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Original Research Article

BRIDGING THE DIAGNOSTIC GAP: A STEPWISE MULTIMODAL ALGORITHM FOR MALIGNANT PLEURAL EFFUSION IN RESOURCE-CONSTRAINED SETTINGS

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ABSTRACT

Background: Current guidelines for the diagnosis of malignant pleural effusion (MPE) derive predominantly from high-resource contexts, and validated stepwise algorithms for low- and middle-income countries (LMICs) are lacking. This study aimed to develop a stepwise diagnostic algorithm for MPE using sequential cytology, cell block, and selective pleural biopsy, identifying clinical scenarios where each modality offers optimal yield.

Materials and Methods: This prospective observational study enrolled 60 consecutive patients with suspected MPE at a tertiary care hospital in Hyderabad, India (January 2023–June 2025). All patients underwent thoracentesis with conventional cytology, cell block preparation, and closed pleural biopsy. The primary outcome was cumulative sequential diagnostic yield. Secondary outcomes included rescue biopsy success rate in inconclusive cell block cases and tumour-type-specific detection patterns.

Results: Conventional cytology detected malignancy in 18.3% (11/60), cell block in 48.3% (29/60), and pleural biopsy in 53.3% (32/60). Among 9 patients with inconclusive cell blocks, all 9 (100%) were subsequently diagnosed by pleural biopsy. Biopsy detected 90% (9/10) of non-pulmonary metastases versus 10% (1/10) by cell block. The proposed sequential algorithm (cytology → cell block → selective biopsy) achieved 95% cumulative diagnostic yield with approximately 30% cost savings compared to a universal biopsy strategy.

Conclusion: A stepwise algorithm — cytology first, cell block for cytology-negative cases, and pleural biopsy reserved for inconclusive cell blocks or suspected non-pulmonary metastatic disease — may optimise diagnostic yield in resource-constrained settings. External validation in adequately powered multicentre cohorts will be necessary before formal clinical integration.

Keywords: Malignant pleural effusion, Algorithms, Cell block, Pleural biopsy, Resource-limited settings.

INTRODUCTION

Malignant pleural effusion (MPE) affects approximately 1 million patients annually worldwide and carries a median survival of 3–12 months depending on histological subtype and stage.[1] The diagnosis of MPE requires tissue or cytological confirmation of malignancy, yet the optimal

sequence and combination of diagnostic modalities remain poorly defined, particularly in low- and middle-income countries (LMICs) where access to advanced procedures such as thoracoscopy is limited.[2,3]

Current international guidelines, including those from the British Thoracic Society (BTS) and the American College of Chest Physicians (ACCP), recommend pleural fluid cytology as the initial investigation, followed by image-guided or thoracoscopic biopsy for cytology-negative cases.[4,5] However, these recommendations derive predominantly from high-resource settings where thoracoscopy is readily available. In many LMICs, closed pleural biopsy remains the most accessible tissue-sampling technique, yet guidelines provide limited direction regarding when to escalate from fluid-based diagnostics to biopsy.[6]

Conventional cytology has a widely reported sensitivity of 40–60% for MPE, while cell block preparation has demonstrated improved yields of 50–96% across various series.[7,8,9] Closed pleural biopsy, though associated with procedural morbidity, provides architectural tissue that may be essential for certain tumour types.[10,11] The critical clinical question in resource-constrained settings is not merely which test performs best overall, but rather when each test should be deployed to maximise cumulative yield while minimising unnecessary invasive procedures and costs.

We hypothesised that a systematic stepwise approach — stratifying patients based on initial test results and clinical characteristics — could achieve high cumulative diagnostic yield while reserving invasive biopsy for scenarios where it offers demonstrable added value. The present investigation was designed to develop such an algorithm from prospective data and to identify specific clinical scenarios, including inconclusive cell block results and suspected non-pulmonary metastatic disease, where selective escalation to biopsy may be particularly beneficial.

MATERIALS AND METHODS

Study Design and Setting: This prospective observational study was conducted at the Department of Pulmonary Medicine of a tertiary referral hospital in Hyderabad, Telangana, India, over 18 months (January 2023–June 2025). The hospital serves a predominantly low-income population. Ethical clearance for this work was obtained from the Institutional Review Board (IEC/OMC/2022/457). Prior to any study procedure, each participant provided written informed consent. The study was following the ethical principles set out in the Declaration of Helsinki. This manuscript is one of three companion papers arising from the same prospective cohort; the companion papers report comparative diagnostic efficacy and procedural safety respectively.[13,14]

Patient selection

Sixty consecutive patients with moderate-to-large pleural effusions and clinical suspicion of malignancy were enrolled. Inclusion criteria were: age ≥18 years, exudative effusion by Light's criteria,[12] and clinical or radiological features suspicious for malignancy. Exclusion criteria included known coagulopathy, inability to consent, empyema, and previously confirmed malignancy with established tissue diagnosis.

