Critical Review Form
Therapy

Aspiration versus tube drainage in primary spontaneous pneumothorax: a randomised study, *Eur Respir J* 2006; 27: 477-482

Objective: **"To evaluate the efficacy and complications of aspiration versus tube thoracostomy for patients with a first episode of PSP". (p.478)**

Methods: **From Jan 2001 to Jan 2003 consecutive patients presenting to the Chest Diseases Hospital in Safat, Kuwait (the only thoracic hospital in Kuwait) with a first episode primary spontaneous pneumothorax were enrolled then randomized to one of two treatment arms (simple aspiration or chest thoracostomy). Inclusion criteria included symptoms (chest pain or dyspnea) or size >20%. Exclusion criteria included prior PTX, secondary PTX, tension PTX, bilateral PTX, iatrogenic PTX, haemopneumothorax or size < 20% without symptoms.**

Simple aspiration was performed in semi-supine position using a 16-gauge plastic catheter inserted into the second anterior intercostal space in the mid-clavicular line. Aspiration occurred via a one-way water seal vacuum system at 15cm H_20 negative pressure until cessation of air occurred for maximum of 30-minutes. Catheter was then withdrawn and chest x-ray repeated. If resolved, patient was discharged. If not resolved a second catheter was inserted and aspiration attempted again. If second attempt unsuccessful, chest tube was placed. Tube thoracostomy was performed with 20F plastic tubes in the 4^{th} or 5^{th} intercostal space at the mid-axillary line. Chest tubes were left connected to underwater seal suction at 20cm H_20 for 24 hours after bubbling ceased and chest x-ray demonstrated lung re-expansion. If leakage persisted beyond 7-days VATS was performed. Follow-up on all patients occurred at 1-week, 3-, 6-, 12-, and 24-months.

The primary outcome was immediate success. The following outcome definitions were used.

Simple aspiration

- **Immediate success – complete or nearly complete lung expansion following aspiration.**
- **1-week success – complete lung expansion at 7-days**

Tube thoracostomy

- **Immediate success – absence of air leak, complete lung re-expansion and chest tube removal within 3-days of the insertion of the tube.**
- **1-week success – complete lung expansion followed by tube removal within 7-days post tube insertion.**

For both groups success was defined by no recurrence at each follow-up visit.

Secondary endpoints included 1-week success rates, recurrence rates at 3-months, 1-year and 2-years, hospitalization rates, hospital length of stay, analgesia (Pethidine, acetaminophen) requirements, and quantity of analgesia in 24 hours, complication, and inability to work.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	Yes. "Randomisation was performed by self-selecting a sealed envelope that indicated the respective treatment". (p.478)
2.	Was randomization concealed (blinded)?	No. One limitation of this study was "the inability to mask the patients or investigators to the treatment arm. Lack of masking can lead to information bias. However, the investigators used standard clinical definitions of pneumothorax resolution in evaluating ''success'' of resolution or recurrence of pneumothorax. It is unlikely, therefore, that any significant bias was present in the outcome ascertainment". (p. 481)

3.	Were patients analyzed in the groups to which they were randomized?	Yes. "a 1-week success rate was defined on an intention-to-treat basis in both groups". (p. 478)
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. "There were no differences in age, sex, weight, body mass index, smoking status or radiographical appearances". (p. 478, Table 1, p. 479)
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes, blinding not possible for this study design.
2.	Were clinicians aware of group allocation?	Yes.
3.	Were outcome assessors aware of group allocation?	Yes, although outcome assessors could have been blinded via sham chest tube scars or no physical contact with patients.
4.	Was follow-up complete?	No loss to follow-up described. (Fig 1, p. 480)
II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect?	• Over two years, 208 enrolled but only 137 randomized with 71 non-randomized including 42 recurrent PTX, 16 asymptomatic small PTX, 10 tension PTX, and three hemopneumothorax. • 65/137 allocated to simple aspiration and 40/65 (62%) had success on first aspiration attempt. Of the remaining 25, eight had success after second aspiration (discrepancy between text and CONSORT diagram on p. 480 so went with more conservative report). • 49/72 (68%) chest tube patients had immediate success (within three days). • Simple aspiration had significantly earlier recurrence (12 weeks vs. 15 weeks, p=0.02) but the earliest recurrence was 4-weeks after discharge. There was no significant difference in recurrence at 3-months (15% aspiration vs. 8% chest tube, p=0.2), 1-year (25% vs. 24%) or 2-years (31% vs. 25%). • Chest tube patients were more likely to be admitted (100% vs. 26%) with longer hospital length of stay (4.0 days ± 2.9 vs. 1.8 ± 3 days) and more frequently required analgesia (56% vs. 34%, p=0.01) with more lost work days (6 days vs. 3.6 days). • Complications (subcutaneous emphysema, tube blockage, exit site infection) were more common in the chest tube group (N = 6 vs. N = 1).
2.	How precise was the estimate of the treatment effect?	No CI's are reported.
III.	**How can I apply the results to patient care (answer the questions posed below)?**	

1.	Were the study patients similar to my patient?	Although these are Kuwaiti patients presenting to a specialized chest hospital, they are probable similar to spontaneous PTX patients worldwide.
2.	Were all clinically important outcomes considered?	Yes – success rates, hospitalization, pain needs and lost work days. Could have incorporated patient satisfaction and clinician acceptability.
3.	Are the likely treatment benefits worth the potential harm and costs?	Absolutely, if admissions and painful procedures can be safely avoided without compromising patient outcomes.

Limitations

1) **Not adequately powered for equivalence study and no *a priori* power calculation.**
2) **Envelope-based allocation generally not adequate.**
3) **No assessment of patient satisfaction, pain control, cost-effectiveness, or clinician acceptability.**
4) **Outcome assessors not blinded.**
5) **Discrepant reporting in text and CONSORT diagram (Fig 1, p. 480) on second aspiration attempt success.**
6) **No 95% CI reported by which to judge precision.**

Bottom Line

Simple aspiration of stable, uncomplicated, isolated first-episode primary spontaneous PTX offers equivalent immediate success rates (62% SA vs. 68% chest tube) without increased early recurrence or adverse consequences. Using this method could avoid 74% of admissions thereby reducing lost work days and iatrogenic complications.