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Outpatient management of primary spontaneous pneumothorax

Stéphane Jouneau*^{1,2}, Constance Vuillard*³, Alexandre Salé¹, Yann Bazin⁴, Laurent Sohier⁵,
Mallorie Kerjouan¹, Jean-Damien Ricard^{3,6}, Jonathan Messika^{7,8}

*Both authors contributed equally

¹ Service de Pneumologie, Centre de Compétences pour les Maladies Pulmonaires Rares, Hôpital Pontchaillou, Rennes, France

² IRSET UMR 1085, Université de Rennes 1, Rennes, France

³ Service de Réanimation Médico-Chirurgicale, AP-HP.Nord – Université de Paris, Hôpital Louis Mourier, F-92700, Colombes, France

⁴ Service des Maladies Respiratoires et Infectieuses, Hôpital Broussais, 35400, Saint-Malo, France

⁵ Service de Pneumologie, Centre Hospitalier Bretagne Sud, Lorient, France

⁶ Université de Paris, Infection, Antimicrobials, Modelling, Evolution, IAME, UMR 1137, INSERM, F-75018, Paris, France

⁷ Service de Pneumologie B et Transplantation Pulmonaire, AP-HP.Nord – Université de Paris, Hôpital Bichat Claude Bernard, F-75018, Colombes, France

⁸ Université de Paris, Physiopathology and Epidemiology of Respiratory Diseases, PHERE, UMR1152, INSERM, F-75018 Paris, France

Corresponding author:

Dr Jonathan Messika

Service de Pneumologie B et Transplantation Pulmonaire, AP-HP.Nord – Université de Paris,
Hôpital Bichat-Claude Bernard

46 rue Henri Huchard

75018 Paris France

E-mail address: jonathan.messika@aphp.fr

Tel: +33 1 40 25 69 19; Fax: +33 1 40 25 61 04

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Abstract

The outpatient management of primary spontaneous pneumothorax (PSP) is still debated. The risk of a tension pneumothorax is used to justify active treatment like chest-tube drainage, although outpatient management can reduce both the time in hospital and the cost of treatment. It is also likely to be the patient's choice. This report is a reappraisal of the situations for which outpatient management, by monitoring alone, or using minimally invasive techniques, can be considered.

Keywords

primary spontaneous pneumothorax; outpatient management; conservative strategies; needle aspiration; one-way valve.

Abbreviations

ACCP: American College of Chest Physicians

BTS: British Thoracic Society

CTD: Chest-tube drainage

ERS: European Respiratory society

NA: Needle aspiration

PSP: Primary spontaneous pneumothorax

Introduction

Spontaneous pneumothorax (SP) is considered to be primary if it occurs in subjects with no known respiratory disease (PSP) and secondary when it is associated with respiratory disease. Successful management of PSP is designed to correct the immediate problem and reduce its rate of recurrence, which can reach 29% in the first year (2). But just how to manage PSP is still debated (1, 3). Most cases are hospitalized for several days and treated by chest-tube drainage (CTD) (4). Some clinicians prefer this active treatment because of the risk of a tension pneumothorax occurring after the patient has returned home, although this complication is rare (1). Others consider this invasive treatment disproportionate for a benign condition that affects young subjects with no comorbidity. Outpatient management, where it is appropriate, might consist of simple observation (5–7), with or without needle aspiration (NA) (8, 9), or leaving a chest tube that is not connected to a vacuum source in place (10–12). Outpatient management can limit the patient's time in hospital, ensure his/her comfort, and be the patient's preferred choice. But this option must, above all, be safe.

This review is a reappraisal of the situations in which outpatient management can be appropriate. It might be simple monitoring, or involve therapeutic intervention. We also explore the situations in which intervention is necessary, and the devices most likely to lead to an early discharge. Finally, a risk-benefit analysis in conjunction with the patient must be carried out to choose the best option.

Outpatient care challenge

Conservative management can avoid the risk of adverse events associated with chest interventions (CTD, NA, catheter insertion), some of which can be serious (hemothorax, perforation of the diaphragm or other organ) (7, 13, 14), while also reducing the cost of hospitalization (12). But physicians are quite reluctant to opt for outpatient care for fear of legal claims. They may also be cautious about implementing management strategies established by others. Some may also look on in-hospital care as an anti-smoking strategy.

A recent retrospective study (15) of PSP management in 14 French Emergency Departments found that only 217/1868 patients (11.6%) were managed as outpatients. Most of those with small PSPs received no therapy. Just 25 cases (1.6% of all pneumothoraces) underwent an intervention before discharge. There are two main kinds of ambulatory management. One is conservative management by observation alone; the other includes intervention, which could be NA, CTD, or a catheter with a one-way valve.

