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Simple Aspiration versus Large Bore Chest-Tube Drainage for Complete Primary Spontaneous Pneumothorax: Is the Chest Tube Necessary?

The clinical question

Is simple aspiration by thoracentesis drainage kit a non-inferior alternative to 16 or 20 Fr chest tube drainage to obtain lung re-expansion in patients with first episode of complete primary spontaneous pneumothorax?

Take home message

For uncomplicated patients with complete primary spontaneous pneumothorax needing evacuation, simple aspiration by thoracentesis resulted in a higher failure rate of lung re-expansion than 16 or 20 Fr chest tube placement but also demonstrated marginal improvements in pain tolerance and a significant decrease in adverse events. This study did not investigate the role of small-bore catheters as an option to improve comfort and reduce failure rate of simple aspiration.

Background

The Clinical Question

Is simple aspiration by thoracentesis drainage kit a non-inferior alternative to 16 or 20 Fr chest tube drainage to obtain lung re-expansion in patients with first episode of complete primary spontaneous pneumothorax?

Study Conclusion

Simple aspiration by thoracentesis drainage kit had a numerically higher rate of failed re-expansion of the lung, but was statistically non-inferior, compared to large-bore chest tube placement. Simple aspiration was associated with decreased pain, especially limiting breathing, and decreased incidence of device kinking.

Study Background
While chest tube drainage is utilized as a first-line intervention for primary spontaneous pneumothorax, large-bore chest tube placement can be associated with adverse events such as pain, hemothorax and prolongation of hospital stay. Simple aspiration has been considered as an alternative with reduced complications and increased patient comfort and tolerance, but the effectiveness of aspiration has been debated and major societies differ on clinical recommendations. A Cochrane systematic review including six total randomized controlled trials with a population of 435 patients from heterogeneous populations and clinical presentations suggested that simple aspiration presented an "attractive first-line treatment option" due to improvement in immediate success rate from prior literature but that these results needed to be validated with additional randomized controlled trials. This study further investigates simple aspiration by thoracentesis as an option to improve patient comfort and decrease complication risk from chest tube placement.

Current Practice and Guidelines
The authors note conflicting recommendations between the most consensus statement by the American College of Chest Physicians, published in 2001, and the British Thoracic Society guidelines, originally published in 2003 (and subsequently updated in 2010). The ACCP consensus statement recommends the use of either a large-bore chest tube or small-bore catheter for evacuation of large pneumothorax, in contrast to the BTS guidelines, which recommends simple aspiration as first line treatment for all primary spontaneous pneumothoraces followed by small-bore catheter evacuation if unsuccessful. Standard of care varies with regard to use of simple aspiration, type of catheter used for evacuation and method of placement, and duration of hospital observation.

Study Design

Type of trial: Open-label Randomized Controlled Trial
N: 402 enrolled patients
Study groups: Simple aspiration (n=189) vs large-bore chest tube insertion (n=190)
Settings: 31 hospitals with emergency departments in France meeting eligibility criteria
Enrollment: Patients enrolled by investigators at time of presentation for treatment in the emergency department at participating sites
Intervention: Simple aspiration by thoracentesis kit versus placement of 16 or 20 Fr chest tube
Treatment period: All participants monitored in hospital for 24 hours, persistent pneumothorax monitored per hospital protocol
Follow up: 24 hours, 7 days, and 1 year
Primary outcome: Rates of residual pneumothorax < 2 cm at 24 hours

Population

Inclusion criteria: Adult patients aged 18-50 years without underlying lung disease presenting for symptomatic chest pain or dyspnea onset within 48 hours with radiographic demonstration of pneumothorax with complete separation of pleura from lung base to apex of pleural space.

Exclusion criteria: presence of tension, traumatic, or recurrent pneumothorax, presence of underlying lung disease, presence of pleural effusion, patients who are pregnant or lactating women, patients not able to complete follow-up, and patients unable to give consent.

Baseline Characteristics: Of the 379 study participants, population predominantly male (82%) with a mean age of 28. Majority of population presenting symptomatic chest pain (98%) often with dyspnea (75%) with most participants currently or previously using inhaled tobacco (87%).

Interventions

Patients randomized to simple aspiration versus large-bore chest tube placement.

