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Original Article

Evaluation of the Role of D Dimer in the Diagnosis of Different Types of Pleural Effusion

Mostafa Ibrahim Ragab [1], Saad Rabie Samra [1], Mohammed Omar Alshaybani[2]*, Reda Mohamed Abdallah Elghamry [1]

1- Chest Diseases Department, Faculty of Medicine, Zagazig University, Zagazig, Egypt
2 -Chest Diseases Department, Faculty of Medicine, Tripoli University, Libya

***Corresponding author:**
Mohammed Omar Alshaybani.
E-mail:
mohamedalshybany778@gmail.com
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ABSTRACT

Background: D-dimer level marker of solid phase fibrin dissolution is found to be high in patients with exudative pleural effusion. This study aimed to compare between D dimer concentration in pleural effusions in order to investigate the predictor value of D dimer to differentiate the cause of pleural effusion. **Methods:** This observational descriptive cross-sectional study was carried out at Chest department at Zagazig University Hospitals on 108 patients with pleural effusion. The diagnosis of pleural fluid is based on radiological base (chest x-ray and/or CT when needed, chest ultrasonography) and thoracocentesis of pleural fluid analysis for (biochemical, bacteriological, and cytological examination). Thoracoscopy and pleural biopsy were done for patients who were not diagnosed, and laboratory investigations measurement of serum and pleural fluid D-dimer levels by ELFA-ELISA. **Results:** There was high statistically significant pleural D- dimer, serum D- dimer value, in exudate compared to transudate pleural effusion, $p<0.05$.at cut of value pleural d dimer (≥3.5ug/dl): showed sensitivity 100%, specificity 92.9% and accuracy 98.1% and serum D-dimer at cut of value (≥2.4ug/dl): showed sensitivity 73.8%, specificity 78.6% and accuracy 75% ($p<0.05$) in exudate compared to transudate effusion. These findings also demonstrate a higher significancy in both pleural D-dimer and serum D-dimer value in pleural effusion due to malignancy, when it was compared to other exudative pleural effusions ($p<0.05$). **Conclusions:** The level of pleural D -dimer at cut off value 3.5 ug/dl can differentiate between transudate and exudate, and may differentiate between malignant and non-malignant effusions at cut off value 5 ug/dl.

Keywords: Malignant Pleural Effusion; D-dimer; Pleural Effusion.

INTRODUCTION

There are many etiological factors that cause pleural effusion disease. The most common causes include congestive heart failure, cancer, pneumonia, and pulmonary embolism. A delayed etiological diagnosis can account for markedly higher morbidity and mortality. The diagnosis of pleural effusion (PE) is almost based on physical examination but paraclinical tests like chest X-ray and computed tomography (CT) can help to confirm it. Pleural fluid cytology, thoracoscopy pleural biopsy, and all have been employed to diagnose PE etiology some methods have their own set of limitations such as; closed pleural biopsy [1].

To diagnose and decide the treatment plan for pleural effusions, the fluid must be examined and classified. By doing this, one can differentiate transudate from exudate

effusion. The established criteria to differentiate exudates from transudates is only (Light's criteria). But results may be false positive and may occur in patients with transudative effusions when (Light's criteria) were applied [2].

Coagulation system plays an important role in pleural diseases. Understanding the pathophysiological mechanisms of the coagulation and pleural disorders may open possibilities for novel diagnostic and therapeutic approaches. Several studies have reported that exudative pleural effusion is associated with enhanced local fibrinolytic activity. D-dimer is a degradation product of cross-linked fibrin. Thus, D-dimer level; a marker of solid phase fibrin dissolution; was found to be high in patients with exudative pleural effusion [3].

Prospective study was conducted by the researcher to assess and determine the role of pleural D-dimer assay in predicting the malignant pleural effusion. That studies aimed at comparing serum and pleural D-dimer levels between malignant pleural effusion (MPE) and non-malignant pleural effusion (NMPE). The outcomes elucidate that the D-dimer levels were significantly different between the two groups. For this reason, pleural D-dimer can be considered as non-invasive tool for diagnosis of MPE [4].

