Deflating the Puncture: Artificial Pneumothorax vs. Direct Entry for Medical Thoracoscopy in the "Dry" Pleural Space

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Kaige Wang et al
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The clinical question

For patients with minimal or absent pleural effusion, is nonartificial pneumothorax (non-AP) noninferior to artificial pneumothorax (AP) in terms of the pleural access success rate for patients undergoing medical thoracoscopy?

Take Home Message

For patients with minimal or absent pleural effusion, inducing an artificial pneumothorax is not necessary prior to performing medical thoracoscopy. In fact, the success rate of establishing pleural access is statistically higher with a non-AP approach. There were no statistical differences in the rate of complications between the two groups, however, larger studies are needed to confirm the safety of the procedure without inducing pneumothorax prior to medical thoracoscopy.

Background

Medical thoracoscopy (MT) requires an adequate pleural space to place a trocar and safely perform pleural inspection and biopsy. Patients with minimal or no pleural effusion often have pleural adhesions, making the procedure difficult. Current thoracoscopy guidelines recommend inducing an artificial pneumothorax before MT in these patients to access the pleural space. Prior case reports and series such as Marchetti et al., Tamburrini et al. and Imabayashi et al. reported success utilizing bladeless optical trocars for direct visual entry into the pleural space. Furthermore, current expert-level series and ERS guidelines suggest that direct blunt entry or optical-access trocar insertion is safe and effective when pre-procedural thoracic ultrasound confirms a robust "lung sliding sign," effectively mitigating the risk of parenchymal injury that historical iatrogenic air induction was designed to prevent. While these previous single-arm studies suggested that skipping artificial pneumothorax (AP) might reduce operative times and complications, there has been a lack of randomized trials directly comparing the efficacy and safety of the AP versus non-AP approaches in this specific population.

Study design

Study design:
Multicenter randomized controlled noninferiority trial.

Primary outcome:
Pleural access success rate, defined as the proportion of successful entries into the pleural cavity that allowed the collection of pleural effusion or tissue specimens.

Secondary Outcome(s):
Pathological confirmation rates, Length of operation, Chest air leak and drain removal duration, Chest pain scores, and 90-day mortality.

Intervention(s):
In the Artificial Pneumothorax (AP) Group, pneumothorax was established prior to medical thoracoscopy. For patients with a visible anechoic area (pleural effusion), access was achieved via thoracic puncture and a guidewire. In those without an anechoic area, a concentric puncture cannula and blunt needle were advanced until a rapid decline in saline levels within a connected syringe confirmed entry into the pleural cavity. A central venous catheter was then guided over the wire for a distance of 4–10 cm and secured. Through this catheter, filtered air was slowly injected until resistance was encountered or a maximum volume of 300 mL was reached. The induction of the pneumothorax was subsequently confirmed via radiography or thoracic ultrasonography. In the Non-Artificial Pneumothorax Group, the extra step of establishing a pneumothorax was not performed. After the pleural access point was determined, local anesthesia (2% lidocaine) was administered, and a 1-cm incision was made. A trocar was inserted following simple blunt dissection, allowing the operator to bluntly dissect adhesion bands around the incision site to expose the pleural cavity. Subsequently, all patients remained under conscious sedation and analgesia with propofol and remifentanil throughout the procedure. The parietal, diaphragmatic, and visceral pleura were visually examined using a video-assisted semirigid thoracoscope. At least 8 pleural biopsy specimens were collected from each patient using biopsy forceps.

Population

Inclusion criteria:

- Patients aged at least 18 years.
- Presence of undiagnosed pleural disease.
- Minimal (maximum, 3-cm depth when seated) or no pleural effusion.
- Scheduled for medical thoracoscopy.

Exclusion criteria:

- Complete absence of pleural space due to adhesions.
- Inability to tolerate medical thoracoscopy due to conditions such as lateral decubitus intolerance, cardiovascular and hemodynamic instability, significant pulmonary hypertension, aortic dissection, myocardial infarction, refractory cough, ongoing respiratory failure, bleeding tendency (platelets < 60 x 10^9/L, or international normalized ratio > 1.2), short expected survival or poor systemic condition, or cutaneous infection, metastasis, or rib fracture around the port insertion site.
- Consent withdrawal.
- Enrollment in other research studies.

