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Research Article

Pleural Fluid and Serum Albumin Gradient to Differentiate from Transudative and Exudative Pleural Effusion

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Abstract

In a prospective investigation of 30 pleural effusion patients, pleural fluid protein of 3 gm/dl correctly classified 53.3% as exudates and 46.7% as transudates. This measure had 100% sensitivity and specificity. A 0.5 pleural fluid to blood protein ratio correctly classified 53.3% of exudates as exudates and 46.7% as transudates with 100% sensitivity and specificity. With a sensitivity of 92.9% and specificity of 87.5%, pleural fluid LDH of 200 U/L separated 50% as exudates and 50% as transudates, with a misclassification rate of 6.7% in exudative and 3.3% in Transudative. With a sensitivity of 85.7% and specificity of 93.8%, pleural fluid LDH to serum LDH of 0.6 distinguished 56.7% as exudates and 43.3% as transudates, with a misclassification rate of 3.3% of exudates and 6.7% of transudates. Lastly serum effusion albumin gradient (SEAG) of 1.2 g/dl separated 53.3% as exudates and 46.7% as transudates without misclassification with a sensitivity and specificity of 100%. Hence, we conclude that pleural fluid to serum albumin gradient has a better specificity as compared to LIGHT criteria, suggesting that serum effusion albumin gradients is a simple, extremely cost effective and useful parameter with better discriminatory capability.

Keywords: *Pleural Effusion (PE); Serum Pleural Effusion Albumin Gradient (SEAG); Lactate Dehydrogenase (LDH); Transudate and Exudate; Light's Criteria*

Introduction

Pleural effusion (PE) is excess fluid that accumulates between the parietal and visceral pleura [1]. PE result from increased fluid production, decreased fluid drainage, increased endothelial permeability, or migration of fluid from extravascular sources. The normal pleural space is filled with approximately 7 - 14 mL of low-protein pleural fluid in a normal adult person and approximately 0.15 mL/kg of fluid is produced hourly by the parietal pleura [2]. More than this will accumulate when the rate of fluid formation exceeds than rate of fluid removal. Fluid production increased in certain conditions such as 1) congestive cardiac failure, portal hypertension in which hydrostatic pressure gradient gets elevated, 2) hypoproteinaemia in which colloid oncotic pressure decreased and 3) infection, malignancy, inflammation- in these conditions permeability of the capillary increased. Contrary, fluid removal decreased in disease condition like 1)

some neoplasms in which lymphatic drainage is impaired and 2) bronchial obstruction, atelectasis in these conditions pressure in the pleural space is decreased. Hence, Light's criteria used to characterise Pleural effusion (PE) as transudate or exudate that permits significant narrowing of the differential diagnosis [3].

In general, PE is due to pleural disease more closely resembles plasma (exudates). An exudative PE develops when fluid leaks across an altered capillary barrier with increased permeability, thus allowing transfer of protein and liquid. It typically represents an inflammatory process of the lung or pleura [2]. While, transudative PE occurring in the presence of a normal pleural membrane is due to low-protein fluid leaks across an intact capillary barrier which leads to hemodynamic alteration or oncotic pressure changes which is an ultrafiltrate of plasma. Therefore, if pleural effusions meet at least two of the following criteria it consider exudative:

- PF protein: serum total protein ratio > 0.5.
- PF LDH > 2/3 upper limit of normal serum LDH.
- PF LDH: serum LDH ratio > 0.6.

Light's criteria identify approximately 25% of transudative effusions as exudates. This mislabeling occurs most commonly when patients with congestive heart failure (CHF), are treated with diuretics before thoracentesis is performed [4,5]. Transudative pleural effusions meet none the above mentioned criteria; therefore serum albumin should taken in account to discriminate transudative effusions from exudates effusion. Therefore, modified Light's criteria adds to the above three criteria that suggested that if protein > 3 g/dl it considered as exudates. Hence, if any of the 4 criteria is met then calculate fluid to serum albumin gradient (SEAG) and if the albumin gradient is > 1.2 g/dl then consider the effusion to be transudate. Therefore, PE serum albumin gradient (SEAG) is useful in diagnosing false exudates in a congestive heart failure (CHF) patient who has undergone diuresis [2]:

- Albumin gradient = serum albumin - PF albumin.
- Albumin gradient > 1.2 g/dl is consistent with a transudate.
- Albumin gradient ≤ 1.2 g/dl is consistent with an exudate.
- Protein gradient > 3.1 g/dl is consistent with a transudate.

