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Original Article

Microbiology Section

Significance of High D-dimer Levels among the Coagulation Dysfunction Patients- A Descriptive Cross-sectional Study

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ABSTRACT

Introduction: D-dimer is one of the reliable biomarker of both coagulation activation and fibrin digestion. This is used for diagnosis of coagulation dysfunction like Venous Thromboembolism (VTE), Disseminated Intravascular Coagulopathy (DIC), assessing the risk of recurrent thrombosis and for guiding anticoagulant therapy.

Aim: To study distribution of D-dimer and other coagulation parameters in coagulation dysfunction.

Materials and Methods: The present descriptive cross sectional study was conducted in the Microbiology department of Ruxmani ben Deepchand Gardi Medical College, Ujjain, Madhya Pradesh, India from 16 January 2023 to 16 March 2023. A total of 104 blood samples received from clinically diagnosed as coagulation dysfunction were tested for D-Dimer, platelet count, Prothombin Time (PT), Activated Partial Prothombin Time (APTT), Fibrin Degradation Product (FDP) and Haemoglobin (Hb) were included in the study. The patients were categorised into three groups according to the plasma D-dimer level and clinically correlated. The plasma D-dimer cut-offs used for each group was as follows: <500 ng/mL, 500 ng/mL to 5000 ng/mL, > 5000 ng/mL to 10,000 ng/mL and >10,000 ng/mL. All statistical calculations were done using Statistical Package for Social Sciences (SPSS).

Results: Of the 104 received blood samples, the female to male ratio was 1.6:1. Clinically diagnosed DIC was 36 (34.6%) followed by exacerbation of COPD 18 (17.3%), venous thrombosis 8 (8%), pneumonia 6 (5.7%), Deep Vein Thrombosis (DVT) 1 (1%) and pulmonary embolism 3 (2.8%). Ultra high plasma D-dimer level >5000 ng/mL were 20 (19%), D-dimer 500 ng/mL to 5000 ng/mL were 67 (64%), D-dimer >5000 ng/mL to 10000 ng/mL were 17 (16.3%), D-dimer >10000 ng/mL were 3 (2.9%) and less than 500ng/mL were 17 (16.3%) patients.

Conclusion: In this study DIC, exacerbation of COPD, VTE, infections, trauma, malignancies, poisoning and old age were leading causes of elevation of D-dimer. DIC is the commonest coagulation disorder detected. PIH, APH and PPH are the commonest predisposing factors leading to DIC. Hence, higher D-dimer levels along with other parameters can be used to categorise the patients of coagulation dysfunction.

Keywords: Activated partial prothombin time, Chronic obstructive pulmonary disease, D-dimer, Venous thromboembolism

INTRODUCTION

D-Dimer is the initial screening test used to diagnose cases of VTE in the emergency department. It is a marker of endogenous fibrinolysis and is detectable in patients with thromboembolic phenomenon [1]. D-Dimer is a generic term referring to multiple peptide fragments derived from plasmin-mediated degradation of cross-linked fibrin. Their presence reflects concomitant activation of both coagulation and fibrinolysis [2]. D-dimer is one of the reliable biomarker of both coagulation activation and fibrin digestion [3], D-dimer is used for ruling out VTE, assessing the risk of recurrent thrombosis and for guiding anticoagulant therapy, for diagnosing and monitoring DIC, for excluding 2 Acute Aortic Dissection (AAD), and for predicting and managing thrombotic complications in patients with severe infections and sepsis, prognostic indicator of peripheral artery disease, identification of vaso-occlusive crisis in sickle cell disease, screening of intracardiac thrombus [4].

Many clinical conditions are accountable for elevation of D-dimer level for instance DIC, Chronic Obstructive Pulmonary Disease (COPD), pancreatitis, advance age, heart failure, Acute Respiratory Distress Syndrome (ARDS), Post-transplantation complications, Alzheimer, Hemolysis, Elevated Liver enzymes, and Low Platelet count (HELLP) syndrome, pregnancy or puerperium, aneurysm, haemolysis (falciform anaemia), recent surgery, aortic dissection, haemorrhage, renal disease, arthritis, hospitalisation, severe chronic urticaria, atrial fibrillation, inflammatory bowel disease, thrombolytic therapy, burns, ischemic cardiopathy, trauma, cancer, liver disease, venous or arterial thrombosis, chronic inflammation, localised or systemic infection, disability, neonatal period [5-7].