Simple Aspiration: sterile aspiration conducted at second intercostal space at midclavicular line with thoracentesis device with 15 minutes of free drainage followed by 30 minutes of aspiration at -25 cm H2O. If lung not re-expanded, 30 additional minutes of negative pressure aspiration conducted. If persistent absence of re-expansion, large bore chest tube placed. For patients with lung re-expansion on aspiration attempts, repeat radiograph conducted at 24 hours with patient discharge if maintained re-expansion or chest tube placement if re-accumulation of pneumothorax.

Chest tube: 16 or 20 F chest tube placed by trocar with continuous -25 cm H2O evacuation after 15 minute free drainage period. Radiograph repeated at 30 minutes and 24 hours of evacuation. Hospital management per location of hospitalization.

Outcomes

Primary Outcomes (per protocol outcomes reported)

- Treatment failure at 24 hours: Simple Aspiration 53/181 (29%), chest tube drainage 32/178 (18%), difference in failure rate 0.113 [0.026, 0.2].
- Both per-protocol and intention-to-treat confidence intervals less than noninferiority δ, calculated to be 0.205 by taking 25% of efficiency rate of chest tube treatment.

Secondary Outcomes

- Treatment failure at 7 days: Simple Aspiration 27/171 (16%), chest tube drainage 26/169 (15%), difference in failure rate 0.004 [-0.073, 0.081].
- Pneumothorax recurrence at 1 year: Simple aspiration 20%, chest tube 27%, frequency difference -0.07 [-0.16, 0.02].
- Chest pain at 24 hours by mean visual analog response: Simple Aspiration 2.2, chest tube 3.6, mean difference -1.4 [-1.89, -0.91]
- Chest pain at 7 days and 1 year - no statistically significant difference
- Anxiety and Dyspnea by mean visual analog response at 24 hours, 7 days, 1 year - no statistically significant difference

Adverse events

- 1 patient with hemothorax at 24 hours in chest tube intervention
- 3 patients with accidental device ablation in chest tube intervention
- 2 patients with organ perforation noted at 7 days in chest tube intervention
- 5 patients with persistent bubbling or leaking at insertion site after 24 hours in chest tube intervention compared with 1 patient in simple aspiration intervention
- Statistically comparable rates of bleeding at insertion site and subcutaneous emphysema at 24 hours
- Pain limited breathing significantly decreased at 24 hours in simple aspiration (16%) vs chest tube intervention (34%) frequency difference -0.18 [-0.27, -0.09]

Funding

French Ministry of Solidarity and Health Research Program
Centre Hospitalier Universitaire de Besanc
Fondation Don du Souffle

Commentary

Study Strengths

- The study included a large relatively homogenous population with a well-defined case definition. Due to the rigor of the protocol, this study successfully completed a randomized controlled trial of comparing a time sensitive intervention applied in a controlled, repeatable manner. By nature of study design, the study appropriately examined population primarily composed of patients at highest risk for pneumothorax, though it did not mention the number screened for the 402 subjects enrolled. The study demonstrated relatively low attrition and included intention-to-treat analysis.

Study Limitations and Potential for Bias

- As mentioned by the authors, the study did not examine the use of small bore/pigtail catheters, which has significant relevance in the applied clinical situation. Selection of participating physicians based on skill and expertise as well as additional device specific training may limit external validity of study by interfering with role of provider error in complication rates. Due to the limited definition of treatment failure utilized in this study, it is difficult to ascertain the role of other important factors that may or may not have been evaluated, such as additional imaging findings or size of the pneumothorax.

Suggested Reading

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Article citation

Marx T, Joly LM, Parmentier AL, Pretalli JB, Puyraveau M, Meurice JC, Schmidt J, Tiffet O, Ferretti G, Lauque D, Honnart D, Al Freijat F, Dubart AE, Grandpierre RG, Viallon A, Perdu D, Roy PM, El Cadi T, Bronet N, Duncan G, Cardot G, Lestavel P, Mauny F, Desmettre T. Simple Aspiration versus Drainage for Complete Pneumothorax: A Randomized Noninferiority Trial. Am J Respir Crit Care Med. 2023 Jun 1;207(11):1475-1485. doi: 10.1164/rccm.202110-2409OC. PMID: 36693146.

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