

Is conservative management noninferior to interventional treatment for moderate to large primary spontaneous pneumothoraces?

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INTRODUCTION

Background: Current American and British Pulmonology Guidelines advise immediate interventional management of most large (>2 cm at hilum; >3 cm at apex) primary spontaneous pneumothoraces.^{1,2}

Objectives: Is observation of moderate-to-large primary spontaneous pneumothoraces (> 32% by Collins method) noninferior to immediate interventional management assessed by complete lung re-expansion within 8 weeks.

METHODS

Design

Multicenter randomized, open-label, noninferiority trial, with 9% noninferiority margin to demonstrate conservative management is not inferior to interventional treatment.

Setting

Thirty-nine hospitals in Australia and New Zealand.

Subjects

Patients aged 14–50 years with first-time unilateral primary spontaneous pneumothorax of $\geq 32\%$.

Intervention

Conservative (repeat imaging after 4 hours, discharge if no supplemental oxygen required; chest tube inserted

if clinically unwell) v. intervention (chest tube (≤ 12 F) with suction; remove and discharge if resolved on chest x-ray at 4 hours or admission).

Outcomes

The primary noninferiority outcome was complete radiographic resolution of the pneumothorax 8 weeks after randomization. Numerous secondary outcomes.

RESULTS

A total of 316 of the 2,637 screened patients underwent randomization; 154 patients to the intervention group, and 162 in the conservative-management group. The prespecified noninferiority margin was (-9%) for re-expansion by 8 weeks. The authors based this on an expected resolution rate of 99% for the intervention group and believed a failure rate of 1 in 10 would be clinically acceptable. A margin this size may bias toward finding statistical noninferiority where there is clinical inferiority.

In the Complete Case analysis, the resolution rate in the intervention group was 129/131 (98.5%). Five patients were lost to follow-up, and 18 did not have chest radiography data available at 8 weeks. In the conservative group, 118/125 (94.4%) had a resolved pneumothorax on chest radiography at 8 weeks, 3 patients were lost to follow-up, and 34 did not have complete data. The Risk Difference was -4.1%, 95% CI -8.6 to 0.5, $p = 0.02$.

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APPRAISAL

Strengths

- First study to assess conservative v. interventional therapy in moderate-large primary pneumothoraces
- Used both clinician and patient-centered secondary outcomes that can impact a shared decision-making model
- In addition to a complete case analysis, they also performed two sensitivity analyses, including one in which missing data were imputed as treatment failure (i.e. worst-case scenario).

Limitations

- This study was unblinded, which could bias findings (treating physicians were more likely to report radiographic resolution of pneumothorax in the intervention group when compared with blinded radiologists)
- The two sensitivity analyses identify potential statistical fragility in the main findings
- A shorter-term primary outcome might reveal greater disparity between conservative v. treatment groups
- The noninferiority margin of 9% is large
- 15.4% of patients (25) in the conservative treatment group required intervention
- 19% of randomized patients (60) lost to follow-up or had missing outcome data
- Radiographic resolution is not a patient-centered outcome.

CONTEXT

Conservative management has been the standard of care for small primary spontaneous pneumothoraces for many years. The British Thoracic Society¹ and the American College of Chest Physicians² both currently

recommend that clinically stable patients with large primary spontaneous pneumothorax undergo interventional management with a small-bore catheter or chest tube, followed by hospitalization in many cases. In Canada, these patients are commonly treated with a pigtail catheter and discharged home from the emergency department (ED). This study is a step toward validating an observational approach to large pneumothoraces in a carefully selected population.

BOTTOM LINE

Although this study contains some statistical fragility, there is modest evidence that a conservative approach may be noninferior to intervention in carefully selected patients with first time, moderate to large spontaneous pneumothorax. While many Canadian ED physicians may choose a pigtail catheter, any form of tube thoracostomy has potential adverse consequences. This study may identify an alternative option that can be used in shared decision-making with the appropriately selected patient.

Keywords: Emergency medicine, respiratory medicine, research: patient outcomes

Competing interests: None declared.

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