

A Prospective, Randomized trial of Initial management of well tolerated but voluminous primary pneumothorax : The PRINTED trial

Essai prospectif randomisé sur la prise en charge initiale d'un pneumothorax primitif bien toléré et abondant : L'essai PRINTED

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ABSTRACT

Introduction: Although needle aspiration (NA) has demonstrated comparable efficacy to chest tube drainage (CT) for primary spontaneous pneumothorax (PSP), its routine use remains limited, particularly for large PSP. This study aimed to assess the efficacy and safety of NA compared to CT in the initial management of large PSP in Tunisia.

Methods: We conducted a monocenter, prospective, randomized, open-label, non-inferiority trial at Abderrahmen Mami Hospital from 2019 to 2023. Eligible patients presented with a first episode of PSP occupying more than 40% of hemithorax volume (based on the Collins index) but were still clinically stable. Patients were randomly assigned to undergo either CT or NA. The first primary outcome was successful lung re-expansion. The second primary outcome was the recurrence rate during one year of follow up.

Results: A total of 77 patients were enrolled. NA (n= 34) was associated with a significantly shorter hospital stay, reduced analgesic use, and fewer iatrogenic complications than CT (n= 43). The overall success rate of NA was equivalent to that of CT (64.7% vs. 65.1%, p= 0.97). The absolute difference in success rates was -0.4% (95% CI, [-3.9% to +4.7%], margin error-10%). Recurrence rates after one year were comparable in the two groups.

Conclusion: Needle aspiration is an effective and less invasive alternative to chest tube drainage for managing large but well-tolerated PSP. Wider adoption of this strategy could reduce the hospital burden and enhance patient care. Increased awareness among clinicians is essential to shift established practices.

Key Words: Primary spontaneous pneumothorax ; Needle aspiration ; Chest tube ; Randomized controlled trial

RÉSUMÉ

Introduction : Bien que la ponction à l'aiguille (NA) ait démontré une efficacité comparable au drainage thoracique (CT) pour le pneumothorax spontané primaire (PSP), son utilisation systématique reste limitée, notamment pour les PSP de grande taille. Cette étude visait à évaluer l'efficacité et la sécurité de la NA par rapport au CT dans la prise en charge des PSP de grande taille en Tunisie.

Méthodes : Nous avons mené un essai de non-infériorité monocentrique, prospectif, randomisé, ouvert et de non-infériorité à l'hôpital Abderrahmen Mami de 2019 à 2023. Les patients éligibles avaient un premier épisode de PSP occupant plus de 40 % du volume de l'hémithorax (sur la base de l'indice de Collins) mais étaient cliniquement stables. Les patients ont été randomisés pour avoir soit un CT, soit une NA. Le critère principal de comparaison était la réexpansion pulmonaire. Le deuxième critère principal était le taux de récurrence à un an.

Résultats : Un total de 77 patients ont été inclus. La NA (n = 34) était associée à une durée d'hospitalisation significativement plus courte, un usage réduit d'analgésiques et moins de complications iatrogènes que le CT (n = 43). Le taux de réussite de la NA était équivalent à celui du CT (64,7 % vs 65,1 %, p = 0,97) avec différence absolue de -0,4 % (IC à 95 %, [-3,9 % à +4,7 %], marge d'erreur à -10 %). Les taux de récurrence à un an étaient comparables dans les deux groupes.

Conclusions : La NA est une alternative efficace et moins invasive que le CT pour la prise en charge des PSP volumineux bien tolérés. Une large diffusion de cette technique pourrait réduire la charge hospitalière et améliorer les soins aux patients. Une sensibilisation des cliniciens est essentielle pour faire évoluer les pratiques établies.

Mots clés: Pneumothorax spontané primaire , ponction à l'aiguille , drain thoracique , Essai contrôlé randomisé

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INTRODUCTION

Primary spontaneous pneumothorax (PSP) is defined as a spontaneous pneumothorax that occurs in a person without an underlying lung disease. It is a common pathology in daily pulmonary practice and accounts for significant health-care expenditures.

The treatment of choice for a PSP is influenced by clinical presentation, size, recurrence risk, (à un degré moindre) daily activities, patient preference and economical considerations. Treatment options consist of: therapeutic abstinence (bed rest and oxygen), chest tube (CT), needle aspiration (NA), and thoracoscopic or even open surgical intervention thoracotomy).

