

EVALUATION OF PLEURAL FLUID CYTOLOGY AND ITS ROLE IN THE CLINICAL APPROACH TO PLEURAL EFFUSION: A PROSPECTIVE STUDY

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Received : 15/07/2025
Received in revised form : 05/09/2025
Accepted : 23/09/2025

Keywords:

Pleural effusion, Cytology, Tuberculous effusion, Malignant effusion, Diagnostic utility.

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DOI: 10.47009/jamp.2025.7.6.20

Source of Support: Nil,

Conflict of Interest: None declared

Int J Acad Med Pharm
2025; 7 (6); 106-111



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ABSTRACT

Background: Pleural effusion is a common clinical problem with diverse etiologies including tuberculosis (TB), malignancy, parapneumonic infections, and systemic disorders. Cytological examination of pleural fluid offers a simple, rapid, and minimally invasive diagnostic tool, particularly valuable in resource-limited, TB-endemic settings. This study aimed to evaluate the cytological spectrum of pleural effusions and assess the diagnostic utility of pleural fluid cytology in guiding clinical decision-making. **Materials and Methods:** This prospective observational study included 316 patients presenting with pleural effusion at a tertiary care center. Detailed clinical history, physical examination, and radiological findings were recorded. Pleural fluid was aspirated under aseptic conditions, and gross appearance, biochemical parameters, and cytological examination were performed. Cytological diagnosis was correlated with the final diagnosis established by clinical, microbiological, histopathological, and radiological data. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated for cytology across major etiologies. **Result:** The mean age of patients was 46.8 ± 17.2 years, with a male predominance (65.2%). The most common presenting symptom was cough (75.9%), followed by dyspnea (66.5%) and chest pain (56.3%). Exudative effusions predominated (75.3%), with TB being the most frequent etiology (32.3%), followed by malignant effusions (22.1%) and parapneumonic effusions (14.6%). Lymphocyte predominance was seen in 78.4% of exudates. Malignant effusions were mostly adenocarcinomas (48.6%), with cytology yielding a positivity rate of 76.1%. Diagnostic utility analysis demonstrated that cytology had the highest sensitivity for TB (86.3%) and malignant effusions (76.1%), with high NPVs (88.3% and 81.7%, respectively), though specificity and PPV remained modest. Overall diagnostic accuracy was 53.2% for malignancy, 61.4% for TB, 46.2% for parapneumonic effusions, and 14.6% for transudates. **Conclusion:** Pleural fluid cytology remains a valuable first-line diagnostic investigation, particularly for TB and malignant effusions in TB-endemic regions. Its high sensitivity and NPV make it an excellent screening tool, but low specificity necessitates confirmatory testing using cell blocks, immunocytochemistry, or pleural biopsy for definitive diagnosis. Integration of molecular assays (GeneXpert/CBNAAT) and biochemical markers (ADA) into diagnostic algorithms can further enhance specificity and guide appropriate management.

INTRODUCTION

Pleural effusion, the abnormal accumulation of fluid in the pleural space, is a common clinical presentation with an estimated incidence of around 320 per 100,000 population annually worldwide.^[1] The causes are diverse, ranging from benign systemic

diseases (e.g., congestive heart failure, cirrhosis, nephrotic syndrome) to infections (notably tuberculosis) and malignancies. In high-burden countries such as India, tuberculous pleural effusion accounts for up to 60% of exudative effusions, whereas malignant pleural effusion (MPE) is

responsible for a significant proportion of recurrent effusions.^[2,3]

Cytological examination of pleural fluid is a minimally invasive, cost-effective, first-line diagnostic tool. It not only helps differentiate between transudative and exudative effusions but also plays a crucial role in identifying malignant cells, thereby reducing the need for more invasive procedures such as pleural biopsy or thoracoscopy.^[4] The diagnostic yield of pleural fluid cytology varies, with reported sensitivities ranging from 40–87% depending on tumour type and sample quality.^[5] Adenocarcinomas have the highest detection rate (up to 80–85%), whereas mesothelioma and squamous cell carcinoma have lower yields (<40%).^[6]

Early and accurate cytological diagnosis allows clinicians to initiate specific treatment such as antitubercular therapy or oncologic management without delay, improving patient outcomes and reducing morbidity.^[7] Furthermore, correlation of cytology with clinical and radiological findings enhances diagnostic accuracy and guides further investigation in cases where cytology is negative but suspicion remains high. So, this study aimed to evaluate the cytological features of pleural effusion samples in our setting and assess their utility in guiding clinical management.

