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A prospective, randomised trial of pneumothorax therapy: Manual aspiration versus conventional chest tube drainage

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Summary
Background: No consensus exists on the exact treatment of pneumothorax (PTX). Some guidelines are proposing manual aspiration (MA) to be preferred over tube thoracostomy (TT) in uncomplicated primary spontaneous pneumothorax (PSP). However, only a few studies reported a direct comparison of both methods. Our aim was to re-evaluate this with a randomised trial in a single centre in the Netherlands.
Methods: Patients with a first episode of symptomatic PTX admitted to the ER or asymptomatic PTX with a size of ≥20% were recruited during 2007–2009 and followed-up for one year. Randomisation between MA and TT was balanced by a computer minimisation program for cause of PTX, smoking and gender. When first MA attempt failed, a second attempt was not undertaken and patients underwent TT. (registered at ClinicalTrials.gov (NCT00556335).
Results: 56 patients were included. Baseline characteristics were similar. Immediate success rates were 68.0% for MA versus 80.6% for TT ($p = 0.28$). Two week success rates were 100% in both groups. There was a significant difference in hospital stay in favour of MA: 2.4 ± 2.6 versus 4.4 ± 3.3 days ($p = 0.02$). One year recurrence rates in MA were lower than in TT, although not statistically significant (4.0% and 12.9% $p = 0.37$). Predictors of immediate success were traumatic PTX and female sex. One patient died during follow-up due to heart failure.
Conclusion: MA is simple, safe, cheap, minimal invasive in uncomplicated PSP/traumatic PTX with similar success and recurrence rates and a shorter hospital stay in comparison to TT and therefore the treatment of choice.

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Introduction

Primary spontaneous and traumatic pneumothorax (TPTX) are common pathologies in daily pulmonary practice that account for significant health-care expenditures.[1,2]

A primary spontaneous pneumothorax (PSP) is defined as a spontaneously occurring PTX in a person without an underlying lung disease.[3] TPTX is a PTX due to a trauma of variable origin. Incidence is estimated at 18–28 per 100,000 males and 1.2–6 per 100,000 females.[4] Hospital admission rates for combined primary and secondary PTX are reported between 16.7 per 100,000 men per year and 5.8 per 100,000 women per year.[5] A PTX is called secondary when caused by underlying parenchymal lung diseases predisposing to PTX like emphysema, pulmonary fibrosis of any cause, cystic fibrosis, aggressive or cavitating pneumonia and cystic interstitial lung diseases such as Langerhans' cell histiocytosis and lymphangiomyomatosis.[6]

A secondary pneumothorax (SPTX) is the result of distal airway inflammation and obstruction due to internal (bronchial abnormalities)[7] and external factors (smoking).[8] Distal airway obstruction may lead to the development of emphysema-like changes increasing the chance on ruptures leading to visceral pleural air leaks, the development of direct visceral pores[9] or to mediastinal pleural leaks.[10] The treatment of choice for PSP is influenced by clinical presentation, size, recurrence risk, daily activities, patient preference and economical considerations. Treatment options consist of the following: therapeutic abstinence (bed rest and oxygen), TT, MA and immediate thoracoscopic or even open surgical intervention (thoracotomy). The size of a PSP estimated by means of the Light index correlates strongly with the amount of air present in the pleural space.[3] In asymptomatic patients with a PTX size less than 20% of the hemithorax no treatment is recommended. Active treatment is required in symptomatic patients and/or a PTX size $\geq$20%; efforts to remove the air and expand the lung are indicated.[11] Treatment options and recommendations vary related to the differences in treatment goals[1]: simple air removal versus prevention of recurrences in combination with the availability of only a few prospective, comparative studies.[12] Whether to treat patients presenting with a first episode of PSP with a form of pleurodesis treatment or to wait for a first recurrence should be decided after analysis of recurrence risk and direct and indirect costs of the procedure.[1,13] Schramel and colleagues suggest that Video-Assisted Thoracic Surgery (VATS) is more effective in first or recurrent PTX than TT resulting in less morbidity and costs, hereby recommending that all symptomatic patients should be subjected to thoracoscopy.[14] However, this is a very aggressive approach since half of the patients who develop an initial PSP will never have another[3] and most of these patients underwent surgery unnecessarily.[14] Nevertheless, no consensus has been defined concerning the exact treatment of PTX patients. A consensus statement from the American College of Chest Physicians recommended that the pleural air be removed via placement of a small bore catheter ($\leq$14 F) or a 16 F–22 F chest tube that may be attached to a Heimlich valve or to a water seal device.[1] In contrast the British Thoracic Society guidelines for the management of PSP recommend the removal of pleural air by aspiration. When post-aspiration chest radiograph reveals that the PTX is small or resolved, the system could be removed and the patient not be hospitalised.[15] The British Thoracic Society Research Committee study detected similar success rates for MA and TT in first PSP episodes with MA being less painful. Lower admission rates and a reduction in pleurectomy need without an increase in one year recurrency were other benefits of MA.[16]

