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Correlation between plasma D-Dimer levels and the severity of patients with chronic urticaria

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Abstract
Background: Chronic urticaria (CU) is a common skin disorder characterized by the recurrent appearance of wheals and/or angioedema lasting more than six weeks. It significantly impacts patients' quality of life due to its chronic and unpredictable nature. Several studies have investigated the association between plasma D-dimer levels and the severity of CU, aiming to elucidate potential biomarkers for disease activity and prognosis. Understanding this correlation could have significant clinical implications, including improved risk stratification, treatment selection, and monitoring of therapeutic response in CU patients.
Objective: To evaluate the relationship between plasma D-Dimer level and the severity of chronic urticaria patients.
Methods: A total of 40 cases with chronic urticaria and 40 healthy controls were included after getting informed written consent. Socio-demographic profile, clinical features, duration, severity of disease and plasma D-dimer were collected in separated case-record form and analyzed by SPSS 26.0
Results: Mean age of Group I was 33.90±11.21 years with male predominance (52.5%). Both groups were statistically similar in terms of age and sex distribution($p>0.05$). In Group I, the majority experienced severe symptoms (50.0%), while 32.5% had moderate and 17.5% had mild CU. Significant differences were observed in plasma D-Dimer levels between Group I and Group II, with mean levels of 0.97±1.24 µg/ml and 0.31±0.15 µg/ml, respectively ($p<0.001$). There is a significant positive correlation between the UAS-7 score and Plasma D-Dimer level (r=+0.472, p= 0.002)
Conclusion: In conclusion, the study revealed significant differences in plasma D- Dimer levels between CU patients and controls, with higher levels observed in CU patients. Within CU patients, plasma D-Dimer levels varied significantly among different disease severity categories, increasing with severity.

Keywords: Chronic urticaria, plasma D-Dimer

Introduction
Urticaria is a condition characterized by the development of short-lived itchy wheals, angio-oedema or both [1]. It can be classified as acute or chronic. Acute urticaria is defined as recurrent urticaria that lasts less than six weeks and recurrent episodes of urticaria lasting more than six weeks are Chronic Urticaria [2]. Chronic Urticaria (CU)is divided into two categories: inducible chronic urticaria (ICU) and chronic spontaneous urticaria (CSU). The etiology of chronic urticaria has been attributed to an immense number of factors including foods, drugs, aero-allergens, infections, contact allergens, and autoantibodies to the high affinity immunoglobulin E (IgE) receptor or free IgE. It is supposed that several etiological factors of chronic urticaria act synergistically or sequentially, as either independent or interlinked mechanism, to produce the final clinical expression of chronic urticaria [3]. It is commonly recognized that mast cells (MCs) and basophils in the skin become activated by various stimuli, releasing a number of biologically active substances, the most important one being histamine, which causes vasodilation, enhances the permeability of blood vessel, and activates sensory nerve endings, resulting in the development of erythema, wheals, and itch. Other biologically active ingredients, such as serotonin, C3a and C5a anaphylatoxins, platelet-activating factor (PAF), neuropeptides, and arachidonic acid metabolites