MATERIALS AND METHODS

Study Design and Setting: This was a hospital-based, prospective, observational study carried out in the Department of Pathology, at a tertiary care teaching hospital. The study was conducted over a period of 24 months from July 2023 to July 2025. Institutional Ethics Committee approval was obtained before the commencement of the study, and written informed consent was taken from all participants prior to sample collection.

Study Population: All patients presenting to the Department of Medicine or Respiratory Medicine with clinically and radiologically confirmed pleural effusion during the study period were considered for inclusion. A total of 316 patients were enrolled. Inclusion criteria were patients of all ages and both sexes with pleural effusion of undetermined etiology undergoing diagnostic thoracentesis. Patients with minimal effusions not amenable to aspiration, those who had already undergone therapeutic procedures elsewhere, and those who refused consent were excluded. Clinical details including age, sex, presenting complaints, past medical history, and relevant radiological findings were recorded in a structured proforma.

Sample Collection: Pleural fluid was aspirated under all aseptic precautions by thoracentesis, usually in the sitting position, after confirming the site by clinical examination and imaging (ultrasonography or chest X-ray). Approximately 20–50 mL of pleural fluid was collected in sterile containers. The physical characteristics of the aspirate such as volume, color,

and appearance (clear, straw-colored, turbid, hemorrhagic, purulent, or chylous) were noted at the time of collection.

Laboratory Processing and Cytological Examination: The pleural fluid samples were processed without delay. Each sample was centrifuged at 1500 revolutions per minute for 10 minutes. The supernatant was discarded and direct smears were prepared from the cell button. Smears were fixed in 95% ethanol for Papanicolaou staining and air-dried smears were stained with May–Grünwald–Giemsa (MGG). In cases where infection was suspected, Ziehl–Neelsen (ZN) stain for acid-fast bacilli was performed. Special stains were employed wherever indicated.

Cell block preparation was done for cases where cytology smears showed atypical cells or were suspicious for malignancy but not conclusive. The sediment was fixed in 10% buffered formalin, processed routinely, and paraffin-embedded. Sections were stained with hematoxylin and eosin and examined microscopically for architectural patterns, which helped in confirming the diagnosis and subtyping of malignancy where feasible.

Cytological Classification: Cytological findings were categorized into transudative effusion, exudative effusion of inflammatory or tubercular etiology, and malignant effusion. Transudates showed low cellularity with few mesothelial cells, whereas exudates revealed increased cellularity with neutrophil or lymphocyte predominance depending on the underlying pathology. Malignant effusions were diagnosed by the presence of malignant cells with characteristic cytological features such as high nuclear–cytoplasmic ratio, nuclear pleomorphism, and prominent nucleoli. Wherever possible, malignant effusions were subtyped as adenocarcinoma, squamous cell carcinoma, small cell carcinoma, or metastatic carcinoma.

Clinical Correlation and Final Diagnosis: Cytological findings were correlated with clinical features, radiological findings, biochemical parameters (protein, LDH, glucose, ADA), and follow-up investigations including pleural biopsy or histopathology when available. This correlation allowed confirmation of the final diagnosis and assessment of the diagnostic utility of cytology in the clinical decision-making process.

Statistical Analysis: All data were entered in Microsoft Excel and analyzed using SPSS version 20.0. Descriptive statistics were used to summarize the clinical profile and cytological findings. Diagnostic performance of pleural fluid cytology was calculated in terms of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) using the final confirmed diagnosis as the gold standard. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were expressed as frequencies and percentages. Statistical significance was assessed using Chi-square test or Fisher's exact test as

appropriate, and a p-value <0.05 was considered statistically significant.

