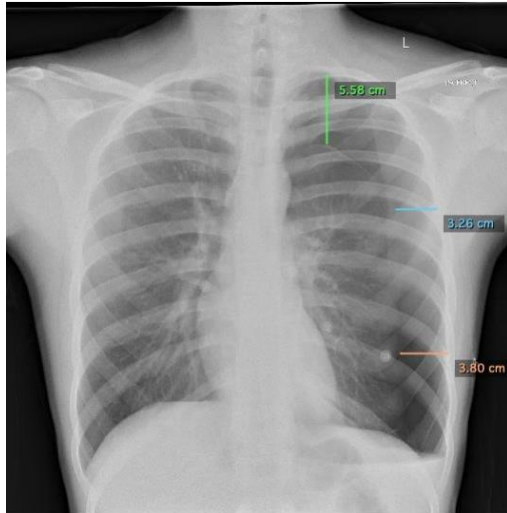


## Clinical update no. 552

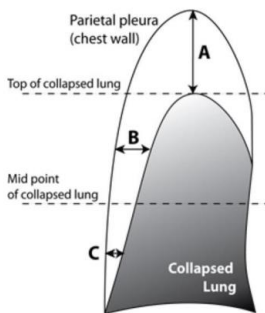
5 February 2020



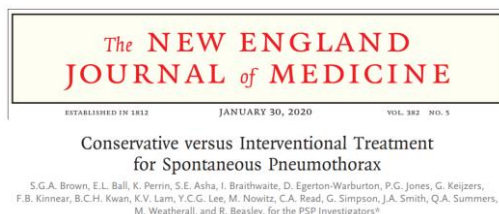
Calculated size is:  $4.2 + 4.7(A+B+C) = 4.2 + (4.7 \times 12.64) = 63.6\%$

Does this pneumothorax need a drain if the patient is stable and tolerating symptoms?

Figure S1: Graphic of Collins Method for determining the 'sum of interpleural distances', from which pneumothorax size is estimated. %Collins =  $4.2 + 4.7(A+B+C)$



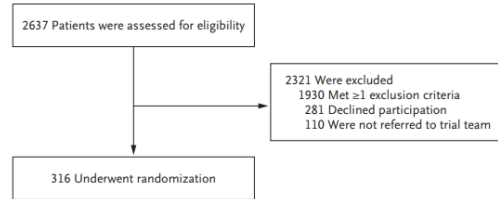
There are various methods to measure size. The above formula can be simplified to give a sum of the 3 distances shown.  $>6\text{cm}$  approximates to 1/3 collapse. The formula calculates the size in this CXR as 63%, with the sum of the 3 measures being 12.6cm.



This study done with ACEM funding provides evidence to support a conservative approach.

N=316, noninferiority trial; 14-50yr; first-known primary spontaneous pneumothorax  $>32\%$  (sum of distances as above  $>6\text{cm}$ );

randomised to immediate drainage v observation. Primary outcome was lung re-expansion within 8 weeks. 2,637 were assessed with 1930 meeting exclusion criteria and 281 declining, with 316 randomised.



15.4% in the observation group required interventional management. There was re-expansion within 8 weeks in 98.5% with intervention v 94.4%; risk difference  $-4.1\%$ , 95% CI  $-8.6 - 0.5$ ,  $P=0.02$  for noninferiority, being within the pre-specified  $-9\%$  margin.

There were less adverse events and a lower rate of recurrence in the conservative group.

“This trial provides modest evidence that conservative management was noninferior to interventional management for radiographic resolution of moderate-to-large primary spontaneous pneumothorax within 8 weeks.”

There is a bit of statistics involved which lead to a cautious conclusion.

– **Non-Inferiority Trials with Dr. David Ho**  
– [Curbside Consults Podcast — 2 May 2020](#)

Non inferiority trials are discussed on a NEJM podcast. They are designed to demonstrate whether a new drug or intervention carries risk compared to an existing treatment, such as potential CV side effect with diabetic medications otherwise effective at managing glucose. The null hypothesis is that the new approach is worse, and there is a prespecified cut off as to how much worse would be of concern. In this study it was a  $-9\%$  margin based on 90% success with observation being acceptable. A non-significant P-value implies that the null hypothesis of inferiority is accepted. However the adverse outcome is a need for intervention, which is the standard

treatment being compared, i.e. the adverse outcome is to subsequently have what is standard care. It is not a more concerning complication such as AMI from diabetic medication. Therefore although the basic statistics lead to a conservative conclusion as "modest evidence", it is clear that 85% of pneumothorax >32% (and up to 85%) can be managed by observation and do not need intervention. There is less recurrence in the observation group, possibly related to lack of a drain allowing the pleural defect to heal.

#### Intervention Group

A ≤12 French Seldinger-style chest tube and underwater seal drain, without suction. CXR done at 1hr. If the lung re-expanded with no bubbling then the drain was closed with repeat CXR at 4hr, and discharge if remained re-expanded. If no initial re-expansion or recurrence then admitted.

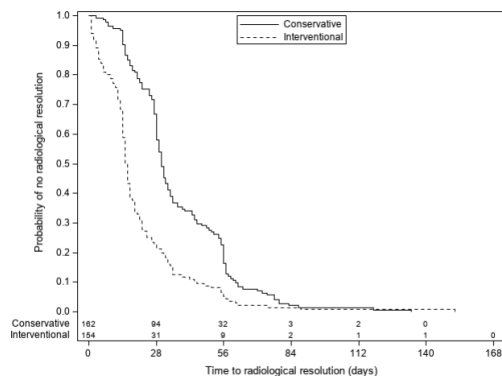
#### Conservative-Management Group

Observed, with repeat CXR at 4hr, and discharge if stable and comfortable. Subsequent intervention if ongoing pain, hypoxia or otherwise unstable, dyspnoea, not resolving or patient preference.

All patients were seen at 24 and 72hr and then at intervals to 8 weeks.

#### SECONDARY OUTCOMES

Resolution on CXR was at a median time of 16 days (IQ range 12-26) with intervention v 30 days (IQ range, 25-54) in the observation group. 10 patient assigned to intervention declined an IC drain.



At 4wk there was residual pneumothorax in about 25% with intervention v 75%; with

essentially complete resolution in both groups by 3mth.

Symptom resolution by 8wk was about 94% in both groups. Median time to resolution was about 15 days and did not differ.

Recurrence by 12mth was more frequent in the intervention group at 17 v 9%

Adverse events and surgical intervention were more in the intervention group, who also had more inpatient days and lower patient satisfaction. There was 1 death (suicide).

## DISCUSSION

The trial provides modest, but statistically fragile, evidence that conservative management was noninferior to interventional management, with 85% managed without requiring intervention. The study group was moderate-large (>32%; mean size 65%, up to 85%) pneumothorax for whom most clinicians would insert a drain.

**Table 1. Characteristics of the Patients at Baseline.\***

	Intervention	Conservative
Pneumothorax size		
Mean — % of lung	67	63
		Up to 85%

## EDITORIALS

### Clearing the Air — A Conservative Option for Spontaneous Pneumothorax

we can include a conservative approach as a reasonable management option for moderate-to-large pneumothoraxes in otherwise healthy young people.

Provisos are informed consent, access to outpatient follow up, and no plans for flying or scuba diving.

It is time to incorporate these findings into new guidelines

These updates are a review of current literature at the time of writing. They do not replace local treatment protocols and policy. Treating doctors are individually responsible for following standard of care.