(prostaglandin D2, leukotrienes C4, D4, and E4), are thought to have similar effects. However, the exact process and cause in many patients with CU are yet unknown, but it can be caused by immunological (formation of immune complexes, complement activation, IgE cross- linking), nonimmunological (pseudoallergy, infection, or direct effect of agents on MCs), or mixed mechanisms [4]. A number of significant aspects of the disease pathogenesis have received attention recently, including the hypothesis that 30-50% of patients with CU have symptoms linked to autoimmune reactions, the generation of autoantibodies against IgE and/or the high-affinity IgE receptor (Fc€RI) α-subunit on MCs and basophils, and an increased frequency of HLA DRB1*04 (DR4), which is seen in other autoimmune diseases. It is thought that coagulation and inflammation interact closely in CU sufferers. When autoantibodies to the low-affinity IgE receptor (FcεRII) or cytokines (such as GM- CSF and PAF) activate eosinophils, they express tissue factor, which in turn activates the coagulation cascade. Thrombin is produced as a result, which produces vasodilation, raises vascular permeability, and triggers direct MC degranulation. Furthermore, the production of several inflammatory mediators by eosinophils cantrigger MC degranulation, one of which being the major basic protein (MBP) [4]. It is possible to find high levels of D-dimer (DD), a fibrin degradation product formed during the lysis of a thrombus, during increased fibrinolytic activity [5]. D-Dimer (DD) is a specific product of the degradation of fibrin clots that results from the actions of three enzymes: thrombin produced when the coagulation cascade is activated, that converts fibrinogen into fibrin clots, activated factor XIII that cross-links fibrin clots by means of covalent bonds between fibrin monomers, and plasmin, the ultimate enzyme of fibrinolysis that degrades cross-linked fibrin. DD elevations are detected in plasma during the onset of thrombus formation and its elevation usually lasts about a week. For this reason, it is possible to find high levels of DD during increased fibrinolytic activity. It occurs in high concentrations in many clinical conditions, such as deep vein thrombosis and pulmonary embolism. Level of DD was found to be elevated in a patient with exacerbation of chronic urticaria compared with patients in remission. So, the measurement of DD can be used for assessing the severity of the disease [6].

Material and Methods

This was a Cross sectional comparative study. A total of 40 cases with chronic urticaria and 40 healthy controls were included after getting informed written consent. The study was carried out in the Department of Dermatology and Venereology, Bangladesh Medical University (BMU), Dhaka, Bangladesh. The study was carried out from April, 2023 to March, 2024. Study population were clinically diagnosed Patients with chronic urticaria attending at out-patient.

Selection Criteria

Inclusion Criteria

- All Patients who were diagnosed as chronic urticarial clinically by dermatologist
- Age ≥ 18 years
- Both gender
- Willing to take part in the study
- Participant who given informed written consent

Exclusion Criteria

- Pregnancy or lactation
- Immunocompromised individual
- Patients with comorbid systemic disease
- Patients with acute urticaria, urticarial vasculitis
- Systemic steroid therapy within last 6 weeks

Data processing and analysis

Data were collected on proposed data sheets and also recorded in digital formats for security and convenience for analysis. Continuous variables were expressed as mean and standard deviation (SD), whereas categorical variables were condensed using numbers and percentages. The Unpaired student's t-test/Mann-Whitney test (if data were skewed) was used to compare continuous variables. Differences in the distribution of categorical variables were assessed by chi-square analysis. For the correlation study, Pearson and Spearman analyses were employed. Statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS) software version 26.0 for Windows (SPSS Inc, Chicago, Illinois, USA). A value of $P < 0.05$ was considered statistically significant. Different tables, graphs, diagrams, etc. were used to present the results of this study.

Utility of the study

The study helped to identify a cost-effective biomarker, plasma D-Dimer level, that was easy to access for predicting the severity of chronic urticaria. This contributed to predicting, screening, and following up a subset of patients at risk of developing severe chronic urticaria and provided valuable insights into the use of plasma D- Dimer level for future clinical research into chronic urticaria.

Ethical Consideration

Regarding ethical considerations, the medical ethics committee of BMU gave the study approval. The eligibility of each individual was assessed, and they were informed about the procedure and the study objectives, with assurance that there was no chance of any harm to the individuals by inclusion in the study. Individuals were also informed that they were free to refuse to participate or to withdraw at any time. Each individual who willingly took part in the study provided consent, and individual confidentiality was strictly maintained. The study did not result in any harm to the individuals and did not affect the standard of their treatment. No drug or placebo was used for this study.

Results

Total forty-nine patients with chronic urticaria and forty-one control were found during study. Ten participants (nine case and one control) were excluded due to - recent drug intake history that could altered the coagulation pathway, significant co-morbidities, liver disease, pregnancy. A total forty patients of chronic urticaria and forty control were included in this study and evaluated.