There is a high prevalence of PE in patients in the intensive care unit (ICU) and many study were done on PE to distinguished between transudative and exudative PE using serum plural effusion albumin gradient (SEAG). However, this study reports on patients those admitted in ICU and found PE during clinical examination and investigation, during course of ICU stay. Therefore, this study aims to analyse Pleural Fluid and distinguished between transudate and exudate PE. It is important to consider SAEG to differentiate into transudative and exudative, because some proteins like albumin and globulin fraction in pleural fluid are believed to derive from serum via diffusion. However other protein like lactate dehydrogenase (LDH) is originated from pleural space (i.e. from pleural fluid leukocytes). Therefore, SEAG should be considering more effective means correctly identifying exudates from transudates. It relies in PE and serum albumin concentration. Albumin gradient cut off value of 1.2 gm/dl more precisely classified all the transudates from exudates (95% exudates) especially when patient is suspected to have hypoalbuminemia. Bielsa., *et al*. reported that the albumin gradient identified more of these effusions correctly than did the protein gradient [6]. It is suggested that the protein gradient first be examined because it is already available from Light's criteria.

Methodology

This prospective study has been conducted in Sree Balaji Medical College and Hospital, Chennai India during the period of July 2019 - July 2021, after obtaining the Ethics Committee approval (Ref. No. 002/SBMC/IHEC/2019/1258). Patients who are all > 18 yrs old diagnosed with PE has been taken in this study, using X-ray and other radiological imaging modalities we have confirmed the PE. Thora-

centesis was performed and a relevant investigation has been done to monitor the outcome. Data was collected and analysed using SPSS version 16. Chi Square, Diagnostic test, ROC, t-test and descriptive statistical analysis was performed to find out the result. Significant result will be considered if p value < 0.05.

Sample size

Sample size was calculated based on a similar study done other groups on Diagnostic Value of SEAG in Differentiating Exudative and Transudative Pleural Effusion, and correctly identified transudative PE in 97.22%. During the given period we were able to get 30 patients for our study.

Procedure and investigation for the PE:

- Complete blood count
- Pleural fluid- Glucose, protein, albumin, LDH
- Pleural fluid cell count
- Pleural fluid- Gram stain, fungal, AFB smear, gene expert
- Pleural fluid- Adenosine deaminase (ADA)
- Pleural fluid- Cytology
- Chest X-ray- PA view
- Ultrasound chest, ECG, 2D-ECHO
- Liver function test
- Renal function test
- Sputum- Gram stain, fungal, AFB
- Serum- Glucose, protein, albumin, LDH.

Results

Out of 30 patients 53.3% (16) were male and 46.7% (14) were females. Maximum number of cases is in the age group more than 61, minimum cases are in the age group of less than 20 years.

Age Group	Male	Female	Total
Less than 20	3.3% (1)	0	3.3% (1)
21 - 40	13.3% (4)	10.0% (3)	23.3% (7)
41 - 60	16.7% (5)	16.7% (5)	33.3% (10)
More than 61	20.0% (6)	20.0% (6)	40.0% (12)
Total	53.3% (16)	46.7% (14)	100% (30)

