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Role of D-Dimer in assessing severity, monitoring, and predicating outcome in COVID-19 pneumonia: A single center study

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ABSTRACT

Objectives: Robust data are available regarding role of D-dimer in analyzing coagulation status in pulmonary embolisms and deep vein thrombosis. As thrombogenic nature of coronavirus disease 2019 (COVID-19) has been evolved in this pandemic, we have studied its role in predicting disease severity, correlation with durations of illness and oxygenation status, and ventilatory support requirement with prediction of deep vein thrombosis and pulmonary embolism in these cases.

Materials and Methods: Prospective, observational follow-up study, included 2000 COVID-19 cases confirmed with reverse transcription–polymerase chain reaction. All cases were assessed with high-resolution computed tomography (HRCT) thorax, oxygen saturation, inflammatory marker as D-Dimer at entry point and follow-up. Age, gender, comorbidity, and use of bilevel-positive airway pressure (BIPAP)/non-invasive ventilation (NIV) and outcome as with or without lung fibrosis were key observations. In selected cases, lower limb venous Doppler and computed tomography (CT) pulmonary angiography to rule out deep vein thrombosis or pulmonary thromboembolism. Statistical analysis is done using Chi-square test.

Results: CT severity score at entry point with D-Dimer titer has significant correlation ($P < 0.00001$). Age (<50 and >50 years) and gender (male vs. female) have significant association with D-Dimer level ($P < 0.00001$) and ($P < 0.010$), respectively. D-Dimer titer has significant association with duration of illness before hospitalization ($P < 0.00001$). Comorbidities have significant association with D-Dimer level ($P < 0.00001$). D-Dimer titer has significant association with oxygen saturation ($P < 0.00001$). BIPAP/NIV requirement has significant association with D-Dimer level ($P < 0.00001$). Timing of BIPAP/NIV requirement during hospitalization has significant association with D-Dimer level ($P < 0.00001$). Follow-up D-Dimer titer during hospitalization, as compared normal and abnormal to entry point level has significant association with post-COVID lung fibrosis, deep vein thrombosis and pulmonary thromboembolism ($P < 0.00001$).

Conclusion: D-Dimer has documented very crucial role in COVID-19 pneumonia in predicting severity of illness, ventilatory support requirement and course in critical care setting. D-Dimer follow-up titer has documented role in predicting lung fibrosis and deep vein thrombosis and pulmonary embolism. D-Dimer serial titers have documented significant role in step-up or step-down interventions in critical care setting.

Keywords: Coronavirus disease 2019 pneumonia, D-Dimer, lung fibrosis, Deep vein thrombosis, Pulmonary embolism, Inflammatory marker

INTRODUCTION

The current pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), originally emerged from China, has documented

274,628,461 confirmed cases and 5,358,978 deaths globally, and 34,752,164 confirmed cases 478,007 deaths in India.[1] The International Federation of Clinical Chemistry and Laboratory Medicine Task Force on COVID-19 has been established to synthesize up-to-date information on the epidemiology, pathogenesis, and laboratory diagnosis and monitoring of COVID-19, as well as to develop practical recommendations on the use of molecular, serological, and biochemical tests in disease diagnosis and management.[2,3]

COVID-19, the pandemic disease caused by infection with the novel virus, SARS-CoV-2 can now be added to the already extensive list of conditions that may be associated with elevated D-dimer. The discovery that D-dimer may be elevated in COVID-19 was first reported by physicians in Wuhan, China where the epidemic started. A study of 191 patients with COVID-19, who were hospitalized in Wuhan during January 2020 at the outset of the pandemic, revealed that D-dimer was elevated in many of these patients and the magnitude of the elevation was greatest in those who did not survive.[4,5]

