Randomised comparison of needle aspiration and chest tube drainage in spontaneous pneumothorax

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ABSTRACT Guidelines on spontaneous pneumothorax are contradictory as to intervention between needle aspiration (NA) and chest tube drainage (CTD). Studies show poor adherence to guidelines.

Three Norwegian hospitals included patients with primary (PSP) and secondary (SSP) spontaneous pneumothorax. Patients underwent NA or CTD as the primary intervention. The main outcome was duration of hospital stay. Secondary outcomes were immediate- and 1-week success rates and complications.

127 patients were included, including 48 patients with SSP. 65 patients underwent NA, 63 patients CTD. Median (interquartile range) hospital stay was significantly shorter for NA: 2.4 days (1.2–4.7 days), compared with CTD: 4.6 days (2.3–7.8 days) ($p<0.001$). The corresponding figures for the SSP subgroup were 2.54 days (1.17–7.79 days) compared with 5.53 days (3.65–9.21 days) ($p=0.049$) for NA and CTD, respectively. Immediate success rates were 69% for NA compared with 32% for CTD ($p<0.001$). The positive effect of NA remained significant in sub-analyses for SSP. There was no significant difference in 1-week success rates. Complications occurred only during the CTD-treatment.

Our study shows shorter hospital stay and higher immediate success rates for NA compared with CTD. Subgroup analyses also show clear benefits for NA for both PSP and SSP.

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Introduction

Spontaneous pneumothorax is defined as air in the pleural cavity without any previous trauma or intervention [1]. The condition is divided into primary spontaneous pneumothorax (PSP) and secondary spontaneous pneumothorax (SSP) depending on the absence or presence of any underlying lung disease.

When spontaneous pneumothorax causes significant dyspnoea, intervention is required to evacuate the intra-pleural air [1–3]. The most commonly used treatment options are chest tube drainage (CTD) and needle aspiration (NA). CTD has been the standard treatment and is regarded as the most efficient way to obtain re-expansion of the lung. NA is proven to be quick and simple, causing limited annoyance to the patient [4]. The drawback of NA is its lack of effect if the air leakage is still present at the time of treatment.

It is not clear which of these two options should be the first choice of treatment of spontaneous pneumothorax. Six randomised trials comparing NA and CTD have been reported [4–9]. Of these, only one study [8] of 60 patients was found eligible as the basis for the Cochrane review of 2007 for the first episode of PSP [10]. Only Andrivet *et al.* [5] included patients with SSP (n=8).

In other studies, NA has been compared with mini chest tubes attached to a Heimlich valve [11] or NA/CTD has been compared with pleurodesis [12]. European and American guidelines [13–15] are contradictory on the role of NA in the treatment of spontaneous pneumothorax. The British Thoracic Society (BTS) guideline [14] and European Respiratory Society (ERS) task force statement [15] recommend aspiration as the first intervention, when needed, for all PSP without tension. The BTS guideline is more modest for SSP: NA can be considered for symptomatic patients with small spontaneous pneumothorax in an attempt to avoid CTD [14, 16]. The American College of Chest Physicians (ACCP) guideline [13] does not suggest NA for any patients. Several studies [17–22] have demonstrated a lack of adherence to guidelines on the treatment of spontaneous pneumothorax, and overuse of thick chest drains [22].

Based on clinical experience, we hypothesised that NA would be preferable to CTD in the initial treatment of both PSP and SSP. We aimed to test the hypothesis in a randomised study using the duration of hospitalisation as the primary end point.

Methods

Patients

The study was carried out at three Norwegian university hospitals with the participation of one thoracic surgery (Oslo) and two pulmonary medicine (Bergen, Trondheim) departments. The inclusion criteria were as follows: Patients above 18 years of age with spontaneous pneumothorax in need for intervention. Intervention was defined as required if the size of the pneumothorax on an erect PA chest radiograph was greater than 30% for PSP and greater than 20% in SSP, as defined by Rhea [23, 24] (See Figure S1A. Tool for pneumothorax size.) **or** if the patient answered "yes" to the following question: "Do you feel significantly more breathless than usual?"

Patients with a tension pneumothorax, severe respiratory failure or need for assisted ventilation, bilateral pneumothorax, as well as patients previously included in the study for an ipsilateral pneumothorax were excluded from the study.

All patients provided written informed consent. The study was approved by the ethical Committee of Western Norway in April 2002 (REK III nr.005.01).

