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Use of a novel ultrasound sign in the management of malignant pleural effusions: a prospective observational trial

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Abstract

The management of malignant pleural effusion (MPE) is influenced by the lung's ability to re-expand following fluid drainage. Lung entrapment can complicate this process and may be predicted using pleural manometry. Recently, a novel lung ultrasound (LUS) marker—the sinusoidal sign—has emerged as a potential tool to differentiate between expandable and entrapped lung prior to thoracentesis. A prospective observational study was conducted to evaluate the role of pre-drainage LUS in identifying entrapped lung and compare its diagnostic accuracy with pleural manometry. A total of 30 patients with MPE were enrolled. Prior to thoracentesis, targeted ipsilateral LUS was performed at the level of the atelectatic lung. M-mode displacement <1 mm was considered indicative of an absent sinusoidal sign. Simultaneously, pleural manometry was conducted during thoracentesis to measure pressure changes and calculate pleural elastance. Lung expandability was determined based on pleural elastance and post-thoracentesis imaging findings (computed tomography thorax). A pleural elastance >13.6 cm H_2O/L was considered diagnostic of lung entrapment. A pleural elastance cut-off of 13.6 cm H_2O/L demonstrated 100% sensitivity, 93% specificity, a 100% positive predictive value, and 84.2% negative predictive value. The absence of the sinusoidal sign on LUS had a sensitivity of 78.6% and specificity of 100% in identifying entrapped lung. Both absent sinusoidal sign on pre-drainage LUS and elevated pleural elastance (>13.6 cm H_2O/L) during thoracentesis are reliable indicators of lung entrapment in MPE. LUS may serve as a useful, non-invasive bedside tool for early identification of nonexpandable lung.

Key words: malignant pleural effusion, manometry, USG lung.

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Introduction

Malignant pleural effusion (MPE) is a leading cause of exudative pleural effusion worldwide, associated with an average survival of 4-7 months [1]. MPEs are primarily caused by lung cancer in men and breast cancer in women, accounting for 50-65% of all cases [2]. The incidence of MPE has been reported to be up to 50% in lung cancer patients over the entire disease course [3]. While some patients may initially be asymptomatic, most eventually experience dyspnea at rest. Given the limited survival (average 4-7 months), treatment aims to relieve dyspnea through minimally invasive, accurate, and definitive procedures to ensure the best quality of life, minimal morbidity, and increased hospital-free days [1]. Standard management options include pleurodesis or repeated therapeutic aspiration, depending on expected survival and post-drainage lung expansion [4]. The selection of definitive therapeutic management depends upon the patient's expected survival and post-drainage expansion of the lung [5].

Pleurodesis often fails in cases of "nonexpandable lung", where the lung cannot fully expand, preventing the visceral and parietal pleura from adhering. This condition may result from active pulmonary or pleural disease, such as malignancy, infection, hemothorax, or lung cancer with endobronchial obstruction (lung entrapment), or from remote disease causing pleural fibrosis or scarring (trapped lung) [6]. Patients with entrapped lung usually do not benefit from therapeutic aspiration in terms of dyspnea relief. However, if there is symptomatic relief, repeated thoracentesis or an indwelling pleural catheter (IPC) is recommended for these patients. Currently, no pre-drainage methods are available to detect lung entrapment, which often necessitates multiple procedures for effective management [7]. Lung entrapment and successful thoracentesis can be predicted by recording pressure changes during the procedure. Monitoring pleural pressure (Ppl) during thoracentesis offers

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valuable insights into the real-time physiology of the pleural space, helps prevent multiple procedure-related complications, and aids in predicting the success of pleurodesis [8]. An expandable lung does not show significant changes in Ppl during thoracentesis, which is why pleural elastance (PEL) is on the lower side. In contrast, a nonexpandable lung shows significant changes in Ppl, leading to higher PEL. Appropriate management of MPE depends on the lungs' ability to expand after fluid drainage. There is no recommended diagnostic test to guide further management decisions, such as choosing between no aspiration, pleurodesis, or continuous tube drainage. Wong *et al.* developed an ultrasound sign to differentiate between expandable and nonexpandable lung [9]. They hypothesized that an entrapped lung would not show any movement on M-mode lung ultrasound (LUS) due to lack of movement in that region. On LUS, this is reflected by an absent sinusoidal sign [9]. The absent sinusoidal sign is a meaningful early diagnostic indicator of lung entrapment (Figure 1).

