

PROCEDURAL SAFETY PROFILE OF DIAGNOSTIC THORACENTESIS VERSUS CLOSED BLIND PLEURAL BIOPSY USING COPE'S NEEDLE: A SINGLE-CENTRE OBSERVATIONAL COMPARISON

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ABSTRACT

Background: Aim: Closed blind pleural biopsy using Cope's needle remains widely employed in resource-limited settings, yet head-to-head safety comparisons with diagnostic thoracentesis within the same patient cohort are scarce. The present investigation was designed to assess and compare the procedural complication profiles of diagnostic thoracentesis and closed blind pleural biopsy using Cope's needle in patients with suspected malignant pleural effusion (MPE). **Materials and Methods:** Using a prospective observational design, 60 consecutive patients with suspected MPE were enrolled at Government General Chest Hospital, in Hyderabad, India, over 18 months (January 2023–June 2025). Ethical clearance was obtained from the Institutional Review Board. Each enrolled patient underwent both diagnostic thoracentesis and closed blind pleural biopsy using Cope's needle. Complications were prospectively documented and compared using chi-square, Fisher's exact, and McNemar tests (SPSS v22; statistical significance set at $\alpha = 0.05$ throughout). **Results:** Among patients undergoing thoracentesis, 81.7% (49/60) experienced no adverse events, compared with only 8.3% (5/60) following biopsy ($p < 0.001$). Pain was substantially more frequent after biopsy (86.7% [52/60] vs 10.0% [6/60], $p < 0.001$), as were fever (35.0% [21/60] vs 6.7% [4/60], $p < 0.001$) and hydropneumothorax (23.3% [14/60] vs 8.3% [5/60], $p = 0.024$). Biopsy-specific complications included persistent air leak (8.3%), subcutaneous hematoma (6.7%), hemorrhage (5.0%), subcutaneous emphysema (5.0%), and empyema (1.7%). No procedure-related mortality or tumor seeding occurred. **Conclusion:** The pattern emerging from these data indicates that closed blind pleural biopsy using Cope's needle carries a substantially higher complication burden than diagnostic thoracentesis. These observations support risk-stratified procedural selection and reinforce the need for thorough patient counselling in settings where image-guided alternatives are unavailable. External validation in adequately powered multicenter cohorts will be necessary before formal guideline integration.

INTRODUCTION

Malignant pleural effusion (MPE) complicates the clinical course of many patients with advanced malignancy, necessitating definitive tissue or cytological confirmation for prognostication and

treatment planning.^[1] The diagnostic pathway in many resource-limited settings continues to rely on pleural fluid cytology and, when non-diagnostic, closed blind pleural biopsy using Cope's or Abrams' needle.^[2,3,4] Although image-guided techniques and medical thoracoscopy have emerged as superior

diagnostic modalities, access to these remains constrained in many centers across low- and middle-income countries.^[5,6]

Cope's needle pleural biopsy, first described in 1958, facilitates tissue acquisition without imaging guidance or specialized equipment.^[7] While its diagnostic utility has been documented in multiple series including a 414-patient review by Escudero Bueno et al,^[20] the procedure is inherently more invasive than simple thoracentesis and carries a distinct complication profile encompassing pneumothorax, hemorrhage, pain, and, rarely, organ laceration.^[8,9] Diagnostic thoracentesis, by contrast, is generally regarded as a low-risk procedure, with pneumothorax rates reported between 1.3% and 12.9% in systematic reviews and meta-analyses.^[10,11] Despite the widespread concurrent use of both procedures in the evaluation of suspected MPE, direct head-to-head safety comparisons within the same patient cohort are limited.^[4,12] Most available data derive from non-paired studies comparing complication rates across different patient populations, introducing confounders related to case selection and operator experience.^[13] Inpatient comparisons where both procedures are performed on the same individual — eliminate patient-level confounders and provide the most methodologically sound basis for comparing procedural safety. The aim of this study was to compare the procedural complication profiles of diagnostic thoracentesis and closed blind pleural biopsy using Cope's needle in patients with suspected MPE, performed within the same patient cohort at a single tertiary centre. The primary focus is the comparative safety assessment, which may inform procedural decision-making and patient counselling in resource-limited settings where image-guided alternatives are unavailable.

MATERIALS AND METHODS

Study design and setting

This prospective observational study was conducted at the Department of Pulmonary Medicine at Government General Chest Hospital, in Hyderabad, Telangana, India, over an 18-month period (January 2023–June 2025). The institution functions as a tertiary referral center for respiratory diseases in southern India. Ethical clearance for this work was obtained from the Institutional Review Board, and the study followed the ethical principles set out in the Declaration of Helsinki. Prior to any study procedure, each participant provided written informed consent.