Baseline data

The following variables were recorded at baseline: Time from debut of first symptoms to hospital admission, self-reported smoking status, pack years (calculated by multiplying number of packs of 20 cigarettes smoked per day with number of years smoked), self-reported pulmonary disease, self-suspected and confirmed previous episodes of pneumothorax. In case of a previously confirmed pneumothorax on the same side, the present one was defined as a recurrent pneumothorax.

The spontaneous pneumothorax was defined as PSP if the patient had no pulmonary disease and as SSP if the patient had a pulmonary disease or was ⩾50 years old with a significant smoking history, according to the current BTS guideline [14]. Significant smoking history in this case was defined as ⩾10 pack-years.

Intervention

Eligible patients were randomised to either NA or CTD. Randomisation was done by centre and type of pneumothorax (PSP/SSP). NA was performed with a 16G subclavian catheter (Secalon-T©; Argon critical care systems, Singapore) connected to a three-way valve, 60-mL syringe and a drainage bag. The most commonly used site was the second intercostal space immediately lateral to the mid-clavicular level with the patient in a semi-supine position.

The procedure was terminated when no more air could be aspirated, or if the amount of aspirated air exceeded 3.5 L. Shortly after, a chest radiograph was performed to assess the change in pneumothorax size. If the pneumothorax size was less than 20% and the patient reported no breathlessness, the patient was observed for 6 h. If pneumothorax size was still greater than 20%, or the patient still reported breathlessness, or if a patient who initially showed improvement deteriorated after the 6-h observation period, a second aspiration was performed. The chest radiograph was postponed to the next morning if the 6 h control was scheduled between 22:30 and 06:00 h.

The patient was treated with CTD (see below) if neither the first nor the second aspiration showed adequate response. Adequate response was defined as a pneumothorax size less than 20% and no reported breathlessness, followed by persistent stable condition on subsequent chest radiographs. A failure was defined if the pneumothorax size was >20% or the patient still reported breathlessness following two NA attempts.

CTD was performed with insertion of a 12–28 Ch (commonly 14–20 Ch) chest tube (Kendall Argyle; Tyco healthcare, Ireland), connected to a chest drainage system (Pleur-evac©; Genzyme corporation, USA) with water seal. The most commonly used sites of insertion were the 4th or 5th intercostal space in the mid-axillary line. A chest radiograph was performed shortly after drain insertion to evaluate the drain position and preliminary effect. Suction was applied only if re-expansion of the lung was modest, at the discretion of the physician. The chest radiograph was repeated the next morning and always following cessation of bubbling in the water seal in the chest drainage system. Clamping of the drain for some hours was allowed before removal. Referral for surgical treatment was recommended if there was persistent air leakage after 7 days of chest drainage. Chemical pleurodesis [14] and autologous blood patch [25] were alternative options in patients considered to have a high risk for surgical treatment.

Adequate response of CTD was defined by cessation of bubbling with no visible pneumothorax or a pneumothorax size less than 10%, and a stable clinical condition for a minimum of 12 h prior to chest drain removal.

Both procedures were performed under local anaesthesia, and a flow chart was used to ensure standardised treatment in each centre (See figure S1B and S1C.)

All patients were given supplementary oxygen for as many hours as possible a day, using 3 $L \cdot min^{-1}$ as a standard [26]. Oxygen flow was reduced if there was a tendency for CO_2 retention. After discharge, patients were seen in the outpatient clinic, wherein a chest radiograph was performed within 7–10 days to detect short-term relapse.

Outcomes

Our primary outcome was duration of hospital stay due to pneumothorax, analysed on an intention-to-treat basis.

Secondary outcomes were:

1. Immediate success: For NA defined by persistent adequate response following the aspirations. For CTD defined by adequate response with removal of drain within 72 h after initial treatment. This corresponds to the definition of Ayed *et al.* [6] and Noppen *et al.* [8].
2. One-week success: defined by discharge from hospital within 7 days (⩽168 h) of initial treatment. Here, data were analysed on an intention-to-treat basis.
3. Complications related to the procedures (infection, bleeding, re-expansion pulmonary oedema, subcutaneous emphysema), and mortality. See online supplement for predefined definitions.

Statistics

The *a priori* sample size calculation was based on the main outcome variable, *i.e.* duration of hospital stay. In the BTS Research Committee Study [4], the mean hospital stay was 3.2 days (SD 4 days) in the aspiration group, and 5.3 days (SD 4 days) in the drainage group. With a two-sided significance level of 5%, a total enrolment of 63 patients in each group was needed to attain a power of 80% to detect a difference in hospital stay of 2 days between the two treatment options.

