



Student's Journal of Health Research Africa

e-ISSN: 2709-9997, p-ISSN: 3006-1059

Vol.6 No. 9 (2025): September 2025 Issue

<https://doi.org/10.51168/sjhrafrica.v6i9.2154>

Original Article

Diagnostic utility of pleural fluid/serum bilirubin ratio versus light's criteria in differentiating exudative and transudative pleural effusions. A cross-sectional observational study.

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Abstract

Background

Differentiation between exudative and transudative pleural effusions is fundamental for guiding clinical management. Light's criteria remain the standard, though reports suggest misclassification in certain cases, necessitating exploration of alternative biochemical markers.

Objectives

To evaluate the efficacy of the pleural fluid/serum bilirubin ratio in differentiating exudative from transudative pleural effusions in comparison with Light's criteria.

Methods

A cross-sectional observational study was conducted on 60 patients with pleural effusion at a tertiary care center from January 2021 to June 2022. Patients underwent detailed clinical evaluation, radiological assessment, and biochemical analysis of pleural fluid and serum for protein, lactate dehydrogenase (LDH), and bilirubin. Ratios of pleural fluid to serum concentrations were calculated. Exudates and transudates were classified using clinical criteria, and diagnostic performance of Light's criteria and bilirubin ratio was compared.

Results

Of the 60 patients, 33 (55%) had exudative and 27 (45%) transudative effusions. Exudates were more common in males (57.5%) and in the age group 31–50 years, whereas transudates predominated among females and those aged 51–70 years. Tuberculosis (48.5%) and malignancy (36.4%) were the leading causes of exudates, while congestive cardiac failure (44.5%) and chronic liver disease (37%) were the main transudative etiologies. The mean pleural fluid/serum bilirubin ratio (0.74 vs. 0.32, $p < 0.001$) significantly differentiated exudates from transudates. Diagnostic accuracy was highest for the bilirubin ratio (96.67%) compared to Light's criteria (95%), with superior specificity in identifying transudates.

Conclusion

The pleural fluid/serum bilirubin ratio is a simple, cost-effective, and reliable parameter, with diagnostic accuracy comparable to Light's criteria.

Recommendations

The bilirubin ratio can be used as an adjunct or alternative to Light's criteria, especially in resource-limited settings, to minimize misclassification. Larger multicentric studies are recommended to validate its clinical utility and establish standardized cut-off values.

Keywords: Pleural effusion, Exudates, Transudates, Light's criteria, Bilirubin ratio

Submitted: July 11th, 2025. **Accepted:** August 27th, 2025. **Published:** September 30, 2025

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Introduction

Pleural effusion is a frequent clinical problem encountered in both inpatient and outpatient practice, resulting from diverse etiologies including congestive cardiac failure, chronic liver disease, chronic kidney disease, tuberculosis, malignancy, and parapneumonic infections. Differentiating exudative from transudative effusions is a crucial first step in diagnostic evaluation, as it guides further investigations and therapeutic decisions [1].

Light's criteria, introduced in 1972, remain the most widely accepted standard for distinguishing exudates from transudates [1]. According to these criteria, an effusion is classified as exudative if one or more of the following are present: pleural fluid to serum protein ratio >0.5 , pleural fluid to serum lactate dehydrogenase (LDH) ratio >0.6 , or pleural fluid LDH greater than two-thirds the upper limit of normal serum LDH. Despite their extensive use, Light's criteria are known to misclassify up to 20% of transudates as exudates, particularly in patients receiving diuretic therapy for cardiac failure [5]. This limitation has encouraged the search for additional, reliable, and cost-effective parameters.

The pleural fluid/serum bilirubin ratio has been investigated as an alternative diagnostic marker. Meisel et al. first reported that a ratio >0.6 reliably separated exudates from transudates, with diagnostic accuracy comparable to Light's criteria [3]. Subsequent studies, including those by Metintaş et al., demonstrated that bilirubin ratio, along with cholesterol and other biochemical parameters, can serve as valuable tools in classification [4]. More recently, Agrawal et al. highlighted the pleural fluid/serum bilirubin ratio as a simple and reproducible marker, especially relevant in resource-limited settings [2].

However, available literature indicates variability across populations, with tuberculosis being a predominant cause of exudates in endemic regions, while malignancy and cardiac failure dominate in Western cohorts [2,5]. Against this background, the present study was designed to assess the diagnostic utility of the pleural fluid/serum bilirubin ratio in differentiating exudative from transudative pleural effusions and to compare its performance directly with Light's criteria.