Table 1: *Age group wise distribution.*

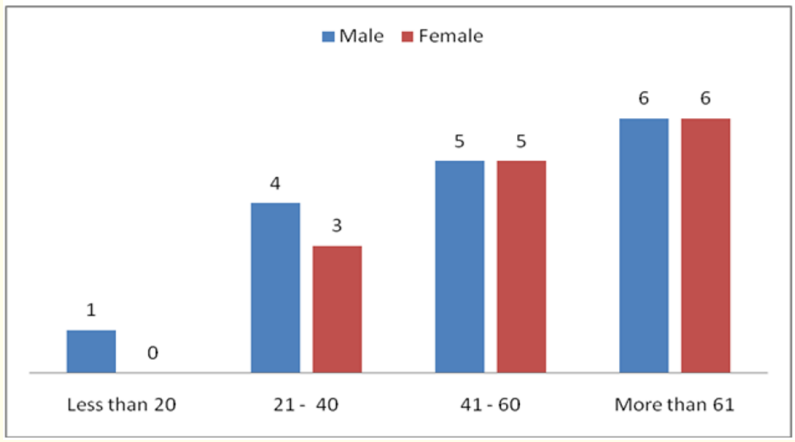

Figure 1: *Showing age wise distribution.*

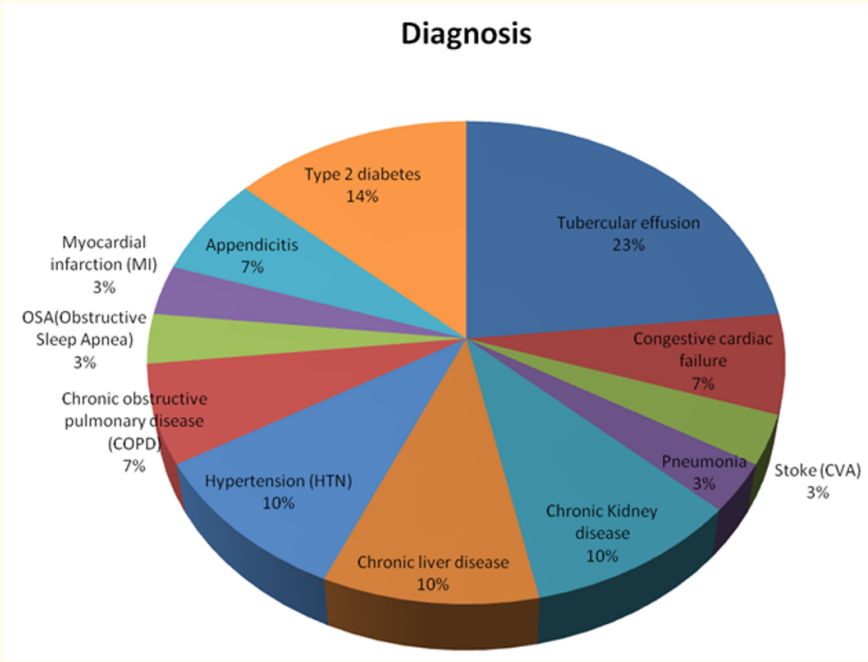

Figure 2: *Diagnosis status of the study participants, N = 30.*

Diagnosis	Participants (n)	Percentage (%)
Tubercular effusion	7	23.3
Congestive cardiac failure	2	6.7
Stoke (CVA)	1	3.3
Pneumonia	1	3.3
Chronic Kidney disease	3	10.0
Chronic liver disease	3	10.0
Hypertension (HTN)	3	10.0
Chronic obstructive pulmonary disease (COPD)	2	6.7
(OSA) Obstructive sleep apnea	1	3.3
Myocardial infarction (MI)	1	3.3
Appendicitis	2	6.7
Type 2 diabetes	4	13.3

Table 2: *Diagnosis status of the study participants.*

Figure 2 represents the tubercular effusion in 7 (23.3%), congestive cardiac failure in 2 (7%), Stoke (CVA) in 1 (3.3%), pneumonia in 1 (3.3%), chronic kidney disease in 3 (10%), chronic liver disease in 3 (10%), hypertension (HTN) in 3 (10%), chronic obstructive pulmonary disease (COPD) in 2 (6.7%), OSA (Obstructive sleep apnea) in 1 (3.3%), myocardial infarction (MI) in 1 (3.3%), appendicitis in 2 (6.7%), type 2 diabetes in 4 (13.3) cases were diagnosed.

Risk Factors	Transudate n = 14	Exudates n = 16	P-Values
	Mean (se) or %	Mean (se) or %	
Age (yrs)	56.29 ± 13.79	46.88 ± 20.8	0.162
Male	6 (37.5%)	10 (62.5%)	0.317
Female	8 (57.1%)	6 (42.9%)	0.593
Pleural fluid protein (gm%)	2.0850	5.0938	< 0.0001
Pleural fluid/serum protein ratio	0.3129	0.7719	0.090
Pleural fluid LDH	140.51	647.06	< 0.0001
Pleural fluid serum LDH ratio	0.5964	1.9519	0.013
Serum to pleural fluid albumin gradient	2.7071	0.6625	< 0.0001