Both Kaplan–Meier and kernel density plots were used to compare the duration of hospital stays between aspiration and drainage. Kernel distribution is a nonparametric way to represent the probability density function of a random variable, and the produced plot illustrates the distribution of hospital stay in a smooth and continuous manner (much like a smoothed histogram). The data was highly skewed and included outliers. The Kaplan–Meier and kernel density plots were therefore presented with a 7-day cut-off to illustrate the clinically relevant period. Corresponding plots for all patients without cut-off were presented as supplementary data. Owing to the skewed data and outliers, the median was considered the

appropriate measure of central tendency. We used the two-sample Wilcoxon rank-sum test to test for differences in distributions. The Chi-squared test was applied to assess differences in success rates between the aspiration and drainage groups. Sub-analyses were conducted, stratifying on pneumothorax type (PSP and SSP) and episode of pneumothorax (first and recurrent).

All statistical analyses were conducted using the software STATA version 13.1. All p-values were 2-sided, and values less than 0.05 were considered statistically significant.

Results

Patient characteristics

A total of 127 patients (107 males) underwent randomisation to NA or CTD. Characteristics of study participants, randomised to NA or CTD, are given in table 1. The size of the pneumothorax was slightly larger for those randomised to drainage (CTD) as compared with those randomised to aspiration (NA).

Altogether, 48 (38%) subjects had an SSP. These patients suffered from at least one of the following conditions: chronic obstructive pulmonary disease (COPD or asthma) (n=35), pulmonary cancer (n=5), pneumonia (n=5), interstitial lung disease (n=2), other (*e.g.* cystic fibrosis, Marfan syndrome, sarcoidosis) (n=9). Further, 14 patients were diagnosed with chronic pulmonary diseases for the first time during this episode of pneumothorax (13 with COPD, one with cancer). Seven patients were defined as having an SSP on the basis of the BTS-guideline definition [14].

In total, 33 patients were reported with confirmed previous episodes of pneumothorax.

Flow of patients in the NA group

Of those patients randomised to aspiration, half had adequate response on the first aspiration. Three quarters of those with failure received a second aspiration, of whom nearly half had an adequate response (figure 1). Eight patients required only one attempt at aspiration before being treated further with CTD. Because of a protocol violation, a single patient had a third aspiration, with adequate response.

Main outcomes

The duration of hospitalisation was two-fold longer in the CTD group than the NA group. According to intention-to-treat analysis, the median (25, 75 percentiles) hospital stay for the patients in the NA group and CTD group was 2.4 (1.2, 4.7) days and 4.6 (2.3, 7.8) days, respectively ($p<0.001$). Figure 2 shows the corresponding Kaplan–Meier and density plots with a hospital stay of 7 days as cut-off. (Corresponding plots for all patients are shown in online Supplementary Figure 2E.)

We then analysed PSP and SSP separately. For those with PSP randomised to NA and CTD, the median (25, 75 percentile) number of hospital days were 2.20 (1.2, 4.5) and 4.1 (2.2, 5.9), respectively ($p=0.008$). The corresponding data for those with SSP were 2.5 (1.2, 7.8) and 5.5 (3.7, 9.2), respectively ($p=0.049$) (figure 3 and table 2). (Corresponding plots for all patients are shown in online Supplementary Figure 3E.)

TABLE 1 Characteristics of participants

Characteristics	Needle aspiration	Chest tube drainage (CTD)
Patients n	64	63
Men	54 (84.4)	53 (84.1)
Age years	40.5±21.5	40.9±19.5
Height cm	177.1±10.5	179.4±9.6
BMI kg·m^{-2}	21.3±3.2	22.1±3.2
Current smoker	30 (47.6)	27 (44.3)
Smoking history pack-years	6.5 (0.0–17.5)	10.8 (1.8–20.0)
First episode of pneumothorax	38 (69.1)	42 (72.4)
Size of pneumothorax %	47.5±19.8	57.0±25.0
Secondary pneumothorax	22 (34.4)	26 (41.3)
Right-sided pneumothorax	39 (60.9)	36 (57.1)
Hours from first symptoms until treatment	20.5 (6.0–60.0)	15.5 (5.0–72.0)

Data are presented as n (%), mean±SD or median (interquartile range), unless otherwise stated. Data on height was missing for 7 subjects (5 from aspiration), on BMI for 9 subjects (6 from aspiration), on current smoking status for 3 subjects (1 from aspiration), on pack-years for 11 subjects (6 from aspiration), on first episode of pneumothorax for 14 subjects (9 from aspiration), on size of pneumothorax for 3 subjects (2 from aspiration) and on hours from first symptoms until treatment for 1 subject (from drainage).