Methodology

Study Design and Setting

Gandhi Medical College, Secunderabad, is a major tertiary-care teaching institution catering to a wide urban and semi-urban population in Telangana. The hospital houses extensive specialty and super-specialty services, well-equipped diagnostic laboratories, and one of the busiest respiratory units in the region. The Department of Respiratory Medicine handles a high volume of pleural diseases, offering an ideal environment for conducting observational research. This setting ensured robust diagnostic practices, standardized laboratory procedures, and reliable patient evaluation throughout the study period. The present study was designed as a cross-sectional observational investigation and was conducted in the Department of Respiratory Medicine, Gandhi Medical College, Secunderabad, over 18 months from January 2021 to June 2022.

Study Population

A total of 60 patients with clinically and radiologically confirmed pleural effusion were recruited after obtaining written informed consent. Participants were selected using a systematic approach. All adults presenting to the Department of Respiratory Medicine with newly diagnosed pleural effusion during the study period were screened. Eligibility was confirmed through clinical assessment, chest radiography, and ultrasound findings. Those meeting the inclusion criteria and providing written informed consent were enrolled. Patients with empyema, hemorrhagic effusion, or underlying hepatic dysfunction were excluded to ensure clean biochemical comparisons.

Study Size

A total of 60 patients were included based on the average monthly case load of pleural effusion in the department and the feasibility within the 18-month study period. Previous regional studies evaluating bilirubin ratios and Light's criteria have used sample sizes ranging between 50 and 80, indicating that a cohort of 60 provides sufficient variability for comparison of diagnostic performance. Given the observational design, the objective was to generate



reliable estimates of accuracy rather than test small-effect hypotheses; therefore, a pragmatic sample size approach was adopted. This number was adequate to compare sensitivity, specificity, and overall diagnostic accuracy without compromising statistical validity.

Inclusion criteria

Age above 18 years.

Patients with clinical and radiological evidence of pleural effusion willing to participate.

Exclusion criteria

Patients with hemorrhagic effusion or empyema.

Individuals with abnormal liver function tests, deranged serum bilirubin, or hypoproteinemia.

Clinical Evaluation

All participants underwent detailed history taking, physical examination, and baseline investigations, including complete blood picture, ESR, random blood sugar, renal and liver function tests, urine examination, ECG, chest radiography, and ultrasonography wherever indicated.

Bias and Measures for Minimization

Several steps were taken to minimize potential bias during data collection and analysis. Consecutive eligible patients were included to reduce selection bias. Uniform procedures were followed for thoracentesis, sample handling, and laboratory analysis to prevent measurement bias. Classification of exudates and transudates was based on predefined clinical, biochemical, and radiological criteria to avoid misclassification bias. The investigators adhered to standardized data entry formats, and statistical analysis was performed using coded identifiers to limit observer and analytical bias.

Pleural Fluid Analysis

Thoracentesis was performed under aseptic precautions. Pleural fluid samples were analyzed for total protein (Biuret method), bilirubin (Diazotization method), and lactate dehydrogenase (LDH). Additional cytological examination and culture were carried out for diagnostic confirmation.

Simultaneous serum samples were obtained to calculate pleural/serum ratios.

Diagnostic Classification

Final diagnosis was established by integrating clinical, biochemical, radiological, and microbiological findings:

Tubercular effusion: classic clinical features, positive AFB smear, high ADA, or response to therapy.

Parapneumonic effusion: fever with productive cough, positive pleural fluid/sputum culture.

Malignant effusion: positive cytology, pleural biopsy, or evidence of a primary malignancy.

Transudates: due to cardiac, hepatic, or renal causes based on clinical findings, imaging, and biochemical support.

Patients were further classified into exudates and transudates using Light's criteria and pleural fluid/serum bilirubin ratio. Protein and LDH ratios were also assessed.

Statistical Analysis

Data were entered in Microsoft Excel and analyzed using SPSS version 26.0. Continuous variables were expressed as mean \pm standard deviation, and categorical data as percentages. Student's *t*-test. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated. A *p*-value <0.05 was considered statistically significant.

Ethical Consideration

The study protocol was reviewed and approved by the Institutional Ethics Committee of Gandhi Medical College, Secunderabad. All participants provided written informed consent prior to enrolment. Confidentiality and patient privacy were strictly maintained throughout the study in accordance with the Declaration of Helsinki guidelines.