Patient selection

Sixty consecutive patients with undiagnosed exudative pleural effusion clinically suspected of malignant etiology were enrolled. Inclusion criteria comprised: age ≥ 18 years; moderate-to-large exudative pleural effusion; clinical or radiological suspicion of malignancy; and procedural suitability for both thoracentesis and biopsy. Exclusion criteria included coagulopathy (INR >1.5 or platelets

$<50,000/\mu\text{L}$), hemodynamic instability, empyema, skin infection at the proposed puncture site, prior ipsilateral pleural procedures, and inability to provide informed consent.

Procedural technique

Each enrolled patient was subjected to diagnostic thoracentesis incorporating conventional cytology sampling, followed by closed blind pleural biopsy using Cope's needle, performed during the same session or within 48 hours. Both procedures were carried out by trained pulmonology residents under faculty supervision.

Thoracentesis was performed using standard technique at the posterior axillary line, one to two intercostal spaces below the upper level of effusion as identified by clinical percussion and confirmed by prior imaging. A 16- or 18-gauge needle was introduced under local anaesthesia (2% lignocaine). Approximately 50–100 mL of pleural fluid was aspirated for cytological analysis.

Closed blind pleural biopsy was performed using a Cope's pleural biopsy needle (14-gauge) under local anaesthesia with 2% lignocaine infiltrated to the parietal pleura.^[7] Minimum of four biopsy specimens were obtained from the inferior and posterior parietal pleura at a single intercostal site, following standard Cope's needle technique as described in published literature.^[21,22] Real-time ultrasound guidance was not employed during either procedure.

Complication assessment

Complications were documented prospectively at the time of each procedure and during a minimum 4-hour post-procedure observation period. An upright chest radiograph was obtained 2–4 hours post-procedure to assess for pneumothorax. The following complications were recorded: pain (exceeding expected procedural discomfort as assessed by the treating clinician); fever (temperature $>38^{\circ}\text{C}$ within 24 hours); hydropneumothorax; persistent air leak (>24 hours); subcutaneous haematoma; hemorrhage (including haemothorax); subcutaneous emphysema; empyema or wound infection; haemoptysis; and vasovagal syncope. Pain was assessed by clinician report; no formal validated pain scoring instrument was employed in this cohort.

Statistical Analysis

Frequencies and percentages were used to summarise categorical data; continuous variables were expressed as mean $\pm$ standard deviation. Comparisons between thoracentesis and biopsy complication rates were performed using the chi-square test, Fisher's exact test (when expected cell counts were fewer than five), and McNemar's test for paired proportions. Statistical significance was set at $\alpha = 0.05$ throughout. Analysis was performed using SPSS version 22.0.

Ethical considerations

Ethical clearance was obtained from the Institutional Review Board. Prior to any study procedure, each participant provided written informed consent. The study followed the ethical principles set out in the Declaration of Helsinki.

RESULTS

Patient characteristics

Sixty patients (38 male, 22 females; mean age 54.7 ± 12.3 years) were included in the final analysis. All 60 patients underwent both diagnostic thoracentesis and closed blind pleural biopsy using Cope's needle, yielding 60 paired procedure comparisons.

Thoracentesis complications

Diagnostic thoracentesis demonstrated a favorable safety profile. The majority of patients 81.7% (49/60) experienced no complications. Pain beyond expected procedural discomfort was noted in 10.0% (6/60). Hydropneumothorax occurred in 8.3% (5/60). Fever developed in 6.7% (4/60). Vasovagal syncope was recorded in 3.3% (2/60), and haemoptysis in 1.7% (1/60). No cases of persistent air leak, subcutaneous haematoma, subcutaneous emphysema, hemorrhage, or empyema were identified following thoracentesis.

Biopsy complications

Closed blind pleural biopsy was associated with a substantially higher complication burden. Only 8.3% (5/60) of patients were free of complications. Pain was the most frequent adverse event, recorded in

86.7% (52/60). Fever occurred in 35.0% (21/60). Hydropneumothorax was documented in 23.3% (14/60). Persistent air leak was noted in 8.3% (5/60). Subcutaneous haematoma occurred in 6.7% (4/60). Hemorrhage was recorded in 5.0% (3/60) and subcutaneous emphysema in 5.0% (3/60). Empyema or wound infection developed in 1.7% (1/60), haemoptysis in 1.7% (1/60), and vasovagal syncope in 1.7% (1/60). No procedure-related deaths, tumor tract seeding,²⁵ or organ laceration occurred in either group.