The purpose of this study is to compare between D-dimer concentration in various pleural effusion cases and to investigate the predictor value of D-dimer concentration among of hopping to differentiate between causes of pleural effusion.

METHODS

After having received the protocol approval by our Local Ethics Committee (IRB#10750-7-5-2023), this observational descriptive cross section study was conducted at Chest Diseases department at Zagazig University Hospitals during the period from May 2023 to October 2023. A total of 108 patients with pleural effusion were eligible for the nonrandomized study. Mean age of all patients was 57.28±12.9 years ranged from 26- 81 years, 50 of them (46.3%) were females and 58 of patients (53.7%) were males.

Inclusion criteria were; age above 18 years who was presented with pleural effusion was eligible for the study. Exclusion criteria were; patients who refused to participate in the study, patients younger than18 years, patients who had received anticoagulation treatment or who had history of primary coagulopathy disease or surgery in the month preceding the study. Recent pulmonary embolism.

Methods:

After the consent forms had been signed, the following criteria were adapted to gather the target data. The diagnosis of pleural effusion was based on clinical examination (full medical history, general and local chest examination). Radiological (plain chest X-ray postero–anterior, lateral views and chest tomography (CT) with contrast when needed chest ultrasonography u/s), thoracocentesis, pleural fluid analysis for biochemical, bacteriological, and cytological examination. Thoracoscopy and pleural biopsy for patients who were not diagnosed. Laboratory investigations included complete blood picture, kidney function tests, liver function tests, prothrombin time [PT], international normalized ratio [INR] and sputum examination for acid fast bacilli (AFB). Measurement of serum and pleural fluid D-dimer level by ELFA-ELISA based technique.

The pleural effusion was divided after fulfilling investigations and reaching final diagnosis into four groups types. This classification is basically based on the underlying disease/ light criteria (Lepusa-Vivero-2018

Type1: Transudate pleural effusion.

Type2: Malignant effusion was diagnosed

when malignant cells were found on cytologic examination or in a biopsy specimen by thoracoscope.

Type3:Exudate non-malignant pleural effusion (T B, parapneumonic effusion).

Type4:Exudate undiagnosed after thoracoscopy biopsy with negative result**.**

As for ethics, a consent form was signed by each single patient, who aged above 18 years to gain approval to take part in this study protocol conformed to the ethical guidelines of the Declaration of Helsinki (1975) for studies involving humans. Some cases were excluded from the study for different reasons. These include those who refuse to sign the consent form, patients who had received anticoagulation treatment or who had primary coagulopathy disease, or patient who had recent surgery (less than a month) and who had recent pulmonary embolism.

Sample collection and D-dimer assays:

A sample of 4 ml of blood and 3 ml pleural effusion were collected in 3.2% buffered sodium citrate and centrifuged at 2000 g for 15 minutes within 4 hours of collection. All supernatant fluids were stored at 20°C until assayed. All pleural samples were diluted 1:1000 before assay (due to the high D-dimer levels compared to plasma). Pleural fibrin D-dimer was assayed by Vidas D-dimer (ELFA-ELISA based technique, Bio M'erieux, Lyon, France). The procedures were performed as recommended by kit/assay manufacturer. Specimen batch was assayed together with controls purchased from the manufacturer.

Statistical analysis:

The study results were collected, analyzed, tabulated, and summarized using SPSS software (Statistical Package for Social Sciences analysis, version 26). Data management using SPSS IBM Corp. Released 2015. IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp. Quantitative data were expressed as the mean standard deviation (± SD) & median (range), and qualitative data were expressed as absolute frequencies (number) & relative frequencies (percentage). T-test was used to compare between two groups of normally distributed variable. As for non-normally distributed variables, a Mann- whitnney U-test was run to compare between the two groups. Anova (F) test was also utilized to compare between more than two groups of normally distributed variables. Additionally, the non-parametric counterpart of the one-way ANOVA test Kruskall Wallis test was used to compare between more than two groups of non- normally distributed variables. Moreover, the percentage of categorical variables were compared using Chi-square test. Generally, P-value < 0.05 was considered statistically significant (S), and p-value ≥ 0.05 was considered statistically insignificant (NS).