Diagnostic procedures

All enrolled patients underwent the following standardised sequential investigations:

Step 1 — Conventional cytology: Pleural fluid (50 mL) obtained by thoracentesis was processed for routine cytological examination using Papanicolaou and May-Grünwald-Giemsa stains.

Step 2 — Cell block preparation: Additional pleural fluid (50–100 mL) was processed using the cell block technique with formalin fixation and paraffin embedding, enabling histological sectioning and immunohistochemistry (IHC) where indicated.

Step 3 — Closed pleural biopsy: Abrams needle biopsy was performed in all patients, obtaining 4–6 tissue cores from the parietal pleura under local anaesthesia.

For the purposes of algorithm development, all three modalities were performed in every patient regardless of preceding test results, enabling calculation of sequential and additive diagnostic yields.

Algorithm development

The stepwise algorithm was developed using decision-tree analysis incorporating: (a) diagnostic yield at each sequential step, (b) incremental yield of subsequent tests conditional on preceding results, (c) tumour-type-specific detection patterns, and (d) estimated procedural costs. The algorithm was designed to identify decision points where escalation to a more invasive modality would offer clinically meaningful diagnostic gain.

Outcome measures

The primary outcome was cumulative diagnostic yield of the sequential algorithm. Secondary outcomes included: (a) rescue biopsy success rate (proportion of inconclusive cell blocks subsequently diagnosed by biopsy), (b) tumor-type-specific optimal modality, and (c) estimated cost savings of the stepwise approach versus universal biopsy.

Statistical analysis

Diagnostic yields were calculated as proportions with 95% confidence intervals. Comparisons between modalities for categorical outcomes used McNemar's test for paired proportions. Fisher's exact test was used for subgroup comparisons. Cost analysis used institutional fee schedules. All analyses were performed using SPSS version 26.0. Given the sample size of 60, the present study is best regarded as descriptive and hypothesis-generating.

RESULTS

Cohort characteristics

Of 60 enrolled patients, 29 (48.3%) were male and 31 (51.7%) were female. The mean age was 54.6 ± 12.8 years. Hemorrhagic effusions were present in 50 (83.3%) patients. Right-sided effusions predominated (58.3%). Final diagnoses included primary lung malignancy (n=28), mesothelioma (n=10), non-pulmonary metastatic disease (n=10), lymphoma (n=2), and cases remaining undiagnosed after all three modalities (n=10).

Sequential diagnostic yields

Conventional cytology identified malignancy in 18.3% (11/60) of patients. Cell block analysis, performed in all 60 patients, detected malignancy in 48.3% (29/60). Pleural biopsy diagnosed malignancy in 53.3% (32/60). Using the proposed sequential algorithm (cytology → cell block → selective biopsy for inconclusive or high-suspicion cases), the cumulative diagnostic yield reached 95% [Figure 1 and Algorithm 1].

The rescue biopsy phenomenon

A notable finding was the performance of pleural biopsy in cases where cell block yielded inconclusive results. Of 60 patients, 9 (15%) had cell block results classified as inconclusive (atypical cells suspicious but not diagnostic of malignancy). All 9 of these patients (100%) were subsequently confirmed as malignant on pleural biopsy. This "rescue biopsy phenomenon" is derived from a small subgroup and requires validation in larger cohorts. If confirmed, this pattern would suggest that inconclusive cell block results may serve as a strong indicator for escalation to tissue biopsy rather than repeat fluid sampling.

Tumor-type-specific detection patterns

A substantial difference in detection rates for non-pulmonary metastatic disease between cell block and biopsy was observed. [Table 1] Among 10 patients with metastases from non-pulmonary primaries (breast, renal, ovarian, gastric, thyroid), biopsy detected malignancy in 9 (90%) compared to only 1 (10%) by cell block. This difference was statistically significant (Fisher's exact test, p=0.004). This may reflect differences in the mechanism of pleural involvement, with non-pulmonary metastases potentially involving the parietal pleura via hematogenous spread rather than by free exfoliation into the pleural space, though this mechanistic explanation requires further investigation.[15,16]

In contrast, for primary lung adenocarcinoma, cell block performed comparably to biopsy (77.8% vs 83.3%). Mesothelioma showed intermediate results with biopsy superiority (60.0% vs 30.0% for cell block), consistent with known challenges in cytological diagnosis of mesothelioma. [17,18]

Algorithm performance and cost implications

The proposed stepwise algorithm [Figure 1] demonstrated the following performance characteristics in this cohort:

- If applied sequentially (biopsy reserved for inconclusive cell blocks and suspected non-pulmonary metastases), approximately 35% of patients would require invasive biopsy rather than 100% under a universal biopsy strategy.
- Estimated cost savings were approximately 30% compared to universal biopsy, based on institutional fee schedules (cytology □500, cell block □1,200, biopsy □3,000).
- Cumulative diagnostic yield of 95% was achieved with the sequential approach.