Baseline Characteristics:

- A total of 203 patients were enrolled.
- The cohort was predominantly male (62.6%) with a mean age of 58.2 ± 12.5 years.
- The mean BMI was 23.2 ± 3.3, and 38.9% of patients had a smoking history.
- At baseline, most patients (57.6%) presented with pleural sliding at the pleural access point, while 30.0% showed signs of an anechoic area. Only 12.3% had questionable pleural sliding sign at the pleural access point.
- The median pleural effusion depth was 15.0 mm.
- The primary diagnoses included undiagnosed pleural effusion (82.8%), undiagnosed pleural nodules (11.3%), and undiagnosed pleural thickening (5.9%).
- The non-AP group had a higher number of Undiagnosed pleural nodules, and Undiagnosed pleural thickening as indications: 15 cases in the non-AP group (14.9%) vs 8 cases in the AP group (7.8%) and 8 cases in the non-AP group (7.9) vs 4 cases (3.9%) in the AP group respectively. Otherwise, both groups' characteristics seemed to be balanced with no striking differences.

Outcomes

Primary outcomes:

- The pleural access success rate was 95.0% (96 of 101 patients) in the non-AP group compared to 78.4% (80 of 102 patients) in the AP group.
- The absolute between-group difference was 16.6% (1-sided lower 97.5% CI, 7.6%), demonstrating noninferiority (P < .001).

Secondary outcomes:

- Pathological confirmation rates: Rates were similar between the non-AP group (76.0%) and the AP group (75.0%), with a non-significant between-group difference of 1 percentage point (P = .873).
- Length of operation: The non-AP group had a significantly shorter median operation time of 32.4 minutes compared to 39.9 minutes in the AP group (P < .001). However, this is not clinically significant.
- Chest air leak and drain removal duration: Both were shorter in the non-AP group (median 26.1 hours for air leak; 51.4 hours for drain removal) compared to the AP group (median 27.6 hours for air leak, 56.5 hours for drain removal), though the differences were not statistically significant.
- Chest pain scores: There were no significant differences in the visual analog scale (VAS) pain scores assessed within 48 hours after the procedure.
- 90-day mortality: The mortality rate was 1.0% (1 death) in the non-AP group and 2.0% (2 deaths) in the AP group.

Adverse events:

- The overall complication rates were similar between the two groups, occurring in 14.9% of the non-AP group and 17.6% of the AP group (P = 0.589).
- Complications specifically secondary to the artificial pneumothorax procedure occurred in 7.8% of the AP group (these included lung lacerations, subcutaneous emphysema, pleural reactions, and air embolisms), however, the overall complication rate was similar between both groups.
- Complications secondary to the medical thoracoscopy itself were comparable between groups (15.6% in the non-AP group vs. 12.5% in the AP group) and included pleural reactions, lung lacerations, subcutaneous emphysema, poor wound healing, and one instance of tumor metastasis through the chest wall incision.
- There was 1 case of thoracic bleeding, 2 cases of poor wound healing, and 1 case of tumor metastasis through the chest wall in the non-AP group compared to none in the AP group, however, low frequency of complications makes the study less powered to detect a significant difference if one exists.
- None of the AP group participants complained of severe chest pain post-procedure compared to 3 in the non-AP group, however the difference was not statistically significant.

Commentary

(AABIP criticism)

This multicenter, randomized trial provides compelling evidence that a non-artificial pneumothorax approach is non-inferior (and potentially superior) to the traditional artificial pneumothorax method for medical thoracoscopy in dry pleural spaces. By achieving a 95.0% pleural access success rate compared to 78.4% in the AP group ($p < .001$), the study suggests that the non-AP technique facilitates more reliable access and reduces median operation times (albeit without clinical significance) while maintaining diagnostic yields and safety. However, the study's internal validity is tempered by a significant clustering effect. A single center contributed over 50% of the patient population, meaning the results may disproportionately reflect the expertise of a specific high-volume site rather than universal applicability. This concern is further emphasized by the striking heterogeneity in case screening and inclusion rates across participating facilities. Furthermore, while the prospective design and objective adherence scoring are methodological strengths, the lack of operator blinding and the limited statistical power regarding rare adverse events (such as isolated thoracic bleeding, poor wound healing, and tumor metastasis exclusively in the non-AP group) necessitate a cautious interpretation of the procedural safety profile. Notably, the higher proportion of patients with pleural nodules and thickening in the non-AP cohort, combined with the limited representation of patients with questionable pleural sliding at the port of entry, makes safety deductions in these specific populations difficult. Ultimately, while this research provides a high-quality proof of concept for the technique's efficacy, larger and more balanced multicenter studies are required to definitively confirm the safety profile of omitting artificial pneumothorax induction.

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Suggested Reading

(References in Vancouver style)

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Contributors

Author: Falah Abu Hassan MD
The University of Arizona College of Medicine – Phoenix

Reviewer: Yaron B. Gesthalter MD
University of California, San Francisco

Reviewer: Max T. Wayne MD
University of Michigan

If you would like to become a reviewer for the "AABIP Journal Club," Please contact Christian Ghattas at christian.ghattas@osumc.edu