RESULTS

Table1: Showed that transudate pleural effusion was in 28 (25.9%) patients and exudate pleural effusion was in 80 (74.1%) patients, distributed as following: exudate effusion due to malignant cause was in 46 (42.6%) patients, and other diagnosed exudate was 10 & 9 (20.4%) patients due to tuberculous pulmonary infection. Para pneumonic pleural effusion in another exudate group was undiagnosed in 12 (11.1%) patients after thoracoscopy was done.

Table2: Showed that there was high statistically significant pleural D- dimer, serum D- dimer value, and pleural D- dimer /serum D- dimer ratio value in exudate compared to transudate pleural effusion, p<0.05.

Table 3: Pleural D-dimer at cut off value ≥3.5 (ug/dl): showed sensitivity 100%, specificity 92.9% and accuracy 98.1% to discriminate between exudate versus transudate pleural effusion. Serum D-dimer at cut off value ≥2.4 (ug/dl): show sensitivity 73.8%, specificity 78.6% and accuracy 75% to discriminate between exudate versus transudate pleural

effusion. Pleural/Serum D-dimer ratio at cut off value ≥1.2: show sensitivity 81.3%, specificity 57.1%, and accuracy 74.1% to discriminate exudate versus transudate pleural effusion.

The area under the curve (AUC) is 0.993 with 95% confidence interval (0.98-1), p=0.0001, so pleural D – dimer was a very good predictor for exudate secretion from transudate secretion. While serum D- dimer fair to predict exudate secretion from transudate secretion, as the area under the curve (AUC) is 0.781with 95% confidence interval (0.688-0.874), p=0.0001, pleural /serum D- dimer ratio fair to diagnose exudate from transudate pleural effusion. The area under the curve (AUC) is 0.7 with 95% confidence interval (0.563-0.828), p=0.002 **Figure 1.**

Table 4: Showed that there was statistically high significant pleural D-dimer value and serum D-dimer value in pleural effusion due to malignancy compared to other exudate (type 2 and type 3) pleural effusion, p<0.05. While there was no significant difference between pleural D-dimer /serum D-dimer ratio in malignant type 2 pleural effusion compared to other exudate pleural effusion, p>0.05.

Pleural D-dimer at cut off value ≥5 (ug/dl): show sensitivity 73.9%, specificity 64.7% and accuracy 70% to discriminate malignant exudate versus other exudate pleural effusion and serum D-dimer at cut off value ≥ 2.75 (ug/dl): show sensitivity 65.2%, specificity 44.1%, and accuracy 56.3% to discriminate malignant exudate versus other exudate pleural effusion as shown as **table 5.**

The area under the curve (AUC) is 0.803 with 95% confidence interval (0.7-0.902), p=0.0001, So pleural D-dimer was good predictor for malignant exudate rather than non-malignant exudate pleural effusion. While receiver operating characteristic (ROC) curves of serum D-dimer, the area under the curve (AUC) is 0.65 with 95% confidence interval (0.53-0.78), p=0.019, So serum D-dimer was fair to predict malignant exudate type2 from other exudate type3 pleural effusion **Figure 2**.

Table 6: Showed that there was high statistically significant pleural D-dimer and pleural D-dimer /serum D-dimer ratio value in pleural effusion due to malignant compared to undiagnosed exudate pleural effusion, p<0.05. While there was no significant difference in serum D-dimer in malignant pleural effusion compared to undiagnosed exudate pleural effusion, p>0.05.

Table 7: Pleural D.dimer at cut off level ≥5 (ug/dl): showed sensitivity 82.6%, specificity 66.7% and accuracy 97.3% to discriminate malignant exudate versus undiagnosed exudate pleural effusion. Pleural/serum D. dimer ratio at cut off level ≥1.2: showed sensitivity 82.6%, specificity 50%, and accuracy 78.6% to discriminate malignant exudate versus undiagnosed exudate pleural effusion.