These cost estimates are specific to the institutional context and may not be directly generalizable to other settings.

Table 1: Tumor-Type-Specific Detection Patterns by Diagnostic Modality (N=60)

Primary Tumor Site	Total (n)	Cytology n (%)	Cell Block n (%)	Biopsy n (%)	Suggested Approach
Primary lung	28	10 (35.7)	21 (75.0)	22 (78.6)	Cell block
— Adenocarcinoma	18	7 (38.9)	14 (77.8)	15 (83.3)	Cell block
— Squamous cell	6	2 (33.3)	4 (66.7)	4 (66.7)	Cell block
— Small cell	3	1 (33.3)	2 (66.7)	2 (66.7)	Cell block
Mesothelioma	10	0 (0)	3 (30.0)	6 (60.0)	Biopsy
Non-pulmonary metastases	10	1 (10.0)	1 (10.0)	9 (90.0)	Biopsy
— Breast	3	0 (0)	1 (33.3)	3 (100)	Biopsy
— Renal	2	0 (0)	0 (0)	2 (100)	Biopsy
— Ovarian	2	0 (0)	0 (0)	2 (100)	Biopsy
— Gastric	2	1 (50.0)	0 (0)	1 (50.0)	Biopsy
— Thyroid	1	0 (0)	0 (0)	1 (100)	Biopsy
Lymphoma	2	0 (0)	0 (0)	1 (50.0)	Flow cytometry
Undiagnosed	10	0 (0)	4 (40.0)	4 (40.0)	—
Total	60	11 (18.3)	29 (48.3)	32 (53.3)	—

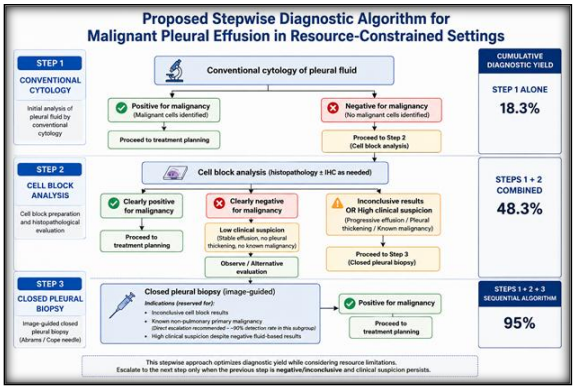
Non-pulmonary metastases showed a 9-fold higher detection rate by biopsy vs cell block (90% vs 10%, p=0.004, Fisher's exact test). This observation requires validation in larger cohorts.

[Figure 1 & Algorithm 1] Proposed Stepwise Diagnostic Algorithm for Malignant Pleural Effusion in Resource-Constrained Settings

The algorithm depicts three sequential decision nodes:

- **Step 1 — Conventional cytology:** Patients with positive cytology proceed directly to treatment planning. Cytology-negative patients proceed to Step 2.
- **Step 2 — Cell block analysis:** Patients with clearly positive cell blocks proceed to treatment. Patients with clearly negative cell blocks and low clinical suspicion may be observed or undergo alternative evaluation. Patients with inconclusive cell blocks or high clinical suspicion (progressive effusion, pleural thickening, known malignancy) proceed to Step 3.
- **Step 3 — Closed pleural biopsy:** Reserved for: (a) inconclusive cell block results; (b) patients with known non-pulmonary primary malignancy (direct escalation recommended based on 90% biopsy detection rate in this subgroup); (c) high clinical suspicion despite negative fluid-based results.

Cumulative diagnostic yield at each node: Step 1 alone 18.3%; Steps 1+2 combined 48.3%; Steps 1+2+3 sequential algorithm 95%.



DISCUSSION

Contextualizing the stepwise approach

The present data suggest that a stepwise diagnostic algorithm may offer a practical framework for MPE diagnosis in resource-constrained settings. The concept of sequential testing is not new — BTS guidelines recommend cytology followed by biopsy for negative cases[4] — but this algorithm introduces two refinements: (a) an intermediate cell block step between cytology and biopsy, and (b) tumor-type-specific recommendations for early escalation to biopsy.

