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Original Article

Comparative efficacy and complications of Transthoracic Ultrasound guided Pleural biopsy versus Medical thoracoscopic Pleural biopsy in Undiagnosed Exudative Pleural Effusion: Experience from a Tertiary Care Institute of Eastern India

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Abstract

Background: Approximately 20% of exudative pleural effusions remain undiagnosed even after diagnostic thoracentesis. In such situations, pleural biopsy is essential for establishing a diagnosis. Pleural biopsy can be obtained either through invasive procedures, such as medical or surgical thoracoscopy, or through semi-invasive techniques, such as closed pleural biopsy, with or without image guidance. This study compared the efficacy and complications of transthoracic ultrasound-guided versus medical thoracoscopic pleural biopsy for undiagnosed exudative pleural effusion.

Methodology: This prospective observational comparative study included 110 patients who were randomly assigned to undergo either ultrasound-guided pleural biopsy (UPB) or medical thoracoscopic pleural biopsy (TPB) under local anesthesia. The specimens were sent for histopathological examination (HPE) and GeneXpert for Mycobacterium tuberculosis (CBNAAT).

Results: Conclusive diagnosis was achieved in 96% of TPB cases and 95% of UPB cases. Malignancy predominated in TPB (56%), whereas tuberculosis in UPB (47%). Among the tuberculosis cases, CBNAAT was positive in 18 UPB and 12 TPB cases, with two rifampicin-resistant cases in each group. The mean hospital stay was longer in TPB (11.3 days) than in UPB (1.5 days), and complications were fewer in UPB.

Conclusion: Both UPB and TPB can be used in undiagnosed pleural effusion cases. Although TPB is the gold standard for diagnosing pleural diseases, UPB is a less invasive, relatively safer, and simpler procedure.

Keywords: pleural effusion, thoracoscopic pleural biopsy, ultrasound-guided pleural biopsy, tuberculosis, malignancy, histopathology

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Quick Response Code:

Introduction:

Pleural effusion can result from increased fluid production or decreased fluid absorption. Pleural effusion is a common medical condition with more than 60 identified causes, including pleural or lung diseases, organ dysfunction, drug-related, and systemic causes.[1] Conventionally, the causes of pleural effusions are classified as exudative or transudative based on Light's criteria.[2] Even after diagnostic thoracentesis with complete biochemical, microbiological, and cytological analyses, approximately 20% of all exudative pleural effusions remain undiagnosed. Hence, undiagnosed exudative pleural effusion remains a diagnostic dilemma for physicians.[3]

Therefore, obtaining pleural tissue samples is often necessary to confirm the diagnosis. The various techniques available for obtaining biopsy samples from parietal pleura include invasive procedures under vision, such as medical or surgical thoracoscopy, or semi-invasive procedures like closed pleural biopsy, with or without image guidance.[4]

Closed pleural biopsy has a diagnostic yield of 90% for tuberculous pleural effusions and 65% for malignant pleural effusions.[5] Image-guided biopsy can be performed using ultrasonography or computed tomography. Ultrasound-guided pleural biopsy (UPB) offers real-time visualization of the biopsy needle with no risk of radiation exposure to the patient. While the size of the target lesion affects the procedure's ease, pleural thickening of even 5 mm can be successfully biopsied.[6]

In comparison, the diagnostic yield of medical thoracoscopic pleural biopsy (TPB) is approximately 91%–95% for malignant pleural effusions and nearly 100% for tuberculous pleural effusions.[7,8] It allows multiple biopsies with direct visualization of the pleura and drainage of large-volume effusions through a single port to be performed.[9] This enables us to perform a biopsy of the target abnormal area even when radiological signs are minimal.[10] However, the procedure has certain disadvantages, including the need for patients to remain in the lateral decubitus position for at least 30 minutes, which may cause significant discomfort or persistent coughing, and intolerance in individuals with compromised lung function who are unable to maintain adequate oxygen saturation in the supine position.[4]

This study aimed to evaluate whether UPB offers a diagnostic efficacy similar to that of TPB, with fewer complications. This study compared the efficacy and complications of UPB and TPB in undiagnosed exudative pleural effusions.