Table 3: *Average values obtained in transudative and exudative pleural effusion. Se=Standard Error of the mean. %=Percentage.*

Patient demographic, clinical data and statistical comparisons are shown in table 3. Compared to the normal group the Transudate group had a higher age (56.29 ± 13.79. vs. 46.88 ± 20.8., p = 0.162 from t testing) and a comparable percentage of Gender (Male (37.5% vs. 62.5%), 0.317 and female (57.1% vs. 42.9%), 0.593 from Chi-square testing). As per all pleural fluid parameters are significant (Pleural fluid protein (p = 0.000), Pleural fluid/serum protein ratio (p = 0.090), Pleural fluid LDH (p = 0.000), Pleural fluid serum LDH ratio (0.013), Pleural fluid/serum albumin gradient (0.000) from t testing).

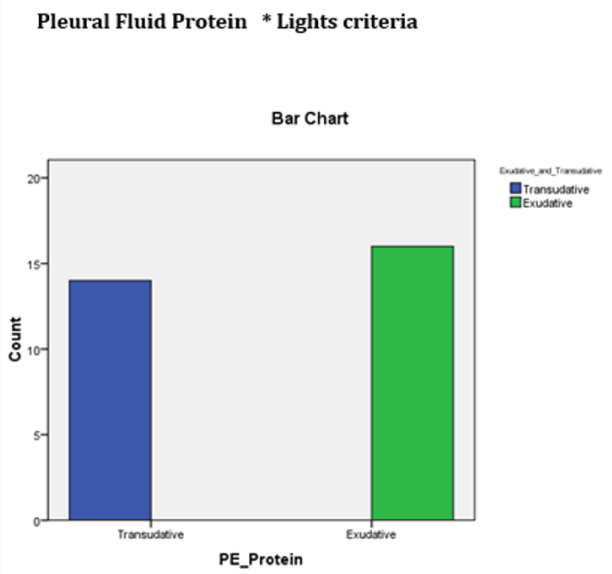

Figure 3: *Study the differences between pleural fluid protein and light criteria.*

Pleural Fluid Protein	Lights criteria		Total	Chi Square	df	p- value
	Transudative	Exudative				
Transudative	14 (46.7%)	0	14 (46.7%)	30.000[a]	1	< 0.0001
Exudative	0	16 (53.3%)	16 (53.3%)			
Total	14 (46.7%)	16 (53.3%)	30 (100%)			
Sensitivity: 100%, Specificity: 100%, PPV: 100%, NPV: 100% and Diagnostic Accuracy: 100%						

Table 4: *Pleural fluid protein vs lights criteria.*

The above table 4 indicates p-value is 0.000 < 0.05. Hence we conclude that there is a statistically significantrelationship between Pleural Fluid Protein and Lights criteria. There is no misclassified Case. The sensitivity of Pleural Fluid Protein was 100% with specificity of 100%. The PPV and NPV value of Pleural Fluid Protein was 100%. The diagnostic accuracy of Pleural Fluid Protein was 100%.

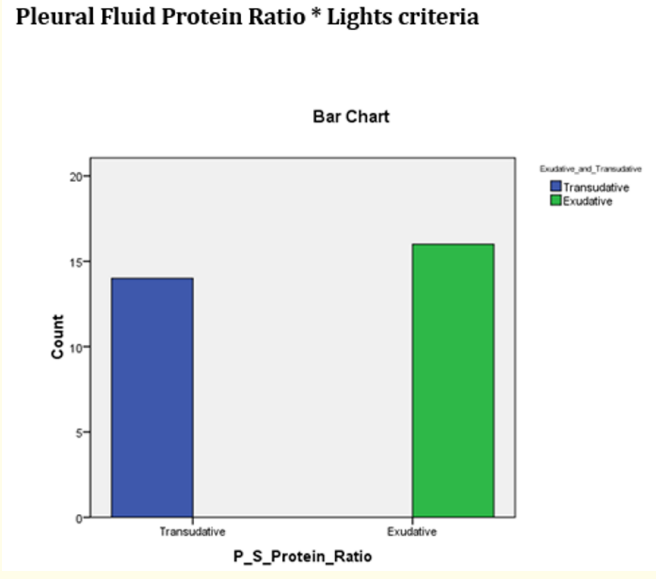

Figure 4: *Study the differences between pleural fluid protein ratio and lights criteria.*