Fibrin degradation products are a highly heterogeneous group of soluble fragments that appear in the circulation as a result of two simultaneous physiological processes: (1) Coagulation, resulting in the conversion of soluble fibrinogen into insoluble stabilized fibrin by the enzymes thrombin and factor XIIIa, (2) Fibrinolysis, resulting in the dissolution of the fibrin clot by the enzyme plasmin. The D-dimer fragment is the terminal product of this process.[5] A number of subsequent studies conducted around the world have confirmed that D-dimer is elevated in those with severe COVID-19 and highest in those who are most critically ill and those who do not survive. Much COVID-19 research over the past months has been directed at understanding the significance of D-dimer elevation and the COVID-19 related coagulopathy that is presumed responsible for the elevation.[4,5]

D-dimer has been extensively investigated for the diagnosis, monitoring, and treatment of venous thromboembolism for which it is used routinely.[5,6] D-dimer levels are also elevated in conditions of chronic inflammation, such as active malignancy, rheumatoid arthritis, sickle cell disease, and asthma.[7] In the setting of COVID-19, D-dimer has been reported to be higher in subjects who are critically ill or those who expire.[4,8-11]

MATERIAL AND METHODS

Ethical approval

This study was approved by the Institutional Review Board/ Ethics Committee at Venkatesh Hospital and Critical Care Center Latur India and MIMSR Medical College Latur India, (Approval number: VCC/63-2020-2021; Approval date 09/08/2020).

Data source

Prospective, observational, 12 weeks follow-up study, conducted during July 2020–May 2021, in MIMSR Medical College Latur and Venkatesh Hospital Latur India, included 2000 COVID-19 cases confirmed with reverse transcription–polymerase chain reaction (RT-PCR), to find out role of D-Dimer in assessing severity, monitoring and predicating risk of deep vein thrombosis, pulmonary embolism, and post-COVID lung fibrosis in diagnosed COVID-19 pneumonia cases admitted in indoor unit. A total of 2000 cases were enrolled in study after IRB approval and written informed consent of all included cases were taken at respective centers of study in Venkatesh Hospital and MIMSR Medical College Latur.

Inclusion criteria

COVID-19 patients, confirmed with RT-PCR, above the age of 18 years, hospitalized in the study centers, including those with comorbidities irrespective of severity and oxygen saturation were included in the study**.**

Exclusion criteria

Those not willing to give consent, not able to perform D-Dimer and not willing to remain in follow-up, and cases that died during hospitalization or before 12 weeks of discharge from hospital were excluded from the study.

Methodology of CRP titer assessment: Immunoturbidimetry

Normal values: Normal values up to 6 mg/L.

All study cases were undergone following assessment before enrolling in study

COVID-19 RT-PCR test was performed on nasopharyngeal samples collected with all standard institutional infection control policies, if first test results were negative and radiological features clearly documenting pneumonia, we have repeated RT-PCR test and enrolled all cases with positive COVID-19 RT-PCR test. HRCT Thorax to assess severity of lung involvement as per COVID-19 Reporting and Data System,[12] and categorized as mild if score <7, moderated if score 8–15 and severe if score >15 or 15–25. Clinical assessment and routine biochemistry and hematological workup with viral inflammatory markers as C-reactive protein (CRP), Ferritin, lactate dehydrogenase, interleukin 6 (IL-6) titers, and D-Dimer in all cases. Entry point D-Dimer titer was utilized as an assessment tool of severity of illness with clinical parameters. If D-dimer analysis was normal at entry point, then D-Dimer titer was repeated on day of discharge from hospital or done during hospitalization if clinical course deteriorates. If D-dimer analysis was abnormal

at entry point, we repeated it every 72 h as follow-up to assess severity, progression of illness and also titer utilized to assess response to medical treatment. Follow-up HRCT thorax was done after 12 weeks of discharge from hospital for analysis of post-COVID lung fibrosis in selected cases with abnormal D-Dimer titer at discharge and required BIPAP/NIV during hospitalization and cases required oxygen supplementation at home [Figure 1].