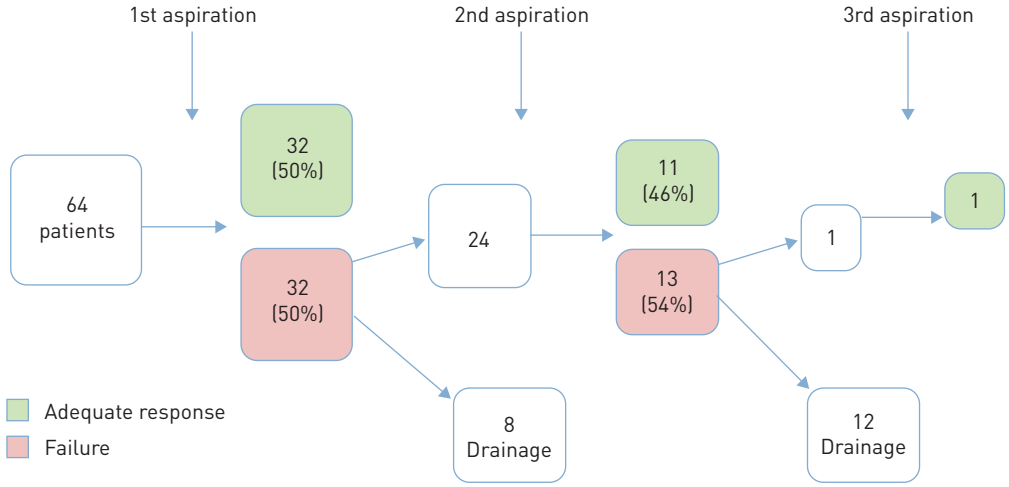

FIGURE 1 Flow of patients in the needle aspiration group.

Further, we separately analysed data from the group with the first episode of pneumothorax and the group with confirmed previous episodes (recurrent pneumothorax) separately. We found a similar positive pattern for NA compared with CTD, reaching a level of significance for the first episode of pneumothorax (figure 4 and table 2). (Corresponding plots for all patients are shown in online Supplementary Figure 4E.)

Secondary outcomes

The secondary outcomes in terms of immediate success and success after 1 week are shown in table 2. The immediate success was significantly higher for NA than for CTD both for PSP and SSP as well as for both first and recurrent episodes of pneumothorax. After 1 week, there was no difference between the two treatment groups (table 2).

The number of patients with adequate response for NA as sole treatment was 44 out of 64 (69%).

Complications

No treatment related complications were reported during the NA treatment.

During the CTD, the following were recorded: wound infection (n=4), bleeding (n=2), subcutaneous emphysema (n=7), pneumonia (n=1) and empyema (n=1). The patient suffering from empyema subsequently died of the complication. It should be noted that insertion of a new chest drain was necessary in 16 patients because of displacement or blockage of the drain during the treatment period.