Pleural Fluid Protein Ratio	Lights criteria		Total	Chi Square	df	p- value
	Transudative	Exudative				
Transudative	14 (46.7%)	0	14 (46.7%)	30.000[a]	1	<0.0001
Exudative	0	16 (53.3%)	16 (53.3%)			
Total	14 (46.7%)	16 (53.3%)	30 (100%)			
Sensitivity: 100%, Specificity: 100%, PPV: 100%, NPV: 100% and Diagnostic Accuracy: 100%						

Table 5: *Pleural fluid protein ratio vs lights criteria.*

The above table 5 indicates p-value is 0.000 < 0.05. Hence we conclude that there is a statistically significantrelationship between pleural fluid protein ratio and lights criteria. There is no misclassified case. The sensitivity of pleural fluid protein ratio was 100% with specificity of 100%. The PPV and NPV value of pleural fluid protein ratio was 100%. The diagnostic accuracy of pleural fluid protein ratio was 100%.

Pleural Fluid LDH	Lights criteria		Total	Chi Square	df	p- value
	Transudative	Exudative				
Transudative	13 (43.3%)	2 (6.7%)	15 (50%)	19.286[a]	1	<0.0001
Exudative	1 (3.3%)	14 (46.7%)	15 (50%)			
Total	14 (46.7%)	16 (53.3%)	30 (100%)			
Sensitivity: 92.9%, Specificity: 87.5%, PPV: 86.6%, NPV: 93.3% and Diagnostic Accuracy: 90.0%						

Table 6: *Pleural fluid LDH vs lights criteria.*

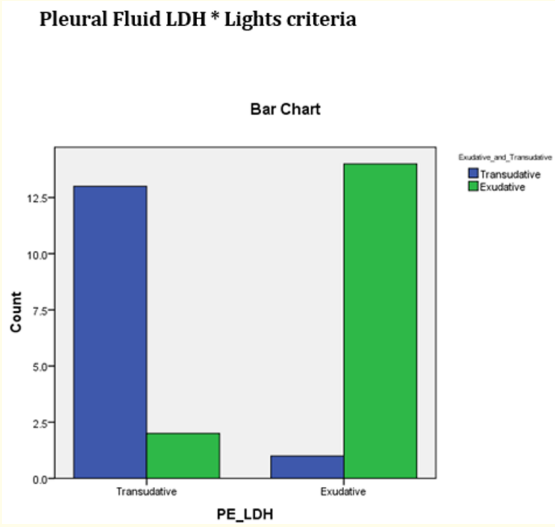

Figure 5: *Study the differences between pleural fluid LDH and lights criteria.*

The above table 6 indicates p-value is 0.000 < 0.05. Hence, we conclude that there is a statistically significantrelationship between pleural fluid LDH and lights criteria. As per lights criteria out of 14 transudates 1 (3.3%) cases were misclassified as exudates and 2 (6.7%) exudates were misclassified as transudates. The sensitivity of Pleural Fluid LDH was 92.9% with specificity of 87.5%. The PPV value of Pleural Fluid LDH score was 86.6% and NPV value was 93.3%. The diagnostic accuracy of Pleural Fluid LDH was 90.0%.

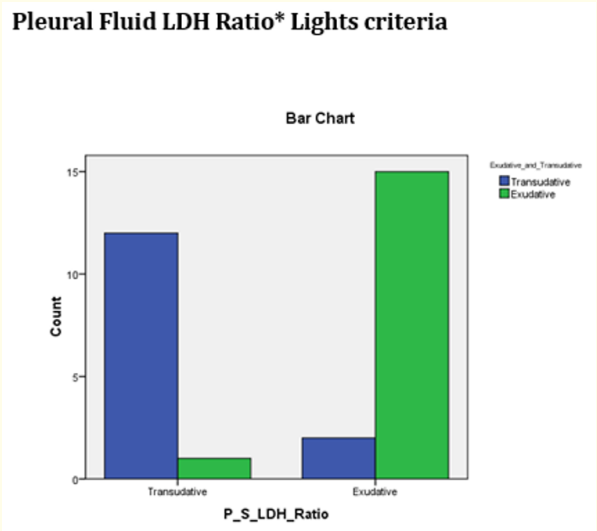

Figure 6: *Study the differences between pleural fluid LDH ratios and lights criteria.*