Results

Participant Flow Diagram

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A total of 74 individuals with suspected pleural effusion were screened during the study period. Of these, 66 patients met the initial clinical and radiological eligibility criteria and were examined

further. Six individuals were excluded because they had hemorrhagic effusion ($n = 3$), empyema ($n = 2$), or markedly deranged liver function tests ($n = 1$). The remaining 60 participants provided written informed consent and were enrolled. All 60 patients completed the required investigations, and none were lost to analysis. Thus, the final analysis was performed on all 60 enrolled participants.

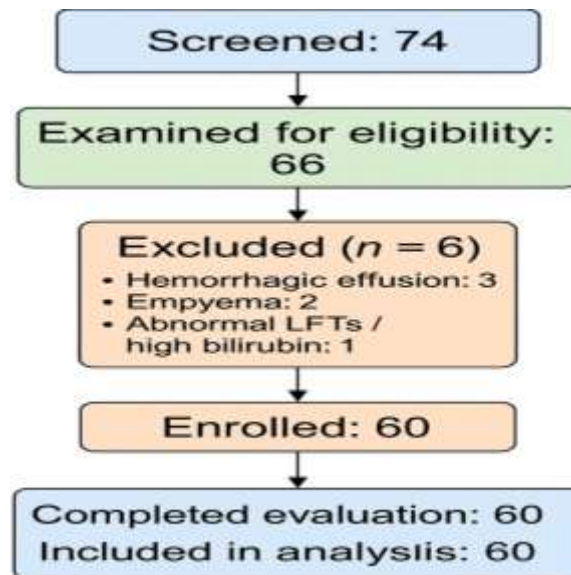


Figure 1: Participant Flow Diagram

A total of 60 patients with pleural effusion were evaluated, of whom 33 (55%) were classified as exudates and 27 (45%) as transudates (Table 1).

Demographic Characteristics

Exudative effusions were most frequently observed in the 31–50 years age group, accounting for 72.7%

of all exudates. Conversely, transudative effusions predominated in the 51–70 years category (47.4%). The mean age was comparatively lower among patients with exudates. Females comprised 56.7% of the study cohort, although exudative effusions were more common in males (57.5%) than in females (42.4%) (Table 1).

Table 1. Demographic Profile of Study Subjects (n=60)

Variable	Exudates (n=33)	Transudates (n=27)	Total (%)
Age Distribution (years)			
18–30	1 (3.1%)	3 (11.1%)	4 (6.7%)
31–40	7 (21.2%)	1 (3.7%)	8 (13.3%)
41–50	17 (51.5%)	9 (33.3%)	26 (43.3%)
51–60	8 (24.2%)	11 (40.7%)	19 (31.7%)
61–70	0 (0%)	2 (7.4%)	2 (3.3%)
>70	0 (0%)	1 (3.7%)	1 (1.7%)
Gender Distribution			

Male	19 (57.5%)	7 (25.9%)	26 (43.3%)
Female	14 (42.4%)	20 (74.1%)	34 (56.7%)

Clinical Evaluation

Baseline laboratory and clinical parameters were recorded for all participants. The mean hemoglobin level was 11.4 ± 1.8 g/dL, and 42% of the patients had mild anemia. Total leukocyte count averaged $9,300 \pm 2,150$ cells/mm³, while neutrophilic predominance was noted in 38% of the subjects. Platelet counts remained largely within the normal range ($2.8 \pm 0.7 \times 10^5$ /mm³). Urine examination was normal in 88% of the participants, and no significant proteinuria or active sediment was detected. Random blood sugar values showed a mean of 126 ± 28 mg/dL, with 14 patients demonstrating mild hyperglycemia

at the time of evaluation. These findings served as baseline clinical indicators prior to classification of the effusion.

Etiological Distribution

Among exudative effusions, tuberculosis emerged as the most common etiology (48.5%), followed by malignant pleural effusion (36.4%) and parapneumonic effusion (15.1%). In contrast, transudates were most often associated with congestive cardiac failure (44.5%), chronic liver disease (37%), and chronic kidney disease (18.5%) (Table 2).

Table 2. Etiological Distribution of Pleural Effusion

Etiology	Exudates (n=33)	(%)	Transudates (n=27)	(%)
Tuberculosis	16	48.5	–	–
Malignant	12	36.4	–	–
Parapneumonic	5	15.1	–	–
Congestive Cardiac Failure	–	–	12	44.5
Chronic Liver Disease	–	–	10	37.0
Chronic Kidney Disease	–	–	5	18.5

Biochemical Profile

Biochemical analysis demonstrated that the mean pleural fluid/serum bilirubin ratio was significantly higher in exudates (0.74 ± 0.04) compared to

transudates (0.32 ± 0.16 ; $p < 0.001$). Similarly, the pleural fluid/serum protein ratio (0.54 ± 0.10 vs. 0.42 ± 0.12 ; $p < 0.001$) and pleural fluid/serum LDH ratio (0.75 ± 0.17 vs. 0.47 ± 0.16 ; $p < 0.001$) were markedly elevated in exudates, with all differences being statistically significant (Table 3).