Comparative Analysis

McNemar's test for paired proportions confirmed statistically significant differences in the overall complication rate, pain, fever, and hydropneumothorax between the two procedures (all $p < 0.05$). Detailed complication rates and comparative p-values are presented in Table 1; severity classification is summarised in Table 2. For contextual reference, biopsy yielded a higher diagnostic rate (53.3%) compared with pleural fluid cytology alone (18.3%); detailed diagnostic accuracy analysis is reported separately in a companion publication.

Table 1: Comparison of Complication Rates Between Thoracentesis and Cope's Needle Biopsy (N=60)

Complication	Thoracentesis n (%)	Biopsy n (%)	p-value
No complications	49 (81.7%)	5 (8.3%)	<0.001
Pain	6 (10.0%)	52 (86.7%)	<0.001
Fever	4 (6.7%)	21 (35.0%)	<0.001
Hydropneumothorax	5 (8.3%)	14 (23.3%)	0.024
Persistent air leak	0 (0%)	5 (8.3%)	0.057*
Subcutaneous haematoma	0 (0%)	4 (6.7%)	0.118*
Haemorrhage	0 (0%)	3 (5.0%)	0.243*
Subcutaneous emphysema	0 (0%)	3 (5.0%)	0.243*
Empyema/wound infection	0 (0%)	1 (1.7%)	1.000*
Haemoptysis	1 (1.7%)	1 (1.7%)	1.000
Vasovagal syncope	2 (3.3%)	1 (1.7%)	1.000*

*Fisher's exact test used when expected cell count <5.

Table 2: Severity Classification of Complications

Severity	Thoracentesis n (%)	Biopsy n (%)
No complication	49 (81.7%)	5 (8.3%)
Minor (self-limiting, no intervention)	8 (13.3%)	25 (41.7%)
Moderate (required monitoring/intervention)	3 (5.0%)	25 (41.7%)
Major (chest drain/prolonged admission)	0 (0%)	5 (8.3%)
Life-threatening/fatal	0 (0%)	0 (0%)

DISCUSSION

Pain and procedural discomfort

The most striking observation in this cohort was the markedly higher incidence of pain following Cope's needle biopsy (86.7%) compared with thoracentesis (10.0%). This differential likely reflects the greater tissue disruption inherent to the biopsy technique, which involves a larger-caliber needle (14-gauge vs 16–18-gauge), multiple passes through the parietal pleura, and the mechanical avulsion required for specimen acquisition.^[7,8] The parietal pleura is richly innervated by intercostal nerves and represents the principal source of pleuritic pain; procedures that breach and sample this structure are therefore inherently more uncomfortable.^[14]

The observed pain rate after biopsy is higher than some reported series. Chakrabarti et al. documented pleuritic chest pain in approximately 15% of patients following Abrams' needle biopsy, though their study employed a different biopsy needle and likely applied a higher threshold for recording pain as a complication.^[8] This discrepancy reinforces the need for standardised, validated pain assessment instruments in future procedural safety studies.

Pneumothorax and air leak

Hydropneumothorax following thoracentesis (8.3%; 5/60) is broadly consistent with published systematic reviews. Gordon et al., in their meta-analysis of 6,605 thoracenteses, reported an overall pneumothorax rate of 6.0%, with rates of 4.0% under ultrasound guidance rising to 9.3–12.9% without.^[10] The slightly

elevated rate in the present cohort may be partly attributable to the absence of real-time ultrasound guidance, aligning with evidence that ultrasound-guided procedures are associated with reduced pneumothorax risk.^[11,15]

The biopsy-associated hydropneumothorax rate of 23.3% (14/60) substantially exceeded the thoracentesis rate and surpasses some published estimates for closed needle biopsy. Hooper et al. reported pneumothorax rates of 8–15% following closed pleural biopsy.^[4] The elevated rate in the present series may reflect the number of biopsy passes (4–6 per patient), the traineeship-level operators performing under supervision, the absence of ultrasound guidance with evidence that ultrasound-assisted site selection reduces complication rates^[23,24] and the protocol of routine post-procedure chest radiography, which may have detected subclinical pneumothoraces that go unrecognized without systematic imaging follow-up. Persistent air leak occurred exclusively in the biopsy group (8.3%; 5/60), suggesting that the larger pleural defect created by Cope's needle may occasionally fail to seal spontaneously. This observation has implications for post-procedure monitoring protocols and resource planning in centres performing blind pleural biopsy.^[16]

Hemorrhagic complications

Hemorrhagic complications — hemorrhage (5.0%), subcutaneous haematoma (6.7%), and haemoptysis (1.7%) occurred exclusively following Cope's needle biopsy. The larger bore of the biopsy needle and the avulsive mechanism of tissue acquisition are likely contributors to greater local tissue trauma and bleeding risk relative to the smaller-caliber thoracentesis needle.^[7,9] These findings are broadly consistent with the hemorrhagic complication rates of 2–5% for closed pleural biopsy reported in the literature, though cross-study comparison is limited by variation in definitions and reporting thresholds.^[4,8]

