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Original Research Article

EVALUATION OF UNDIAGNOSED EXUDATIVE PLEURAL EFFUSION WITH SPECIAL REFERENCE TO MEDICAL THORACOSCOPY: A PROSPECTIVE STUDY

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ABSTRACT

Background: Undiagnosed exudative pleural effusion poses a significant diagnostic challenge, particularly in tuberculosis (TB)-endemic regions like India, where malignancy and TB are the leading etiologies. Medical thoracoscopy has emerged as a safe and effective diagnostic tool, offering high diagnostic accuracy with minimal complications. This study is aimed to evaluate the diagnostic yield, safety, of medical thoracoscopy in patients with undiagnosed exudative pleural effusions. **Materials and Methods:** A prospective study was conducted on 75 patients with undiagnosed exudative pleural effusion who underwent medical thoracoscopy. Demographic, clinical, radiological, and pleural fluid biochemical data were collected. Thoracoscopic findings, histopathological results, and complications were analyzed. **Results**: The mean age of the cohort was 56.79 years, with a male predominance (60%). Common symptoms included cough (94.6%), chest pain (93.3%), and dyspnea (88%). Massive pleural effusion (88%) and unilateral involvement (96%) were the most common presentations. Hemorrhagic pleural fluid (50.7%) and low pleural fluid sugar levels (74.97 mg/dL) were significantly associated with malignancy (p =0.03), while sago grain appearance on thoracoscopy was pathognomonic for TB (26.7%). The overall diagnostic yield of medical thoracoscopy was 93.3%, with metastatic adenocarcinoma (58.6%) and TB (20%) being the most common diagnoses. Minor complications occurred in 18.6% of cases, with no mortality. **Interpretation and Conclusion:** Medical thoracoscopy proved to be a safe and effective procedure for diagnosing undiagnosed exudative pleural effusions, particularly in differentiating malignancy from TB in our study.It was associated with high diagnostic yield and minimal complications Early integration of thoracoscopy into the diagnostic workup can prevent mismanagement, and can facilitate timely and accurate treatment.

INTRODUCTION

Pleural effusion, a pathological accumulation of fluid in the pleural cavity, is a frequently encountered clinical condition. Exudative pleural effusion, in particular, is commonly caused by tuberculosis, malignancy, and pneumonia.[1,2] The diagnosis of exudative pleural effusion typically relies on pleural fluid analysis, including cytology,gram stain, culture sensitivity, and biochemical parameters, as per Light's criteria or Extended Light's criteria or CBNAAT (Cartridge-Based Nucleic Acid Amplification Test).[3] However, despite these diagnostic tools, approximately 25% of patients with exudative pleural effusion remain undiagnosed even after thorough physical examination and pleural fluid analysis.[4]

Pleural biopsy, which provides a tissue diagnosis, is considered a definitive diagnostic tool for exudative pleural effusion and is crucial for guiding appropriate management and treatment.[5] Among the available techniques, medical thoracoscopy has emerged as a minimally invasive procedure with significant diagnostic and therapeutic utility. It is characterized by a straightforward technique, low risk, short operation time, minimal patient discomfort, and high diagnostic sensitivity, particularly for malignant pleural effusions, where its sensitivity exceeds 90%.[5,6,7]

The primary aim of this study was to evaluate the diagnostic yield of medical thoracoscopy in patients presenting with undiagnosed exudative pleural effusion. Additionally, the study aimed to assess the safety profile of the procedure and document any complications encountered during or after the intervention.

MATERIALS AND METHODS

Ethical clearance was obtained from the Institutional Ethics comitee (IEC reference no.-1287) .A prospective observational study design was employed. Data were gathered from patients within the Department of Respiratory Medicine at a tertiary care centre. Based on a previous study by Kumar et al (https://doi.org/10.1186/s43168-023-00237-y)(8), and analysing the frequency of findings by thoracoscopy, the minimum sample size was calculated to be 75 in the overall study population considering a Confidence Interval of 95% and power of 80%.(7)The period of the study was from March 2022 to March 2024.Patients with exudative pleural effusion, in whom the diagnosis remains unclear after pleural fluid analysis and who fulfill the inclusion criteria, will undergo medical thoracoscopy. Data will be systematically collected, results will be tabulated, and conclusions will be drawn based on the findings.

