findings appear similar to sepsis-related disseminated intravascular coagulopathy (DIC), some researchers prefer the term COVID-19-induced coagulopathy (CIC). CIC is more pro-thrombotic than hemorrhagic.[4] Elevated D-dimer, the most common coagulation disorder in COVID-19, especially in the elderly and those with comorbidities, is an independent risk factor for death. In critically ill hospitalized patients, low molecular weight heparin, or unfractionated heparin, are preferred over oral anticoagulants because of their shorter half-lives, ability to be administered intravenously or subcutaneously, and fewer drug-drug interactions.[5]

METHODOLOGY

This prospective observational study was conducted over one year at the Chest Disease Hospital, Government Medical College, Srinagar after obtaining approval from the Institutional Ethics Committee. All RT-PCR-confirmed SARS-CoV-2 infected patients of both sexes and over 18 years of age with a diagnosis of moderate to severe COVID-19 required hospitalization for further treatment during the study period were included.

Exclusion criteria

1. Patients who had an acute cardiovascular event in the last three months.

2. Patients who had an acute stroke (ischemic) in the last three months.
3. Patients with a history of active major bleeding.
4. Patients with a history of allergy to enoxaparin, components of heparin products, or heparin-induced thrombocytopenia (HIT).

Data were collected using a pre-structured Proforma and then analyzed using appropriate statistical methods.

RESULTS

A total of 225 patients were included in this study of which included 64% were male and 36% female. The age of the patients in the study varied between 24 and 93 years. The mean age of the patients was 61.83 years with a standard deviation of 15.28 years. 195 (86.7%) patients received enoxaparin (LMWH), of which 121 (53.8%) received enoxaparin 40mg/0.4ml and 74 (32.9%) received enoxaparin 60mg/0.6ml. 30 (13.3%) patients received unfractionated heparin (UFH). Patients had higher D-dimer levels at admission (mean 1.81 ± 1.04 mcg/mL) than at follow-up on the fifth hospital day (mean 0.52 ± 0.44 mcg/mL), with a mean difference of 1.29 mcg/mL.

DISCUSSION

D-dimer levels are directly correlated with the rate of plasmin formation and degradation. Thus, any pathological condition that increases the rate of plasmin generation and degradation would also increase D-dimer levels.[6] COVID-19 coagulopathy is characterized by several laboratory abnormalities, including elevated levels of fibrinogen and D-dimer and a slightly increased prothrombin time or activated partial thromboplastin time.[7] Of the 225 patients, 144 (64.0%) were males and 81 (36.0%) were females. A study published by Vahidy FS et al reported a relatively high number of moderate to severe COVID-19 cases in males.[8] Statistically significant differences in D-dimer levels were observed at admission and on hospital day 5 (P-value<0.001). In 2020, Guan et al. presented the results of a large retrospective study showing for the first time a correlation between abnormal D-dimer and disease severity in patients with COVID-19.[9] Setting a cut-off point Setting a D-dimer cut-off value above 0.5 mg/L, they reported that a significantly higher proportion of subjects with severe COVID-19 had abnormally high D-dimer levels than those with only mild to moderate disease. [9] In addition, Tang et al. reported that D-dimer levels were approximately 3.5-fold higher in patients with severe COVID-19 disease compared to patients with only mild to moderate disease.[10]

CONCLUSION

In conclusion, levels of D-dimer are directly related to disease severity in patients with COVID-19. Novel coronavirus infections promote inflammatory and coagulation responses that increase the number of thrombotic events. Laboratory testing for D-dimer and pro-inflammatory cytokines can help classify patients with COVID-19 based on the severity of the disease. Also doing more research to further investigate the relationship between D-dimer levels and pro-inflammatory cytokine levels and thrombotic pathways, especially in people with COVID-19.

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