Pleural Fluid LDH Ratio	Lights criteria		Total	Chi Square	df	p- value
	Transudative	Exudative				
Transudative	12 (40%)	1 (3.3%)	13 (43.3%)	19.201[a]	1	<0.0001
Exudative	2 (6.7%)	15 (50.0%)	17 (56.7%)			
Total	14 (46.7%)	16 (53.3%)	30 (100%)			
Sensitivity: 85.7%, Specificity: 93.8%, PPV: 92.3%, NPV: 88.2% and Diagnostic Accuracy: 90.0%						

Table 7: *Pleural fluid LDH ratio vs lights criteria.*

The above table 7 indicates p-value is 0.000 < 0.05. Hence, we conclude that there is a statistically significantrelationship between pleural fluid LDH ratio and lights criteria. As per lights criteria out of 14 transudates 2 (6.7%) cases were misclassified as exudates and 1 (3.3%) exudates were misclassified as transudates. The sensitivity of pleural fluid LDH ratio was 85.7% with specificity of 93.8%. The PPV value of pleural fluid LDH ratio was 92.3% and NPV value was 88.2%. The diagnostic accuracy of pleural fluid LDH ratio was 90.0%.

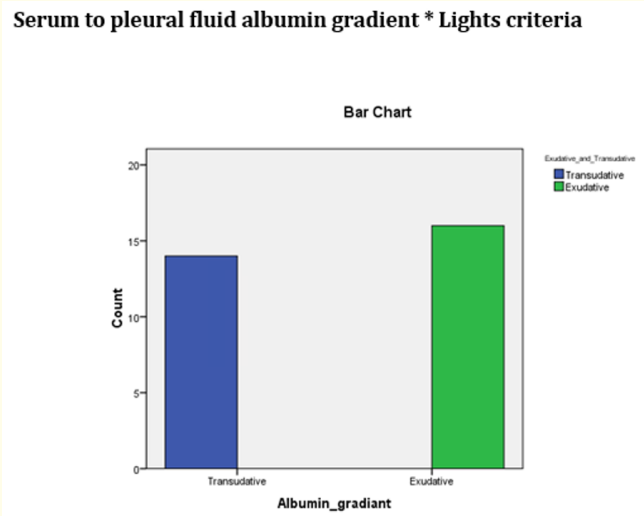

Figure 7: *Study the differences between serum to pleural fluid albumin gradient and lights criteria.*

Serum to pleural fluid albumin gradient	Lights criteria		Total	Chi Square	df	p- value
	Transudative	Exudative				
Transudative	14 (46.7%)	0	14 (46.7%)	30.000[a]	1	<0.0001
Exudative	0	16 (53.3%)	16 (53.3%)			
Total	14 (46.7%)	16 (53.3%)	30 (100%)			
Sensitivity: 100%, Specificity: 100%, PPV: 100%, NPV: 100% and Diagnostic Accuracy: 100%						

Table 8: *Serum to pleural fluid albumin gradient vs lights criteria.*

The above table 8 indicates p-value is 0.000 < 0.05. Hence we conclude that there is a statistically significantrelationship between Serum to pleural fluid albumin gradient and Lights criteria**.** There is no misclassified Case. The sensitivity of Serum to pleural fluid albumin gradient was 100% with specificity of 100%. The PPV and NPV value of Serum to pleural fluid albumin gradient was 100%. The diagnostic accuracy of Serum to pleural fluid albumin gradient was 100%.