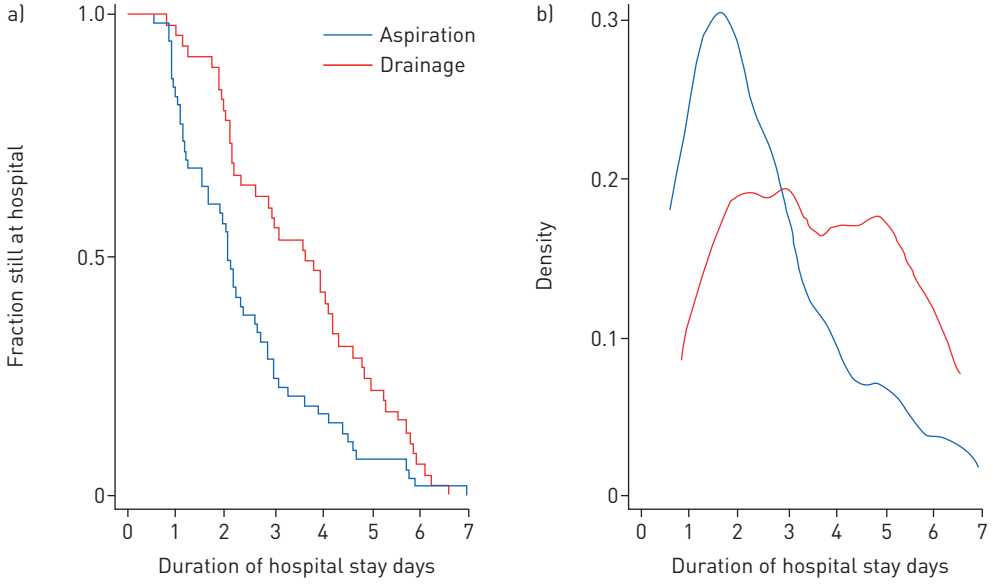

FIGURE 2 Hospital stay, total population. 7-day view.

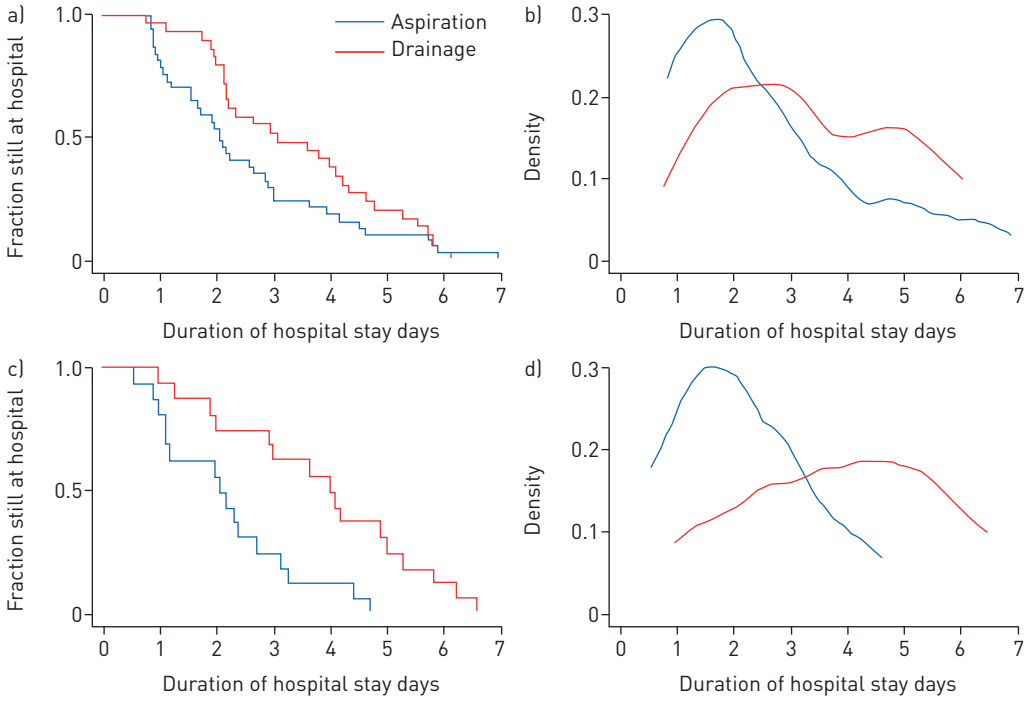

FIGURE 3 Hospital stay, subgroups a, b) primary and c, d) secondary pneumothorax. 7-day view.

Discussion

The duration of hospital stay after NA is almost half the length of that for CTD. This finding was evident in both those with PSP and SSP. The complication rate was negligible for NA as compared with CTD.

To our best knowledge, this is the first randomised study to observe that NA leads to a shorter hospital stay than CTD in both PSP and SSP.

TABLE 2 Main outcome (length of hospital stay) and secondary outcomes (immediate success, 1-week success) in those randomised to needle aspiration and those randomised to chest tube drainage