Inclusion Criteria

Patients with exudative pleural effusion, where the underlying cause cannot be determined through pleural fluid analysis.

Exclusion Criteria

Transudative effusion or empyma

Patients with coagulopathy or thrombocytopenia

Patients who are HIV, HBsAg, or HCV positive

Hemodynamically unstable patients

Patients with malignant cells detected in pleural effusion

Study Procedure: All participants after obtaining written informed consent will undergo a comprehensive evaluation, including clinical history, physical examination, and laboratory investigations such as hemogram, renal and liver function tests, coagulation profile, viral markers, sputum analysis, and a X-ray/CT scan of the chest. Pleural fluid will be analyzed for cell counts, glucose, protein, lactate dehydrogenase (LDH), adenosine deaminase (ADA), Gram's stain, acid-fast bacillus (AFB) smear, culture, and cytopathology. Patients with exudative pleural effusion (as per Light's criteria) but without a definitive etiologic diagnosis will be included in the study. A total of 75 such patients will be enrolled. Thoracoscopic Procedure will be performed in an operating room. Patients will be positioned in the lateral decubitus position with the healthy side down and arms raised above the head. A single-port thoracoscopic procedure will be performed using a 4 mm rigid telescope (Karl Storz) , and 5mm biopsy forceps. The procedure will be conducted under conscious sedation (midazolam 2–8 mg) and local anesthesia (2% lignocaine infiltration at the incision site).Continuous oxygen supplementation will be provided via nasal cannula at 2–6 L/min, with continuous monitoring of pulse rate, blood pressure and saturation of oxygen. All pleural fluid will be suctioned out, and an artificial pneumothorax will be created by allowing air to enter the pleural space during spontaneous breathing. The pleural cavity will be thoroughly inspected, and any abnormalities will be documented. Pleural adhesions will be gently broken down mechanically, where feasible. Three to six biopsies will be taken from abnormal parietal pleura using an alligator jaw forceps and the lift-and-tear technique. Biopsy samples will be immediately placed in a formalin container for histopathological analysis. Patients will be transferred to the ward after the effects of sedation have worn off. A chest X-ray will be performed after procedure to reassess lung expansion. Pain management will include paracetamol and opioid analgesics as needed. The intercostal tube drainage (ICTD) will be removed when pleural fluid drainage is less than 150 ml per day. Pleural biopsy specimens will be dispatched for histopathological examination and subsequent immunohistochemistry with proper sample identification.

Data will be collected from patients with undiagnosed exudative pleural effusion who underwent medical thoracoscopy. Variables included demographic details (age, gender), clinical symptoms, smoking status, comorbidities, pleural fluid characteristics, thoracoscopy findings, and histopathological results. Data were entered into a structured database (e.g., Microsoft Excel or SPSS) and cross-checked for accuracy. Categorical variables (e.g., gender, smoking status, type of effusion, HPE diagnosis) were expressed as frequencies and percentages. Continuous variables (e.g., age, pleural fluid sugar, LDH, ADA levels) were expressed as mean ± standard deviation (SD) or median (interquartile range, IQR) based on the distribution of data. Graphical representations (e.g., bar charts, pie charts) were used to visualize the distribution of key variables. or normally distributed continuous variables, Student's t-test was used to compare means between two groups (e.g., pleural fluid sugar levels in tubercular vs. malignant effusions).For non-normally distributed data, the Mann-Whitney U test was used. Comparison of proportions: Chi-square test or Fisher's exact test was used to compare categorical variables (e.g., pleural fluid appearance in malignant vs. tubercular effusions).Analysis of variance (ANOVA):One-way ANOVA was used to compare means across more than two groups (e.g., pleural fluid LDH levels across different HPE diagnoses). Logistic regression analysis was performed to identify independent predictors of malignancy (e.g., age, smoking status, pleural fluid LDH levels). Software Used Statistical analysis was performed using SPSS (version 21.0)A p-value <0.05 was considered statistically significant.