Nowadays regular therapy of PSP consists mostly of TT which is associated with higher levels of pain and anxiety requiring opioid premedication and local anaesthesia[4] and a longer hospital stay with higher costs without a significant difference in immediate and recurrence rates in comparison to MA.[12] In conclusion literature suggests similar immediate and long-term efficacy of MA and TT. Because of its minimal morbidity, simplicity, non-invasiveness (less pain), outpatient-based implementation, safety, equal efficacy in comparison to TT[12,17] and low cost by MA followed by immediate discharge and follow-up, several trials are advocating MA as the treatment of choice in uncomplicated PSP.[12,13,15,17,18] Our effort was to confirm the former findings with a mono-centred study set-up for the first time in the Netherlands. The study aimed to evaluate the efficacy of MA in comparison to TT in PTX therapy; whether MA will shorten hospital admission and whether the lung will expand assessed by means of clinical and radiological findings.

Methods

Study design

Our study is a mono-centred prospective parallel group randomised (1:1 ratio) controlled trial during 2007–2009 with a one year follow up performed in the Isala klinieken in Zwolle, the Netherlands. Approval of the local ethics committee was achieved. This trial is registered at ClinicalTrials.gov (NCT00556335).

Study population

Patients with an age between 18 and 85 years with a first episode of a symptomatic (spontaneous or traumatic) PTX admitted to the ER of the hospital or patients with an asymptomatic pneumothorax (APTX) with a size of $\geq$20% as estimated by Light's formula ((1 minus length divided by height) multiplied by 100) were recruited. Exclusion criteria were pregnancy, severe comorbidity, prior randomisation, recurrent or tension PTX, limited decision making, patients with a chronic lung disease, HIV or Marfan syndrome.

Randomisation

After written informed consent was given, patients were randomised by a computer minimisation program between MA or TT initiated by the doctor at the ER. The minimisation program balanced patients for the following factors: cause of PTX (spontaneous or traumatic), smoking status (past,

actual) and gender (male/female). Finally patients underwent MA or TT according to protocol.

Interventions

Patients with PSP or traumatic PTX admitted to the ER underwent MA or TT. MA was performed as follows: After skin desinfection and field preparation, an angio intravenous (I.V.) catheter with a diameter of 1.3 mm was introduced in the second or third intercostal space midclavicular of the affected site after local anaesthesia (lidocaïne 1%). In case of extreme obesity a pneumocatheter was used. After fixation to the skin, the I.V. catheter was connected with a three-way valve to a 50 ml syringe and air was manually aspirated until a resistance was felt and no air was acquired any longer. In case of success with an expanded lung at the chest X-ray, the drainage system was disconnected and patient was observed during 24 h. If MA had failed, no second attempt was made and TT was chosen. After the observation period a new chest X-ray was made with a final evaluation. When the lung was still expanded at the chest X-ray, discharge followed. When no lung expansion was reached or in case of absorption of >2000 ml air (prolonged air leak), TT drainage was performed.

Chest tube drainage was initially perfomed like MA. The difference consisted of connection of a drain to a drainage system (tube thoracostomy with two reservoirs; Abbott laboratories) with a negative pressure of −10 mmHg H_2O. When airway leakage has ceased, expansion of the lung was radiologically evaluated. The drain was clipped for 4 h when the lung was expanded. When expansion of the lung still existed after 4 h, the drain was removed and patient was discharged. After discharge patients were seen at day seven and after one year at the outpatient clinic with a chest X-ray to evaluate a possible recurrence of the PTX. Otherwise patients with complaints were seen earlier.

Study endpoints

The main study endpoint was the duration of hospital stay. The secondary study endpoint was immediate success rate defined as complete success after first attempt (without need for TT) with discharge after 24 h for NA (needle aspiration). MA success was defined as a complete expansion, success rate at two weeks (continuous expansion) and one year (no recurrence of PTX in the interval period). Immediate TT success was defined as expansion of the lung, counteraction of the air leak and removal of the drain with discharge within 72 h. Finally, predictors for immediate success were assessed.