	Needle aspiration	Chest tube drainage	p-value
All patients (n=127)			
Hospital stay days	2.4 (1.2–4.7)	4.6 (2.3–7.8)	<0.001
Immediate success	44 (68.8)	20 (31.8)	<0.001
One-week success	52 (81.3)	45 (71.4)	0.193
Patients with primary SP (n=79)			
Hospital stay days	2.2 (1.2–4.5)	4.1 (2.2–5.9)	0.008
Immediate success	31 (73.8)	14 (37.8)	0.001
One-week success	36 (85.7)	29 (78.4)	0.394
Patients with secondary SP (n=48)			
Hospital stay days	2.5 (1.2–7.8)	5.5 (3.6–9.2)	0.049
Immediate success	13 (59.1)	6 (23.1)	0.011
One-week success	16 (72.7)	16 (61.5)	0.413
Patients with first episode (n=80[#])			
Hospital stay days	2.3 (1.2–4.7)	4.5 (2.2–7.5)	0.006
Immediate success	25 (65.8)	14 (33.3)	0.004
One-week success	32 (84.2)	30 (71.4)	0.172
Patients with recurrent episode (n=33)			
Hospital stay days	3.3 (2.3–7.8)	5.4 (3.9–11.4)	0.150
Immediate success	11 (64.7)	3 (18.8)	0.008
One-week success	11 (64.7)	11 (68.8)	0.805

Data are presented as n (%) or median (interquartile range). Data are for all patients and subgroups. [#]: Missing information on first episode of pneumothorax for 14 subjects (9 from aspiration).

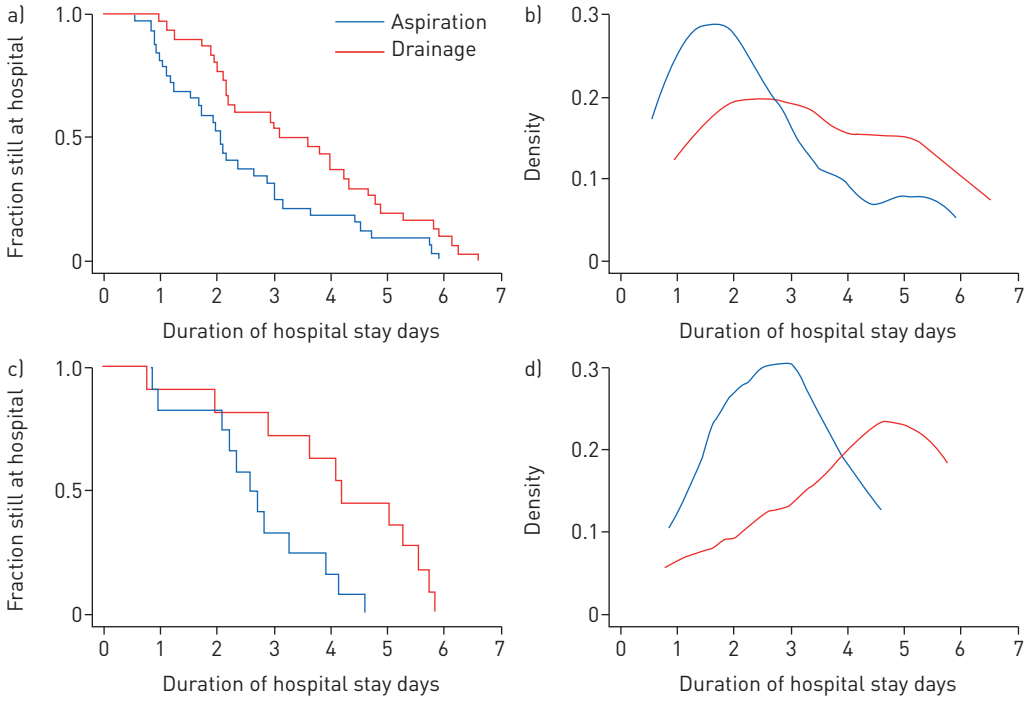

FIGURE 4 Hospital stay, subgroups a, b) first and c, d) recurrent episode of pneumothorax. 7-day view.

Other randomised studies comparing NA and CTD have shown contradictory findings as to the effect on the length of hospitalisation. Some found no difference between the two treatment options despite a 72-h delay in intervention for NA [5]. Others found a shorter hospital stay in those treated with NA compared to CTD [4, 6–9]. All six studies [4–9] concluded that NA is simple, safe, with minimal discomfort for the patient, and no significant difference in 1-year recurrence rates. None of the studies [6, 8, 9] were powered to show statistical significance between the two treatment groups for immediate and 1-week success [15].

Furthermore, most of the studies cited [4, 6–9] were restricted to patients with PSP.

There is however a striking paucity of data on efficacy of NA for SSP. To our knowledge, only Andrivet *et al.* [5] included SSP (n=8), but without any corresponding information on response rates.