Simple ambulatory monitoring of PSP

Most guidelines agree that small PSPs can be managed by ambulatory management alone (1, 3). The problem is that the definition of a "small" PSP varies greatly. The British Thoracic Society (BTS) considers it to be the presence of a visible rim between the lung margin and the chest wall that is < 2 cm across at the hilum (1) while the American College of Chest Physicians (ACCP) used a distance between the apex and the cupola of less than 3 cm (3). Some clinicians use other methods to assess the size of a pneumothorax in their daily practice (5). The most recent guidelines of the European Respiratory Society (ERS) suggest that a first or only slightly symptomatic PSP should be managed conservatively, regardless of its size. This is based on the fact that a tension pneumothorax rarely complicates the course of a PSP (16), and that the visceral pleura heal faster when the lung is collapsed (17).

While physicians typically base their decisions on PSP size and completeness (4), pneumothoraces have long been known to heal spontaneously. As long ago as 1966, Stradling and Poole showed that PSP could be treated conservatively in an outpatient department, with re-expansion rates of 78% at 4 weeks and 97% at 8 weeks (18).

A recent Australian multicenter randomized trial (5) included 316 patients who suffered initial episodes of large PSP. The outcome of a conservative treatment with simple monitoring was compared to that of an interventional management with a rapid discharge. The conservative strategy patients were observed for 4 hours and discharged after a second chest X-ray. The PSPs of patient in the interventional arm were drained via a small-bore chest tube. The tube was clamped after the underwater drain no longer bubbled, and removed 4 hours after a second chest X-ray if the PSP had not reoccurred. No patients were discharged until they were clinically stable. The outcome measured was the proportion of participants with complete pulmonary re-expansion at 8 weeks. Radiological re-expansion at 8 weeks was considered complete for 94.4% of the conservatively treated patients and for 98.5% of the interventional strategy patients . The conservative strategy was therefore not inferior to the interventional strategy (noninferiority margin set at 9%); the patients were at less risk of adverse events and had shorter stays in hospital. In addition, the one-year recurrence rate for the conservative patients (8.8%) was significantly lower than that for the interventional ones (16.8%, relative risk (RR) 1.90 (1.03–3.52)). This interesting study therefore shows that conservative management of PSP is safe and effective, despite the missing data for the primary endpoint.

To date, one can think these results are too weak to lead to a revision of international guidelines (1, 3, 16). The present guidelines propose a strictly conservative strategy only for small PSPs stable after observation for 3 to 6 hours (3); or only for some rare completely asymptomatic patients with large PSP (1). Nevertheless, such strategies might be considered if the patient is clinically stable and rapid re-intervention is available should the patient's condition deteriorate (3, 16), in organized and trained centers. The clinician can then confidently follow a patient's choice of simple observation provided he/she is clinically stable, and if a very strict follow-up can be rigorously planned.

Outpatient management after PSP evacuation

Some cases could be quickly discharged after a PSP has been evacuated in hospital. A range of procedures are available, including evacuation with a device that is removed

immediately (NA), or by installing a small caliber drainage system (drain or catheter) sealed with a one-way valve. The patient remains ambulatory with the device in place.

Simple needle aspiration (NA)

While several devices can be used to remove air from the pleural cavity the general technique is always the same. Blunt-ended needles with a removable or retractable introducer are designed for insertion in the pleura. The needle is placed anteriorly, and only the blunt-ended catheter is left in place (19). Air is aspirated manually using a syringe or with a vacuum system.

NA is simple, minimally invasive, painless, and easy to perform; its immediate success rate varies between 32% and 83%, depending on the study and when it is assessed (8, 14, 20–23). The risk of recurrence is similar to that of thoracic drainage, whatever the assessment time (14, 20–23): 7% after one week (14) and 26% after one year (14). Adverse events (vagal discomfort, subcutaneous emphysema or hemothorax - see Table 1 for details) are rare (8).

The main advantage of NA is that almost half the cases do not need hospitalization (14) as it can be performed in Emergency. A survey of 178 physicians found that 93% of them preferred to perform a CTD, despite the fact that it required hospitalization (4). This choice seems to be based on the risk of a recurrence (50%) within 24 hours of NA and the fear of a tension pneumothorax once the patient had returned home (14, 16). A CTD is also theoretically associated with a shorter stay in Emergency. CTD and the second chest X-ray to confirm correct pulmonary re-expansion can be performed sooner than the 4 to 6 hour wait required after NA. Lastly, a second intervention may be needed (CTD or a repeat NA) if the NA fails; this can be painful, cause anxiety or stress, delay the patient's discharge, or even require re-admittance to hospital.