Sample size calculation

Sample size calculation was based on results of the Noppen study.[12]

The following data were used: mean hospital stay of population 1: 3.4, mean hospital stay of population 2: 4.5, common standard deviation: 2.0, significance level: 0.05. The study had 80% power to demonstrate a difference of one day in hospital stay between MA and TT. Allowing for 10% withdrawal, we aimed to recruit 114 patients ($n = 57$ for both groups).

Statistical analysis

Baseline characteristics were described using descriptive statistics. The main study endpoint (hospital stay) was analysed with the Student's *t*-test (2-tailed) for independent groups. Success rates were assessed with the chi-squared test or Fisher's exact test when appropriate. Multivariate logistic regression was used to assess predicting factors associated with immediate success. Statistical significance was accepted as a $p < 0.05$. Data analysis was performed using SPSS version 18.

Results

Recruitment fell short of expectation and finally, 56 patients were included ($n = 25$ MA and $n = 31$ TT) during 2007−2009. As a result the power of the study decreased from 80% to 54%. Patient characteristics for each group are listed in Table 1. There were no differences in gender, age, percentage of total PTX, PTX size (Light index), body mass index (weight in kilogrammes divided by height in m^2) and smoking status. In the MA group, the left side was more frequently affected. There was one missing Light index in the MA and three missing in the TT group. A study flow chart is given in Fig. 1. There was a significant difference in hospital stay in favour of MA: 2.4 ± 2.6 versus 4.4 ± 3.3 days ($p = 0.02$). Immediate success rates were not significantly different in both groups: 17/25 (68.0%) of MA patients versus 25/31 (80.6%) of TT ($p = 0.28$). Of the 8 patients in whom MA was unsuccessful, TT was successful within two weeks. Two week success rates were 25/25 (100%) for MA patients and 31/31 (100%) for TT. The 1 year recurrence rates were not significantly different for both groups: 1/25 (4.0%) for MA versus 4/31 (12.9%) for TT ($p = 0.37$). Predictors of immediate success were TPTX and female sex independent of type of treatment (Table 2). One patient died during follow up of our study due to heart failure (cardiomyopathy).

Table 1 Patient characteristics.

	Manual aspiration	Chest tube drainage
n	25	31
Sex, m/f (%m)	17/8 (68)	23/8 (74)
Age, yrs	47 ± 19	40 ± 20
Total pneumothorax (%)	15/25 (60)	22/31 (71)
Affected side (right/left; %right)	8/17 (32)	15/16 (48)
Light index[a]	60.5 ± 25.4	63.8 ± 22.8
Spontaneous/traumatic cause (%spontaneous)	14/11 (56)	20/11 (65)
Body mass index (kg/m^2)	23.9 ± 3.1	22.0 ± 3.1
Current smoker (%)	13/25 (52)	16/31 (52)

[a] One missing in MA group and three missing in TT group.

Table 2 Predictors of immediate success (≤72 h).

Predictor	Odds ratio	95%CI	*p*-value
Cause (traumatic versus spontaneous)	11.1	1.3; 95.4	0.028
Sex (female versus man)	5.6	0.6; 50.8	0.124

95%CI: 95% confidence interval.

Discussion

Our study is the first prospective, randomised monocentred study in the Netherlands comparing MA and TT as a first treatment for patients presenting with a first episode of PSP. This study was based on the study of Noppen et al.[12] Fifty-six patients with a first episode of symptomatic PTX admitted to the ER or asymptomatic PTX with a size of ≥20% were recruited during 2007—2009 and followed-up for one year. There is no significant difference in success rates between MA and TT either immediate or at two weeks. Hospital stay however was significant shorter in MA. Predictors of immediate success were traumatic PTX and female sex, independent whether MA or TT was used.