The intermediate cell block step is supported by multiple series demonstrating substantial incremental yield over conventional cytology.[7,8,9,19] In this cohort, cell block increased the cumulative yield from 18.3% to 48.3%, representing a 30-percentage-point gain without additional procedural invasiveness. This finding aligns with Saha and Bonnier's advocacy for routine cell block preparation as a bridge between cytology and tissue biopsy.[20]

The rescue biopsy observation

Perhaps the most clinically relevant observation from this data is the 100% diagnostic yield of biopsy in patients with inconclusive cell blocks. While the number of patients (n=9) precludes definitive conclusions, this preliminary finding, if validated, could have important implications for clinical decision-making. Currently, inconclusive cytological results often prompt repeat thoracentesis or prolonged observation.[4,5] These data suggest that in settings where closed pleural biopsy is readily available, direct escalation to biopsy may be preferable to repeat fluid sampling in this subgroup.

This observation is biologically plausible. Inconclusive cell blocks — containing atypical but non-diagnostic cells — may reflect tumors with poor exfoliation that nonetheless involve the parietal pleura in a pattern amenable to needle biopsy.[10,15] DiBonito et al. noted that certain tumor types, particularly those with desmoplastic or sclerotic growth patterns, shed fewer diagnostic cells into the pleural space while maintaining parietal pleural involvement.[21]

The non-pulmonary metastases observation

The finding that biopsy markedly outperformed cell block for non-pulmonary metastases (90% vs 10%) warrants cautious interpretation given the small subgroup size (n=10). Hypothetically, non-pulmonary malignancies may reach the pleura via hematogenous dissemination to the parietal pleura rather than through visceral pleural invasion and free cellular exfoliation.[15,16] If confirmed in larger cohorts, this finding would support a recommendation for early biopsy in patients with known non-pulmonary malignancies presenting with pleural effusion.

Porcel noted that the mechanism of pleural involvement varies by primary tumor site, with some extra thoracic malignancies preferentially involving the parietal pleura through chest wall or mediastinal lymph node metastases.[22] These observations are consistent with this hypothesis, though the sample size is insufficient to establish causality or rule out confounding factors.

Comparison with existing algorithms

The BTS 2023 guidelines recommend a pathway of cytology followed by local anesthetic thoracoscopy (LAT) or image-guided biopsy for cytology-negative cases.[4] The ACCP guidelines similarly recommend thoracoscopy as the procedure of choice for undiagnosed exudative effusions.[5] The proposed algorithm differs in two key respects: (a) it incorporates cell block as an explicit intermediate step, and (b) it positions closed pleural biopsy — rather than thoracoscopy — as the escalation procedure, reflecting resource constraints where thoracoscopy may be unavailable.[6,23]

Villena et al. demonstrated that combining cytology with closed pleural biopsy achieved sensitivity of approximately 74% in their series,[24] while Maskell et al. showed that CT-guided biopsy improved upon blind biopsy yields.[25] The sequential approach in the present study, by incorporating cell block between cytology and biopsy, achieved a higher cumulative yield (95%) in this cohort, though direct comparison

across studies is limited by differences in patient populations and disease prevalence.

Limitations

Several important limitations must be acknowledged. First, the sample size of 60 patients limits statistical power, particularly for subgroup analyses. The rescue biopsy phenomenon (n=9) and the non-pulmonary metastases observation (n=10) represent findings from small subgroups that require external validation before clinical adoption. Second, this is a single-center study from a tertiary referral hospital with high disease prevalence, which may limit generalizability to primary care or lower-prevalence settings. Third, the observational design precludes causal inference; we cannot determine whether the sequential algorithm would perform equivalently if biopsy were truly withheld in low-risk subgroups. Fourth, all patients received all three tests, and the algorithm's performance is modelled rather than prospectively validated in a true sequential implementation. Fifth, operator expertise in closed pleural biopsy at this center may not reflect performance achievable elsewhere. Finally, thoracoscopy — which remains the gold standard — was not included in this study as it was unavailable during the study period.[4,5]

CONCLUSION

In this single-centre observational study of 60 patients with suspected MPE, a stepwise diagnostic algorithm incorporating cytology, cell block, and selective pleural biopsy achieved a cumulative diagnostic yield of 95%. Two preliminary observations — the rescue biopsy phenomenon (100% yield in inconclusive cell blocks) and the apparent superiority of biopsy for non-pulmonary metastases — suggest potential refinements to existing diagnostic pathways for resource-constrained settings. The observations reported here are preliminary and warrant further inquiry and require validation in larger, multicentre cohorts before translation into clinical practice guidelines.

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