Interpretation of results

Normal values: Normal values 70–470 mg/dL

1. Normal: D-Dimer value up to 470 mg/L
2. Positive: Value above 470 mg/dL
3. Significant: Two-fold raised D-Dimer level
4. Highly significant: Four-fold raised D-Dimer titer
5. Follow up significance: Values raised or decreased in two-to-four-fold change.

Statistical analysis

The statistical analysis was done using Chi-square test in R-3.4 software. Significant values of χ^2 were seen from probability table for different degree of freedom required. *P* value was considered significant if it was below 0.05 and highly significant in case if it was <0.001.

RESULTS: COVARIATES

In the present study, 2000 COVID-19 pneumonia cases confirmed by COVID-19 RT-PCR, males were 1300/2000 and females were 700/2000, age >50 were 1200 cases, and age <50 were 800 cases. Significant association in D-Dimer and COVID-19 pneumonia has been documented with variables such as age, gender, diabetes mellitus, ischemic heart disease (IHD), hypertension, chronic obstructive pulmonary disease (COPD), and obesity ($P < 0.00001$) [Table 1].

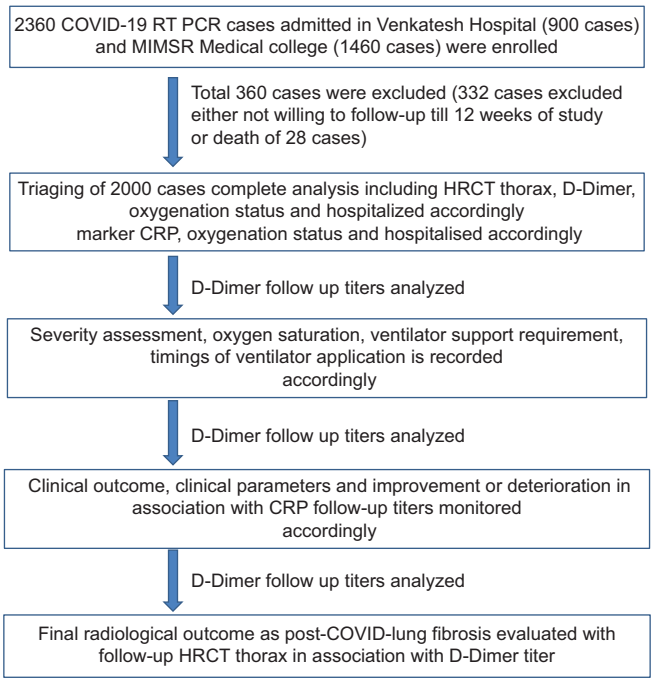

Figure 1: Flow of the study.

Observations and analysis

Computed tomography (CT) severity score at entry point with D-Dimer titer has significant correlation in COVID-19 pneumonia cases ($P < 0.00001$) [Table 2]. D-Dimer titer has significant association with duration of illness (DOI) in COVID-19 pneumonia cases ($P < 0.00001$) [Table 3]. Significant association in D-Dimer and COIVD-19 pneumonia has been documented with variables such as age, gender, diabetes mellitus, IHD, Hypertension, COPD, and obesity ($P < 0.00001$) [Table 4]. D-Dimer titer has significant association with oxygen saturation in COVID1-19 pneumonia cases ($P < 0.00001$) [Table 4]. BIPAP/NIV requirement during course of COVID-19 pneumonia in critical care setting has significant association with D-Dimer level ($P < 0.00001$) [Table 5]. Timing of BIPAP/NIV requirement during course of COVID-19 pneumonia in critical care setting has significant association with D-Dimer level ($P < 0.00001$) [Table 6]. Follow-up D-Dimer titer during hospitalization as compared to entry point abnormal D-Dimer has significant association in post-COVID lung fibrosis ($P < 0.00001$) [Table 7]. Follow-up D-Dimer titer during hospitalization as compared to entry point normal D-Dimer has significant association in post-COVID lung fibrosis ($P < 0.00001$) [Table 8]. Follow-up D-Dimer titer during hospitalization as compared to entry point abnormal D-Dimer has significant association in presence of deep vein thrombosis ($P < 0.00001$) [Table 9]. Follow-up D-Dimer titer during hospitalization as compared to entry point normal D-Dimer has significant association with pulmonary thromboembolism ($P < 0.00001$) [Table 10].