Table 1: Demographic characteristics of the study subject (n=50)

Age group (years)	Group I (Case n=40)	Group II (Control n=40)	p-value
18- 20	5(12.5%)	2(5.0%)	0.689
21-30	10(25.0%)	16(40.0%)	
31-40	17(42.5%)	11(27.5%)	
41-50	4(10.0%)	8(20.0%)	
51-60	4(10.0%)	2(5.0%)	
61-70	0(0.0%)	1(2.5%)	
Total	40(100.0%)	40(100.0%)	
Mean±SD Range (min-max)	33.90±+11.21 (18-60)	34.90±11.08 (18-63)	
Sex			
Male	21 (52.5%)	23 (47.5%)	0.653
Female	19 (47.5%)	17 (42.5%)	
Occupation			
Service	10(25.0%)	10(25.0%)	0.854
Business	8(20.0%)	7(17.5%)	
Student	3(7.5%)	5(12.5%)	
Housewife	13(32.5%)	1(32.5%)	
Other	6(15.0%)	5(12.5%)	
Total	40(100.0%)	40(100.0%)	
Educational Status			
Illiterate	2(5.0%)	0(0.0%)	0.312
Primary	10 (25.0%)	7 (17.5%)	
SSC	11(27.5%)	10 (25.0%)	
HSC	8 (20.0%)	15 (37.5%)	
Graduate	9 (22.5%)	8 (20.0%)	
Total	40(100.0%)	40(100.0%)	
Socioeconomic status			
Lower income	1(2.5%)	1(2.5%)	0.841
Middle income	37(92.5%)	38(95.0%)	
Upper income	2(5.0%)	1(2.5%)	
Total	40(100.0%)	40(100.0%)	

Table-1 shows the distribution of study subjects by age in two groups, The data revealed a comparable age distribution between the two groups, with Group I having a mean age of 33.90±11.2 years and Group II with a mean age of 34.90±11.08 years, showing no significant difference (p=0.689). Among the age groups, the highest proportion in both groups fell within the 31-40 years, with Group I at 42.5% and Group II at 27.5%. Notably, Group II exhibited a slightly higher percentage of individuals aged 21-30 years (40.0%) compared to Group I (25.0%). The data revealed a comparable distribution of males and females between the two groups, with Group I having 52.5% males and 47.5% females, while Group II had 57.5% males and 42.5% females. Statistical analysis indicated no significant difference in sex distribution between the groups (p=0.653). The most common occupational status was Housewife (32.5%), followed by service (25.0%), business (20.0%), other (15.0%) and Student (7.5%). Among the controls, the most common occupational status was Housewife (32.5%), followed by service (25.0%), business (17.5%), Student (12.5%) and other (12.5%). The results indicate that there was no significant difference in the distribution of occupational status between the cases and controls (p=0.854). The most common level of education was SSC (27.5%), followed by primary (25.0%), graduate (22.5%), HSC (20.0%), and illiterate (5.0%). Among the controls, the most common level of education was HSC (37.5%), followed by SSC (25.0%), graduate (20.0%), primary (17.5%) and illiterate (0.0%). The results indicate that there was no significant difference in the distribution of education level between the cases and controls (p=0.312). Majority belonged to the middle-income group (92.5%), And two cases belonged to the upper income group (5.0%). while only one case (2.5%) belonged to the lower income group. Among the controls, the majority also belonged to the middle-income group (95.0%), followed by the lower income group (2.5%) and the upper income group (2.5%). The results indicate that there was no significant difference in the distribution of socioeconomic status between the cases and controls (p=0.841)

Table 2: Distribution of the study subject by clinical feature, duration of disease and disease severity in group I (n=40)