Common Obstetrical Complications causing DIC are Pregnancy Induced Hypertension (PIH), Postpartum Haemorrhage (PPH), Antepartum Hemorrhage (APH), abruptio placentae and Intra uterine death [8]. D-dimer testing became routine practice during Covid 19 pandemic, used to assess diagnosis and prognosis of the condition.

The aim of present study was to assess significance of high D-dimer level besides other coagulation parameters such as platelets, PT, APTT, Fibrinogen Degradation Product (FDP) and haemoglobin in addition to their relation with various coagulation dysfunction presenting to our hospital in a potential manner.

MATERIALS AND METHODS

The present study is a descriptive cross-sectional study and data is secondary data collected from case file conducted in the Microbiology department of a tertiary care hospital during January 2023 to March 2023. Data is secondary data collected from case files. This was a time bound study and all subjects available during the study period were taken into consideration. Ethical clearance certificate not taken as data was collected from patients case file.

Inclusion criteria: All patients blood samples received in the Microbiology laboratory for the testing of D-dimer.

Exclusion criteria: Blood samples of patients did not receive in the Microbiology laboratory for the testing of D-dimer and patient without the diagnosis of coagulation dysfunction were excluded from the study.

Study Procedure

A total of 104 blood samples received during the study period from clinically diagnosed as coagulation dysfunction patients were included in the study. Sample was received in an appropriately filled Vacutainer with citrate as anticoagulant in the Microbiologist Laboratory was processed immediately by Immunoturbidimetric method by Model Turbodyne SC, model number 18650. Clinically diagnosed coagulation dysfunction further confirmed by laboratory coagulation parameters. These were D-dimer, platelet count, PT, APTT, FDP and haemoglobin. The patients were categorised into three groups according to the plasma D-dimer level and clinical history of the patients was recorded. The plasma D-dimer cut-offs used for each group were as follows: <500 ng/mL, 500 ng to 5000 ng, >5000 ng/mL to 10,000 ng/mL and >10,000 ng/mL [9]. Ultra-high D dimer levels were defined as plasma D-dimer levels >5000 ng/mL previously described in the literature [9]. Patients were treated with anticoagulant drugs and follow-up was done for prognosis of coagulation disorders. For assessment of the prognosis of the patient on treatment of anticoagulant drugs plasma D-dimer test were not advised by clinicians due to high cost of the test but other laboratory test were advised beside clinical evaluation and improvement in condition of patients was observed clinically.

STATISTICAL ANALYSIS

All statistical calculations were done using computer software SPSS (Statistical package for the social science; SPSS Inc., Chicago, IL, USA) version 21 for Microsoft Windows. Data were statistically described in terms of mean, standard deviation, or frequencies (number of cases) and percentages when appropriate.

RESULTS

The 104 blood samples, 64 (62%) were from women and 40 (38%) were from men. Female: male ratio is 1.6:1. Maximum samples were received from 21 years to 30 years age 33 (31.73%). The mean age of the patients was 42.09±18.33 (15-80) years. Demographic distribution of study patients describe in [Table/Fig-1].

Age (years)	Male (%)	Female (%)	Total (%)
0-10 y	0 (0%)	0 (0%)	0 (0)
>10-20 y	1 (0.96%)	9 (8.65%)	10 (9.61)
>20-30 y	6 (5.76%)	27 (25.96%)	33 (31.73)
>30-40 y	3 (2.88%)	10 (9.61%)	13 (12.5)
>40-50 y	6 (5.76%)	4 (3.84%)	10 (9.61)
>50-60 y	13 (12.5%)	6 (5.76%)	19 (18.26)
>60 y	11 (10.57%)	8 (7.69%)	19 (18.26)
Total	40 (38.46%)	64 (61.53%)	104 (100)

[Table/Fig-1]: Demographic distribution of study population n (%) (N=104).

In the present study, maximum samples were received from Obstetrics and Gynaecology Department 37 (35.57%) followed by Pulmonary Medicine 33 (31.73%) and Medicine 22 (21.15%) showed in [Table/Fig-2].