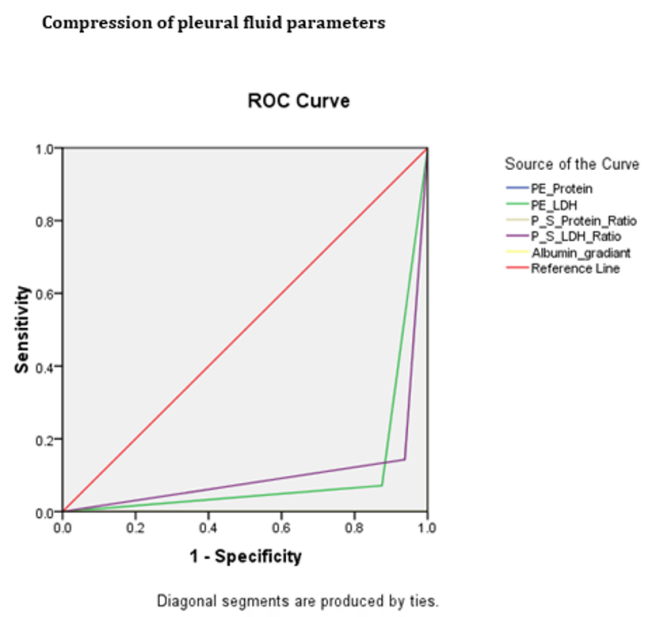

Figure 8: *Compression of pleural fluid parameters.*

The above figure 8 comparison of receiver operating characteristic (ROC) curves of the pleural fluid parameters. The areas under the ROC curves (AUROCs) for panel are pleural fluid protein and pleural fluid protein ratio, 0.00 (95% confidence interval [CI], 0.00 - 0.00), p-value is 0.000< 0.05; pleural fluid LDH, 0.98 (95% CI, -0.026 - 0.22), p-value is 0.000 < 0.05; pleural fluid LDH ratio, 0.10 (95% CI, - 0.027 - 0.23); pleural fluid/serum albumin gradient, 0.00 (95% confidence interval [CI], 0.00-0.00), p-value is 0.000< 0.05. When comparing the ROC curves of pleural fluid parameters regarding all parameters are best predictive capacity, there was a significant difference. Exactly we says serum to pleural fluid albumin gradient best predictive capacity and 100% sensitivity compared lights criteria.

Parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Efficacy (%)
Pleural fluid protein	100	100	100	100	100
Pleural fluid/serum protein	100	100	100	100	100
Pleural fluid LDH	92.9	87.5	86.6	93.3	90.0
Pleural fluid serum LDH	85.7	93.8	92.3	88.2	90.0
Serum to pleural fluid albumin gradient	100	100	100	100	100

Table 9: *Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and efficiency of parameters studied.*

Parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Efficacy (%)
Lights criteria	92.86	93.76	92.96	93.83	93.33
Serum to pleural fluid albumin gradient	100	100	100	100	100

***Table 10**: Comparison of lights criteria and serum to pleural fluid albumin gradient.*

The sensitivity of lights criteria was 92.86% with specificity of 93.76%. The PPV value of pleural fluid LDH score was 92.96% and NPV value was 93.83%. The diagnostic accuracy of pleural fluid LDH was 93.33% and the sensitivity of serum to pleural fluid albumin gradient was 100% with specificity of 100%. The PPV and NPV value of serum to pleural fluid albumin gradient was 100%. The diagnostic accuracy of serum to pleural fluid albumin gradient was 100%. Exactly we says serum to pleural fluid albumin gradient best predictive capacity and 100% sensitivity compared lights criteria.

Pleural fluid serum LDH had maximum number of misclassified cases in transudates 1 (3.3%) as over exudates 2 (6.7%) and also Pleural fluid LDH have some number of misclassified cases in transudates 2 (6.7%) as over exudates 1 (3.3%) while pleural fluid protein and serum to pleural fluid gradient had 0 number of misclassified cases.

As per lights criteria out of 14 transudates 2 (6.7%) cases were misclassified as exudates and 1 (3.3%) exudates were misclassified as transudates. As per serum pleural fluid albumin gradient 0 number of misclassified cases. The overall p-value is 0.000< 0.05. Hence we conclude that there is a statistically significant.

Discussion

In disease states, pleural fluid can be accumulated due to conditions like congestive cardiac failure, cirrhosis of liver, chronic kidney disease hypoproteinaemia, infection, malignancy and bronchial obstruction, atelectasis etc [7]. Distinguishing if the effusion is an exudate or transudate is a practical first step for differential diagnosis of the PE. Light's criteria (Total protein and lactate dehydrogenase) used to characterise PE as transudate or exudates since year 1972 [8]. Later some other markers were added such as cholesterol, bilirubin and triglycerides and the ratio of pleural fluid to serum cholesterol, pleural fluid to serum bilirubin, pleural fluid to serum triglycerides but none of these specific and sensitive to diagnose exudate from transudate. However, a measurement of fluid to serum ration seems not much useful to diagnose exudates.