The size of a PSP estimated by the Collins index correlates strongly with the amount of air present in the pleural space (1).

The risk of recurrence of pneumothorax is directly related to smoking cessation and to underlying lung disease. Treatment choice for a first episode of PSP is influenced by clinical presentation, size of pneumothorax, and the assessment of risk of recurrence. To a lesser degree, physicians may consider professional/occupational activities of the patient, patient preferences about treatment, and economic considerations. Experts tend to avoid any "unjustified" aggressive approach for PSP, since half of the patients presenting a first episode will never have another.

In 2001, a consensus statement from the American College of Chest Physicians recommended that pleural air be removed via placement of a small-bore catheter (14 F) or a (16 to 22 F) CT that may be attached to a Heimlich valve or to a water seal device (2). The British Thoracic Society guidelines for PSP management recommend a removal of pneumothorax using NA (3). Many large-scale prospective studies have defended the use of conservative techniques to treat a well-tolerated primary pneumothorax. The authors provided evidence of non inferiority in terms of safety, evacuation of intrapleural air and risk of recurrence compared with CT (4–6). The conservative mini-invasive approach brings lower admission rates, safer procedures and a reduction in pleurectomy need with no increase in first-year recurrence (6). In conclusion, the literature suggests immediate and long-term efficacy of NA, because of its minimal morbidity, simplicity, mini-invasiveness (less pain), outpatient-based implementation, safety, equal efficacy compared with CT, and low cost by NA followed by immediate discharge and follow-up. Several trials are advocating NA as the treatment of choice in uncomplicated PSP. The absence of a study targeting specifically large PSP patients may be a cause explaining the reticence of practitioners to routinely perform NA. In fact, there is an obvious lack of directive data from randomized controlled trials comparing mini-invasive with interventional management.

Currently in Tunisia, regular therapy for large PSP still consists mostly of CT (7,8). This management induces higher levels of pain and anxiety requiring opioid

medication, local anesthesia, a longer hospital stay and higher costs without a significant difference in immediate success or recurrence rates compared to NA. We aimed to confirm the former findings with a mono-centered study set-up for the first time in Tunisia. This study aimed to evaluate the efficacy of NA in comparison to CT in large PSP management; whether NA will shorten hospital admission and whether the lung will expand as assessed by means of clinical and radiological findings.

METHODS

Trial design

This was a monocenter, prospective, randomized, open-label, non-inferiority trial that was conducted in Abderrahmen Mami Hospital, Ariana, Tunisia. The study protocol was approved by the local ethics committee (Approval Number = 14/2019). Written informed consent was obtained from every patient. This study lasted for 4 years (July 2020 to July 2024). Patients inclusion lasted 3 years (July 2020 to July 2023).

Study population - Inclusion criteria

Patients aged between 18 and 50 years who presented to the emergency department with a first episode of symptomatic PSP with a size exceeding 40% of the hemithorax estimated by Collins Formula were recruited. Non inclusion criteria were secondary pneumothorax, poorly tolerated pneumothorax, recurrent pneumothorax, hydropneumothorax, chronic dyspnea or cough, HIV, Marfan Syndrome, pregnancy, detention, or mental impairment.

According to Collins Formula, a PSP is considered to have a volume > 41.8% of the chest volume if the sum of the inter-pleural distances (IPD) is greater than 8 cm (1).

Poorly tolerated pneumothorax is characterized by a concomitant polypnea (30 cycles per minute), desaturation ($\leq 94\%$) or a shock index < 1.

Exclusion criteria were consent withdrawal, missing during follow-up and identification of any underlying pleuropulmonary or bronchopulmonary disease.

Calculation of study sample size

Sample size calculation was based on the results of Brown and al (9). We aimed to recruit 100 patients (50 patients in each study group). Our results aimed to reveal a significant difference in the success of drainage with a margin of error of 0.01 and a 95% confidence interval.

Randomization

After written informed consent was obtained, the patients were randomized using an adaptive biased-coin (urn) technique. The two groups of patients were individualized.