The current guidelines [13–16, 27] do not routinely recommend NA as the first treatment option in patients with secondary pneumothorax. The rationale for initial drainage treatment in this group has been that SSP might have a difficult-to-heal air leakage [28, 29] and lower tolerance to the pneumothorax' effect on breathlessness [30, 31]. Separate analyses of those with SSP in our study showed that the duration of hospital stay in the NA group was about half of that of the CTD group. We also found a significant advantage for NA over CTD for immediate success for both PSP and SSP. If this finding can be confirmed in other studies, the guidelines for initial treatment of pneumothorax should be re-evaluated. A short hospitalisation and limited invasive management like NA are particularly important in a group of patients with serious underlying diagnoses often characterised by frequent hospitalisations and higher risk of complications.

Those randomised to NA were treated with up to two aspirations. At both attempts, the success rate was near 50%. This finding contradicts the BTS guidelines [14] and the results of Noppen *et al.* [8] where none of the six patients showed a response to the second aspiration.

The complications associated with CTD observed in our study were consistent with other reports [5–9]. In addition, the low number of complications related to NA has been found in other studies. Patients with pneumothorax suffering from an underlying lung disease may be less fit to tolerate complications from drainage treatment and immobilisation, such as infections, subcutaneous emphysema, bleeding, anxiety or opiate-demanding pain. This is a further argument that even patients with SSP should be offered initial treatment with NA.

In a recent report in Lancet Respiratory Medicine, Bintcliffe *et al.* [27] pointed out that distinguishing between PSP and SSP in terms of treatment, has never been validated prospectively. They challenged the traditional view on PSP and SSP as separate entities. This view is in agreement with our study that patients with non-tension spontaneous pneumothorax may initially be treated the same way regardless of it being a PSP or an SSP and also regardless of whether the pneumothorax is a first-time or recurrent event.

Anticipated studies on the conservative treatment of spontaneous pneumothorax (ACTRN12611000184976) may provide new insights on tolerance and safety for conservative and minimally invasive approaches like NA, with the potential to influence the whole chain of pneumothorax management.

This study has several strengths. First, it covered two pulmonary departments and one surgical department. Second, the procedures were carried out by junior doctors on call, reflecting daily routine in clinical practice. Third, in Norway, all patients with spontaneous pneumothorax are admitted to the hospital, minimising the risk of missing out on early relapse. Finally, our study included both PSP and SSP, and both first and recurrent episodes of pneumothorax.

Some limitations should also be acknowledged. First, the pneumothorax was somewhat larger in those randomised to drainage as compared to those randomised to aspiration. However, the difference between the two groups in pneumothorax size is within the range for clinically important differences as shown in our study on the reliability of pneumothorax-size estimation [24]. Second, a possible limitation is that we used the Argyle chest type drains of greater calibre than the more recently developed use of small-bore drains inserted by the Seldinger technique [32]. One could argue that this may have influenced the rate of complications caused by the chest drain and length of hospital stay. Some retrospective studies like those of Benton and Benfield [33] and Iepsen and Ringbæk [22] found a lower complication rate for small-bore drains than large-bore intercostals catheters, whereas Vedam and Barnes [34] reported an opposite trend. Overall, even though our CTD complication rate was low, we might have seen an even lower number of complications using small-bore drains.

In an editorial, Maskell *et al.* [35] argued that the same array of problems may be caused by small-bore drains as with larger drains. Several studies [22, 33, 36–39] have shown that small-bore drains have similar efficacy as the larger drains; however, it is not yet proven whether small-bore drains resolve a spontaneous pneumothorax more rapidly than large-bore drains. The risks and consequences due to the CTD principle of continuous drainage with an indwelling catheter still remain, as opposed to simple NA.

Consequently, our findings indicate that both patients with PSP and those with SSP should be considered for NA as the initial intervention. Thus, guidelines [13–15] may be unnecessarily complicated on the key criteria guiding the choice of intervention. As a result, adherence is far from optimal [17–21, 40]. Our results suggest a possibility to simplify subgrouping in treatment logarithms, and consequently achieve better adherence to guidelines.

In conclusion, in our randomised study of spontaneous pneumothorax, we have shown that starting intervention with NA leads to shorter hospitalisation stay and fewer complications than intervention with CTD. These findings were observed both in PSP and SSP and regardless of prior history of spontaneous pneumothorax. Guidelines on pneumothorax treatment should be considered and revised accordingly.

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