RESULTS

56% of patients were aged 50–70 years, 21.3% were 30–50 years, 18.6% >70 years, and 4% were <30 years.60% were male, and 40% were female. Common symptoms included cough (94.6%), chest pain (93.3%), and shortness of breath (88%). Less common symptoms were fever, weight loss, haemoptysis, and hoarseness.66.7% were non-smokers, 26.6% were ex-smokers, and 6.6% were current smokers. The most common comorbidities were COPD (10.6%), systemic hypertension (8%), and type 2 diabetes (8%).88% had massive effusion, 6.6% moderate, and 5.4% encysted.49.8% right-sided, 46.2% left-sided, and 4% bilateral. Common findings included effusion with mass lesions (32.8%) and adjacent lung collapse (20.54%).50.7% hemorrhagic and 49.3% straw yellow. Demographic and clinical characteristics are summarised in Table 1 and 2Pleural fluid Sugar levels: 54.6% between 60–100 mg/dL. LDH levels: 41.3% between 1000–2000 U/L.Lymphocyte-predominant effusion in 88% of cases.(Table 2)Common observations included multiple nodules with thickened pleura (26.6%), hyperemia/neovascularization (28%), and anthracotic pigmentation (20%).

Metastatic adenocarcinoma from the lung was the most common diagnosis, accounting for 58.6% (n=44) predominantly from lung primaries (adenocarcinoma) followed by tubercular accounting for 20% (n=15).Metastatic squamous cell carcinoma from the lung was seen in 5.3% (4 cases).Mesothelioma and metastatic carcinomatous deposits each contributed 4% (3 cases).Metastatic renal cell carcinoma was the least common at 1.3% (n=1).Non-significant findings were reported in 6.6% (5 cases).

IHC analysis revealed TTF1 (56.8%) and Napsin A (18.2%) positivity in adenocarcinoma while P40 and CALR IHC was positive in 100% of cases of squamous cell carcinoma and mesothelioma respectively.(Table 3)Tubercular cases had higher mean sugar levels (122.93 mg/dL) compared to malignant cases. Higher in metastatic adenocarcinoma (1192.09 U/L) compared to tubercular cases (808.67 U/L).Tubercular cases had higher ADA levels (15.88 U/L) than malignant cases.37.2% of metastatic adenocarcinoma cases were smokers. Hemorrhagic effusion was more common in malignant cases (67.3%), while straw yellow effusion was common in tubercular cases (93.3%).(Table 4) Medical thoracoscopy achieved a diagnostic yield of 93.3%, with only 6.7% of cases remaining undiagnosed. Clinical and pleural fluid correlations are summarised in Table 4.

Table 1: Demographic and Clinical Characteristics

Parameter	Category	Number of Patients (n=75)	Percentage (%)
Age Distribution	>70 years	14	18.6
	50–70 years	42	56
	30–50 years	16	21.3
	<30 years	03	4
Gender	Male	45	60
	Female	30	40
Smoking Status	Current smoker	05	6.6
	Ex-smoker	20	26.6
	Non-smoker	50	66.7
Symptoms	Cough	71	94.6
	Chest pain	70	93.3
	Shortness of breath	66	88
	Fever	05	6.7
	Significant weight loss	05	6.7

Table 2: Pleural Effusion Characteristics

Parameter	Category	Number of Cases (n=75)	Percentage (%)
Type of Effusion	Massive effusion	66	88
	Moderate effusion	05	6.6
	Encysted effusion	04	5.4
Site of Effusion	Right	37	49.8
	Left	35	46.2
	Bilateral	03	4
Pleural Fluid Appearance	Straw yellow	37	49.3
	Hemorrhagic	38	50.7
Pleural Fluid Analysis	Sugar <60 mg/dL	20	26.6
	Sugar 60–100 mg/dL	41	54.6
	LDH 1000–2000 U/L	31	41.3
	Lymphocyte-predominant effusion	66	88

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Table 3: Thoracoscopy and Histopathological Findings

Parameter	Category	Number of Cases (n=75)	Percentage (%)
Thoracoscopy Findings	Multiple nodules with thickened pleura	21	26.6
	Multiple nodules with hyperemia/ulceration	20	28
	Sago grain appearance	04	5.3
HPE Diagnosis	Metastatic adenocarcinoma	44	58.6
	Tubercular	15	20
	Mesothelioma	03	4
	Metastatic squamous cell carcinoma	04	5.3
	Non-significant	05	6.6
Parameter	Category	Number of Cases (n=75)	Percentage (%)
Diagnostic Yield	Diagnosed	70	93.3
	Undiagnosed	05	6.7
Pleural Fluid Sugar	Tubercular (mean ± SD)	122.93 ± 59.81	-
	Metastatic adenocarcinoma (mean ± SD)	74.97 ± 36.28	-
Pleural Fluid LDH	Tubercular (mean ± SD)	808.67 ± 548.46	-
	Metastatic adenocarcinoma (mean ± SD)	1192.09 ± 615.72	-
Pleural Fluid ADA	Tubercular (mean ± SD)	15.88 ± 8.17	-
	Metastatic adenocarcinoma (mean ± SD)	12.15 ± 4.42	-