The American Thoracic Society guideline for MPE recommends using LUS for pleural interventions and evaluating for nonexpandable lung before thoracentesis in MPE cases [5]. Nonexpandable lung occurs in at least 30% of MPE patients [10,11]. In patients whose dyspnea improves after thoracentesis, the absence of complete lung expansion following fluid evacuation should prompt clinicians to avoid pleurodesis and use IPCs [IPCs]. Several methods exist to assess post-aspiration lung expansion or entrapment: (i) large fluid aspiration [at least 500 ml] to confirm symptomatic improvement and detect nonexpandable lung [12]; (ii) measurement of Ppls or elastance (change in pressure over volume drained) to predict lung expansion; and (iii) post-procedure imaging to assess lung expansion. Among all these methods, complete lung expansion on post-thoracentesis imaging is the most accurate to predict expandable or nonexpandable lung. However, it is not always practically possible because major pressure shifts may limit thoracentesis, especially due to breathlessness or cough in the patient. Therefore, one must rely on other methods as well. In symptomatic MPE patients, large-volume thoracentesis is recommended if it is unclear whether symptoms are related to effusion or if the lung is expandable. IPC is suitable for both expandable and nonexpandable lung and is a viable alternative to pleurodesis in patients with expandable lung [5]. Lung entrapment can be caused by visceral pleural thickening, endobronchial obstruction, or increased elastic recoil. Assessing lung expandability is crucial when considering pleurodesis, as pleural apposition is essential for adequate adhesion [8,13-16]. Pleural manometry estimates PEL and lung mechanical properties, with a PEL greater than 20-25 cm H_2O/L indicating a nonexpandable lung [13]. Techniques for Ppl measurement include U-tube water manometers, commercial digital manometers, simple manometry systems, and customized manometers. Preprocedural diagnosis of trapped lung using LUS can reduce unnecessary procedures, hospital costs, and complications [13,17].

Materials and Methods

We conducted a prospective cross-sectional study at a tertiary care hospital in western India, approved by the ethical committee (approval number: AIIMS/IEC/2020/3318). Patients with suspected MPE secondary to lung malignancy were enrolled, specifically patients with moderate to massive effusion. Exclusion criteria included MPE from extrapulmonary malignancy, lung cancer with non-malignant effusion (*e.g.*, infective, paramalignant, undiagnosed), hemodynamic instability, or cardio-pulmonary failure.

Study objective

The primary objective of our study was to assess the diagnostic yield of LUS in identifying entrapped lung and compare its performance with pleural manometry. The secondary objective was to evaluate the utility of LUS in predicting the appropriate management strategies for MPE.

Data was collected using a structured proforma, including demographics, radiology, pathology findings, and performed interventions. MPE was diagnosed based on pleural fluid cytology or pleural biopsy, with cases excluded if follow-up reports did not