Materials and methods:

This hospital-based prospective observational study was conducted on 110 subjects for 12 months, from March 2023 to March 2024, after obtaining approval from the institutional ethics committee (approval number: 671/IEC/IGIMS/2022). All subjects were enrolled in the study after obtaining written informed consent.

Study population:

The sample size was calculated based on an expected diagnostic yield of 95% for medical thoracoscopy (TPB) and 75% for ultrasound-guided biopsy (UPB), derived from previous studies.[3,4,10] Using a power of 80% and a two-sided alpha of 0.05, a minimum of 49 patients per group was required. Accounting for a potential attrition rate of 10 %, a sample size of 110 was targeted. All patients aged > 18 years with pleural effusion who visited our OPD were included in this study. The inclusion criteria were exudative pleural effusion as per Light’s criteria, age 18-70 years, ADA level < 70 IU/L, no endobronchial growth on assessment with fiberoptic bronchoscopy, and surgically fit for the procedure.

The exclusion criteria were pleural fluid cytology positive for malignancy, pregnancy and lactation, hemodynamic instability (e.g., myocardial infarction or arrhythmias), and excessive rib crowding.

Intervention:

Baseline investigations including complete blood count, renal and liver function, blood glucose levels, prothrombin time, activated partial thromboplastin time, electrocardiography, HIV I and II, anti-HCV, and HBsAg were performed, followed by pleural fluid analysis and contrast-enhanced computed tomography (CECT) of the thorax.

Each patient with pleural effusion was divided into transudative and exudative based on Light's criteria. Patients with exudative effusion were subjected to further analysis (glucose, adenosine deaminase, Gram staining, culture/sensitivity, AFB smear, GeneXpert MTB/RIF, and malignant cytology). Patients with undiagnosed exudative effusions, despite detailed investigations, were randomly assigned to undergo either UPB or TPB through simple random sampling using computer-generated randomization.

Transthoracic UPB was performed using a convex probe with a frequency of 2–5 MHz. Based on the CT findings, ultrasonography was performed to localize and mark the lesion site. With the patient in the proper position and aseptic measures in place, a 2% lignocaine injection was administered locally. Under ultrasound guidance, a 16-gauge Tru-cut biopsy needle was inserted into the pleural space and 3-4 biopsy samples were collected.

For TPB, the patient was positioned in the lateral decubitus position. After marking the point of maximum depth of effusion and diaphragm position using ultrasound, local anesthesia was administered under aseptic precautions. A small incision was made, followed by blunt dissection. A trocar and cannula were inserted, followed by fluid drainage and creation of an artificial pneumothorax. A semi-rigid thoracoscope was introduced, and biopsy was performed from suspicious lesions, such as pleural nodules, pustules, and pleural irregularity, to 4-6 biopsy samples were obtained. A 24 Fr intercostal drainage tube was inserted and secured. All patients in both groups underwent routine post-procedure monitoring and chest radiography.

Both procedures were performed on inpatients by a team of trained pulmonologists who had performed at least 100 procedures prior to this study, assisted by residents and nursing staff. The biopsy specimens obtained by either procedure were subjected to histopathological (HPE) and microbiological examinations (GeneXpert MTB/RIF and MGIT 960 liquid culture).

Outcome measures:

The outcome measures included final diagnosis, complications, and length of hospital stay.

Statistical analysis:

Statistical analyses were conducted using SPSS software (version 23). Data are expressed as mean ± standard deviation. Significant differences between the two cohorts were analyzed using the t-test, with a p-value significance threshold of 0.05. Diagnostic outcomes were compared using chi-squared (χ^2) and Fisher's exact tests.

Results:

UPB was performed in 53 cases, whereas TPB was performed in 57 cases. The two groups were well matched in terms of mean age (p=0.7317) and sex distribution (p=0.849), indicating successful randomization. However, a significant baseline imbalance was present in presenting symptoms, with chest pain being more common in the UPB group (96.2% vs. 73.7%, p=0.001) and dyspnea being more frequent in the TPB group (80.7% vs. 24.5%, p=0.0001), which could reflect underlying differences in disease severity or etiology [Table 1].