The factors associated with successful NA were assessed in a recent retrospective study on 98 PSPs, and validated prospectively on 71 others (8). The delay between the onset of symptoms and treatment and the size of the pneumothorax were the two independent factors predicting its immediate success. The success rate at 24 hours was low (40%) and ambulatory management was not allowed. However, early outpatient assessment of a PSP and a patient who understood and complied with the instructions should invariably lead to a rapid discharge from hospital.

Use of a one-way valve

This method involves inserting a drainage system into the pleura and sealing it with a one-way valve. The system may be a small-bore catheter and a “Heimlich valve”, or a dedicated system, such as the Rocket[®] Pleural Vent (Rocket Medical plc, Watford, UK) (11).

Small bore catheters or drains connected to a one-way valve

There are several models of small-bore catheters and drains. The most common are the Furhman catheter (also known as a pigtail catheter) (8.5 French diameter) and a central single-lumen venous catheter (5 mm French diameter). They are inserted into the second or third intercostal space in the midclavicular line using the Seldinger technique. This technique is simple, painless, and can be performed by non-specialist physicians. These catheters result in fewer complications, especially pain (Table 1) (24, 25) and infection (26) than do large diameter drains (16-30 French).

The one-way valve was first described by Heimlich (27). The inserted drain is sealed with the valve, and can be fixed to the patient (arm, thorax), allowing him/her to remain mobile; he may even consider going back to work. The valve can be connected to a vacuum system at any time without requiring any new procedure. The few complications that have been reported are all harmless (catheter displacement, inflammation at the puncture site, catheter obstruction by exudate – see Table 1 for details) (13, 10, 12).

Rocket[®] Pleural Vent

This new device includes a small-bore catheter (8 French) and a one-way valve. It is inserted percutaneously into the 2nd or 3rd intercostal space using a retractable needle. Few data are available apart from descriptions of clinical cases. They suggest that this technique is effective and safe (11). The recent RAMPP trial on 236 patients with a large PSP compared ambulatory management with the Rocket[®] Pleural Vent device (117 patients) with on a standard guideline based-management (NA, and/or CTD) (119 patients) (28). Patients in the ambulatory arm spent significantly less time in hospital (0 days [0-3]) than did the reference group (4 days [0-8], $p < 0.0001$). There was no difference in the dyspnea and the decrease in pain between the groups. Serious adverse events were defined as those needing hospitalization. As all the patients in the standard arm were treated in hospital, only the

ambulatory patients required hospital admission. Therefore, significantly more serious adverse events occurred in the ambulatory arm (12 % vs 0, $p < 0.0001$). This trial confirms that the ambulatory management of PSP with the Rocket[®] Pleural Vent device is safe and effective.

Which patients would benefit from drainage and one-way valve ambulatory management?

While many reports are in favor of outpatient management because it is effective, safe and less invasive, current practice still relies on catheter insertion and hospitalization (4). One-way valves are, as yet, rarely used. Only a few centers in France have adopted exclusively ambulatory management (7, 10, 12).

What is the evidence?

The review of one-way valve use for the outpatient management of PSP by Brims and Maskell (13) included 18 studies (992 cases of spontaneous pneumothorax, including 58% of PSP and 243 iatrogenic pneumothorax). All the patients were treated with a drainage system sealed by a one-way valve but only 2 of the studies were randomized trials (29, 30). The studies (therapeutic and comparative strategies), and their methodologies are too diverse for any formal conclusion on treatment by one-way valve to be drawn. Nonetheless, it provides some interesting data. First, the immediate and one-week success rates (no second intervention) were 85.8%, with strictly ambulatory management possible in 77.9% of cases. The recurrence rate over a follow-up period of 6 to 31 months was 15% and side effects were rare (21/1235 drainages; 1.7%). Most of them were perfectly mild, with only one episode of tension pneumothorax due to incorrect connection.

This technique is more cost-effective than pleural drainage as patients are treated as outpatients and not hospitalized. Despite the limitations imposed by the varying quality of the included studies, the data indicate that outpatient management of spontaneously drained pneumothorax with a one-way valve is effective and safe.

More recent studies have provided additional data. A French monocenter retrospective study has confirmed that it is feasible to treat a large spontaneous pneumothorax (PSP and SSP) with a pigtail catheter sealed by a one-way valve (10). Patients were discharged from Emergency immediately after the catheter had been inserted, without

a chest X-ray, and were thoroughly assessed as outpatients every two days. The 132 patients (110 PSP, 22 SSP) included 103 who were treated exclusively as outpatients with success obtained on day-2 or day-4, for a success rate of 82.5% . The recurrence rate after 1 year was 25% for PSP and 35% for SSP. The average cost of successful treatment, including up to 2 outpatient visits and a chest x-ray, was 926 US dollars (686 euros), while the cost of inserting a chest drain and hospitalization for 4 days was 4,276 US dollars (3,167 euros).