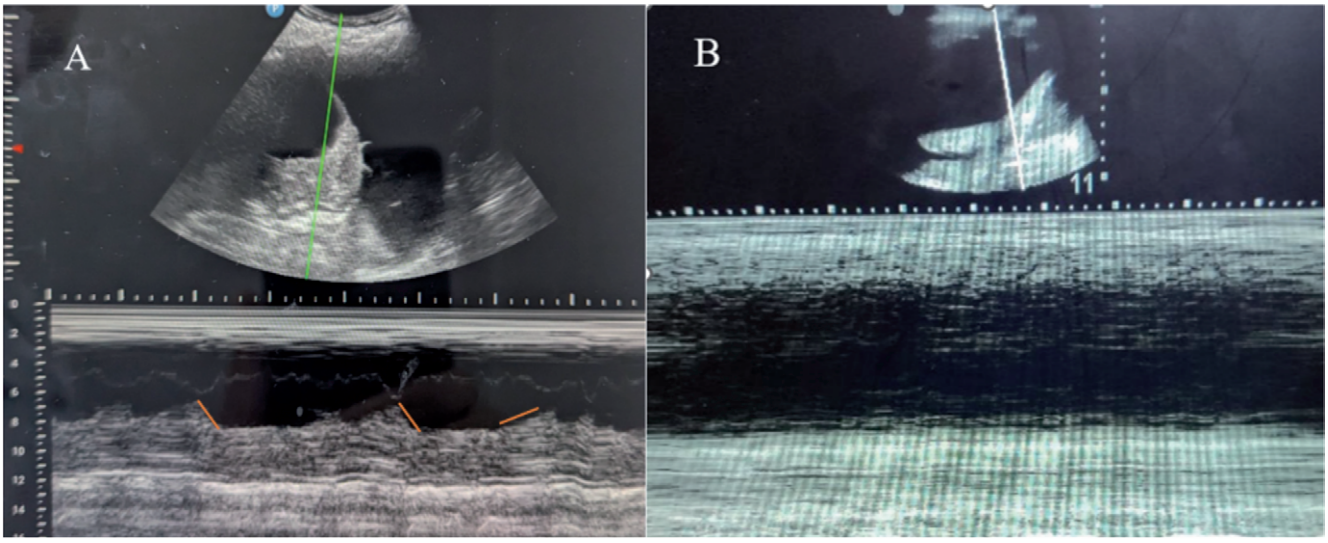


Figure 1. A) Sinusoid sign, respiratory variation of atelectatic lung; B) absent sinusoid sign, no respiratory variation because of entrapped lung.

confirm MPE. Only patients with positive pleural fluid cytology were enrolled, confirming malignant effusion secondary to lung malignancy. LUS images were obtained before intervention using a 2- to 5-MHz transducer probe. The pleural fluid amount was initially measured in the sitting upright posture. Effusion was considered moderate if it spanned at least three interspaces on ultrasonography with a depth of 3 cm or greater in at least one interspace while upright. At the level of atelectasis, lung displacement was recorded using M mode in the supine posture. The "sinusoid sign", a sinusoidal pattern of atelectatic lung movement within surrounding pleural fluid, indicates an expandable lung. An M mode waveform value of <1 mm was used as the cut-off for identifying an entrapped lung. The absence of sinusoidal respiro-phasic lung motion, known as the "absent sinusoid sign", suggests a nonexpandable lung. The presence or absence of the sinusoidal sign was recorded for each patient (Figure 1).

Pleural manometry

Pleural manometry was performed to monitor pressure changes and calculate PEL. After administering local anesthesia, a pleural pigtail catheter (10 gauge) was inserted under LUS guidance into the pleural cavity (4th to 5th intercostal space) in the midaxillary line while the patient was supine. The catheter was connected to a pressure transducer and an electric cardiac monitor (Mindray UMEC 12 Patient), with the transducer fixed at the catheter level to nullify height-related pressure differences. A three-way stopcock was placed between the pressure transducer and the pleural catheter, connecting to a drainage bag and a 50 ml syringe (Figure 2). Pleural fluid was aspirated with the syringe and collected in the drainage bag. The pressure zero point was set on the monitor. Repositioning the stopcock handles allowed fluid aspiration, ejection into the drainage bag, and pressure measurement. Initial pressure measurement was taken after aspirating 50 mL of fluid. After every 100 to 200 mL of fluid removal, subsequent measurements were taken, up to 1000 mL. Drainage was stopped if patients experienced chest discomfort, intractable cough, procedural complications, or if pressure dropped below –20 cm H_2O or declined by more than 10 cm H_2O between measurements. The –20 cm H_2O limit was based on historical definitions and current practice guidelines [15]. The procedure was done using sterile techniques, and complete fluid evacuation was attempted via manual aspiration with a 50 mL syringe. A minimum of 100 to 150 mL of fluid was aspirated from each patient. Patients were asked about chest discomfort during aspiration. Ppl was recorded in mmHg and converted to cm H_2O [1 mmHg = 1.36 cm H_2O]. PEL was calculated as the pressure change (cm H_2O) per L of pleural fluid drained.

The gold standard for diagnosing entrapped or expandable lung was post-drainagecomputed tomography (CT) chest findings. We did not use definitive criteria for the entrapped lung. There had to be air between the visceral and parietal pleura around the lower lobe without an air leak through the chest catheter for an entrapped lung on a CT chest. However, this condition is difficult to achieve due to extreme negative pressure and severe pain during thoracentesis. In our study, a lung was considered entrapped if: (i) extreme negative Ppl (<-10 cm H_2O) was recorded; (ii) High PEL (>20 cm H_2O/L) was noted during the procedure; (iii) severe chest pain occurred during the procedure.

