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Journal club

Conservative *versus* interventional treatment for spontaneous pneumothorax

Commentary on:

Brown SGA, *et al.* Conservative *versus* interventional treatment for spontaneous pneumothorax. *N Engl J Med* 2020; 382: 405–415.

Context

For a primary spontaneous pneumothorax (PSP) (in a person with no underlying lung disease) with a visible rim of >2 cm between the lung margin and the chest wall (at the level of the hilum) on a chest radiograph, current guidelines recommend aspiration with a 16–18-gauge cannula and insertion of a small-bore chest drain (8–14 French) if the pneumothorax size cannot successfully be reduced below the 2 cm rim or the patient remains breathless [1]. As interventional management of PSP is associated with potential complications and a patient with a chest drain needs to be admitted to hospital, evaluation of conservative management as a potential alternative to interventional management of larger PSPs is desirable. Before the current trial, there were a few observational studies suggesting that moderate to large sized PSPs can potentially be successfully managed without intervention but evidence from randomised trials was lacking [2]. The PSP trial aimed to determine

whether conservative management is an acceptable alternative to interventional management for uncomplicated, moderate-to-large PSP [3].

Methods

The PSP trial was a multicentre, prospective, randomised noninferiority trial conducted across 39 metropolitan and rural hospitals in Australia and New Zealand [3]. It included 316 patients between the ages of 14 and 50 years who presented with a unilateral moderate to large PSP ($\geq 32\%$ or more on chest radiography, as measured by a volumetric Collins equation). Patients were randomised to a conservative or interventional approach. All patients received standard care with analgesia as needed and oxygen supplementation. In the conservative management group, patients were observed for a minimum of 4 h, at which time a repeat chest radiograph was obtained. Interventions were permitted in the conservative group for a number of prespecified conditions including pain or dyspnoea preventing mobilisation, haemodynamic instability, and radiological progression. In the intervention group, a small bore (≤ 12 French) Seldinger-style chest tube was placed and attached to an underwater seal for 1 h, without suction. If the lung had re-expanded and there was no leak, the tube was clamped for 4 h and if the lung remained fully expanded, the chest tube was removed and the patient was discharged. Follow-up consisted

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Conservative management (with a treatment escalation plan in case the patient deteriorates) is a safe alternative to interventional management of a primary spontaneous pneumothorax
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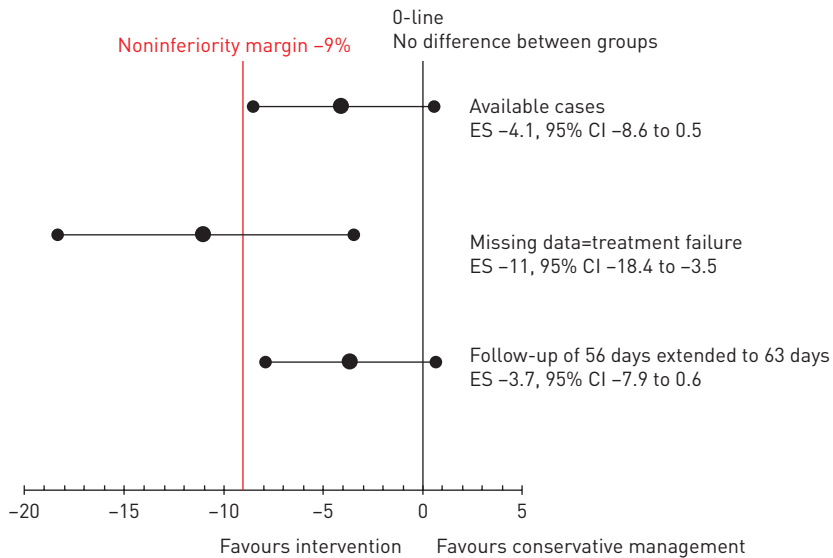


Figure 1 Effect size (ES) for lung re-expansion at 8 weeks using different analytical methods.

of a clinical follow-up, chest radiograph, and a structured interview between 24 and 72 h after randomisation, and again at 2, 4 and 8 weeks follow-up.

The primary outcome was complete radiographic resolution of the primary pneumothorax (full lung re-expansion) within 8 weeks after randomisation using intention-to-treat analysis. Secondary outcomes included the time until radiographic resolution, the time until resolution of symptoms, the risk of a recurrent pneumothorax, adverse events, length of hospital stay, number of invasive procedures and radiological investigations, number of days off work, persistent air leak, and patient satisfaction.