Department	Total n (%)
Obstetrics and Gynaecology	37 (35.57)
Pulmonary medicine	33 (31.73)
Medicine	22 (21.15)
Surgery	7 (6.73)
Orthopaedic	4 (3.84)
Dermatology	1 (0.96)
Total	104 (100)

[Table/Fig-2]: Department wise distribution of study patients % (n=104).

[Table/Fig-3] explained predisposing factors associated with coagulation dysfunction were COPD 20 (19.23%), followed by PIH 15 (14.42%), lung diseases 10 (9.6%) and Intrauterine Death (IUD) 9 (8.65%), diabetes mellitus and hypertension 5 (4.8%), tuberculosis and old age 4 (3.8%) [5-8].

Predisposing Factor	Total (%)
Intrauterine Death (IUD)	9 (8.65)
Pregnancy Induced Hypertension (PIH)	15 (14.42)
Abortion	3 (2.88)
Antipartum Haemorrhage (APH)	6 (5.76)
Postpartum Haemorrhage (PPH)	1 (0.96)
Chronic Obstructive Pulmonary Disease (COPD)	20 (19.23)
Lung disease	10 (9.61)
Chronic kidney disease	3 (2.88)
Coronary artery disease	5 (2.88)
Intestinal perforation	3 (2.88)
Facture	4 (3.84)
Diabetes mellitus	5 (4.80)
Hypertension	5 (4.80)
Tuberculosis	4 (3.84)
Old Age	4 (3.84)
Poisoning disease	1 (0.96)
Liver disease	1 (0.96)
Heart failure	3 (2.88)
Cerebrovascular accident	1 (0.96)
Renal failure	3 (2.88)
Others	6 (5.76)

[Table/Fig-3]: Predisposing factors of coagulation dysfunction % (n=112).

DIC 36 (34.6%) was the most common diagnosis present across all study patients, followed by exacerbation of COPD 18 (17.3%), venous thrombosis 8 (8%), pneumonia 6 (5.7%), infection and trauma 4 (3.8%), DVT 1 (1%) and pulmonary embolism 3 (2.8%) [Table/Fig-4].

Diagnosis	Total (%)
Disseminated Intravascular Coagulopathy (DIC)	36 (34.6)
Exacerbation of COPD	18 (17.3)
Venous thrombosis other than DVT	8 (8)
Deep Vein Thrombosis (DVT)	1 (1)
Pulmonary Embolism (PE)	3 (2.8)
Pneumonia	6 (5.7)
Infection	4 (3.8)
Trauma	4 (3.8)
Sepsis	1 (0.9)
Malignancy	1 (0.9)
Surgery	1 (0.9)
Other	21 (20.1)
Total	104 (100)

[Table/Fig-4]: Diagnosis of study patients with elevated D-Dimer level stratified by group% (n=104).

In this study, PIH 15 (14.42%), IUD 9 (8.65%), APH 6 (5.76%), PPH 1 (0.9%) and abortion 3 (2.88%) were common leading causes of DIC identified. Patients with DIC 36 (34.6%) had plasma D-dimer level of 500 ng/mL to 5000 ng/mL were 26 (72%), >5000 ng/mL to 10000 ng/mL were 3 (8.3%), >10000 ng/mL 2 (5.5%) and less than 500 ng/mL were 5 (14%) and platelet count less than 1.5 lac/µL were 9 (25%), FDP positive in 4 (11%) and haemoglobin level less than 11 gm/dL in 14 (39%) female patients detected. Acute exacerbation of COPD in 18 (17.3%) patients had plasma D-dimer level of 500 ng/mL to 5000 ng/mL were 11 (61%), >5000 ng/mL to 10000 ng/mL were 6 (33%) and less than 500 ng/mL were 1 (5.5%)

and platelet count less than 1.5 lakh/µL were 4 (22%), FDP positive in 2 (11%) and haemoglobin level less than 11gm/dL in 3 (17%) female and in male less than 14 gm/dL in 6 (33%) detected. Venous thrombosis cases were 9 (8.6%) had plasma D-dimer level ranges from 500 ng/mL to 5000 ng/mL in 3 (33%), >5000 ng/mL to 10000 ng/mL in 2 (22%), more than 10000 ng/mL in 1 (11%) and <500 ng/mL 3 (33%) other markers such as platelet count less than 1.5 lac/µL in 1 (11%) and haemoglobin level less than 11 gm/dL in 1 (11%) female and in male less than 14 gm/dL 3 (33%) were detected. In all patients prolongation of PT and APTT were seen described in [Table/Fig-5].