Many researchers studied pleural fluid to identify the cause of PE on patients admits in ICU and most of these studies relies on light's criteria. In a study done by Fartoukh., *et al*. screened 1351 patients in the medical intensive care unit (MICU) and found that 113 patients (8.4%) had a PE detectable by physical examination and obscuring one third of the lung field [9]. Thoracentesis on 82 of these patients revealed transudates in 20 (24.4%), parapneumonic effusion or empyema in 35 (42.7%) and non-infectious exudates in 27 (32.9%) [9]. These studies proves that there is a high incidence of empyema in the patient with effusion in the MICU. A thoracentesis is recommended for patients in the ICU with more than a minimal PE particularly if the effusion is septated or hyper echoic. Patients in the ICU who are receiving mechanical ventilation and have large pleural effusions appear to benefit if the fluid is drained. Post thoracentesis, the mean $Pa0_2$ increased from 82 to 115 mm Hg and the P: F ratio increased from 169 to 237 [10]. These improvements were maintained for 48 hours [10]. Liang and co-workers [11] have demonstrated that drainage of large PE in the ICU via pigtail catheters is effective regardless of the etiology of the effusion. Most of these studies confirm that PE is effective to take decision on patients admitted however little or no information is available on SEAG of these patients to classify PE.

Therefore, this study considers significance of SEAG in differential diagnosis of PE and compared with already established Light's criteria that permit significant narrowing of the differential diagnosis. Although, Light's criteria widely accepted for differentiating exudates from transudates, however, by applying Light's criteria some studies showed high sensitivity but low specificity particularly for exudates.

Roth., *et al*. showed that serum-pleural fluid albumin gradient (SEAG) had a sensitivity and specificity of 95 and 100%, respectively in their study samples [12]. Whereas Burgess., *et al*. reported 87% sensitivity and 92%, specificity [13]. Similarly, Muzaffer Metintas., *et al*. reports a 63% sensitivity and 81% specificity in their study to differentiate patients correctly using SEAG [14]. These studies indicate that the serum-fluid albumin gradient has advantage over the Light's et al., criteria for specificity in case of exudates. In addition to this studying other markers have added advantages over Light's criteria. A study done by Meisel et al. utilizing pleural fluid/serum bilirubin ratio [15] confirm that, using a cut-off ration of level of 0.6, for differentiating exudates from transudates, can attain approximately 90% sensitivity and specificity. Similarly, Das., *et al*. confirm that SEAG value of 1.2 gm/dl, which correctly classified 96.15% of exudates and 93.6% of transudates with a sensitivity, and specificity of 96.1% and 93% [16]. These studies indicates that SEAG should consider over Light's criteria for the differential diagnosis of the patients 100%.

Also, additional test such as pleural fluid pH, glucose adenosine deaminase, interferon gamma levels, cholesterol, bilirubin, cholinesterase, alkaline phosphatase, creatinine kinase, uric acid and cytology may be useful in specific condition such as parapneumonic effusion, rheumatoid arthritis, tuberculosis, chylothorax and malignancy etc [17].

Thus, in our study of well characterized sample of PE we have correctly diagnosed and found 53.3% (N = 16) (Table 4) exudates and 46.7% (N = 14) (Table 4) transudate using SEAG with 100% Sensitivity, specificity, PPV, NPV and Efficacy (Table 9). Whereas, as per Lights criteria out of 14 transudates 2 cases (6.7%) (Table 8) were misclassified as exudates and 1 exudates (3.3%) (Table 8) were misclassified as transudates. Hence, SEAG diagnose with 100% accuracy or in other words 0 number of misclassified cases. The overall p-value is 0.000 < 0.05. Hence we conclude that there is a statistically significant in both the methods but SEAG is more specific.

Taken together be believe that measurement of SEAG is better but we should consider other makers for the differentiation of exudates and transudates in clinical practice. This again may clarify the pathophysiology of plural effusion whether its exudates and/or transudates to make accurate diagnosis of plural disease.

Conclusion

On the basis result we concluded that pleural fluid to serum albumin gradient has a better specificity as compared to LIGHT's criteria, suggesting that serum effusion albumin gradients is a simple, extremely cost effective and useful parameter with better discriminatory capability.

Conflict of Interests

Authors declared no conflict of interest to this work.

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