Main results

Of 316 patients, 154 patients were randomised to the intervention group and 162 to the conservative management group. In the intervention group, 10 patients (6.5%) declined an intervention; in the conservative management group, 25 patients (15.4%) underwent interventions to manage the pneumothorax for reasons pre-specified in the protocol. Chest radiography follow-up at 8 weeks was missing for 23 patients in the intervention group and for 37 in the conservative management group. When only including patients who had a chest radiograph performed at 8 weeks, 129 (98.5%) out of 131 patients having an intervention and 118 (94.4%) out of 125 patients managed conservatively had pneumothorax resolution (risk difference -4.1 percentage points, 95% CI -8.6 – 0.5 ; $p=0.02$ for noninferiority). In this analysis, the lower boundary of the 95% confidence interval was within the prespecified noninferiority margin of -9 percentage points, and therefore conservative

management was assessed as noninferior to interventional management. In a sensitivity analysis in which all missing data after 56 days were imputed as treatment failure (with re-expansion in 129 (93.5%) of 138 patients in the intervention group and in 118 (82.5%) of 143 in the conservative-management group), the risk difference of -11.0 percentage points (95% CI -18.4 – -3.5) was outside the pre-specified noninferiority margin, indicating that conservative management is inferior to interventional management. Figure 1 illustrates the point estimates and 95% confidence intervals for lung re-expansion at 8 weeks using different analytical methods.

The median time until radiological resolution was 16 days (interquartile range 12–26 days) in the intervention group and 30 days (interquartile range 25–54 days) in the conservative management group (hazard ratio 0.49, 95% CI 0.39–0.63). Complete resolution of symptoms by 8 weeks was reported in 128 (93.4%) out of 137 patients in the intervention group and in 139 (94.6%) out of 147 in the conservative management group. Conservative management also resulted in fewer hospitalisation days, a lower likelihood of prolonged chest tube drainage, less need for surgery, fewer adverse events and fewer pneumothorax recurrences during the first 12 months (25 (16.8%) out of 149 as compared with 14 (8.8%) of 159; absolute risk difference 8.0 percentage points, 95% CI 0.5–15.4).

Commentary

The PSP trial is the first randomised trial to compare conservative with interventional management for moderate to large PSP. It showed that conservative management was noninferior (defined as 9% worse or less) compared with interventional management for lung expansion within 8 weeks when only patients were included who had a chest radiograph available at that time point but was inferior when missing data were imputed as treatment failure.

Almost 85% of patients in the conservative management group did not require any intervention and their symptoms resolved as quickly as the intervention group with fewer days in hospital, fewer days off work, less need for surgery and fewer adverse effects.

The study has significant limitations. The study protocol did not specify the window for the 8-week visit or outline how missing radiographic data were to be handled for the primary outcome of pneumothorax resolution at 8 weeks. The study authors addressed this problem by conducting an analysis including only cases with complete follow-up data at the 8-week mark (56 days), as well as two sensitivity analyses to test the robustness of this assessment. The first sensitivity analysis imputed all missing data at 56 days as treatment failure and the second sensitivity analysis extended the follow-up duration to 63 days, thus

allowing inclusion of an additional five patients in the intervention group and 11 patients in the conservative management group who had their chest radiograph between 56 and 63 days. As illustrated in figure 1, in one sensitivity analysis, the result did not fall within the prespecified noninferiority margin, therefore making the results for the pneumothorax resolution at 8 weeks uncertain. The prespecified noninferiority margin of –9 percent was chosen by the steering committee of the study and was not based on any previously established noninferiority margin. If this margin would have been –7.8 percent or less, all three analysis methods would have failed to establish noninferiority for the primary outcome.

Another limitation of the study was that the chest radiograph assessment for the primary outcome was done by the treating clinicians, who were aware of the trial-group assignments. Compared with independent radiologists who were unaware of the trial-group assignments (but did not assess all radiographs at 8 weeks), the clinicians were more likely to report full resolution in the group receiving interventional management. This bias would therefore have worked against overestimating the benefit of conservative management.

The trial was conducted across a spectrum of rural, urban, secondary and tertiary centres, making the results applicable to different healthcare settings. However, of 2637 patients screened for eligibility, only 316 underwent randomisation; 1930 screened patients had at least one exclusion criterion. This indicates that the study results apply to a select subgroup of patients and may not be generalisable to the majority of patients with a pneumothorax. Eligible participants were young

otherwise healthy patients with their first moderate to large PSP, without haemodynamic compromise.

Implications for practice

While it is uncertain based on the study results if conservative management of a PSP is noninferior to interventional management for the outcome of resolution within 8 weeks, the study provides evidence that conservative management (with a treatment escalation plan in case the patient deteriorates) is a safe alternative to interventional management. It is therefore reasonable to offer patients comparable to those included in the study (aged between 14 and 50 years with a unilateral moderate to large PSP) a conservative management approach. The best course of action in patients who are clinically stable and, therefore, potentially eligible for conservative management should be evaluated together with the patient, taking into account the patient's values and preferences. The possible advantages of less adverse events, a shorter hospital stay and a reduced risk of a recurrent pneumothorax within 1 year with conservative management have to be weighed against the prolonged time to radiographic resolution, which, for example, delays fitness to fly and the ability to safely lift heavy objects. Different patients will weigh these outcomes differently; for example, somebody who has a flight booked in 5 weeks might value a quick resolution of the pneumothorax more, while another person is happy to wait longer for pneumothorax resolution if that means that they do not have to stay in hospital and have a lower risk of having another pneumothorax once it is healed.

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Conflict of interest

S.L. Ennis has nothing to disclose. C.C. Dobler has nothing to disclose.

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