RESULTS

Among the 316 patients with pleural effusion, the majority belonged to the 41–60 years age group (37.3%), followed by 21–40 years (32.3%), with a mean age of 46.8 ± 17.2 years. Males constituted 65.2% (n = 206) of the study population, resulting in

a male-to-female ratio of approximately 1.9:1, reflecting a higher prevalence of pleural effusions among males in this cohort [Table 1].

Cough (75.9%) was the most frequent presenting symptom, followed by dyspnea (66.5%) and chest pain (56.3%). Systemic symptoms such as fever (42.4%) and weight loss/night sweats (30.4%) were also commonly reported, suggesting an underlying infective or chronic inflammatory etiology in a significant subset. Hemoptysis was relatively uncommon (8.9%) [Table 2].

Table 1: Demographic Profile of Patients with Pleural Effusion (n = 316).

Variables	Frequency	%
Age Group (years)		
<20	28	8.9
21–40	102	32.3
41–60	118	37.3
>60	68	21.5
Mean Age (years)	46.8 ± 17.2	
Gender		
Male	206	65.2
Female	110	34.8

Table 2: Clinical Presentation of Patients (n = 316).

Clinical Symptom/Sign	Frequency	%
Cough	240	75.9
Dyspnea	210	66.5
Chest Pain	178	56.3
Fever	134	42.4
Weight Loss/Night Sweats	96	30.4
Hemoptysis	28	8.9

A large proportion of samples (67.1%) yielded >20 mL of pleural fluid, allowing adequate cytological analysis. Grossly, the fluid was most commonly clear or straw-colored (55.1%), followed by hemorrhagic

(25.3%), turbid (13.3%), purulent (3.8%), and chylous (2.5%), indicating a wide spectrum of underlying causes ranging from transudates to infectious and malignant effusions [Table 3].

Table 3: Volume and Gross Appearance of Pleural Fluid (n = 316).

Variables	Frequency	%
Volume of Fluid Collected (mL)		
<10 mL	20	6.3
10–20 mL	84	26.6
>20 mL	212	67.1
Appearance		
Clear/Straw-Colored	174	55.1
Hemorrhagic	80	25.3
Turbid/Cloudy	42	13.3
Purulent	12	3.8
Chylous	8	2.5

Exudative effusions were predominant, with tuberculous effusion being the most common (32.3%), followed by nonspecific/parapneumonic effusion (14.6%). Transudative effusions accounted for 24.7% of cases. Among exudates (n = 148), lymphocyte predominance was seen in 78.4% of

cases, consistent with tuberculous etiology, whereas neutrophil predominance was observed in 17.6% and mixed cell pattern in 4%. Malignant effusions were confirmed in 22.1% of cases, and 6.3% were reported as suspicious for malignancy but inconclusive [Table 4].

Table 4: Cytological Classification of Pleural Effusions (n = 316).

Cytological Category	Frequency	%
Transudate (CHF, Cirrhosis, Nephrotic Syndrome)	78	24.7
Exudate – Nonspecific/Parapneumonic	46	14.6
Exudate – Tuberculous (Lymphocyte Predominant $\pm$ Granulomas)	102	32.3
Cell Type Predominance in Exudate (n=148)		
Lymphocyte Predominant (>50%)	116	78.4
Neutrophil Predominant (>50%)	26	17.6
Mixed/Other	6	4
Suspicious for Malignancy (Atypical Cells, Inconclusive)	20	6.3

Malignant (Confirmed)	70	22.1
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Among the 70 malignant cases, adenocarcinoma was the most common type (48.6%), followed by squamous cell carcinoma (14.3%) and metastatic deposits from breast and gastrointestinal/other primaries (11.4% each). Small cell carcinoma (5.7%)

and mesothelioma (2.9%) were less frequently detected. This distribution highlights the predominance of lung primary adenocarcinoma as the leading cause of malignant effusions in this cohort [Table 5].