Variable	Frequency	Percentage
Clinical features		
Wheal, pruritus without angioedema	33	82.5
Wheal, pruritus with angioedema	7	17.5
Duration of disease		
<1 year	13	32.5
1-5 years	23	57.5
>5 years	4	10.0
Mean±SD Median Range (min-max)	25.60±25.98 months 18.0 months (2-96) months	
Disease severity (Based on UAS-7 score)		
Mild (0-14)	7	17.5
Moderate (15-29)	13	32.5
Severe (30-42)	20	50.0

Table-2 shows the distribution of clinical features in Group I(Case) revealed that the majority experienced wheal and pruritus without angioedema (82.5%), while a smaller proportion reported wheal and pruritus with angioedema

(17.5%). Regarding the duration of the disease, most subjects had been affected for 1 to 5 years (57.5%), followed by those with less than a year of disease duration (32.5%), and a minority had experienced symptoms for over 5 years (10.0%). The mean duration of disease was 25.60±25.98 months, ranging from 2 to 96 months. In terms of disease severity, the majority of subjects experienced severe symptoms (50.0%), followed by moderate (32.5%) and mild (17.5%) symptoms.

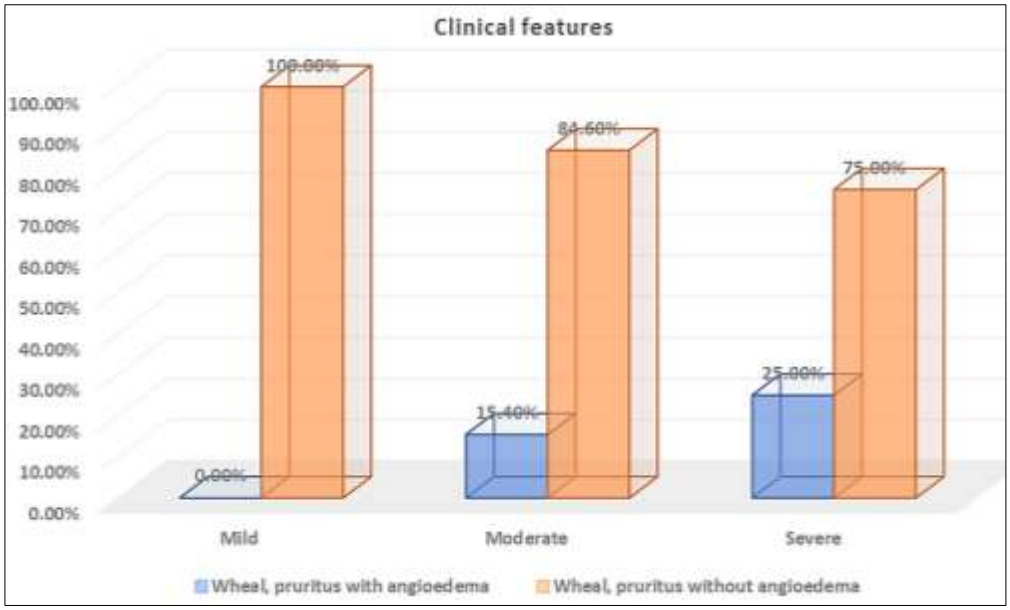

Fig 1: Comparison of Clinical features with disease severity in Group-I (n=40)

Figure 1 shows a comparison of Clinical features with disease severity in Group-I. The presence of angioedema was observed in varying proportions across the severity levels: none of the cases with mild severity experienced angioedema, while 15.4% of moderate cases and 25% of severe cases did. This difference was not statistically significant, suggesting that the presence of angioedema does not significantly correlate with the severity of the disease in this group.

Table 3: Comparison of duration of disease among disease severity in Group-I (n=40)

Duration of disease (months)	Mild (n=7)	Moderate (n=13)	Severe (n=20)	p-value
Mean±SD	33.43±15.44	19.54±20.77	26.80±31.43	
Median	24.0	12.0	12.0	0.194
Range (min-max)	18 - 60	2 - 72	2.0 - 96	

Table- 3 compares the duration of disease among different disease severities within Group I(case). Among patients with mild disease severity, the mean duration of disease was 33.43 months (±15.44), with a range from 18 to 60 months. For patients with moderate disease severity, the mean duration was 19.54 months (±20.77), ranging from 2 to 72 months. In the severe disease category, the mean duration was 26.80 months (±31.43), ranging from 2 to 96 months. The analysis indicates no statistically significant difference in the duration of disease among the disease severity categories (p = 0.194).