Standard interventional care group (SIG)

These patients had a chest tube. A large-bore 24-French Seldinger-style chest tube was inserted and attached to an underwater seal connected to a -12 cm H₂O suction. Patients are kept on bed rest. A follow-up chest X-ray is performed once bubbling ceases. Otherwise, it is done if bubbling persists for more than 12 hours.

In cases of persistent pneumothorax, mild pleural aspiration is maintained, and a thoracic surgeon is notified. A more invasive treatment, such as surgical pleurodesis, is proposed after a minimum of five days of aspiration without lung expansion. This decision and the total duration of drainage were left to the discretion of the attending pulmonologist and the surgeon.

If the chest X-ray showed successful drainage, mild aspiration is maintained for five days. A follow-up physical pleuro-pulmonary examination was performed, along with monitoring at 6, 12, 24, and 48 hours post-procedure for respiratory status and pain level. The investigator recorded analgesic requirements. A daily chest X-ray is performed as long as the patient remained clinically stable. Then, complete lung re-expansion was necessary to stop aspiration. A partial pneumothorax of the apex with an IPD < 1 cm could be tolerated. After 24 hours with no aspiration, another chest X-ray is performed, followed by CT removal. A post-removal chest X-ray is mandatory before discharge from hospital. Patients were reviewed at 15 days, 3 months, 6 months, one year, or at any time on request if clinical deterioration occurs.

Minimally invasive needle aspiration group (MNG)

These patients underwent a needle aspiration. The puncture required an 18G short venous catheter-type trocar mounted on a 50 ml syringe via a three-way stopcock. This setup allowed initially a manual evacuation of air then switch to a -12 cmH₂O suction with a water seal device. Aspiration is maintained until there was no more bubbling. Finally, the needle is removed.

Chest X-ray is performed to verify the success of procedure. NA is considered successful if there is complete or near-complete lung re-expansion; the persistence of a minimal apical detachment is also considered a success. A detachment is considered minimal if the distance from the pulmonary apex to the pleural dome remains less than 3 cm and the pleural line does not extend beyond the axillary region. NA can be repeated in case of total pleural detachment after the first attempt.

In case of success, strict bed rest is indicated for 5 days. Monitoring at 6, 12, 24, and 48 hours post-procedure for respiratory status, pleuro-pulmonary examination, SaO₂, and pain level was conducted. The investigator recorded analgesic requirements. Systematic daily chest X-rays were performed. A total expansion of the lung was required for patient discharge. A partial pneumothorax of the apex with an IPD inferior to 1 cm could be tolerated. After discharge, the patient continued to rest. Patients were reviewed at 15 days, 3 months, 6 months, one year, or if clinical deterioration occurred.

In case of failure (persistence of a total pneumothorax

after two attempts), a CT was inserted. As for the SIG group, surgical pleurodesis was proposed after five days of aspiration without lung expansion. This decision and the total duration of drainage were left to the discretion of the attending pulmonologist and the surgeon.

Study endpoints – Follow up assessments

- Success of evacuation = For MNG, success of evacuation meant complete or near-complete lung re-expansion. The persistence of a minimal apical detachment is also considered a success. A detachment is considered minimal if the distance from the pulmonary apex to the pleural dome remained less than 2 cm and the pleural line did not extend beyond the axillary region.
For SIG, success of evacuation meant an insertion of a CT with no adverse events, bubbling for less than 48 hours, then a total expansion of the lung in the chest X Ray performed in the fifth day. A partial pneumothorax of the apex with an IPD inferior to 1 cm could be tolerated.
- Persistent bubbling / Persistent air leak = for a patient with an inserted CT, persistent air leak meant bubbling for more than 5 days.
- Procedure failure = For MNG, procedure failure meant a persistent pneumothorax with more than 2 cm from the pulmonary apex to the pleural dome or an extending pleural line beneath the axillary region. In such case, patients had a CT.
For SIG, procedure failure meant a mal-functioning CT, a persistent pneumothorax or a persistent air leak (more than 5 days of mild aspiration) leading to a surgical pleurodesis.

The primary non-inferiority outcomes were success of procedures, lesser need to perform a surgical pleurodesis and lesser rate of recurrence in a year of follow-up.