The same group recently published an extension of their work: a multicenter prospective study of 148 consecutive large SPs, including 129 PSP, treated with the protocol described in Voisin et al. (10, 12). The PSP patients were successfully managed exclusively as outpatients (84.5%) and the one-year recurrence rate was similar to other published rates (33.1%). Clearly, exclusive ambulatory management of spontaneous pneumothoraces can be a success with few complications. This management is in daily use for managing SP (PSP and SSP) in these new French centers and other centers are beginning to implement the methods.

These two studies are quite important since a total of 239 large PSPs were treated by ambulatory management alone with stable success rates of 82 – 84% and recurrence rates similar to those reported by others.

Another prospective French study assessed the efficacy and safety of pigtail catheters and one-way valves for treating patients in ambulatory care (7). The protocol was extremely strictly defined. Large and/or symptomatic PSPs were drained in Emergency and reassessed after 4 hours. Those whose lungs were completely re-expanded were discharge without any device but the catheter left in place if the pneumothorax persisted. They were all assessed after 24 hours, and the drain was removed when the lung was fully re-expanded. Those patients whose lungs were not re-expanded after 7 days were hospitalized and their drain was suctioned for 24 or 48 hours. The 60 patients so treated included 48 (80%) with large pneumothoraces. The success rate on day 7 (full lung expansion) was 83%. Half of the patients were treated exclusively as outpatients and 37.5% of all the patients with a large PSP were exclusively ambulatory (6). No serious adverse event occurred. The average hospital stay was 2.3 days. This outpatient care cost only approximately 40% of standard hospital care.

The recent RAMPP trial has provided more and stronger evidence (prospective randomized controlled trial) in support of the ambulatory management of PSP (28).

A British team very recently reported the results of their outpatient treatment of pneumothorax (31), including 64 PSP and 99 SSP. All 62 large PSPs were treated by NA as ambulatory patients, in line with BTS guidelines (1), and only 47% needed a CTD. The inserted drain was sealed in place with a one-way valve and the patient was discharged with a precise monitoring algorithm. Only 49 of the 99 patients with SSP were eligible for outpatient care and 44 of them (90%) were drained while remaining ambulatory. The pneumothorax of 12 (35%) of them was not resolved by day 5, and 9 underwent surgery. The rates of pulmonary re-expansion on day 5 of the PSP and SSP patients and the numbers of complications were not significantly different; but the SSP patients were hospitalized for longer. The cost saving associated with this management strategy was \$ 1,550 per patient.

The only ongoing randomized controlled trial we know of that compares PSP patient managed with NA or devices with a one-way valve is the French PNEUM-AMBU trial (NCT03691480), which uses pigtail catheters and one-way valves according to the protocol described above (10, 12). The findings of this study will undoubtedly help to determine the best method for managing PSP.

Epidemiological concerns

The epidemiologic differences in the outcomes of the ambulatory management of PSP have not been fully explored. Although PSP is more prevalent in men, women may be at greater risk of recurrence (2). Some data suggest that CTD or NA might be more successful in the first 72hrs in women, but the difference is not significant (OR 5.6 [0.6;50.8], $p=0.124$) (21). There is no evidence that PSP should be managed differently in men and women, although a catamenial pneumothorax should be considered and looked for if the pneumothorax occurs in a woman of child-bearing age (32).

Almost all the teams managing PSP patients as out-patients in the studies described above also manage SSP in the same way. We need more evidence for and details of the type of SSP patients who can benefit from safe effective outpatient management.

Conclusion

While exclusive outpatient care of PSP is still the exception rather than the rule (4, 15), more and more studies, including the recent RAMPP trial, are providing evidence supporting such management. The air need not be evacuated from the pleural space; the decision should be based mainly on the patient's clinical tolerance, rather than the size of the pneumothorax.

Minimally invasive techniques (needle aspiration, mini-drain with one-way valve, Rocket[®] Pleural Vent, Fuhman catheters[®], etc) should also be employed because of their ease of use and the rarity of adverse events. However, these treatments are only safe if the patient clearly understands the issues involved and follows a rigorous monitoring protocol. Figure 1 shows one algorithm that could be used.

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Tables

Table 1. Quality of life assessment, pain and adverse events of the ambulatory management of PSP. Only studies assessing ambulatory management are included.