Table 4: Distribution of plasma D-dimer level in the study population between two groups (n=80)

Plasma D-dimer level (µg/ml)	Group I (n=40)	Group II (n=40)	p-value
Normal (0.0-0.50 µg/ml)	22(55.0%)	38(95.0%)	<0.001[a]
High (>0.50 µg/ml)	18(45.0%)	2(5.0%)	
Total	40(100.0%)	40(100.0%)	
Mean±SD	0.97±1.24	0.31±0.15	<0.001[b]
Median	0.42	0.27	
Range (min-max)	0.13-4.79	0.10-0.97	

Table 4 shows the distribution of plasma D-dimer levels in the study population. The analysis reveals significant differences in D-dimer levels between the groups. In Group I had more patients with D-dimer levels above 0.50 µg/ml compared to Group II. Specifically, 45.0% of Group I patients had D-dimer levels above 0.50 µg/ml, while only 5.0% of Group II patients fell within this range. The analysis also indicates a statistically significant difference in mean D-dimer levels between Group I and Group II. Also, in Group I, the mean D-dimer level was 0.97 µg/ml (±1.24), while in Group II, it was notably lower at 0.31 µg/ml (±0.15) (p<0.001). Additionally, the median D-dimer level in Group I was 0.42 µg/ml, whereas in Group II, it was 0.27 µg/ml. The range of D-dimer levels varied from 0.13 to 4.79 µg/ml in Group I and from 0.10 to 0.97 µg/ml in Group II.

Table 5: Correlation of plasma D-Dimer among disease severity in Group-I (n=40)

Plasma D-dimer level (µg/ml)	Mild (n=7)	Moderate (n=13)	Severe (n=20)	p-value
Mean±SD	0.25±0.05	0.55±0.39	1.48±1.57	0.003
Median	0.24	0.45	0.86	
Range (min-max)	0.19-0.32	0.13-1.64	0.22-4.79	

Table-5 compares plasma D-dimer levels among different disease severities within Group I(case). Among patients with mild disease severity, the mean plasma D-dimer level was 0.25 µg/ml (±0.05), with a range of 0.19 to 0.32 µg/ml. For moderate disease severity, the mean plasma D-dimer level was 0.55 µg/ml (±0.39), ranging from 0.13 to 1.64 µg/ml. In the severe disease category, the mean plasma D-dimer level was notably higher at 1.48 µg/ml (±1.57), with a range of 0.22 to 4.79 µg/ml. The analysis reveals a statistically significant difference in plasma D-dimer levels among the disease severity categories (p = 0.003). Additionally, the median plasma D-dimer levels increased with disease severity.