The area under the curve (AUC) is 0.862 with 95% confidence interval (0.766-0.958), p=0.0001, so pleural D-dimer ratio was good predictor for malignant exudate from undiagnosed cause of pleural effusion, while receiver operating characteristic (ROC) curves of pleural/ serum D-dimer ratio showed that, the area under the curve (AUC) is 0.745 with 95% confidence interval (0.602-0.887), p=0.0001, so pleural/ serum D-dimer ratio was fair predictor for malignant exudate from undiagnosed cause pleural effusion **Figure 3**.

Table (1): Demographic characters of studied cases. (n.108).

		Total n.108	
Age per years Mean ±SD (range)		57.28±12.9 (26-81)	
Sex Female	**N**	50	
	%	46.3%	
Males	**N**	58	
	%	53.7%	
Causes of pleural effusion		**n**	**%**
Type 1 Transudate		**28**	**25.9**
Exudates		**80**	**74.1**
Type 2 Malignant Exudate n.46 (42.6%)	Mesothelioma	12	11.1
	Squamous cell carcinoma	10	9.3
	Adeno carcinoma	12	11.1
	Metastasis	12	11.1
Type 3 Another exudate n.22 (20.4%)	Tuberculosis effusion (TB)	10	9.3
	Para pneumonic	12	11.1
Type 4 n.12 (11%)	Undiagnosed	12	11.1

Table (2): Comparison between transudate and exudate pleural effusion regarding D-dimer value.

	Transudate n.28	Exudate n.80	t/u	P
Pleural D. dimer (ug/dl)				
Mean± SD	2.32±0.63	5.12±0.81	3.16	0.0001*
Median(range)	2.2(1.5-4.2)	5.1(3.8-7.6)		
Serum D. dimer (ug/dl)				
Mean± SD	1.9±0.88	3.05±1.3	4.444	0.018*
Median(range)	1.8(0.36-3.9)	3(0.4-6.2)		
Pleural D. dimer /serum D. dimer				
Mean± SD	1.83 ±1.7	2.27±1.77	3.07	0.002*
Median (range)	1.17(0.54-6.08)	1.69(0.68-9.5)		

Data were expressed as range and Mean ±SD. [SD=standard deviation, range,
t: Student t test, u: Mann whitney test, no significant p>0.05, * significant p<0.05.

Table (3): Cut off value of D- dimer in diagnostic exudate versus transudate Pleural effusion.

Cut off level	Sensitivity	Specificity	PPV	NPV	Accuracy
Pleural D-dimer (ug/dl) ≥3.5	100%	92.9%	97.6%	100%	98.1%
Serum D-dimer (ug/dl) ≥2.4	73.8%	78.6%	90.8%	51.2%	75%
Pleural/serum D-dimer ratio ≥1.2	81.3%	57.1%	84.4%	51.6%	74.1%

Table (4): Comparison between malignant Type2 and other exudative (nonmalignant Type3 and undiagnosed Type 4) pleural effusion regarding D- dimer value.

	Malignant n.46	Another exudate n.34	t/u	P
Pleural D-dimer (ug/dl) **Mean± SD** **Median(range)**	 5.46±0.75 5.4(4.3-7.6)	 4.69±0.65 4.6(3.8-6.09)	4.96	0.0001*
Serum D-dimer (ug/dl) **Mean± SD** **Median(range)**	 3.37±1.19 3.2(1.4-6.2)	 2.62±1.3 2.8(0.4-5.8)	2.34	0.019*
Pleural D-dimer /serum D-dimer ratio **Mean± SD** **Median (range)**	 1.87±0.86 1.6(0.8-4.64)	 2.75±2.46 1.89(0.68-9.5)	1.1	0.29

Data were expressed as median, range and Mean ±SD. [SD=standard deviation,
t: Student t test, u: Mann whitnney test, no significant p>0.05, significant *p<0.05.

Table (5) Cut off value of D-dimer in malignant exudate versus other exudate pleural effusion.