Definitive intervention

Based on pleural manometry and CT chest findings, patients were offered therapeutic options such as therapeutic thoracentesis,

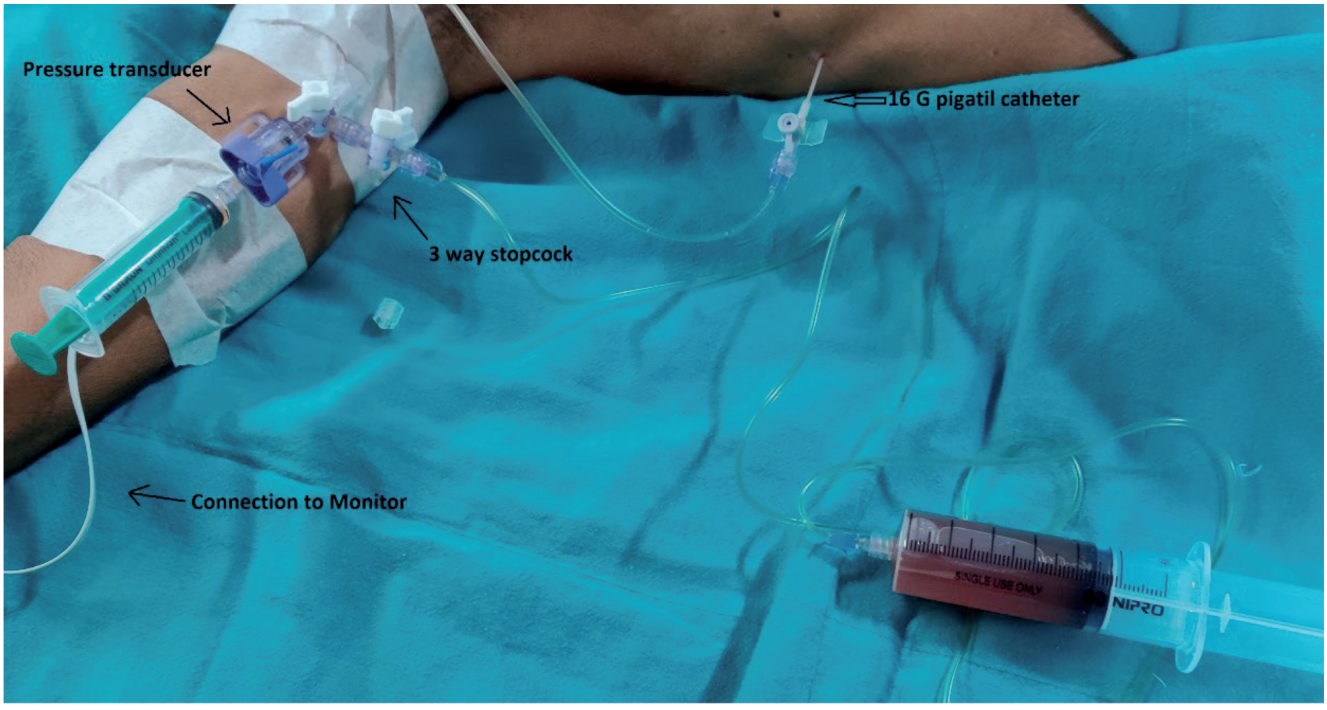


Figure 2. Technique of electrical manometry via a pressure transducer.

IPC, pleural pigtail catheter, intercostal drainage placement, or pleurodesis. No further intervention was performed if there was no symptomatic relief after drainage. A 16F pleural pigtail was used for long-term drainage. Patients were followed up after 1 month for a definitive entrapped or expandable lung diagnosis.

Statistical analysis

The data were entered into Microsoft Excel and analyzed using R software version 4.2.0. Quantitative data were summarized using means, standard deviation (SD), median, and interquartile range. Statistical analyses included the Chi-square test, *t*-tests for means, and t-tests for proportions for quantitative data. The diagnostic performance of PEL and the absence of the sinusoidal sign were evaluated using parameters such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratios (positive and negative). Receiver operating characteristic (ROC) curve analysis was performed, and area under the curve (AUC) values were calculated for each parameter. The cut-off value of PEL to predict an entrapped lung was determined using the Youden method. A significance level of $p<0.05$ was considered statistically significant.

Results

A total of 41 patients with lung mass and suspected/proven moderate to massive MPE were included in the study. A total of 11 patients were ineligible for the study [transudate effusion or cytology negative for malignancy (n=7), loss to follow-up (n=2), multiloculated effusion (n=1) and hemodynamically unstable (n=1)]. A total of 30 patients with lung malignancy with malignant pleaural effusion were enrolled in the study.

