Critical Review Form
Therapy

Manual Aspiration versus Chest Tube Drainage in First Episodes of Primary Spontaneous Pneumothorax: A Multicenter, Prospective, Randomized Pilot Study, *Am J Resp Crit Care Med* 2002; 165: 1240-1244

Objective: **To compare "manual aspiration to chest tube drainage in a homogenous group of patients with a first episode of primary spontaneous pneumothorax". (p. 1240)**

Methods: **Sixty consecutive patients presenting to one of five Belgium hospitals were enrolled if they had first episode of primary spontaneous pneumothorax, if they were a) symptomatic and b) had PTX > 20% by Light's formula. Exclusion criteria included: presence of underlying lung disease, previous PTX, or tension PTX.**

Patients were randomized at each center by a separate random number list. In the treatment group manual aspiration was performed with the patient in the semi-supine position using a 16-gauge intravenous needle catheter introduced into the second or third intercostal space at the midclavicular line after appropriate skin disinfection and local anesthesia. Placement in the pleural space was confirmed by bubbling into the lidocaine-filled syringe after which the needle was directed apically and the catheter advanced 5-10cm into the pleural space. The needle was then removed and the catheter affixed to the skin with tape and connected to a three-way valve and 50mL syringe. Air was manually aspirated until resistance noted and air could no longer be aspirated after which a repeat chest x-ray was obtained. If lung expansion was complete or only a small rim of apical air was present, the patient was discharged. If no re-expansion was noted a second aspiration attempt occurred. If during manual aspiration 4L or greater had to be aspirated without re-expansion or if a second attempt was unsuccessful then a chest tube was placed. After discharge a repeat chest x-ray was ordered within one week and at 2-, 6-, and 12-months when indicated.

In the chest tube group and 16- or 20-F thoracostomy tube was inserted in the anterior midclavicular second interspace or mid-axillary 4th or 5th interspace. Chest tubes were removed when complete re-expansion demonstrated 24 hours after air bubbling ceased for a maximum of seven days after which attending pulmonologist dictated appropriate care.

Three primary endpoints were reported: immediate success, 1-week success, and 1-year success as defined below:

Manual aspiration

- **Immediate success – complete and persistent lung expansion immediately following manual aspiration.**

- **1-week success – complete and persistent lung expansion at 7-days after aspiration (followed by chest tube drainage in case of unsuccessful aspiration).**

Chest tube

- **Immediate success – complete lung expansion, absence of air leakage, and chest drain removal within 72-hours after tube placement.**

- **1-week success – complete lung re-expansion followed by lung chest tube removal within 7-days after the first tube insertion**

Both groups

- **1-year success – absence of recurrent pneumothorax.**

Secondary endpoints included safety, proportion hospitalized, and duration of hospitalization. Post-hoc power analysis was performed with $\alpha = 0.05$ and $\beta = 0.20$ using the observed effect size.

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. "Patients were randomized at each center with separate random number lists into one of the two treatment groups using a computer-generated table numerically corresponding with the treatment group". (p. 1240)
2.	Was randomization concealed (blinded)?	No. Chest tube vs. manual aspiration cannot be blinded.

3.	Were patients analyzed in the groups to which they were randomized?	Yes. "One-week success rates were defined on an intention-to-treat basis in both groups". (p.1241)
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Yes. As demonstrated in Table 1 (p.1241) no significant differences noted in age, gender, BMI, smoking status, or Light's index.
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. Not possible to blind patients to this intervention without sham chest tubes.
2.	Were clinicians aware of group allocation?	Yes.
3.	Were outcome assessors aware of group allocation?	Unclear, though outcome assessors certainly could have been blinded.
4.	Was follow-up complete?	No loss to follow up is reported.
II.	**What are the results (answer the questions posed below)?**	

1.	How large was the treatment effect?	• 60 subjects were recruited yielding 75% power to detect difference should one exist. • Manual aspiration had immediate success rate 59.2% (16/27) compared with chest tube 63.6%. (21/33). However, on second attempt manual aspiration (6/11 initial failures) none was successful. Of the 11 MA failures, nine had chest tube (two requested immediate talc poudrage pleurodesis) and all were successful at one-week. • Hence, 1-week intention-to-treat success rates for MA were 93% (25/27) compared with chest tube 85% (28/33, p=0.40). Explained another way, patients can expect a 59% immediate success rate likelihood with 41% of MA subjects subsequently requiring the chest tube and hospitalization we are seeking to avoid. • In MA group 52% (14/27) were hospitalized for 3.4 ± 1.6 days (including three social admissions) compared with 100% in chest tube group for 4.5 ± 2.7 days. • 1-year recurrence rates were 26% (7/27) MA group vs. 27.3% (9/33) chest tube group. • None of MA discharged have had to be re-admitted for early recurrences. The earliest recurrence occurred at 3-weeks and the mean time to recurrence was 13.4 ± 10 weeks in the MA group vs. 9 ± 8.5 weeks in the chest tube group (Table 2, p.1242)
2.	How precise was the estimate of the treatment effect?	No 95%, CI were reported but they can be computed online (ref),
III.	**How can I apply the results to patient care (answer the questions posed below)?**	

1.	Were the study patients similar to my patient?	Lean (BMI 21) Belgian patients with first episode non-traumatic PTX. Probably no significant differences but would be helpful to validate on US ED populations with more representative (larger) BMI's. Also, \uncertain which clinicians were performing MA or chest tube (EM? Pulmonary? Thoracic Surgery?)
2.	Were all clinically important outcomes considered?	No assessment of patient pain, satisfaction, cost-effectiveness, or clinician acceptability for this technique. What about learning curve for MA technique or procedural time?
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 outcome.

Limitations

1) **No *a priori* sample size calculation and study under-powered to confidently claim equivalence. (CONSORT extension)**
2) **No 95% CI reported for outcomes to gauge precision.**
3) **Insufficient outcomes reported. More convincing argument of outcomes would include patient pain ratings, clinician learning curve and acceptability, and procedural time.**
4) **No assessment of the nine MA failures. Can these patients be identified pre-procedure to facilitate direct-to-chest tube treatment?**

Bottom Line

Belgian patients with acute first-time spontaneous PTX managed with manual aspiration have equivalent immediate, 1-week, and 1-year success rates as those receiving traditional chest tube. While 40% of MA will require a chest tube nonetheless, the remaining 60% can have PTX care simplified with less painful aspiration and significantly decreased admission rates and hospital length of stay. Future trials conducted with appropriate *a priori* power analysis to confidently conclude equivalence should also assess patient satisfaction parameters, clinician learning curves, acceptability, and procedural times as well as cost-effectiveness.