Table 1. Comparison of Baseline Demographic and Clinical features of patients between groups

*Unpaired t test **Fisher's exact test

PARAMETERS		**UPB (n=53)**	**TPB (n=57)**	**P value**
Mean age (in years ± sd)		50.92 ± 19.02 years	49.75 ± 16.66 years	0.7317*
Sex	Male	31 (58.5%)	32 (56.1%)	0.849**
	Female	22 (41.5%)	25 (43.9%)	
Clinical features	Chest pain	51 (96.2%)	42 (73.7%)	**0.001****
	Cough	29 (54.7%)	30 (52.6%)	0.850**
	Dyspnea	13 (24.5%)	46 (80.7%)	**0.0001****
	Fever	24 (45.3%)	18 (52.6%)	0.171**
Smoking history	Present	20 (37.7%)	13 (22.8%)	0.0996**
	Absent	33 (62.3%)	44 (77.2%)	
H/O ATT intake		21 (39.6%)	34 (59.6%)	0.559**
H/o pleural tapping		16 (30.2%)	18 (31.6%)	>0.9999**

Significant differences in pleural fluid biochemistry, including higher protein in UPB (5.3 g/dL vs. 4.2 g/dL, p=0.0002) and higher ADA in TPB (48.40 U/L vs. 30.70 U/L, p<0.0001), were observed. Furthermore, the TPB group had a significantly higher proportion of patients with massive effusions (45.6% vs. 20.8%, p=0.0084). These imbalances confirm that the groups had different underlying pleural pathologies, which is a critical confounder for the primary diagnostic yield comparison [Table 2].

Table 2. Pleural fluid characteristics and radiology findings in both groups

PARAMETERS		**UPB (n=53)**	**TPB (n=57)**	**P value**
PLEURAL FLUID ANALYSIS				
Protein in g/dL, median (IQR)		5.3 (4.5-6.5)	4.2 (3.55-5.4)	**0.0002***
Sugar in mg/dL		76.0 (74.0-90.0)	84.0 (56.0-114.5)	**0.0337***
LDH in U/L		405.0 (337.0-465.0)	427.0 (271.5-681.0)	0.5176*
ADA in U/L		30.70 (22.37-30.70)	48.40 (36.85-55.00)	**<0.0001***
TLC in cells/cu.mm		650.0 (200.0-700.0)	478.0 (242.0-1 205)	0.3747*
DLC	Neutrophils (%)	5.0 (5.0-90.0)	10.0 (10.0-15.0)	**0.0049***
	Lymphocytes (%)	95.00 (10.00 – 95.00)	90.00 (85.00-90.00)	**0.0046***
RADIOLOGY				
Side of effusion on CT	Unilateral	52 (98.1%)	54 (94.7%)	0.6191**
	Bilateral	1 (1.9%)	3 (5.3%)	
Amount of effusion on CT	Mild	3 (5.7%)	2 (3.5%)	0.6706**
	Moderate	39 (73.6%)	29 (50.9%)	**0.0186****
	Massive	11 (20.8%)	26 (45.6%)	**0.0084****

***Mann-Whitney test **Fisher's exact test**

Pleural thickening on USG:

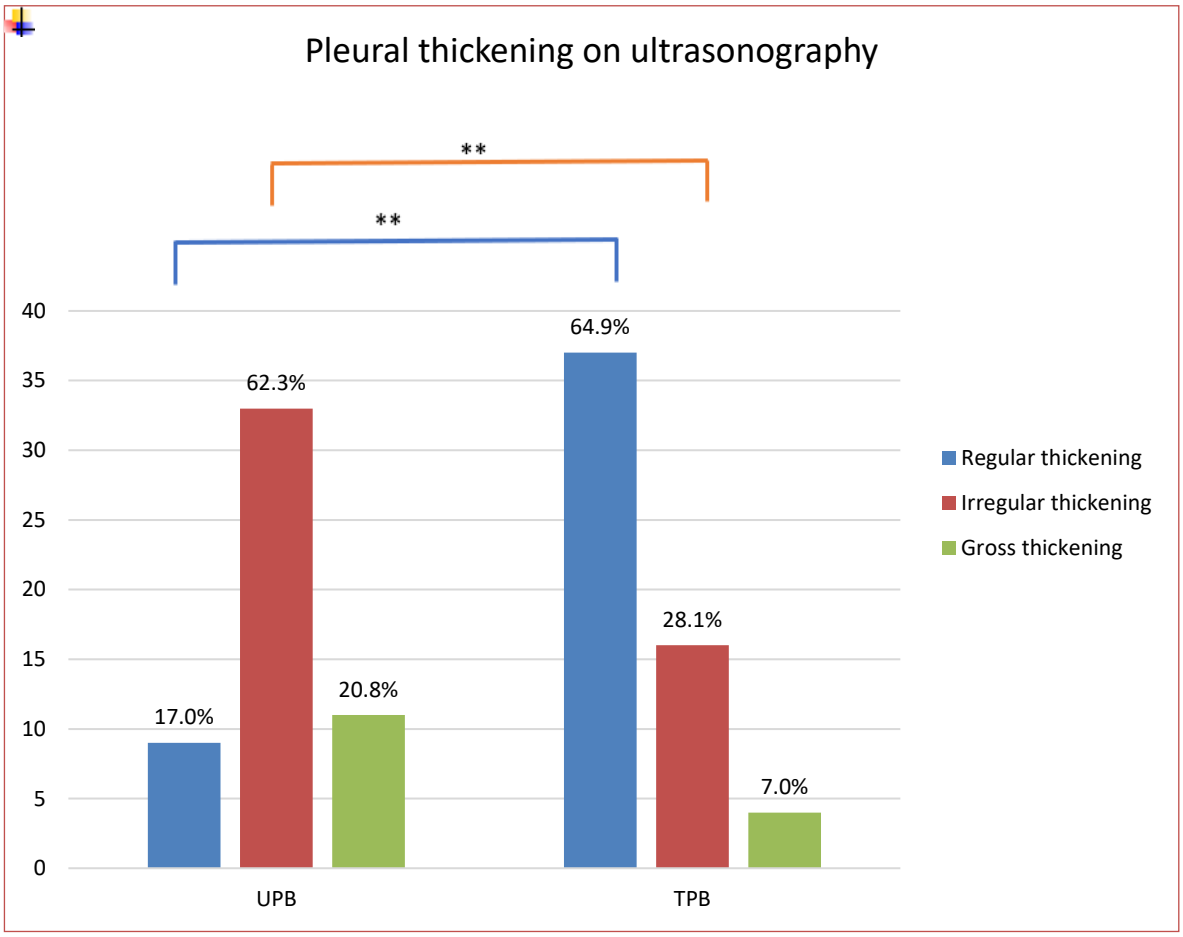

Figure 1. shows pleural thickening (regular, irregular and gross thickening) among the two groups.

The mean pleural thickness in the USG group was 3.528 ± 0.7551 cm and that in the thoracoscopy group was 2.858 ± 0.6147 cm. **There was significant difference in pleural thickening between both groups (Chi-square, df - 26.10, 2; p-value < 0.0001 and 95% CI (-0.9298 to -0.4110) [Figure.1].

USG was preferred in patients with greater pleural thickness, and the difference between the pleural thickness in the USG and thoracoscopic groups was significant.