A total of 30 patients, with 24 males (80%) and 6 females (20%), aged 63.7 years on average (SD ±10.3, range 34-87 years), were enrolled. Adenocarcinoma was the predominant lung malignancy (70%), followed by squamous cell carcinoma (17%) and small cell carcinoma (13%). Table 1 details manometric measurements, including starting Ppl, end Ppl, total drained fluid, and PEL before drainage. The sinusoidal sign was absent in 11 patients, who had a mean PEL of 27.76 (±7.5 $p<0.005$). In contrast, the mean PEL was significantly lower in the 19 patients who exhibited a positive sinusoidal sign (Table 2). A cut-off PEL value of 13.6 cm H_2O/L predicted lung entrapment with 100% sensitivity, 93% specificity, and a 100% PPV, and 84.2% NPV (Tables 3 and 4).

Table 1. Different descriptive values observed during manometry in the study population.

Statistical measures	Starting Ppl (cm H_2O)	End Ppl (cm H_2O)	PEL (cm H_2O/L)	Fluid drained (L)
Mean	9.88	0.54	16.56	0.84
Median	9.52	2.04	12.24	0.75
Mode	12.24	5.44	6.80	1.00
Standard deviation	5.31	6.49	11.79	0.58
Minimum	-2.72	-13.60	2.18	0.15
Maximum	21.76	9.52	40.80	2.50

Ppl, pleural pressure; PEL, pleural elastance.

Table 2. Relation between sinusoidal sign and pleural elastance.

Characteristic	Sinusoidal sign [-] (n=11)	Sinusoidal sign [+] (n=19)	p	Statistical test used
PEL (cm H2O/L)	27.76 (±7.5)	10.07 (±8.5)	0.00001	t-test for means

Table 3. Cut-off value of pleural elastance to predict lung entrapment by the Youden method.

Variable	Cut off value of PEL to predict lung entrapment
Sensitivity	1
Specificity	0.93
PPV	0.93
NPV	1
Optimal criterion	0.93
Cut off (cm H2O/L)	13.6

PEL, pleural elastance; PPV, positive predictive value; NPV, negative predictive value.

Table 4. Odds ratio and accuracy of absent sinusoidal sign in the prediction of lung entrapment.

Variable	No	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Accuracy	OR (95% CI)	p
Absent sinusoidal sign	11	78.57 (49.2-95.3)	100 (79.4-100)	100	84.2 (66.2-93.6)	90 (73.5-97.9)	108.4 (5.1-2306)	0.0027

CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value; OR, odds ratio.

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A total of 14 patients had nonexpendable or entrapped lungs, with an absent sinusoidal sign showing 78.6% sensitivity, 100% specificity, and 90% accuracy (odds ratio 108.4, p<0.005). ROC curves (Figure 3) showed PEL's high predictive value (AUC=0.99) for entrapped lung.

Based on manometry and CT findings, different interventions were performed. Further interventions were avoided in 9 out of 14 patients with entrapped lung. A total of 5 patients had relief in dyspnea with thoracentesis, so further standard recommended interventions were followed, including repeated thoracentesis or placement of an IPC [5]. A pigtail catheter was placed in 1 patient instead of an IPC due to cost constraints, while 4 patients chose repeated thoracentesis and declined both pigtail and IPC insertion. Pleurodesis was performed in 10 out of 16 patients with expandable lung; all achieved successful outcomes without requiring repeat thoracentesis during follow-up. Among the remaining 6 patients with expandable lung, 4 had poor Eastern Cooperative Oncology Group Performance Status (ECOG) scores and were planned for repeated thoracentesis, while two patients declined pleurodesis and had a pigtail catheter placed instead.

Discussion

We enrolled 30 eligible patients, with a male predominance. The mean age was 63.7 years [SD ±10.33], with 76.6% of cases aged between 50 and 70 years, mirroring findings from similar studies [18-20].

MPE occurs in up to 40% of cases, causing breathlessness in 10-15% of patients [1]. Definitive pleural interventions like pleurodesis and IPC can be safely performed in a day-care setting following a thorough evaluation guided by post-aspiration symptoms and radiological findings [5].