Clinical conditions	Total N (%)	D-Dimer level ng/mL				PT (INR1.1) (n=104)%	APTT (n=104)%	Platelet count <1.5 lakh/uL (n=20)%	FDP positive (n=8)%	Hb <11 gm/dL in female (n=35)%	Hb <14 gm/dL in male (n=21)%
		<500 (n=17)%	500-5000 (n=67)%	>5000-10000 (n=17)%	>10000 (n=3)%						
DIC	36 (34.6)	5 (14)	26 (72)	3 (8.3)	2 (5.5)	36 (100)	36 (100)	9 (25)	4 (11)	14 (39)	0
Acute exacerbation of COPD	18 (17.3)	1 (5.5)	11 (61)	6 (33)	00	18 (100)	18 (100)	4 (22)	2 (11)	3 (17)	6 (33)
Venous thrombosis	9 (8.6)	3 (33)	3 (33)	2 (22)	1 (11)	9 (100)	9 (100)	1 (11)	0	1 (11)	3 (33)
PE	3 (2.8)	2 (67)	1 (33)	0	0	3 (100)	3 (100)	0	0	1 (33)	0
Pneumonia	6 (5.7)	1 (17)	5 (83)	0	0	6 (100)	6 (100)	0	0	3 (50)	0
Trauma	4 (3.8)	0	4 (100)	0	0	4 (100)	4 (100)	0	1 (25)	1 (25)	2 (50)
Infection*	4 (3.8)	0	2 (50)	2 (50)	0	4 (100)	4 (100)	1 (25)	1 (25)	3 (75)	1 (25)
Sepsis	1 (0.9)	0	1 (100)	0	0	1 (100)	1 (100)	1 (100)	0	0	1 (100)
Malignancy	1 (0.9)	0	1 (100)	0	0	1 (100)	1 (100)	0		1 (100)	0
Surgery	1 (0.9)	1 (100)	0	0	0	1 (100)	1 (100)	0		0	1 (100)
Other	21 (20.1)	4 (19)	13 (62)	4 (19)	0	21 (100)	21 (100)	4 (19)	0	8 (38)	7 (33)

[Table/Fig-5]: Distribution of coagulation parameters according to clinical conditions.
Infection*: All infections other than sepsis and viral infections including urinary tract infection and so forth; PT: Prothombin time; APTT: Activated partial thromboplastin time; FDP: Fibrin degradation product

All the Patients had elevated plasma D-dimer along with other coagulation profile treated with anticoagulant drugs such as Low Molecular Weight Heparin (LMWH) and Aspirin etc. Prognosis of the patients assessed clinically beside blood coagulation parameters except plasma D-dimer. All patients were shown clinical improvement with normalisation of laboratory tests except one mortality seen during the study period; A female patient 60-year-old was admitted in the Intensive Care Unit (ICU) had congestive heart failure with type 2 diabetes mellitus and her laboratory profile were plasma D-dimer 6945.54 ng/mL, platelet count 60000/µl, FDP positive and prolonged PT and APTT.

DISCUSSION

This study included 104 patients clinically diagnosed with coagulation dysfunction were tested with laboratory parameters like D-dimer, platelet count, PT, APTT, FDP and haemoglobin were analysed. Of 104 patients 64 (62%) were female and 40 (38%) were male (F: M=1.6:1). Of 104 blood samples, ultra high D-dimer >5000 ng/mL was 20 (19%) and the ranges of plasma D-dimer level 500 ng/mL to 5000 ng/mL in 67 (64%) patients, plasma D-dimer >5000 ng/mL to 10000 ng/mL were 17 (16.3%), >10000 ng/mL in 3 (2.9%) and less than 500 ng/mL in 17 (16.3%) patients found. The commonest disease diagnosed was DIC 36 (34.6%), However, exacerbation of COPD 18 (17.3%), venous thrombosis other than DVT 8 (8%), pneumonia 6 (5.7%), infection and trauma 4 (3.8%) were also found in patients. This finding were disparate with previous study reported VTE (71.5%), infectious processes (64.2%) and cancer (35.3%) [9].