Statistical analysis

Demographic and descriptive data were presented in means, standard deviations and compared using a two-tailed Student t test. Categorical variables were compared using chi-square or Fisher exact test, when appropriate. Power analysis was performed considering $\alpha = 0.05$ and $1 - \beta = 0.8$. Statistical significance was accepted at a p value less than 0.05.

A non-inferiority margin (Δ) of -10% was defined as statistically significant. This margin was selected based on clinical judgment and published literature, representing the maximum acceptable difference in success rate that would justify the use of NA given its less invasive nature and favorable safety profile. Similar margins have been used or implied in previous randomized trials that evaluated minimally invasive strategies for PSP management.

The null hypothesis was that NA would be inferior to CT by more than a predefined margin ($\Delta \leq -10\%$). Non-inferiority was determined the difference in success rates (NA minus CT) was greater than -10% and remained within the two-sided confidence interval (CI) of 95%.

Ethical aspects – Trial registration

This study was conducted after obtaining approval from the local ethics committee of Abderrahmen Mami Hospital. The research protocol was reviewed and approved in accordance with the ethical standards outlined in the Declaration of Helsinki. All patients provided written informed consent before their inclusion in the study.

The methodology and protocol of this clinical trial were prospectively registered in the Pan African Clinical Trials Registry (PACTR) under reference number [PACTR202002728476768]. Registration ensured methodological transparency and compliance with international standards for reporting clinical trials.

RESULTS

Over the four-year period, recruitment fell short of expectations and 96 patients were included in the study. Among them, 19 were excluded because the diagnosis of secondary pneumothorax was retained. Ultimately, 77 patients were kept, of whom 43 were initially treated with a CT (SIG) and 34 patients had a needle aspiration (MNG).

Patient characteristics of each group are listed in Table 1. There were no statistically significant differences between the two groups in terms of mean age or tobacco consumption. The right side was more frequently affected in the SIG group.

Table 1. Patient characteristics in each group

Parameter	SIG (n= 43)	MNG (n= 34)	All patients (n= 77)
Age (mean)	30.5 ±7.8	26.2 ±8.3	28.6±8.1
Current smoker (%)	100%	100%	100%
Smoking habit			
Cigarettes	95.3%	82.3%	89.5%
E-Cigarettes	11.6%	23.5%	15.8%
Cannabis	7%	5.9%	6.5%
Affected site (Right/Left)	24/19	15/19	39/38
IPD using Collins formula (mean)	12.9 ±3.4	11.5 ±2.5	12.1 ±3
Volume of the pneumothorax using Collins formula (mean)	67.4 ±20.2	59.4 ±14.4	62.9 ±17.6
completely shriveled lung (%)	25.6%	23.5%	24.7%

All patients were male and had no past medical history. Mean consulting delay was 6 hours considering patients who presented to the emergency department on the same day of symptom's onset. The remaining patients attended hospital in a mean delay of 3 days.

A study flow chart is given in Figure 1.

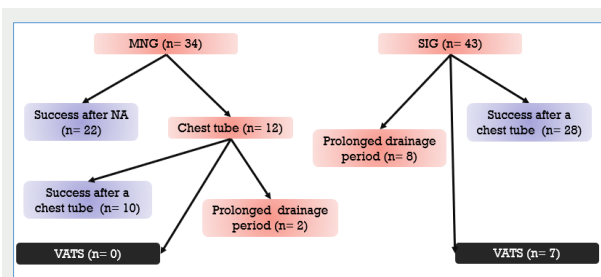


Figure 1. Outcome of study patients during hospitalization

Needle aspiration demonstrated non-inferior efficacy compared to chest tube drainage in terms of short-term success and one-year recurrence. As shown in Table 2 and Figure 1, the primary outcome, defined as a successful evacuation of pneumothorax without need for additional intervention, was achieved in 22 of 34 patients (64.7%) in the NA group and 28 of 43 patients (65.1%) in the CT group.

The absolute difference in success rates between NA and CT was -0.4% with a CI ranging from -3.9% to +4.7%. The non-inferiority of needle aspiration compared to chest tube drainage was demonstrated as the primary outcome.