Table 3. Biochemical Characteristics of Pleural Fluid and Serum

Parameter	Exudates (Mean \pm SD)	Transudates (Mean \pm SD)	p-value
Pleural Fluid / Serum Bilirubin Ratio	0.74 ± 0.04	0.32 ± 0.16	<0.001
Pleural Fluid / Serum Protein Ratio	0.54 ± 0.10	0.42 ± 0.12	<0.001
Pleural Fluid / Serum LDH Ratio	0.75 ± 0.17	0.47 ± 0.16	<0.001



Diagnostic Performance of Criteria

In relation to final clinical diagnosis, Light's criteria and the pleural fluid/serum bilirubin ratio each correctly classified 32 of 33 exudates (96.9%), misclassifying only one case. By comparison, the pleural fluid/serum protein ratio and LDH ratio misclassified 6 (15.2%) and 5 (12.1%) exudates, respectively. For transudates, the bilirubin ratio

achieved the highest diagnostic accuracy, correctly identifying 26 of 27 cases (96.2%), whereas Light's criteria correctly classified 25 of 27 cases (92.5%) (Table 4).

Overall, the pleural fluid/serum bilirubin ratio achieved an accuracy of 96.67%, slightly superior to Light's criteria (95%), particularly due to its higher specificity in identifying transudative effusions (Table 4).

Table 4. Diagnostic Accuracy of Various Criteria for Identifying Exudates

Criteria	Correctly Classified as Exudate	Misclassified as Transudate
Light's Criteria	32 (96.9%)	1 (3.1%)
Pleural Fluid / Serum Bilirubin Ratio	32 (96.9%)	1 (3.1%)
Pleural Fluid / Serum Protein Ratio	27 (84.8%)	6 (15.2%)
Pleural Fluid / Serum LDH Ratio	28 (87.9%)	5 (12.1%)

Discussion

This study evaluated the diagnostic utility of the pleural fluid/serum bilirubin ratio in distinguishing exudative from transudative pleural effusions and compared its performance with Light's criteria. The findings show that exudates were more common than transudates, with tuberculosis and malignancy emerging as the predominant etiologies. This distribution mirrors regional disease patterns where infectious causes and cancer contribute significantly to pleural morbidity [6]. In contrast, transudative effusions mainly resulted from cardiac failure, chronic liver disease, and renal dysfunction, reflecting broader global observations [8–11].

Younger individuals accounted for a larger share of exudates, whereas transudates were more frequent in older adults. This likely reflects the natural rise in chronic systemic illnesses with age. Although the overall cohort had more females, exudative effusions occurred more often in males, a trend that aligns with previously reported demographic tendencies [9].

The biochemical profile demonstrated clear separation between the two categories of effusion. The pleural fluid/serum bilirubin ratio was markedly higher in exudates and showed a strong discriminatory ability. Ratios of protein and LDH also differed significantly between exudates and transudates; however, the bilirubin ratio produced the

most consistent distinction. This study found that the bilirubin ratio offered a diagnostic accuracy of 96.67%, slightly higher than Light's criteria, which achieved 95%. The enhanced specificity for identifying transudates suggests that the bilirubin ratio may be particularly reliable when classical criteria risk misclassification.

Interpretation of these observations suggests that bilirubin movement across the pleura follows patterns similar to protein diffusion during inflammatory processes. Higher permeability in exudative states likely increases bilirubin flux, leading to elevated pleural/serum ratios. This mechanism supports the biological plausibility of the test and reinforces its usefulness in differentiating effusions.

Light's criteria misclassified a small number of cases in this study, echoing well-documented concerns that diuretic therapy and altered systemic fluid status may shift protein and LDH values, creating "pseudoexudates" [10–11]. In contrast, the bilirubin ratio remained stable, reducing false-positive exudate classifications. This suggests that bilirubin behaves more predictably than protein and LDH in the presence of systemic fluid shifts and may serve as a strong adjunctive marker.

The pattern of etiologies observed tuberculosis leading among exudates, cardiac failure among transudates also strengthens the interpretation that the bilirubin ratio can accommodate diverse clinical



backgrounds. In regions with a high burden of TB and malignancy, more accurate classification tools may help reduce unnecessary invasive procedures.