Thoracoscopy findings:

The most common thoracoscopic findings were pleural nodules (15.5%) and cheesy deposits with pustules (10%), which correlated strongly with the final diagnoses of malignancy and tuberculosis, respectively. The other findings were multiple mass lesions in 8 (7.3%), erythematous pleura with pleural patches in 7 (6.4%), and extensive adhesions along with septations in 5 cases (4.5%). Less common findings were sago-grain appearance in three cases (2.7%), smooth, apparently healthy pleura with a few nodules in three (2.7%), and multiple variable-sized pleural nodules accompanied by pleural pustules in three cases (2.7%). The direct visualization of these specific lesions during TPB explains its high diagnostic yield and underscores its advantage in obtaining targeted biopsies from abnormal areas, which is a key factor in its efficacy.

Histopathological examination (HPE) results:

Table 3. HPE findings in both groups

FINDINGS	**UPB GROUP (n=53)**	**TPB GROUP (n=57)**	**P value (Fisher's exact test)**
Chronic granulomatous inflammation	13 (24.5)	21 (36.8%)	0.2157
Fibro-collagenous and fibroadipose tissue fragments showing mild chronic inflammation	15 (28.3%)	3 (5.3%)	**0.0015**
Adenocarcinoma (primary and metastatic)	17 (32.1%)	25 (43.7%)	0.2411
Mesothelioma	6 (11.3%)	4 (7.0%)	0.5172
Chronic non-specific pleuritis	2 (3.8%)	1 (1.8%)	0.6081
Lymphoma	0	1 (1.8%)	>0.9999
Small cell carcinoma	0	1 (1.8%)	>0.9999
Squamous cell lung carcinoma	0	1 (1.8%)	>0.9999
Total	53 (100%)	57 (100%)	

The diagnostic yield for key malignancies, such as adenocarcinoma (UPB: 32.1% vs. TPB: 43.7%, p=0.2411) and mesothelioma (11.3% vs. 7.0%, p=0.5172) was statistically similar. The only significant HPE difference was a higher rate of non-diagnostic, fibrotic tissue in the UPB group (28.3% vs. 5.3%, p=0.0015), suggesting that TPB is more reliable at obtaining adequate pleural tissue [Table 3].

GeneXpert (CBNAAT) results:

In the UPB group, Mycobacterium tuberculosis was detected in 18 cases, and out of the 18, rifampicin resistance was detected in 2 cases.

In the TPB group, Mycobacterium tuberculosis was detected in 12 cases, and out of the 12, rifampicin resistance was detected in 2 cases.

Final diagnosis:

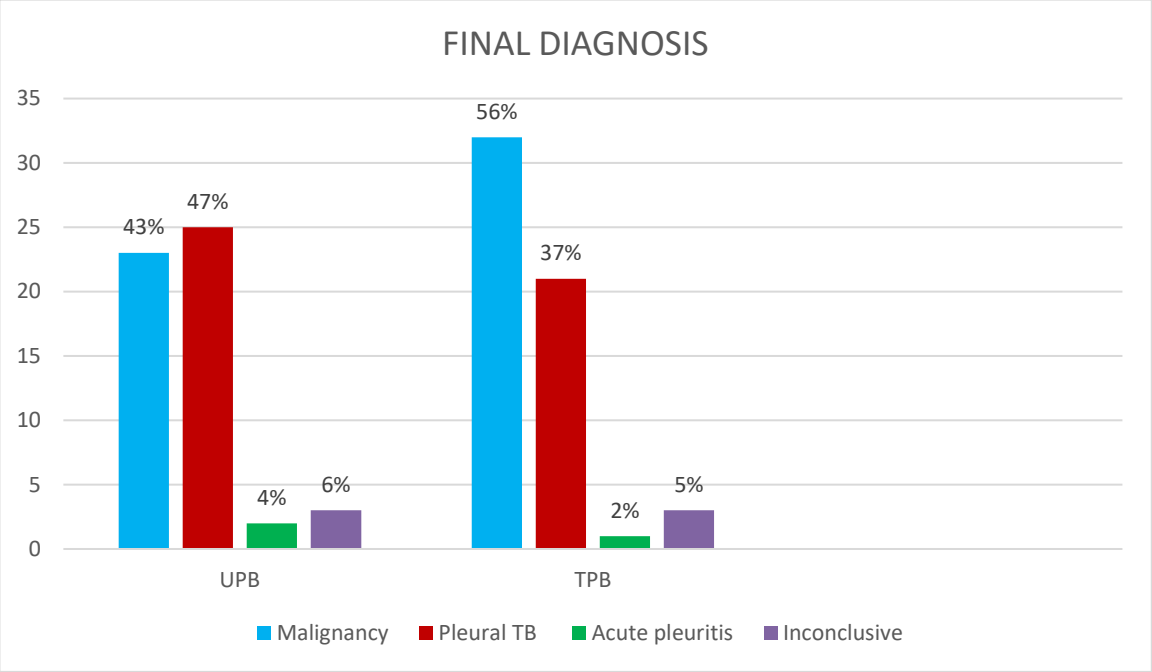

Figure 2. shows the final diagnosis in both groups.

Table 4: Comparison of Diagnostic Yield (Conclusive Findings) between Two Groups

Group	Number of Conclusive Findings (Diagnostic Yield)	%	95% CI of %
UPB group (n=53)	50	94.34%	88.12 – 100.56
TPB group (n=57)	54	94.74%	88.94 – 100.53

Crucially, despite the baseline imbalances, the final diagnostic yield was statistically identical between the two groups (TPB: 94.7% vs. UPB: 94.3%, p>0.999), demonstrating comparable efficacy (diagnostic yield) for the primary objective.[Figure 2 and Table 4].

Procedure Complications:

Table 5. Complications in both groups

	Chest pain	Hemoptysis	Fever	Pneumothorax	Subcutaneous Emphysema	Local wound site infection	Total
UPB group	3 (5.7%)	5 (9.4%)	5 (9.4%)	3 (5.7%)	0	0	16
TPB group	10 (17.5%)	3 (5.3%)	4 (7.0%)	0	12 (21.1%)	2 (3.5%)	31
P value (Fisher's exact test)	0.076	0.478	0.736	0.109	**0.0001**	0.496	**0.0126**

Achieving the objective of comparing safety, TPB was associated with a significantly higher overall complication rate (31 vs. 16 events, p=0.0126), driven predominantly by subcutaneous emphysema (21.1% vs. 0%, p=0.0001). UPB had a different, less severe complication profile, supporting the conclusion that it is a safer procedure [Table 5].

Directly addressing a key objective, the median hospital stay for UPB was dramatically and significantly shorter than that for TPB (1 day vs. 11 days, p<0.0001), underscoring UPB's advantage as a potential outpatient procedure.

Discussion:

Despite the initial baseline differences, TPB and UPB demonstrated nearly identical diagnostic yields (94.7% vs. 94.3%), confirming comparable efficacy. However, TPB showed a significantly higher complication rate, mainly due to subcutaneous emphysema, whereas UPB had a better safety profile. Additionally, UPB led to a markedly shorter median hospital stay (1 day vs. 11 days).

A previous meta-analysis by Wei et al. showed that TPB offers higher diagnostic accuracy, especially for malignant diseases such as mesothelioma, with greater sensitivity (93% vs. 77%) than closed pleural biopsy. However, in our study, the diagnostic outcomes of UPB were comparable to those of TPB. Among the patients with massive pleural effusion, there were more cases of malignancy in the TPB group than in the UPB group. Wei Y, et al. also foundthat closed pleural biopsy was safer, with less complications and had similar accuracy for non-malignant diseases which is similar to our study.[11]

According to Durgeshwar et al., UPB was as effective as TPB for diagnosing undiagnosed exudative pleural effusion, with the added benefits of shorter procedure time, reduced hospital stay, and fewer complications. These findings are similar to our study, with the exception that we had a large number of cases.[4] Ibrahim et al. found that TPB had a higher diagnostic yield (95%) compared to image-guided biopsies (85%), and it had longer procedure times and hospital stays with more complications. However, in this study, the diagnostic outcomes of TPB were similar to those of UPB. TPB had longer hospital stays with more complications.[3] A study by Dixon et al. found that image-guided biopsy had a diagnostic sensitivity of 70% to 94% and a low complication rate versus thoracoscopy with a sensitivity of 97%. While our study showed similar diagnostic outcomes in both the groups.[10]