Cut off value	Sensitivity	Specificity	PPV	NPV	Accuracy
Pleural D-dimer (ug/dl) ≥5	73.9%	64.7%	73.9%	64.7%	70.0%
Serum D-dimer (ug/dl) ≥2.75	65.2%	44.1%	61.2%	48.4%	56.3%

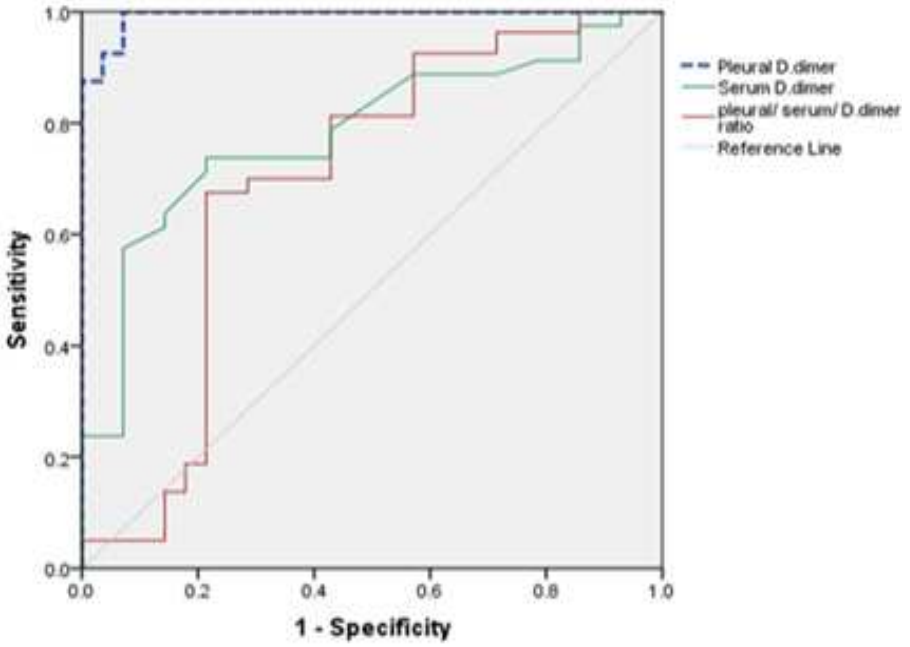

Figure (1): Receiver operating characteristic (ROC) curves of pleural D-dimer of exudate versus transudate.

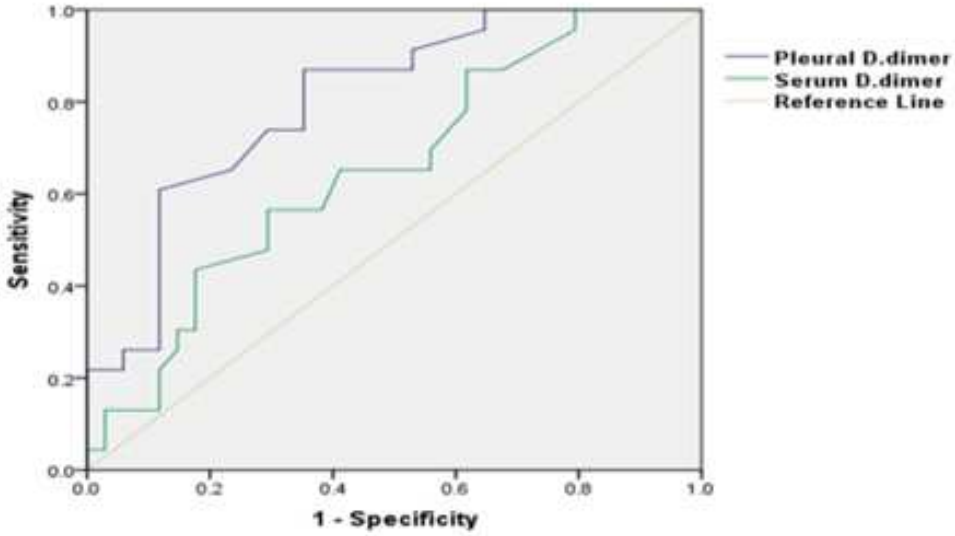

Figure (2): Receiver operating characteristic (ROC) curves of pleural D-dimer of malignant exudate versus non-malignant exudate.