Generalizability

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The findings of this study are particularly relevant to regions where tuberculosis and chronic infectious diseases remain common causes of exudative pleural effusions. The pleural fluid/serum bilirubin ratio, being simple and inexpensive, can be applied in both resource-limited and advanced healthcare settings. However, as the sample size was modest and drawn from a single tertiary care center, caution is needed in extrapolating results universally. Larger, multicentric studies are essential to enhance external validity and confirm applicability.

Conclusion

The present study demonstrates that the pleural fluid/serum bilirubin ratio is a reliable tool for differentiating exudative from transudative pleural effusions. While Light's criteria continue to serve as the reference standard, they are prone to misclassification, particularly in diuretic-treated cardiac failure. In contrast, the bilirubin ratio showed comparable sensitivity with superior specificity and overall diagnostic accuracy. Its ease of estimation, low cost, and applicability in routine laboratories make it a valuable adjunct to conventional criteria. Adoption of this parameter may improve diagnostic precision, especially in resource-constrained settings. Multicentric studies with larger cohorts are recommended to validate and standardize cut-off values.

Limitations

This study was limited by its relatively small sample size and single-center design, which may restrict external validity. Diagnostic accuracy could not be assessed against pleural biopsy in all cases, potentially affecting etiological confirmation. The impact of prior treatment, such as diuretic therapy in cardiac failure, may also have influenced biochemical parameters. Additionally, the absence of long-term follow-up limited assessment of prognostic implications. Larger, multicentric studies are warranted to strengthen these findings and enhance generalizability.

Recommendations

The pleural fluid/serum bilirubin ratio should be considered as a reliable adjunct to Light's criteria in routine clinical practice for differentiating pleural effusions. Its simplicity, cost-effectiveness, and reproducibility make it particularly suitable for use in resource-limited settings where advanced investigations may not be feasible. Integration of this parameter into diagnostic protocols may reduce misclassification, especially in patients on diuretic therapy. Future large-scale, multicentric studies are strongly recommended to validate cut-off thresholds, establish uniform diagnostic standards, and explore its utility in diverse patient populations with varying etiologies.

Acknowledgements

The authors express their sincere gratitude to the faculty and staff of the Department of Respiratory Medicine, Gandhi Medical College, Secunderabad, for their constant support and guidance during this study. We extend heartfelt thanks to all the patients who consented to participate, without whose cooperation this research would not have been possible. Special acknowledgment is given to the Institutional Ethics Committee for their valuable oversight. Finally, we appreciate the assistance of colleagues and laboratory staff who contributed to the smooth conduct of clinical and biochemical investigations.

Abbreviations

ADA – Adenosine Deaminase;
AFB – Acid Fast Bacilli;
CCF – Congestive Cardiac Failure;
CKD – Chronic Kidney Disease;
CLD – Chronic Liver Disease;
ECG – Electrocardiogram;
ESR – Erythrocyte Sedimentation Rate;
LDH – Lactate Dehydrogenase;
LFT – Liver Function Test;
NPV – Negative Predictive Value;
PPV – Positive Predictive Value;
SD – Standard Deviation;
SPSS – Statistical Package for the Social Sciences.

Source of funding:

Study has no funding



Conflict of interest:

Author declares no conflict of interest.

Author contributions

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JM-Concept and design of the study, results interpretation, review of literature and preparing first draft of manuscript. Statistical analysis and interpretation, revision of manuscript. SDR-Concept and design of the study, results interpretation, review of literature and preparing first draft of manuscript, revision of manuscript. BNJ-Review of literature and preparing first draft of manuscript. Statistical analysis and interpretation. PJ- preparing first draft of manuscript. Statistical analysis and interpretation, revision of manuscript

Data availability

Data available on request

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Student's Journal of Health Research Africa
e-ISSN: 2709-9997, p-ISSN: 3006-1059
Vol.6 No. 9 (2025): September 2025 Issue
<https://doi.org/10.51168/sjhrafrica.v6i9.2154>
Original Article

PUBLISHER DETAILS

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Student's Journal of Health Research (SJHR)

(ISSN 2709-9997) Online

(ISSN 3006-1059) Print

Category: Non-Governmental & Non-profit Organization

Email: studentsjournal2020@gmail.com

WhatsApp: +256 775 434 261

Location: Scholar's Summit Nakigalala, P. O. Box 701432,
Entebbe Uganda, East Africa