DISCUSSION

In the present study, CT severity score at entry point with D-Dimer titer has significant correlation in COVID-19 pneumonia cases, score <8, 8–15, and >15 documented normal and abnormal D-Dimer ($P < 0.00001$). We observed that CT severity is best visual assessment and indirect marker of inflammation which can be collaborated with D-dimer, and as CT severity score increases, D-Dimer titer also increases, which is a marker of coagulation abnormality. Numerous studies[13-19] have documented similar observation.

In the present study, D-Dimer titer has significant association with DOI in COVID-19 pneumonia cases, DOI <7 days, 8–15 days, and >15 days of onset of symptoms documented

Table 1: Other variables and D-Dimer titer in COVID-19 pneumonia cases (*n*=2000).

COVID-19 RT-PCR positive (*n*=2000)	D-Dimer titer normal (*n*=640)	D-Dimer titer abnormal (*n*=1360)	Analysis
Age>50 years (*n*=1200)	280	920	χ^2=51.77
Age<50 years (*n*=800)	360	440	*P*<0.00001
Male gender (*n*=1300)	380	920	χ^2=6.5
Female gender (*n*=700)	260	440	*P*<0.0100
Diabetes mellitus (*n*=1200)	300	900	χ^2=33.77
Without diabetes (*n*=800)	340	460	*P*<0.00001
Hypertension (*n*=420)	320	100	χ^2=238.55
Without hypertension (*n*=1580)	320	1260	*P*<0.00001
COPD (*n*=300)	200	100	χ^2=97.46
Without COPD (*n*=1700)	440	1260	*P*<0.00001
IHD (*n*=400)	220	180	χ^2=60.77
Without IHD (*n*=1600)	420	1180	*P*<0.00001
Obesity (*n*=320)	40	280	χ^2=33.28
Without obesity (*n*=1680)	600	1080	*P*<0.00001

RT-PCR: Reverse transcription–polymerase chain reaction, COPD: Chronic obstructive pulmonary disease, IHD: Ischemic heart disease

Table 2: Correlation of CT severity (at entry point) and D-Dimer in COVID-19 cases (*n*=2000).

CT severity	Normal D-Dimer (*n*=640)	Abnormal D-Dimer titer (*n*=1360)	Analysis
<8 score (*n*=600)	380	220	χ^2=224.87
9–15 (*n*=600)	180	420	*P*<0.00001
>15 (*n*=800)	80	720	

CT: Computed tomography

Table 3: DOI at entry point during hospitalization and D-Dimer titerin COVID-19 pneumonia cases (*n*=2000).

DOI	Normal D-Dimer (*n*=640)	Abnormal D-Dimer (*n*=1360)	Analysis
<7 days (*n*=680)	60	620	Chi test
8–15 days (*n*=920)	320	600	value 185.65
>15 days (*n*=400)	260	140	*P*<0.00001

DOI: Duration of illness

Table 4: Oxygen saturation at entry point and D-Dimer titer in COVID-19 pneumonia cases (*n*=2000).

Oxygen saturation	Normal D-Dimer titer (*n*=640)	Abnormal D-Dimer titer (*n*=1360)	Analysis
>90% (*n*=420)	220	200	Chi test
75–90% (*n*=980)	300	680	value 60.37
<75% (*n*=600)	120	480	*P*<0.00001

normal and abnormal D-Dimer levels ($P < 0.00001$). As DOI in COVID-19 pneumonia increases, ongoing inflammation

Table 5: Correlation of BIPAP use with D-Dimer titer in COVID-19 pneumonia cases (*n*=2000).