In present study, PIH 15 (14.42%), IUD 9 (8.65%), APH 6 (5.76%), PPH 1 (0.9%) and abortion 3 (2.88%) were disclosed as leading causes of DIC. Present Findings were correlated with previous studies [8-10]. Patients with DIC had plasma D-dimer level of 500 to 5000 ng/mL were 26 (72%), >5000 to 10000 ng/mL were 3 (8.3%), >10000 2 (5.5%) and less than 500 ng/mL were 5 (14%) and platelet count less than 1.5 lac/µL were 9 (25%), FDP positive in 4 (11%) and haemoglobin level less than 11 gm/dL in 14 (39%) female patients detected. Studies by Sarojini PS and Rathod AT and Nair M et al., also reported association of elevation of D-dimer along with PT, APTT and thrombocytopenia with PIH, APH and PPH that leads to DIC during pregnancy be consistent with present study [11,12].

Acute exacerbation of COPD diagnosed in 18 (17.3%) having plasma D-dimer level of 500 ng/mL to 5000 ng/mL were 11(61%), >5000 ng/mL to 10000 ng/mL were 6 (33%) and less than 500 ng/mL were 1 (5.5%) and platelet count less than 1.5 lac/µl were 4 (22%), FDP positive in 2 (11%) and haemoglobin level less than 11 gm/dL in 3 (17%) female and male less than 14 gm/dL in 6 (33%), PT and APTT were prolonged in all patients. Higher plasma D-dimer than normal in acute exacerbation of COPD is consistent with previous studies [5,13]. Study conducted by Liu M et al., also reported elevation of other coagulation parameters correlated with present findings [14].

Venous thrombosis diagnosed in 9 (8.6%) patients with plasma D-dimer level of 500 ng/mL to 5000 ng/mL were 3 (33%), >5000ng/mL to 10000 ng/mL were 2 (22%) and more than 10000 ng/mL were 1 (11%) and platelet count less than 1.5 lac/µL were 1 (11%), haemoglobin level less than 11 gm/dL in 1 (11%) female and male less than 14 gm/dL in 3 (33%) patients along with prolongation of PT and APTT in 9 (100%). Increased level of plasma D-dimer in VE cases reported in the past [9]. A study from Kashmir reported venous thrombosis association with plasma D-dimer, PT, APTT and platelet count is concordant with present study [15].

Clinical conditions like pneumonia, trauma, infection, sepsis, malignancy and surgery leads to elevation of plasma D-dimer, prolonged PT and APTT, thrombocytopenia and anaemia observed in this study also reported by many studies [9,16,17].

In the present study, 21(20.1%) clinical conditions were grouped in other category included renal diseases 6(28.6%), Acute Coronary Syndrome (ACS) 3(14.3%), cerebrovascular accident 1(4.8%), old age 4(19%), perforation peritonitis 3(14.3%), poisoning 1(4.8%), diabetic ketoacidosis 1(4.8%), avascular necrosis of hip 1(4.8%), chronic pancreatitis 1 (4.8%). In these conditions all the coagulation parameters were raised above the normal level beside plasma D-dimer and these findings were concordance with previous studies [2,7,9,6,18].

Limitation(s)

Present study was single centre based; analysis of result represents a restricted area's data. Multicentre based study is essential for exact data of predisposing factors relation with clinical conditions that leads to coagulation dysfunctions and their association with plasma D-dimer along with various other coagulation parameters.

The study duration was also short; further study for prolong period will be needed to assess seasonal association of various conditions.

CONCLUSION(S)

The present study found predisposing factors and D-dimer along with other laboratory parameters which were very useful in early diagnosis of coagulation disorders. It's useful to diagnose various conditions such as pregnancy related complications; PIH, APH, PPH etc., that leads to development of DIC having high mortality. High plasma D-dimer level found in DIC, exacerbation of COPD, venous thrombosis, Infections, trauma, malignancies, poisoning and old age etc. Timely recognition of predisposing factors and identification of their relation with coagulation disorders accompanied by measurement of coagulation profile with D-dimer will help in prompt diagnosis of the conditions and management of the conditions with available anticoagulant treatment to reduce morbidity and increase patient's life expectancy.

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