Table 5: Distribution of Malignant Effusions by Cytological Type (n = 70).

Cytological Diagnosis	Frequency	%
Adenocarcinoma (Primary Lung)	34	48.6
Squamous Cell Carcinoma	10	14.3
Small Cell Carcinoma	4	5.7
Mesothelioma	2	2.9
Metastatic Breast Carcinoma	8	11.4
Metastatic Ovarian Carcinoma	4	5.7
Metastatic GI / Others	8	11.4

Pleural fluid cytology was positive in 86.3% of tuberculous effusions, 78.3% of parapneumonic/empyema cases, and 76.1% of malignant effusions, whereas only 2.6% of

transudates showed cytological positivity. Overall, cytology yielded a positive diagnosis in 62% (n = 196) of cases, underscoring its utility as a first-line diagnostic tool [Table 6].

Table 6: Correlation of Cytology with Final Diagnosis (n = 316).

Final Diagnosis (Gold Standard)	Cytology Positive	Cytology Negative	Total
Tuberculous	88	14	102
Parapneumonic/Empyema	36	10	46
Transudate	2	76	78
Malignant	70	22	92
Total	196	122	316

Cytology demonstrated the highest sensitivity for tuberculous effusions (86.3%) and malignant effusions (76.1%), with high negative predictive values (88.3% and 81.7%, respectively), making it a reliable screening test for excluding these conditions. However, specificity was relatively low across all

categories, especially for parapneumonic effusions (40.7%) and transudates (18.5%), suggesting that cytology alone cannot definitively confirm the diagnosis and should be interpreted alongside clinical and radiological findings [Table 7].

Table 7: Diagnostic Utility of Pleural Fluid Cytology in Various Etiologies (n = 316).

Etiology	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic Accuracy (%)
Malignant	76.1	43.8	35.7	81.7	53.2
Tuberculous	86.3	49.5	44.9	88.3	61.4
Parapneumonic/Empyema	78.3	40.7	18.4	91.7	46.2
Transudate	2.6	18.5	1	36.7	14.6

Positive Predictive Value: PPV; Negative Predictive Value: NPV

DISCUSSION

In the present study of 316 patients, pleural effusion was most frequently observed in the 41–60-year age group (37.3%), with a mean age of 46.8 ± 17.2 years, and a clear male predominance (male-to-female ratio $\approx 1.9:1$). These findings are consistent with previous Indian studies by Contractor et al., and Rani et al., where a similar demographic pattern has been reported, reflecting both higher exposure to occupational risk factors and higher prevalence of tuberculosis (TB) and smoking-related lung disease among men.^[8,9] Clinical presentation was dominated by cough (75.9%), dyspnea (66.5%), and chest pain (56.3%), which together represent the classic triad of pleural effusion symptomatology. Constitutional symptoms such as fever and weight loss were also

frequent, suggesting a high burden of chronic infective causes, particularly TB, which continues to be the leading cause of exudative effusions in endemic regions.^[10,11] Hemoptysis, although reported in 8.9% of cases, was a less common feature and typically pointed toward pulmonary TB or malignant etiology.

Most pleural fluid samples were of adequate volume (>20 mL in 67.1% cases), which likely contributed to good diagnostic yield on cytology. The fluid was clear or straw-colored in over half the cases (55.1%), while hemorrhagic effusions were seen in 25.3%, most often associated with malignancy or TB with pleural vascular involvement, which were similar to the studies by Goyal et al., and Sharma et al.^[12,13] Purulent and chylous fluids were uncommon, correlating with the relatively lower incidence of

empyema and lymphatic obstruction in our series. Cytological classification revealed that exudative effusions were more common than transudates, with TB accounting for 32.3% of cases, followed by nonspecific/parapneumonic effusions (14.6%). Lymphocyte predominance was observed in 78.4% of exudative samples, consistent with the classical cytological pattern of tuberculous effusion.^[14] Transudates constituted 24.7% of cases, usually secondary to congestive heart failure, cirrhosis, or nephrotic syndrome, where cytology is typically noncontributory apart from excluding infection or malignancy.