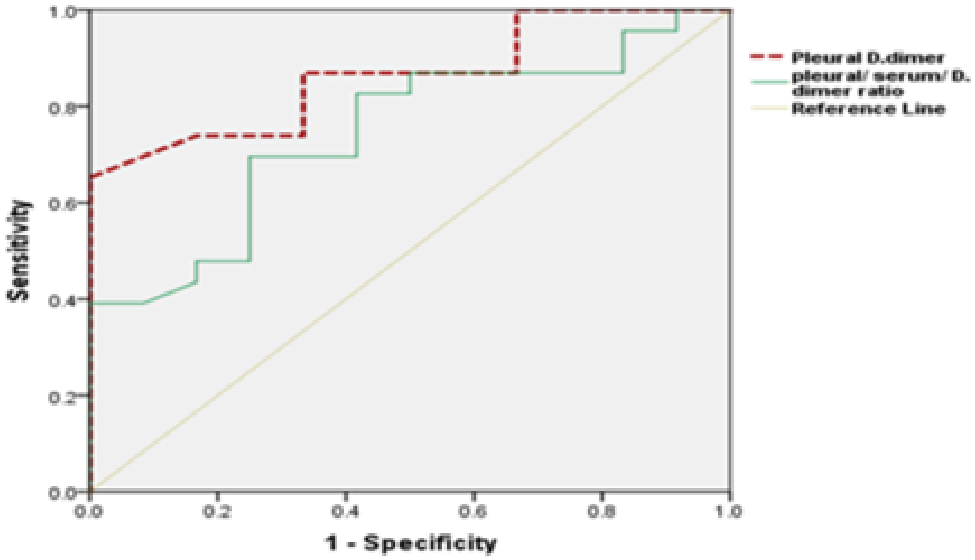

Figure (3): Receiver operating characteristic (ROC) curves of pleural D-dimer of malignant exudate versus undiagnosed pleural effusion.

DISCUSSION

The primary goal of this study was a trial to gain better insight and make a clear-cut distinction between exudative and transudative pleural effusion cases as well as malignant pleural effusion from non-malignant ones.

In this study, 108 patients had pleural effusion, mean age of all patients was 57.28±12.9 years ranged from 26- 81 years, 50 of them (46.3%) were females and 58 of patients 53.7% were males.

In agreement with our study, **Ardestani et al** [4] showed that the mean age was 61.3 ± 12 years and M/F ratio was 35/29. **Shen et al** [5] demonstrated that the mean age was 52±15 years, there were 47 males and 40 females.

The current investigation showed that transudate pleural effusion in studied group was 25.9% and exudate pleural effusion was 74.1%, distributed as following; 42.6% due to malignancy, 9.3% due to tuberculosis. Para pneumonic pleural effusion detected in 11.1% of patients, other 12 cases (11.1%) their causes were undefined exudative effusion (thoracoscopy biopsy was negative).

In agreement with our study, **El-Habashy et al** [6] showed that pleural effusion was 75%. (35% tuberculous, 20% malignant, 10% parapneumonic, 5% empyema and 5% collagen) and 25% were transudative effusions (20% hepatic and 5% cardiac).

Moreover, **Matveychuk et al** [3] indicated that the most common etiology was CHF (41.7%), while malignancy and infections were the next most common at 26.2% and 24.3%, respectively, this difference may be due to selected group in his study was heart failure and collagen vascular disease.

In this study, there was a high significant difference in pleural D-dimer, serum D-dimer, and pleural D-dimer/serum D-dimer ratio, p value <0.05 in exudate compared with transudate pleural effusion. These findings were in agreement with the resulted from the study of **El-Habashy et al** [6]and **Çelik et al** [7] who found that D-dimer levels are higher in exudative pleural fluids and can differentiate between exudative and transudative PE.