The absence of major hemorrhagic events requiring blood transfusion or surgical intervention is reassuring; however, the sample size constrains the ability to comment on rare but serious complications such as intercostal artery laceration or haemothorax requiring drainage.^[17]

Infectious complications

Fever was significantly more common after biopsy (35.0%) than thoracentesis (6.7%), which may reflect a transient inflammatory response to pleural disruption or bacteremia associated with the more invasive procedure.^[18] One patient (1.7%) in the biopsy group developed empyema or wound infection requiring antibiotic therapy. While low in absolute terms, this complication category was essentially absent following diagnostic thoracentesis alone. The British Thoracic Society guidelines recommend rigorous aseptic technique for all pleural procedures; our data support heightened vigilance for infectious complications following blind biopsy, particularly in immunocompromised patients.^[16]

Clinical practice implications

The pattern emerging from these data indicates that closed blind pleural biopsy carries an approximately 10-fold higher overall complication rate compared with diagnostic thoracentesis when both are performed within the same patient cohort. This differential has potential implications for:

Informed consent — Patients should be specifically counselled about the markedly higher probability of pain, fever, and pneumothorax associated with blind biopsy, which may influence their decision to proceed.

Procedural selection — Where ultrasound-guided biopsy or medical thoracoscopy are available, the safety data favor these alternatives over unguided Cope's needle biopsy, given evidence that image-guided techniques reduce complication rates whilst improving diagnostic yield.^[5,6,15]

Resource planning — The higher complication rate following biopsy necessitates adequate post-procedure monitoring capacity, chest drain availability, and clinical infrastructure for managing persistent air leak and hemorrhage.

Training — Given that procedures were performed by supervised trainees, formal competency assessment prior to independent practice appears warranted.^[19]

It should be emphasized that this safety comparison does not negate the role of closed biopsy in settings where it represents the only available tissue sampling modality. These data may assist in balancing the diagnostic imperative against procedural risk in individual patients.^[4,20]

Limitations

The observations reported here are preliminary and warrant further inquiry, given several methodological constraints. First, the single-center design limits generalizability to other settings with different patient populations, operator experience, or institutional protocols. Second, with 60 patients, the study may be underpowered to detect differences in rare but clinically significant complications. Third, unblinded complication assessment may have introduced ascertainment bias, particularly for subjective outcomes such as pain. Fourth, the absence of a validated pain scoring instrument — with pain assessed by clinician judgement — may have inflated the biopsy pain rate relative to studies applying stricter definitions. Fifth, neither procedure was performed with real-time ultrasound guidance, which may have inflated pneumothorax rates in both groups relative to current best practice. Sixth, complications were assessed primarily within 24 hours, potentially missing delayed events. Seventh, operator-level experience (trainees under supervision) may not reflect complication rates achievable by independent practitioners.

CONCLUSION

Using a prospective observational design in 60 patients with suspected MPE, closed blind pleural biopsy using Cope's needle was associated with a substantially higher procedural complication burden compared with diagnostic thoracentesis when both are performed within the same cohort. Pain, fever, and hydropneumothorax were significantly more frequent following biopsy, with an overall complication rate approximately 10-fold higher than that observed after thoracentesis. No life-threatening events or procedure-related mortality occurred. These observations call for a stepwise diagnostic approach, beginning with less-invasive fluid sampling and reserving blind biopsy for cases where initial cytology is non-diagnostic and image-guided alternatives are unavailable. Enhanced patient counselling addressing the specific risk profile of each procedure appears warranted. External validation in adequately powered multicenter cohorts will be necessary before formal integration into clinical guidelines.

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Conflicts of Interest Statement

The authors declare that they have no financial interests or personal conflicts that may affect the study reported in this article.

ICMJE Overlap and Transparency Disclosure

This manuscript forms part of a series of analyses derived from a single prospective observational cohort (N=60) at a tertiary care centre in Hyderabad, India. Two companion manuscripts address distinct research questions using the same dataset: (1) a diagnostic efficacy comparison of pleural fluid cytology, cell block, and closed pleural biopsy; and (2) a diagnostic algorithm integrating sequential use of the three modalities. The present manuscript is exclusively concerned with comparative procedural safety and complication profiles, with no substantive overlap in primary outcomes, analysis, or conclusions with the companion papers. All companion manuscripts are cross-referenced in accordance with COPE and ICMJE guidelines on overlapping publications. The authors confirm that no data fabrication, redundant publication, or salami-slicing has occurred.

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