Regarding secondary outcomes, the recurrence rates at one year were similar for SIG and MNG. In the CT group, persistent pneumothorax or prolonged air leak requiring more than five days of aspiration led to surgical pleurodesis in 11.6% of patients, whereas none of the patients in the NA group required surgical intervention. We noted a significantly higher use of analgesics among patients with chest drains ($p=0.001$), a longer mean drainage time ($p=0.001$) and a longer hospitalization time for SIG patients ($p=0.001$).

In MNG, NA failure occurred on the first same day or within the first 48 hours (Table 3). These patients underwent CT drainage for an average time of 5.6 days. Even in patients with CT insertion, the mean drainage time was significantly longer for SIG than MNG ($p=0.04$). An extended drainage period occurred in seven patients (18.2%) and two patients (16.7%) from SIG and MNG respectively. These rates among the two groups were not statistically different.

NA procedure had no adverse effects. In contrast, there were two cases of localized subcutaneous emphysema in SIG patients (4%). No cases of extended subcutaneous emphysema were observed. In addition, the CT was in an intra-parenchymatous position in two patients. In such cases, VATS was performed to treat the pneumothorax.

Mean recurrence delay during the first year was seven months. There was no statistically significant difference between the MNG and SIG (5.8 VS 8 months, as shown in Table 1).

Notably, NA failed to evacuate the pneumothorax in 24 patients in this study. Among them, 12 patients were excluded because they were found to have secondary pneumothoraces. Therefore, failed NA may be a sign of secondary pneumothorax in young patients.

Table 2. Comparison between study groups

Parameter	SIG (n= 43)	MNG (n= 34)	P
Success rate at day 5 (%)	65.1%	64.7%	0.97
Need to perform VATS (n - %)	7 - 16.3%	0	0.014
Reccurence in 1 st year (n - %)	5 - 11.6%	3 - 8.8%	0.37
Use of Paracetamol (n - %)	37 - 93.1%	11 - 32.3%	0.001
Use of Tramadol (n - %)	6 - 6.9%	1 - 2.9%	0.019
Mean hospitalization length (days)	10.9 ±6.5	6.2 ±2.2	0.001
Mean drainage time (days)	7.9 ±3.2	5.6 ±3.3	0.04
Mean delay of recurrence (months)	8	5,8	0.29
Smoking cessation (n - %)	8 - 18,6%	15 - 44,1%	0.073

Table 3. Radiological outcome after NA during the first five days among MNG patients

MNG (n =34)	Number of patients					
	J0	J1	J2	J3	J4	J5
Disappearance of pneumothorax on chest Xray	8	8	13	15	22	22
Success of procedure	27	23	22	22	22	22
Failure	7	4	1	0	0	0
Mean IPD (cm)	1,8	1,7	1,1	0,7	0	0

DISCUSSION

Key Findings of the Study

In this randomized non-inferiority trial, including patients with large but clinically stable primary spontaneous pneumothorax, NA was shown to be non-inferior to CT drainage with respect to short-term treatment success. Importantly, this comparable efficacy was achieved with a less invasive approach, which was associated with shorter hospitalization, reduced analgesic requirements, and fewer procedure-related complications.

While current international guidelines increasingly endorse conservative or minimally invasive strategies for selected patients with PSP, real-world practice remains heterogeneous, and chest tube drainage is still frequently used as the first-line treatment, particularly for large pneumothoraces and in low- and middle-income settings. Our findings provide pragmatic evidence supporting the broader implementation of needle aspiration even in cases of voluminous PSP, provided that patients are carefully selected and clinically stable.

Our study demonstrated that needle aspiration is an effective and safe alternative to chest tube drainage for managing large but well-tolerated PSP. Similar

success rates for both techniques. However, a significant difference was observed in terms of the need for surgical treatment. The conversion rate to surgical pleurodesis via VATS was significantly higher in the SIG group (16.3%), whereas no patients in the MNG group required surgical intervention ($p=0.014$), suggesting that initial less-invasive strategies may reduce escalation to surgery in selected patients.

Comparison with the Literature

Our results align with those of Parlak (6) and Noppen (5), who demonstrated the non-inferiority of needle aspiration compared to chest tube drainage in terms of initial success and one-year recurrence risk. To date, evidence-based medicine has argued for a conservative approach to well-tolerated PSP (10–13). Additionally, a recent study by Brown (9) highlighted the benefits of a conservative approach, reinforcing the idea that early invasive interventions may not always be necessary.