Table 4: Diagnostic Yield and Key Correlations

Parameter	Category	Number of Cases (n=75)	Percentage (%)
Diagnostic Yield	Diagnosed	70	93.3
	Undiagnosed	05	6.7
Pleural Fluid Sugar	Tubercular (mean ± SD)	122.93 ± 59.81	-
	Metastatic adenocarcinoma (mean ± SD)	74.97 ± 36.28	-
Pleural Fluid LDH	Tubercular (mean ± SD)	808.67 ± 548.46	-
	Metastatic adenocarcinoma (mean ± SD)	1192.09 ± 615.72	-
Pleural Fluid ADA	Tubercular (mean ± SD)	15.88 ± 8.17	-
	Metastatic adenocarcinoma (mean ± SD)	12.15 ± 4.42	-

Table 5: Comparative Table: Key Studies on Medical Thoracoscopy

Study (Reference)	Sample Size	Mean Age (Years)	Diagnostic Yield (%)	Malignancy (%)	Tuberculosis (%)	Key Findings
Current Study	75	56.79	93.3	73.3	20	High yield; hemorrhagic fluid predicts malignancy; sago grain specific to TB.
Mohammed Arif et al. (13)	50	52.74	82	44	38	Nodules (46%) and pleural thickening (40%) common in malignancy.
Laila A. Helala et al. (20)	40	51.3	95	70	22.5	Mesothelioma (53.6%) most common malignancy.
Kumar et al. (7)	160	48.5	98.8	75	17	Metastatic adenocarcinoma (91.7%) dominated; sago grain 100% specific to TB.
Kiani et al. (18)	300	54.2	87	63	37	Pleuroscopy effective in TB/malignancy differentiation.

DISCUSSION

The majority of patients were aged 50–70 years (56%), followed by 30–50 years (21.3%), >70 years (18.6%), and <30 years (4%).The study population predominantly consisted of middle-aged and elderly patients, which is consistent with the epidemiology of pleural effusion. Males (60%) outnumbered females (40%) possibly due to higher smoking rates and occupational exposures. The most common symptoms were cough (94.6%), chest pain (93.3%), and shortness of breath (88%).Non-smokers (66.7%) were the majority, followed by ex-smokers (26.6%) and current smokers (6.6%),suggesting other etiologies like tuberculosis or malignancy. In this study, pleural fluid sugar levels were significantly lower in malignant effusions (74.97 ± 36.28 mg/dL) compared to tubercular effusions (122.93 ± 59.81 mg/dL, p= 0.030). This aligns with prior research, such as Colice et al,[8] who proposed a cutoff of <60 mg/dL as suggestive of malignancy, possibly due to increased glucose consumption by malignant cells or impaired glucose transport across the pleura. Lactate dehydrogenase (LDH), though higher in malignant effusions (1192.09 ± 615.72 U/L vs. 808.67 ± 548.46 U/L in tuberculosis), did not reach statistical significance (p = 0.472). This contrasts with studies

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like Porcel et al., where very high LDH levels were more indicative of empyema or complicated parapneumonic effusions rather than malignancy alone. The overlap in LDH values between malignant and tubercular effusions limits its standalone diagnostic utility, necessitating adjunctive tests. Adenosine deaminase (ADA), a well-established marker for tuberculosis, was higher in tubercular effusions (15.88 ± 8.17 U/L) compared to malignant effusions (12.15 ± 4.42 U/L), though the difference was not statistically significant (p = 0.129). This contrasts with studies in high-TB-burden regions, where ADA levels are typically much higher (e.g., >40 U/L). The modest elevation in this study may reflect differences in laboratory techniques, coexisting conditions, or a lower prevalence of active TB in the cohort.[9,10]

Medical thoracoscopy provided crucial visual and histopathological differentiation between malignant and tubercular effusions.