BIPAP/NIV	Normal D-Dimer (*n*=640)	Abnormal D-Dimer titer (*n*=1360)	Analysis
BIPAP/NIV required (*n*=1200)	310	890	Chi test value 26.21
BIPAP/NIV not required (*n*=800)	330	470	*P*<0.00001

Table 6: BIPAP/NIV initiation time at entry point and D-Dimer titer in COVID-19 pneumonia cases (*n*=1200).

BIPAP used (*n*=1200) with duration of illness	Abnormal D-Dimer (*n*=580)	Four-fold raised D-Dimer (*n*=620)	Analysis
Entry point <1 days (*n*=360)	220	140	χ^2=31.30 *P*<0.00001
3–7 days (*n*=620)	300	320	
After 7 days (*n*=220)	60	160	

increases and having abnormal D-Dimer titer due to abnormal coagulation cascade stimulation. Studies by various author[14-20] have documented similar observation. We have also documented that; entry point abnormal D-Dimer with other inflammatory markers such as CRP and IL-6 with DOI more than a week or 7 days is predictor of prolonged hospital stay with requirement of ventilatory requirement in intensive care unit. Similar observation has been documented in various studies.[20-24]

In the present study, BIPAP/NIV requirement during course of COVID-19 pneumonia in critical care setting has significant association with D-Dimer level ($P < 0.00001$).

Table 7: Abnormal D-Dimer titer at entry point (*n*=1360) and follow-up and its correlation with post-COVID lung fibrosis.

Post-COVID COVID pneumonia fibrosis	D-Dimer titer increased/ abnormal at entry point (*n*=800)	D-Dimer titer four-fold increased during follow up (*n*=560)	Analysis
Pulmonary fibrosis present (*n*=420)	80	340	χ^2=198.45 *P*<0.00001
Pulmonary fibrosis absent (*n*=940)	720	220	

Table 8: Normal D-Dimer titer (*n*=640) at entry point and follow-up and its correlation with post-COVID lung fibrosis.

Post-COVID COVID pneumonia fibrosis	D-Dimer titer normal at entry point and remained less than fourfold (*n*=240)	D-Dimer titer four-fold increased during follow up (*n*=400)	Analysis
Pulmonary fibrosis present (*n*=80)	10	70	χ^2=12.19 *P*<0.00048
Pulmonary fibrosis absent (*n*=560)	230	330	

Table 9: Abnormal D-Dimer titer at entry point (*n*=1360) and its correlation with follow-up titer with deep vein thrombosis.

DVT	D-Dimer titer increased/ abnormal at entry point (*n*=800)	D-Dimer titer fourfold increased during follow up (*n*=560)	Analysis
DVT present (*n*=420)	80	340	Chi test value 198.45 *P*<0.00001
DVT absent (*n*=940)	720	220	

DVT: Deep vein thrombosis

Table 10: Normal D-Dimer titer (*n*=640) at entry point and its correlation with follow-up titer with PTE.

PTE	D-Dimer normal at entry point and remained less than fourfold (*n*=240)	D-Dimer titer fourfold increased during follow up (*n*=400)	
PTE present (*n*=80)	10	70	Chi test value 12.19 *P*<0.00048
PTE absent (*n*=560)	230	330	

PTE: Pulmonary thromboembolism

We have documented positive correlation with hypoxia and resulting in need of ventilatory support during hospitalization with abnormal D-Dimer level. Similarly, various authors[14,20-25] have observed that abnormal or high D-dimer is predictor of poor outcome and these patients require aggressive interventions such as BIPAP/NIV, mechanical ventilation, or ECMO in due course and persistent high level denotes higher chances of mortality.