Our study reinforces everything that has been reported, especially in patients with voluminous primary pneumothorax. In such cases, practitioners tend to care primarily about security and safety. Contou and al. (14) suggested that using small-caliber catheters could provide a balance between efficacy and reduced morbidity. Our results refine the previous observations by showing an early failure of NA (within the first 48 hours), emphasizing the need for close monitoring during the initial post-procedure period to guarantee maximum safety.

Our results support NA for PSPs, followed by a 48-hour hospitalization for voluminous pneumothorax. EXPRED study (15) also targeted and recruited patients with large pneumothorax. However, methodological differences between EXPRED and the present study concerning patient selection, outcome definitions, and parameters of assessment limit direct comparability and warrant cautious interpretation.

Clinical Benefits and Impact on Management

NA has clinical advantages compared to CT drainage. First, it significantly reduces hospitalization duration, translating into decreased hospital burden and healthcare costs (16,17). Second, it was associated with less analgesic use (18).

In terms of complications, no significant adverse effects were observed in the MNG group, in contrast to the SIG group, where two cases of localized subcutaneous emphysema and two cases of intra-parenchymal chest tube misplacement were reported. These findings confirm that needle aspiration reduces iatrogenic risks associated with invasive procedures.

Nonetheless, it is reasonable to attribute the short-term difference in outcomes between the two groups to the evacuation technique (CT drainage) and the application of negative pressure for five days. Some clinical studies have reported that in operated primary pneumothorax cases, better tolerance and fewer complications were observed when using CT without active suction (19,20). Regarding drain size, the study by Korczyński compared

the efficacy and tolerance of 20–24 F chest tubes versus 8 F catheters : the immediate success rates were 82% and 64% respectively, with no statistically significant difference (21). However, the treatment duration was shorter in favor of small-caliber catheters (6 days versus 2 days).

Furthermore in our study, a higher proportion of patients required surgical intervention in the SIG group than in the MNG group. This suggests a potential reduction in the need for surgical management of PSP when an initial minimally invasive approach is adopted. Regarding the need for surgical intervention in PSP : Two major studies found that NA reduced the requirement for VATS (22,23) whereas two other studies reported contrary findings (24,25).

Perspectives and Clinical Implications

While current international guidelines increasingly endorse conservative or minimally invasive strategies for selected patients with PSP, real-world practice remains heterogeneous, and chest tube drainage is still frequently used as first-line treatment, particularly for large pneumothoraces and in low- and middle-income settings (7,8). Our findings provide pragmatic evidence supporting the feasibility and safety of NA even in cases of voluminous PSP, provided that patients are carefully selected and clinically stable.

Our results support the need to re-evaluate current practices even for large but well-tolerated PSP. Close monitoring within the first 48 hours post-intervention could help identify early failures and optimize therapeutic strategies.

Although aspiration failure occurred in 35.3% of patients, a large initial pneumothorax size (IPD >12.5 cm or complete lung collapse) was not a predictive factor for NA failure in our cohort. This finding suggests that pneumothorax size alone should not systematically preclude an initial aspiration strategy, although large multicenter studies are required to confirm this observation.

CONCLUSIONS

The non-inferiority design was chosen in this study to determine whether NA was not clinically worse than CT in terms of short-term treatment success, while potentially offering advantages in invasiveness, patient comfort, and healthcare resource utilization.

Needle aspiration is an effective, well-tolerated, and less invasive alternative to chest tube drainage for the management of large well-tolerated PSP. It reduces hospitalization duration, analgesic use, and iatrogenic complications, while maintaining comparable success rates. However, despite the growing body of evidence supporting conservative strategies, clinical practices often remain anchored to more invasive habits. Therefore, it is essential to raise awareness among healthcare providers and promote updated guidelines to encourage a broader adoption of needle aspiration when appropriate.

Abbreviations:

PSP : Primary spontaneous pneumothorax
IPD : inter-pleural distance
NA : Needle aspiration
CT : Chest tube
SaO₂ : Arterial Oxygen saturation
F : French
ml : milliliter
VATS : video assisted thoracic surgery
PACTR : Pan African Clinical Trial Registry
SIG : Standard interventional care group
MNG : Minimally invasive needle aspiration group

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