During pleural manometry, initial and end Ppl ranged from -2.76 to 21.72 cm H_2O and -13.6 to 9.52 cm H_2O, respectively, with mean values of 9.88 (±5.31) cm H_2O and 0.54 (±6.49) cm H_2O. Study pressure ranges vary; Light *et al*. initially recorded -21 to 8 cm H_2O, dropping to -50 cm H_2O post-aspiration due to various types of pleural effusion, including trapped lung cases [4]. Chopra *et al*. and Feller-Kopman reported similar ranges, focusing on MPEs [21,22]. PEL ranged from 2.18 to 40.8 cm H_2O/L, mean 16.5 (±11.8) cm H_2O/L, consistent with prior studies [21,22]. A PEL cut-off of 13.6 cm H_2O/L predicted lung entrapment with 100% sensitivity, 93% specificity, and high predictive values, supported by an ROC AUC of 0.99 [17,22]. Salamonsen *et al.* noted lower sensitivity (40%) with a higher PEL cut-off (19 cm H_2O/L) and an AUC of 0.69, attributed to differing effusion etiologies [17]. Historical studies cited varying PEL cut-offs (14-15 cm H_2O/L *vs*. 19-24 cm H_2O/L) influenced by study populations [8,15,22]. Our study focused on cytology-proven MPE cases, excluding para-malignant effusions [22].

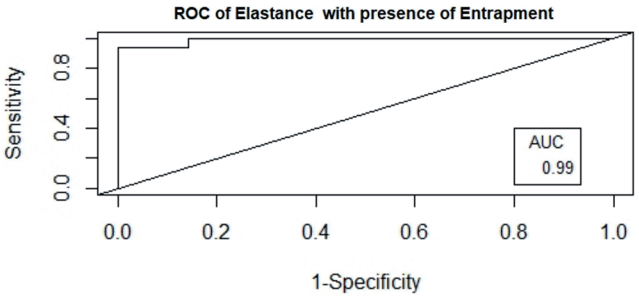


Figure 3. Receiver Operating Characteristic (ROC) curve of fluid drainage with presence of lung entrapment.

The sinusoidal sign was absent in near 40% (11) of patients. Absent sinusoidal sign correlated with higher mean PEL (27.76±7.5 cm H_2O/L) compared to its presence (10.07±8.5 cm H_2O/L, p<0.005), indicating potential lung entrapment with elevated PEL values. Absence of the sinusoidal sign showed 78.6% sensitivity, 100% specificity, and high predictive values (PPV 100%, NPV 84.2%, accuracy 90%) with an odds ratio of 108.4 (p<0.005) for predicting entrapped lung. Salamonsen *et al*. reported lower sensitivity (50%) and near similar specificity (87.5%) in their study on MPE patients with expandable lung, possibly due to the inclusion of non-pulmonary malignancy-related MPEs [17]. Definitive treatment of MPE in our study relied on manometry and post-aspiration radiology. Standard recommended treatments were followed, including repeated thoracentesis or placement of an IPC if thoracentesis relieved dyspnea [5].

Performing LUS before thoracentesis is considered standard of care. By adding sinusoidal sign screening to routine LUS, one can predict potential future management strategies during the first thoracentesis, minimizing the number of future interventions and hospital stay or visits. Therefore, LUS should be practiced in all suspected MPE patients. While pleural manometry is more accurate, screening for the sinusoidal sign can also predict entrapped lung with good accuracy.

The limitations of this study include a small sample size, which restricts the generalizability of the findings to all MPE patients. Using a pressure transducer with an electric cardiac monitor for Ppl measurement needs to be validated, necessitating further research for confirmation. We used a pressure transducer with an invasive pressure monitor, which is time-consuming (around 30 to 40 minutes) and a complex procedure; alternatively, a digital pleural manometer can be used, as it is easy to use and time-consuming. A single observer performed LUS without addressing interobserver variability. One limitation of our study is the broad inclusion criteria for patients with entrapped lung, which may result in lower-than-expected elastance values. Consequently, the predictive elastance value may have lower specificity and could lead to the inclusion of patients without true lung entrapment.

Conclusions

Absent sinusoidal sign in LUS and raised PEL in pleural manometry (>13.6 cm H_2O/L) during the thoracentesis can accurately predict an entrapped lung. Pleural manometry is a more confirmatory tool and can predict expandable and entrapped lung with better sensitivity. The routine use of LUS and pleural manometry can aid in the optimal management of moderate to massive MPEs and assist in determining the appropriate timing for pleural interventions. Further studies are needed to evaluate these parameters and establish the threshold for PEL in manometry.

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