DEM Journal Club

Article Appraisal

Article: Conservative versus interventional treatment for spontaneous pneumothorax

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Resident Reviewer Name(s) and Residency Affiliation: Shari Li R2 FRCPC Vancouver Site and Nathan Stefani R3 FRCPC Victoria Site

Faculty Methodology/Bio-statistics Resource Person: Dr. Frank Scheuermeyer

Background and Study Objective(s):

Spontaneous pneumothorax is a common emergency department presentation. Traditionally, significant intrapleural air has been managed with a chest tube. Conservative management (i.e. no intervention) has been suggested as an alternative treatment method, but the two methods have not been compared. This study sought to explore whether conservative management was noninferior to interventional management of moderate-to-large spontaneous pneumothoraces.

Study Design:

This was a multicenter, prospective, randomized, open-label, noninferiority study that was run from 2011 to 2017 at 39 hospitals across both rural and urban Australia and New Zealand.
The population of interest was 14 to 50 year-olds with a primary, unilateral, spontaneous pneumothorax, moderate to large in size (at least 32% of the lung per Collins method). Eligible patients were randomized to the intervention group (i.e. Seldinger-style placement of chest tube set to underwater seal and no suction, chest radiograph at 1 hour, then observed for 4 hours) or conservative treatment group (i.e. observed for 4 hours with chest radiographs intermittently). Crossover from conservative to intervention was allowed at the discretion of the emergency physician if the patient had persistent clinically significant symptoms, hemodynamic instability, refractory hypoxia, or enlarging pneumothorax on chest radiograph. In the intervention group, if chest radiography showed resolution, the drain was removed and the patient was discharged home. Otherwise, patients were admitted. In the conservative group, patients were sent home at 4 hours if their radiograph was not worse, they were walking without needing supplemental oxygen, and they did not meet any crossover criteria.

The primary outcome was complete radiologic resolution of the pneumothorax as determined by the treating physician 8 weeks later. Any data collected after 8 weeks was considered missing, except recurrence of pneumothorax, which was considered treatment failure. Because not all patients were actually followed-up within the 8 week window, sensitivity analysis was done where the 8 week time frame was extended to 9 weeks and all data from beyond 9 weeks was considered missing (unless it showed a recurrent pneumothorax, which was then deemed treatment failure). An intention-to-treat analysis was also done, where all data collected from beyond 8 weeks was considered treatment failure.

Secondary outcomes included a per-protocol analysis, rates of resolution at 8 weeks as determined by two blinded radiologists, time to symptom resolution, rates of recurrence, adverse events (i.e. prolonged hospitalization, life-threatening illness, or any intervention to prevent these outcomes), length of stay in hospital, number of radiographs, days missed from work, rates of air leaks greater than 72 hours, and patient satisfaction. Follow-up assessment was done in-person with a chest radiograph between 24 and 72 hours and then at 2, 4, and 8 weeks. Pneumothorax status was also assessed by phone at 6 and 12 months.

Results:

Of 2637 patients screened for eligibility, 316 underwent randomization. 154 patients were assigned intervention and 162 were assigned conservative management. In the conservative-management group, 25 (15%) crossed over to intervention. In the intervention group, 10 (6.5%) patients refused treatment and received conservative management. Complete-case analysis showed full lung re-expansion at 8 weeks in 98.5% of the intervention group and 94.4% of the conservative-management group, equating to statistically significant noninferiority. That being said, data was missing for 23 patients in the intervention group and 37 patients in the conservative-management group. Sensitivity analysis where all missing data after 56 days was considered treatment failure demonstrated that risk difference exceeded noninferiority margins. Per protocol analysis demonstrated noninferiority.

For secondary outcomes, the conservative-management group had fewer hospitalization days, fewer chest-tube drainages lasting longer than 72 hours, fewer surgeries, fewer minor and serious adverse events, lower rates of pneumothorax recurrence, fewer radiographs, and higher rates of patient satisfaction. Flinded radiologists, reading chest radiographs from 8 week follow-ups, identified “full resolution” of pneumothoraces less often than the treating emergency physicians did in both intervention and conservative-management groups.

Validity of Results:

This was a methodologically robust study. Randomization and allocation were appropriate but blinding was impossible, and this may have affected ascertainment of the primary outcome, although the direction and magnitude of bias are unclear. In addition, there may have been some variability regarding the “gold standard” primary outcome-- how blinded radiologists provided different results than the treating physicians. Some outcomes were collected after the prespecified 8-week cutoff, which may decrease validity, especially since the conservative group lost more to follow-up.

The authors mitigated bias by providing their most rigorous interpretation as the primary analysis and then conducting additional sensitivity analyses.

This study explored a diverse set of secondary outcomes very relevant to patient care, although a much larger study would have been required to conclusively prove superiority of one method.

Generalizability of Results:

This study involved both community and tertiary centres in two nations comparable to our own. The clinical question is both common and relevant. Most screened patients were not eligibile, suggesting that this is a small subset of pneumothoraces overall.

The Bottom Line:

This randomized, noninferiority study of 316 patients with spontaneous pneumothorax showed noninferiority of conservative management versus interventional (Seldinger) management. Secondary outcomes tended to favour conservative management. Both options can probably be discussed with eligible patients.