PSP and TPTX are common pathologies in daily pulmonary practice accounting for a significant health-care expenditure.[1,2] Generally accepted guidelines are lacking, leading to a variation in daily practice.[1] There is a general consensus on a conservative approach in first episodes of asymptomatic PSP and/or small pneumothoraces <20% (Light index). In symptomatic patients or those with large pneumothoraces treatment options could vary because of treatment goals (simple removal or the prevention of recurrence).[1] This is caused by the lack of prospective, studies comparing various treatment options in homogenous patient populations. The way of treatment (simple removal, pleurodesis or a VATS) of patients with a first episode of PSP depends on the risk of recurrence (an average of 30% after a first episode)[12] and social factors (profession or preference of patient). The American College of Chest Physicians recommended TT or pleural catheters as the preferred intervention in the management of PSP. Simple aspiration was advocated only for stable patients with small pneumothoraces.[1] VATS treatment is suggested to be more cost effective than TT (even in first episodes) but it is a fact that 73% of patients had unnecessary operations. Procedures to prevent recurrence should be reserved for recurrent PTX. Although MA is simple, less invasive and less costly,[1,12,15] TT is the most popular and recommended air evacuation technique. This could be explained by the lack of affinity with MA as well as the scarce and complex (heterogenous groups) literature. Some authors argue against MA for the following reasons: the absence of recurrence prevention, difficult to interpret literature (inhomogeneous population) without a clear consensus. The first point is irrelevant because patients with recurrent PTX are not considered for MA and neither MA nor TT has any recurrence prevention effect.[19—21] Therefore surgery should be undertaken. The immediate success of MA in literature ranges from 38% to 86%, (averaging 72%). Late recurrences (at least 1-year follow-up) vary between 0 and 30%. Complications are rare and not life-treathening (haemothorax, retained catheter tips, subcutaneous emphysema and vasovagal reactions). In the British Thoracic Society Research Committee study[17] MA and TT were reported to be equally successful in first and recurrent episodes of spontaneous (presumably primary) PTX with MA being less painful, leading to less admission rates and a reduced need for pleurectomy without an increase in recurrence rate at one year. MA is recommended as first line treatment for all PSP requiring intervention. Despite the publication of these guidelines, management of PSP continues to be characterised by empiricism rather than being evidence-based.[1]

There are prospective, comparative studies on MA versus TT in spontaneous PTX.[17,22] In the study of Noppen immediate MA had a success rate of 59.2% versus 63.6% ($p = 0.9$) in TT (complete success and discharge within 72 h).[12] One-

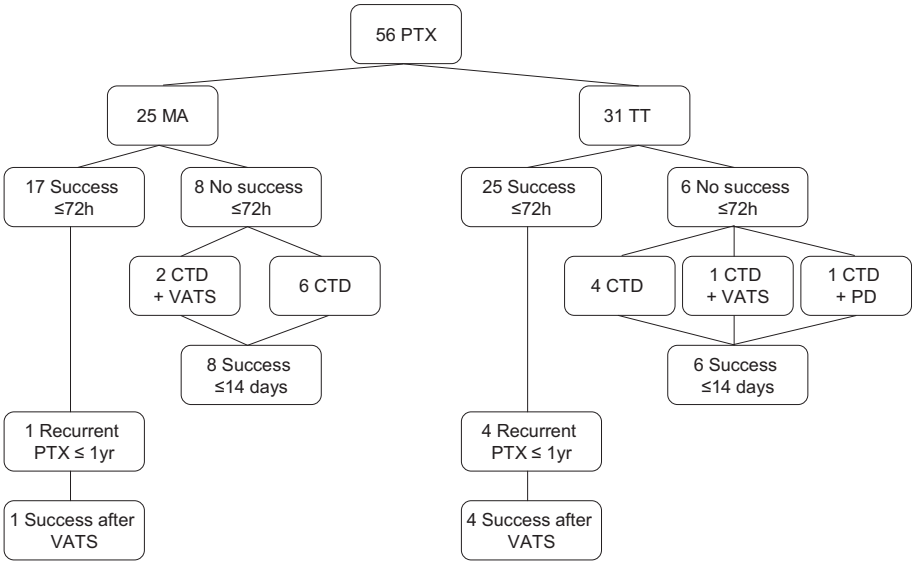

Figure 1 Flowchart of inclusion, randomisation and follow up.

week success rates were 93% in the intention-to-treat MA group and 85% ($p = 0.4$) in TT. In MA patients 52% was hospitalised versus 100% in TT ($p = 0.0001$). We achieved almost the same results as Noppen. A significant shorter hospitalisation was found for MA patients 2.4 $\pm$ 2.6 in MA versus 4.4 $\pm$ 3.3 days in TT ($p = 0.02$). No significant differences in immediate success, 1 year success and one year recurrence rates were seen. In contrast, we found lower one year recurrence rates; 4.0% versus 26% for MA and 13% versus 27.3% for TT. This could be explained by the inclusion of more females (32% versus 26% in MA and 26% versus 16% in TT) and patients with a traumatic PTX in our study. Both traumatic PTX and female sex were found to be predictors of immediate success. Probably this explained the lower recurrence rate also.