We demonstrated that pleural D-dimer at cut off value (≥3.5, ug/dl). This level represented 100% of sensitivity, 92.9% of specificity and 98.1% of accuracy which can help to discriminate exudate from transudate pleural effusion. In addition, serum D-dimer at cut off level (which was ≥2.4, ug/dl) showed sensitivity 73.8%, specificity 78.6%

and accuracy75% to distinguish exudate from transudate pleural effusion. The pleural /serum D-dimer ratio at cut off level (which was ≥1.2) showed sensitivity 81.3%, specificity 57.1%, and accuracy 74.1% to discriminate exudate versus transudate pleural effusion

Current study demonstrates ROC curve showed the ability of pleural D-dimer value as good predictor to differentiate between exudate from transudate pleural effusion. AUC is 0.993 with 95% confidence interval (0.98-1), p=0.0001,

These were explained by **Ucker et al**, who mentioned that local inflammation is rapidly accompanied by vascular extravasation of plasma components including coagulation substrates and procoagulants that initiate coagulation within pleural fluids and within the pleural and subpleural tissues. The procoagulant response occurs mainly via the activation of the extrinsic coagulation pathway and overexpression of tissue factor [8,9].

We showed that there was significant, higher pleural D-dimer, serum D-dimer value in pleural effusion due to malignant compared to other exudate pleural effusion, p<0.05. While there was no significant difference in pleural D-dimer /serum D-dimer ratio in malignant pleural effusion type2 compared to other exudate **(**type3**)** pleural effusion, p>0.05. Also, we demonstrated that there was significant higher pleural D-dimer, pleural D-dimer /serum D-dimer ratio value in pleural effusion due to malignant compared to undiagnosed exudate pleural effusion **(**type 4**),** p<0.05, while there was no significant difference in serum D-dimer in malignant pleural effusion **(**type 2**)** compared to undiagnosed exudate pleural effusion **(**type4**)**, p>0.05.

In agreement with our study, **Ardestani et al** [4] indicated that the pleural D-dimer levels were higher in malignant pleural effusion group in comparison with non-malignant PE patients (P<0.05) while the serum D-dimer levels were not statistically different between 2 groups. Also, **Medani and Perumbeti** [10] found that D dimer was elevated in malignant pleural effusion.

In addition, **Dikensoy et al** [11] showed that the D-dimer levels was significantly higher in malignant effusion group than non-malignant group (P = 0:002).

Gieseler et al [12] found a highly activated coagulation system in the blood and their malignant effusions, as indicated by high levels of prothrombin fragments and D-dimer (both plasma and pleural). They concluded that potential therapeutic approaches should include the application of drugs targeting the coagulation system

Furthermore**, Ardestani et al** [4] informed that there was greater mean pleural and serum D-dimer levels (3.472± 1.312 ug/dl and 3.259±1.220 ug/dl, respectively) in patients with the malignant pleural effusion compared with the patients affected by non-malignant pleural effusion (3.425 ± 0.325 ug/dl and 2.425±1.311 ug/dl, respectively).

We demonstrated that pleural D-dimer at cut off value ≥5 (ug/dl): showed sensitivity 73.9%, specificity 64.7% and accuracy 70% to discriminate malignant exudate versus other exudate pleural effusion. Serum D-dimer at cut off level ≥2.75 (ug/dl): showed sensitivity 65.2%, specificity 44.1%, and accuracy56.3% to discriminate malignant exudate versus other exudate pleural effusion.

Our study also revealed that ROC curve was showing the ability of pleural D-dimer as moderate predictor for diagnosis of malignant pleural effusion from other exudate pleural effusion, this was explained by local pleural effusion causes which activate the normal mesothelial cells, which in turn is followed by activation of a coagulation cascade and the inhibition of fibrinolysis into the pleural space**.** The accumulation of fibrin into the pleural cavity may serve as a reliable marker for determining the cause of the pleural effusion [3].

Limitations: The small sample size of patients who participated in the study. It could explain that this may affect the generalizability of the results, but it would never affect its internal validly. To confirm D-dimer's involvement as a novel marker in the diagnosis and distinction of malignant pleural effusion and non-malignant pleural effusion in a large-scale population, similar studies with a larger participant count are still advised.

CONCLUSIONS

From this study it can be concluded that the level of pleural D -dimer at cut off value 3.5

ug/dl can differentiate between transudate and exudate and may differentiate between malignant and non-malignant effusion at cut off value 5 ug/dl.

Future studies should include larger samples, larger multi-center studies with more studies on different types of exudative effusions.

Declaration of interest

The authors report no conflicts of interest.

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None declared

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