Pleural malignancy was the most common diagnosis (50%) in our study, among which adenocarcinoma was the most prevalent, followed by mesothelioma. This is similar to the studies by Durgeshwar et al. and Ibrahim et al.[3,4] Pleural tuberculosis (TB) was the second most common diagnosis (41.8%) in our study, reflecting its significant burden on pleural diseases. This is in contrast to the study by Kumar S, et al., where pleural tuberculosis was the most common diagnosis followed by pleural malignancy.[12] The study by Zhou X, et al., found that the diagnostic yields of ultrasound-guided and thoracoscopic pleural biopsies in detecting tuberculous pleurisy were similar, which is concordant with our study.[13]

In our study, the TPB group had significantly more complications than the UPB group. The most common complication in the TPB group was subcutaneous emphysema, followed by chest pain, whereas in the UPB group, it was fever and hemoptysis. There was no procedure-related mortality. This is similar to the findings of a meta-analysis by Wei et al., in which the complication rate of TPB was significantly higher than that of UPB. However, the most frequent complication of UPB was pneumothorax, and the most frequent complications in TPB were subcutaneous emphysema and fever.[11]Durgeshwar G, et al., found the most common complication was intraprocedural pain in UPB and subcutaneous emphysema in TPB group, which is partly in agreement with our study.[4] Ibrahim E, et al., also noted similar findings where image guided biopsy had significantly fewer complications.[3] In contrast to our study, Kumar S,

et al., reported that there were no complications in both the groups except pain and one mortality in UPB group which was attributed to the patient's comorbidity.[12]

The duration of hospital stay was recorded from the day of the procedure until discharge. In our study, hospital stays in the thoracoscopy group ranged from 8 to 14 days, with a mean of 11.25 ± 1.75 days, compared to a mean of 1.45 ± 0.95 days with a range of 1 to 5 days in the UPB group. The length of hospital stay was significantly shorter in the UPB group than in the thoracoscopy group. The study by Ibrahim E, et al., also showed image-guided pleural biopsies required lower duration of hospital stay than medical thoracoscopy which was statistically significant.[3] Similarly, in the study by Kumar S, et al., the duration of hospital stay in medical thoracoscopy was significantly more as compared to closed pleural biopsy group.[12] A study by Durgeshwar et al. also showed that the hospital stay in the UPB group was significantly shorter than that in the thoracoscopy group; however, the difference was not statistically significant. However, we found less hospital stay in UPB as compared to TPB group and it was statistically significant.[4]

The strengths of our study include a relatively large sample size and a comprehensive review of prior literature, which enhances the validity and contextual relevance of our findings. Additionally, the use of computer-generated simple random sampling minimized selection bias and ensured balanced group allocation. The study design incorporated clearly defined inclusion and exclusion criteria, contributing to the internal consistency and reproducibility of the results. Although this study provides valuable insights, certain limitations must be acknowledged. A single-center design and a moderate sample size may limit the generalizability of the findings. Furthermore, the study did not address various confounding factors, such as effusion size, lesion location, and other potential confounders. As there were different groups of patients for both procedures (UPB and TPB), no other gold standard diagnostic procedures were applied to calculate sensitivity/specificity. Future research should focus on multicentre studies with larger cohorts to validate these results.

Our study highlights that, rather than sticking to one particular technique, both should be considered complementary techniques. The choice depends on procedural availability, clinical context, patient condition, and whether the benefits outweigh the complications. UPB is an economical and minimally invasive procedure. Thus, it can be a viable first-line tool in resource-limited settings.

Conclusion:

Both ultrasound-guided and thoracoscopic pleural biopsies offer high diagnostic yield in undiagnosed exudative pleural effusion. While thoracoscopy remains the gold standard, ultrasound-guided biopsy provides a simpler, safer, and more accessible alternative, especially suitable for resource-constrained settings.

Conflicts of Interest: none

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