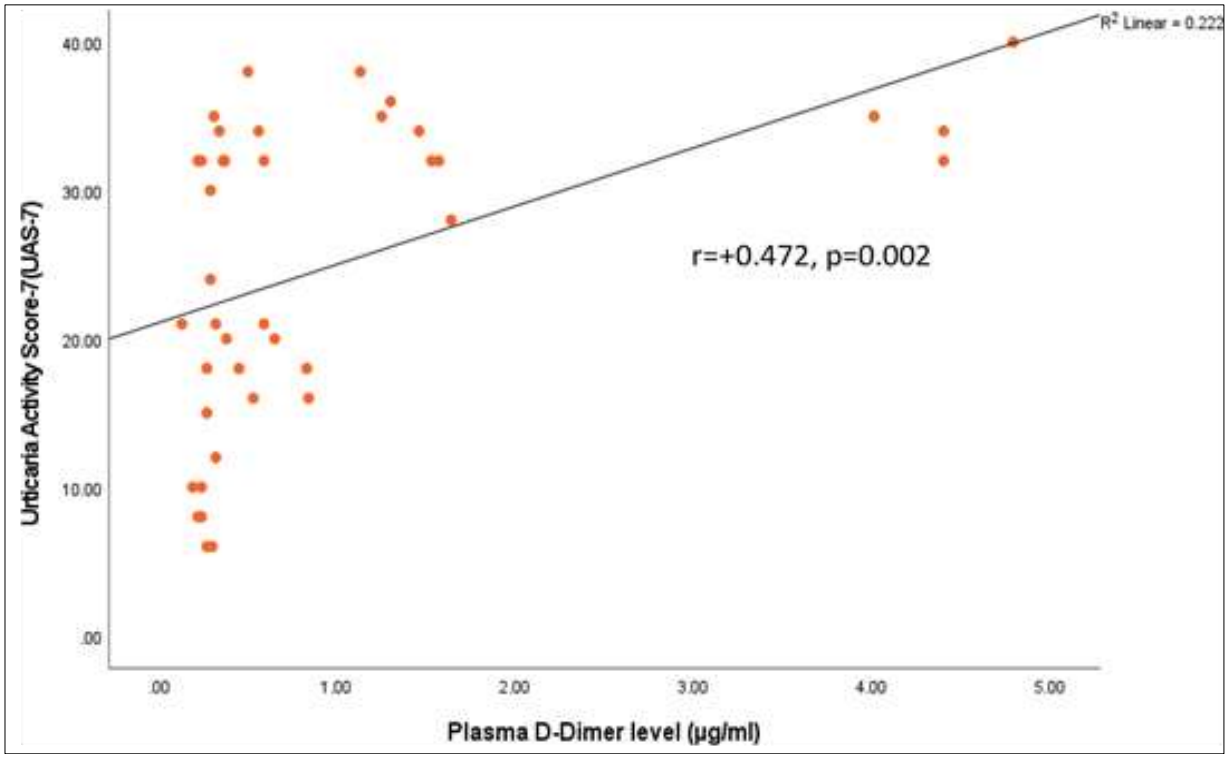

Fig 2: Correlation of urticaria activity score-7(UAS-7 score) with plasma D-Dimer level

Scatter diagram shows, there is a significant positive correlation (r=+0.472) between the urticaria activity score-7(UAS-7 score) and Plasma D-Dimer level. The p-value of 0.002 indicates that this correlation is statistically significant.

Discussion

This research is significant as it addresses gaps in the current understanding of CU pathophysiology and provides valuable insights into the utility of plasma D-Dimer as a biomarker for CU severity, particularly within the context of the Bangladeshi population. A total of 40 cases with chronic urticaria and 40 healthy controls were included after getting informed written consent. By investigating plasma D-Dimer levels in CU patients and healthy controls, the study aimed to elucidate potential differences between the two groups and assess the association between plasma D-Dimer levels and CU severity. The current study shows the mean age of participants in Group I(case) was 33.90±11.21 years and range was (18-60) years. And majority of participants in Group I were in the 31-40 years age category (42.5%). Statistical analysis revealed no significant difference in age between two groups (p=0.689) [7]. Regarding gender distribution, Group I had 52.5% males and 47.5% females, while Group II had 57.5% males and 42.5% females. Statistical analysis showed no significant difference in sex distribution between the groups (p>0.04). In a study by Sharmeen *et al* [8], it was reported that the gender distribution was 55% males and 45% females. Metwali *et al* [9] also support these findings. However, several studies in CU shows female percentage is more than male [5,7,10,11]. In the present study, the majority of patients (82.5%) presented with wheal and pruritus without angioedema, while a smaller proportion (17.5%) experienced wheal and pruritus with angioedema [7]. shows 32.5% had wheal and pruritus with angioedema [12, 13]. Regarding the duration of the disease in present study, a significant portion of patients (57.5%) had been affected for 1-5 years, indicating a chronic nature of the condition, with a mean duration of 25.60±25.98 months. In align with these findings, reported that the disease duration ranged between 6-48 months with a mean±SD of 15.35±11.31 months. Furthermore, the severity of chronic urticaria (CU) varied among patients, with 50.0% experiencing severe symptoms, 32.5% moderate symptoms, and 17.5% mild symptoms. Similarly, Alwafa *et al* [7] observed disease severity distributed as follows: 20% had