Malignant effusions were strongly associated with hemorrhagic fluid (67.3% of cases) and thoracoscopic findings such as multiple nodules (32.7%) and pleural hyperemia/ulceration (32.7%). These findings are consistent with Kumar et al., and Kuwal et al.who reported malignancy in 63% of cases of hemorrhagic effusion.[11,12]

Tubercular effusions predominantly exhibited straw-colored fluid (93.3%), along with pathognomonic sago grain appearance (26.7%) and fibrotic adhesions (66.7%), similar to prior studies by Arif et al. where sago grain nodules were nearly exclusive to TB as such straw-colored effusions should prompt consideration of tuberculosis or other benign etiologies.[13]

Medical thoracoscopy achieved a diagnostic yield of 93.3% in our study .Similar studies conducted from Indian subcontinent and Iran reported diagnostic yeild of 67%,73%,80%,97% and 87% with sample size of 21,45,25,68,300 patients respectively.[14-18] This variability may stem from differences in operator expertise, patient selection, or the prevalence of diagnostically challenging cases (e.g., early-stage mesothelioma or fibrotic TB).

Histopathologically, metastatic adenocarcinoma (58.6%) was the most common malignant diagnosis, aligning with Shresta et al. (57.1%),[19] and Arif et al,[13](75%). Tuberculosis accounted for 20% of cases, which is lower than in high-TB-burden regions (e.g., 37% in Kiani et al.),[18] possibly reflecting differing epidemiological patterns. A comparative summarising key aspects of studies done in the past vs the present study is presented in Table 5.

Safety and Complications

The procedure was well-tolerated, with minor complications (18.6%) such as subcutaneous emphysema (6.7%) and fever (5.3%), comparable to rates reported by Laila A. Helala et al. (10%),[20] and Shresta et al. (57.5%).[19] Importantly, there were no major complications, reinforcing thoracoscopy's safety in experienced hands.

Limitations of the study includes its single-center design limiting generalizability, Small subgroup sizes and lack of long-term follow-up for undiagnosed cases.

CONCLUSION

Medical rigid thoracoscopy has proven to be a safe, effective, and indispensable tool for diagnosing undiagnosed exudative pleural effusions, particularly in regions like India where tuberculosis (TB) and malignancy are the leading etiologies. This study, conducted on 75 patients, demonstrated a diagnostic yield of 93.3%, with no mortality and only minor complications such as subcutaneous emphysema (6.7%) and postoperative fever (5.3%). These findings underscore the procedure's safety and reliability, aligning with global studies In TB-endemic countries, pleural effusions are often misdiagnosed and empirically treated with anti-tubercular therapy (ATT) based on nonspecific findings like elevated adenosine deaminase (ADA) levels or clinical suspicion. This practice leads to delayed diagnosis and mismanagement, particularly in cases of malignancy. Our study highlights this critical issue, revealing that a significant proportion of TB cases (20%) had ADA levels <40 IU/L, while some malignant effusions had ADA levels overlapping with TB. This overlap underscores the limitations of relying solely on pleural fluid biochemistry and reinforces the need for histopathological confirmation through thoracoscopy.

The study also identified key predictors of malignancy, including hemorrhagic pleural fluid (67.3% in malignancy vs. 6.7% in TB) and low pleural fluid sugar levels (74.97 mg/dL in malignancy vs. 122.93 mg/dL in TB, p = 0.030). Conversely, sago grain appearance on thoracoscopy was pathognomonic for TB, observed in 26.7% of tubercular cases. The high diagnostic yield and safety profile of medical thoracoscopy make it a first-line investigative tool for undiagnosed exudative pleural effusions, especially when malignancy and TB are the primary differentials. Early and accurate diagnosis not only prevents unnecessary ATT but also facilitates timely initiation of appropriate treatment, improving patient outcomes. For instance, in our study, one patient with recurrent pleural effusion and a history of microbiologically confirmed TB was found to have metastatic adenocarcinoma on thoracoscopic biopsy, highlighting the procedure's role in concurrent TB and malignancy. Future studies should focus on standardizing thoracoscopy protocols, exploring advanced diagnostic markers, and conducting multicenter trials to further validate its efficacy across diverse populations.

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