In the Andrivet study,[22] delayed needle aspiration (NA) (72 h) was less effective (67% versus 93%) than immediate TT (success was assessed up to 10 days after tube placement) in the first part of their study. In the second part, immediate NA was successful in 68.5% of patients. Hospital stay was similar between both groups. Recurrence rates at 3 months in the various treatment arms (manual versus thoracostomy) did not differ significantly (21% versus 29%) ($p > 0.45$).

The study of Ayed showed comparable results: immediate- and 1 week success rate of 62% and 89% for aspiration versus 68% and 88% for the TT. Recurrence rates did not differ significantly between both groups after 3, 12 and 24 months. Complication rates were 2% versus 7%.[4] The study population consisted mainly of males.

The trial of Harvey had an initial aspiration success rate of 66%. The total higher MA success rate of 80% was explained by second MA efforts in 14% of the patients. No significant difference in one year recurrence rate was seen between MA and TT. We confirmed the safety of MA in literature, observing no side effects, complications or need for urgent readmissions in the MA group.[17]

There were some limitations in our study. Our aim was to enrol 114 patients. Unfortunately we did not reach this sample size due to logistical reasons. Only 56 patients were enrolled. This is the most important limitation of our study. This decreased our study power. However, the current sample based on hospital stay seemed sufficient enough to demonstrate a significant difference. Otherwise our patient number was similar with the study of Noppen: 56 versus 60 patients.[12]

The second limitation of our study (MA) is that large or total pneumothoraces are not suitable for MA because this exceeds the air drainage of $\geq$2 L. In the Noppen study the cut-off point for MA was $\geq$4 L. Also the single attempt for MA could be a limitation. A second aspiration was not likely to be successful in the Noppen study.[12] We did not investigate whether a second aspiration would lead to a failure. That was the reason to exclude a second attempt by a first failure in MA. However the Harvey study described second MA with success in 14% of patients.[17] Second MA failure would be most probably due to a persistent air leak of a large parenchymal tear leading to a high short term recurrence, because MA does not promote pleural symphysis.[4] It was previously thought to be that the irritating effect of the tube promotes pleural symphysis thereby reducing the risk for a recurrent ipsilateral spontaneous PTX. Although this may be intuitively logical, it has not been validated by clinical studies because the recurrence rates between TT and MA were similar.[22]

Finally, we could not calculate the Light index in 4 patients; 3 in TT group and one in the MA group. This was caused by a software problem in the imaging of chest X-rays. Lastly we have not calculated costs, although shorter hospitalisation may suggest a superior cost effectiveness for MA as first line treatment in first episodes of PSP.

Although our study had some limitations, our results meet literature figures: immediate MA success in literature ranges from 38% to 86%. Late recurrences after MA vary between 0 and 30% and show no significant difference with TT.[17,22–26] Hospital stay is significant different in MA compared with TT.[12] Our most important limitation is our small sample size. However, former trials had included similar sample sizes.[12] In daily practice it is difficult and time-consuming to include large populations. Especially, when performed as a mono-centred study like we did. There is a not significant difference in immediate success rates between MA and TT. Maybe success rates of MA could be increased by performing a second attempt.[17] Until future studies will recommend another approach, we will perform MA as the treatment of choice in traumatic and uncomplicated PSP with an exception of total pneumothoraces.

Conclusion

MA is simple, safe, cheap, less invasive in patients with traumatic and uncomplicated PSP with no significant difference in success and recurrence rates and a shorter hospital stay in comparison to TT. In our opinion, MA is the treatment of choice in pneumothoraces with an estimated air evacuation $<$2 L. The treatment of large (total) pneumothoraces are excluded. Further appropriately powered randomised clinical trials employing a larger number of participants could be undertaken to increase the insight in MA.

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Author contributions:

Dr. M. Parlak contributed to data collection, analysis and interpretation of the data and was primarily responsible for writing the manuscript.

Mr. S.M. Uil contributed to the design of the study, analysis and interpretation of the data and critical revision of the manuscript.

Dr. J.W.K. van den Berg contributed to the conception and design of the study, interpretation of the data and critical revision of the manuscript.

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Conflict of interest statement

The authors declare that they have no conflict of interest.

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