Malignant pleural effusions accounted for 22.1% of all cases, aligning with Indian studies by Dharwadkar et al., and Saha et al., that report malignancy as the second most common cause of exudative effusion after TB.^[15,16] Adenocarcinoma was the predominant cytological type (48.6%), followed by squamous cell carcinoma, metastatic breast carcinoma, and gastrointestinal primaries. This distribution mirrors global literature, where adenocarcinoma is reported as the leading cause of malignant pleural effusion, owing to its high tendency to exfoliate malignant cells into pleural fluid.^[17] Cytology achieved a positivity rate of 76.1% in malignant effusions, which is comparable to studies by Loveland et al., and Paintal et al., who reported diagnostic sensitivities of 70–80% using conventional cytology.^[18,19] The remaining false negatives may be explained by paucicellular effusions, extensive fibrosis, or tumour types such as mesothelioma or sarcomas, which are known to have low exfoliative potential.^[20]

The overall cytology positivity rate in our cohort was 62%, with the highest yield observed for tuberculous effusions (86.3%) followed by parapneumonic/empyema (78.3%) and malignant effusions (76.1%). Only 2.6% of transudates were positive, underscoring the limited role of cytology in transudative effusions except for excluding atypical causes. The calculated diagnostic utility metrics demonstrated that cytology had good sensitivity for TB (86.3%) and malignancy (76.1%) with high negative predictive values (88.3% and 81.7%, respectively), making it a reliable initial screening test to rule out these conditions. However, specificity and positive predictive value were relatively low across all groups, especially for parapneumonic effusions, suggesting the possibility of false positives due to reactive mesothelial hyperplasia or nonspecific inflammatory changes.^[21,22] These findings are consistent with studies by Mulkalwar et al., and Puskuru et al., reporting specificity ranging from 40–60% for cytology alone, which can be improved by adjunctive techniques such as cell block preparation, immunocytochemistry, and image-guided biopsy.^[23,24]

Limitations and Suggestions

The present study, while demonstrating the diagnostic value of pleural fluid cytology, has certain limitations. The relatively lower specificity and positive predictive value may, in part, reflect the

inclusion of cases reported as “suspicious” or “atypical,” as well as cytological changes due to reactive mesothelial hyperplasia or inflammatory pleuritis, which can mimic malignancy and lead to overdiagnosis. Misclassification bias cannot be ruled out, particularly in paucicellular specimens or cases with equivocal cytomorphology. The use of adjunctive techniques such as cell block preparation, immunocytochemistry, and immunohistochemistry could improve diagnostic specificity by enabling better architectural evaluation and marker-based typing of malignant cells.

Another limitation is the underrepresentation of certain tumor types such as mesothelioma and small-cell carcinoma, which are known to have poor cytologic detection due to low exfoliation rates. Future studies should stratify cytological yield by tumor histology more comprehensively to better define the utility of cytology across different malignancies.

Finally, in TB-endemic regions such as India, reliance on cytology alone may delay diagnosis in cases with low bacillary load or nonspecific cytological features. Integration of ancillary molecular tests such as GeneXpert or CBNAAT, along with biochemical markers like adenosine deaminase (ADA) and LDH, could enhance diagnostic accuracy and allow for earlier, more targeted management. Prospective multicenter studies using combined diagnostic algorithms are recommended to validate these findings and optimize the clinical approach to pleural effusions.

CONCLUSION

In summary, our findings support that cytological evaluation of pleural fluid remains a useful, relatively low-cost, minimally invasive tool in the diagnostic approach to pleural effusions in India. It performs particularly well for tuberculosis and adenocarcinomatous malignant effusions, though its limitations in specificity and positive predictive power mean it should be part of a multimodal diagnostic strategy rather than a stand-alone test. Further work incorporating cell blocks, immunocytochemical staining, and molecular assays may help improve diagnostic precision.

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