mild CU, 32.5% had moderate CU, and 47.5% had severe CU. The analysis revealed no statistically significant difference in the duration of disease among the disease severity categories (p = 0.194). Among patients with mild disease severity, the mean duration of disease was 33.43±15.44 months, moderate disease severity, the mean duration was 19.54±20.77 months. In the severe disease category, the mean duration was 26.80±31.43 months. Although there were variations in the mean duration across severity categories, the differences were not statistically significant. Similarly, found that the duration of disease ranged from 0.5 to 15 years and showed no significant difference in the duration of disease with severity [14]. In the current study, Group I(case) exhibited a significantly higher prevalence of elevated D-dimer levels (>0.50 µg/ml) compared to Group II (control). Specifically, 45.0% of patients in Group I had elevated D-dimer levels, contrasting sharply with only 5.0% of individuals in Group II. Triwongwarant *et al*. [15] support these findings, which showed 48.3% CU patient had elevated D-dimer levels. Other previous studies also showed increased D-dimer levels with differences in percentage (37.5% by Alwafa *et al* [7], 39.6% by Baek *et al* [16] 54.5% by Criado *et al* [5] 57.58% by Jaiswal and Godse [11], 60% by Asero *et al* [17] 60.8% by Khursheed *et al* [10] 72% by Sharmeen *et al* [8]). The percentage difference is perhaps due to the difference in disease severity in each study. In our study, the mean D-dimer level in Group I was notably higher at 0.97 µg/ml (±1.24), while in Group II, it was significantly lower at 0.31 µg/ml (±0.15). This is supported by Sadowska *et al* [18] who reported statistically higher plasma D- dimer levels (mean: 0.97 mg/L) in patients with chronic urticaria [10, 11, 17, 5]. Furthermore, in the present study, a comparison of plasma D-Dimer levels among different disease severity categories within Group I(case) revealed a statistically significant difference in plasma D-Dimer levels among the severity categories (p=0.003). Notably, as disease severity escalated from mild to severe, there was a notable increase in plasma D-Dimer levels. Patients with mild disease severity had a mean D-Dimer level of 0.25 µg/ml (±0.05), which rose to 0.55 µg/ml (±0.39) in patients with moderate severity and further increased to 1.48 µg/ml (±1.57) in patients with severe severity. In align with these findings, found that the mean plasma D-Dimer levels increased gradually with disease severity [10]. Also, in the present study, a significant positive correlation (r=+0.472, p=0.002) was observed between the UAS-7 score and Plasma D-Dimer level. This correlation is statistically significant, suggesting a strong relationship between the UAS-7 score and Plasma D-Dimer level. This finding is supported by multiple previous studies done in Asia Sharmeen *et al*; Nguyen and Vu; Jaiswal and Godse; Baek *et al* and Triwongwarant *et al* [8, 19, 11, 16, 15], Africa Alwafa *et al*; Farres *et al* [7, 14] and Europe Sadowska *et al*; Ghazanfar *et al*; Kolkhir *et al*; Asero *et al* [17, 18, 20, 21].

Conclusion

In conclusion, the study explores the link between plasma D-Dimer levels and disease severity in chronic urticaria patients. Correlation between elevated D-Dimer levels and disease severity was found, suggesting the potential of D-Dimer as a biomarker for assessing and monitoring chronic urticaria and its potential utility in guiding treatment approaches.

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