In the present study, D-Dimer titer has significant association with oxygen saturation in COVID-19 pneumonia cases (P < 0.00001). We have documented positive correlation with hypoxia at entry point during hospitalization and abnormal D-Dimer titer which is similar to studies by various authors.[14,25] Low oxygen saturation or hypoxia is independent predictor of poor outcome in COVID-19 pneumonia, as hypoxia is trigger for deranged coagulation secondary to increase in hypoxia-inducible transcription factor which will increase D-Dimer level, numerous studies[20-24] have documented similar observation.

In the present study, timing of BIPAP/NIV requirement during course of COVID-19 pneumonia in critical care setting has significant association with D-Dimer titer (P<0.00001) We have documented positive correlation with hypoxia and resulting in need of ventilatory support during hospitalization with abnormal D-Dimer level. Cases with high D-dimer would have required BIPAP/NIV early as compared with normal to slightly raised D-Dimer level, which is in correlation with studies[14,25] documented similar observation.

In the present study, follow-up D-Dimer titer during hospitalization during hospitalization as compared to entry point abnormal D-Dimer has significant association in post-COVID lung fibrosis (P < 0.00001). Follow-up D-Dimer titer during hospitalization as compared to entry point abnormal D-Dimer has significant association in presence of deep vein thrombosis (P < 0.00001). We have observed that ongoing inflammation is the key for rise of D-Dimer titer irrespective of CT severity score as mild cases were also having significant

rise in D-Dimer titer as compared to advanced CT severity, thus it will help in predicting progression of disease in due course during hospitalization and aggressive steps to be taken during management of these cases. Numerous studies[25-31] have documented similar risk of poor outcome and adverse lung outcome as increased D-Dimer is an indication of severe inflammatory response and resulted in lung fibrosis in follow-up of survivors of COVID-19pneumonia.

In the present study, follow-up D-Dimer titer during hospitalization as compared to entry point normal D-Dimer has significant association in post-COVID lung fibrosis ($P < 0.00001$). In this study, a small fraction of non-severe patients developed into severe cases in the first 2 weeks after symptom onset. Therefore, health care institutions should also pay close attention to the mild patients, identify progressor early, and provide appropriate treatment to reduce mortality. Follow-up D-Dimer titer during hospitalization as compared to entry point normal D-Dimer has significant association with pulmonary thromboembolism ($P < 0.00001$). Authors in various studies[14-17,20-25] have documented similar observation.

In the present study, age of patient, that is., <50 years and >50 years has significant association in COVID-19 cases with normal and abnormal D-Dimer titer ($P < 0.00001$). We have also documented that the gender of included cases has significant association with normal and abnormal D-Dimer titer in COVID-19 cases ($P < 0.010$). Studies by various authors[14-19,25-32] have documented similar observation.

In the present study, comorbidities as Diabetes mellitus, COPD, hypertension, IHD, and obesity have documented significant association in COVID-19 cases with normal and abnormal D-Dimer titer at entry point ($P<0.00001$). Numerous studies[14-19,25-32] have documented similar observation.

CONCLUSION

D-Dimer has documented very crucial role in COVID-19 pneumonia in predicting severity of illness, ventilatory support requirement and course in critical care setting. D-Dimer follow-up titer can help in predicting progression of COVID-19 pneumonia, and assessing risk of post-COVID lung fibrosis. D-Dimer serial titers have documented significant role in step-up or step-down interventions in critical care setting.

D-Dimer titer has significant associations with predicting progression of pneumonia, as proportionate number of pneumonia cases with mild variety on CT thorax and normal initial D-Dimer has progressed to critical course and we have documented follow-up titers has played crucial role with other inflammatory markers.

Correlating D-dimer with variables such as DOI, oxygenation status, and timing of BIPAP/NIV at entry point is important to have satisfactory treatment outcome. D-Dimer follow-up titer has documented role in predicting lung fibrosis and deep vein thrombosis and pulmonary embolism.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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