Study	Design	Quality of life	Pain	Adverse events
Harvey, 1994 (22)	RCT, NA vs CTD	ND	No difference in pain score during procedure; NA provided significantly lower average daily and total pain scores.	ND
Noppen, 2002 (14)	RCT, NA vs CTD	ND	ND	No urgent readmissions after discharge in either group
Ho, 2010 (29)	RCT, NA vs ambulatory CTD	ND	ND	NA group - Subcutaneous emphysema 9% NA group - Tension pneumothorax 4%
Parlak, 2012 (21)	RCT, NA vs CTD	ND	ND	ND
Massongo, 2014 (7)	Observational study, ambulatory CTD with one-way valve	ND	ND	One patient with hemothorax One patient with <i>a vacuo</i> re-expansion edema
Voisin, 2014 (10)	Prospective cohort, ambulatory management with CTD and one-way valve	ND	6% of patients using step 2 analgesics; 6% of patients using step 3 analgesics	Two patients with kinked catheters
Salé, 2020 (12)	Prospective cohort, ambulatory management with CTD and one-way valve		87.1% given step 1 analgesics; 27.8% given step 2 analgesics; and 9.3% given step 3 analgesics	8.7% vaso-vagal episodes; 2% minor parietal hematoma
Khan et al. 2019 (31)	Cases of PSP and SSP, ambulatory treatment with CTD and one-way valve	Satisfaction excellent for SSP and PSP (mean score 4.95 and	Mean pain score 3.65 ((SPP) and 3.78 (SSP) (0-	- Drain blockage 4.5% - Emphysema 1.8% - Displaced drain 0.9%

		4.79 on 0-5 scale)	10 pain scale) 32% SSP and 41% PSP required opioid analgesia	
Brown et al, 2020	RCT, Interventional vs conservative management	Fewer days off work after conservative management (6 [2.0-14.0] vs 3 [1.0-8.0])		<p>Interventional management group AE 26.6% (incl. 12.3% serious AE)</p> <ul style="list-style-type: none"> - Hemothorax 3% - Infection 3% - Tension pneumothorax 1% - severe chest pain or breathlessness 7% <p>Conservative management group AE 8% (incl. 3.7% serious AE)</p> <ul style="list-style-type: none"> - Hemothorax 2% - Infection 1% - Tension pneumothorax 0.6% - severe chest pain or breathlessness 2%
Hallifax, 2020 (28)	RCT, ambulatory device (Rocket® pleural vent) vs guideline-based management	ND	Pain at tube site 31 vs 30%	<p>Ambulatory management</p> <ul style="list-style-type: none"> - Any serious adverse event or adverse event 55% - Enlarging pneumothorax 3% - Device blocked or kinked 2% - Device dislodgement 1% - Re-expansion pulmonary edema 1% - Device leakage 1% - Admission for suction 1% - Unrecognized haemopneumothorax 3% - Pleurisy 1% - Haematoma or bleeding 7% - Subcutaneous emphysema 6% - Site infection 1% - Tube displacement 2% - Drainage device failure 3% - Blocked tube 1%

				<ul style="list-style-type: none"> - Fluid in tube 3% - Erythema or itch 2% - Attendance at emergency department 1% - Adverse event not related to treatment 8%
				<p>Guideline-based management</p> <ul style="list-style-type: none"> - Any serious adverse event or adverse event 39% - Haematoma or bleeding 2% - Subcutaneous emphysema 6% - Site infection 1% - Tube displacement 1% - Drainage device failure 1% - Blocked tube 1% - Adverse event not related to treatment 8%

AE: adverse event; RCT: randomized controlled trial; NA: needle aspiration; CTD: chest tube drainage

Figure Legend

Figure 1. Algorithm for the outpatient management of PSP. A stable condition, good access to medical care and a perfect understanding of the instructions are prerequisites for ambulatory management. The first step can be needle aspiration, or insertion of a device that can be left in place at home. Either way, there must be strict clinical and radiological follow-up, and the criteria for failure and hospital admission defined.

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Primary spontaneous pneumothorax

Poor tolerance
Elevated risk of misunderstanding medical instructions
Poor access to medical care

Stable condition
Able to understand instructions
Good access to medical care

In-hospital PSP management

Ambulatory management

- Needle aspiration
- Clinical assessment

- Insertion of a device left in place**
- Pigtail catheter + one-way valve
 - Rocket[®] Pleural Vent

Discharge

48 hrs assessment (clinical and chest X-ray)

- Follow up every 48 hrs**
- Clinical examination (manual suction; insertion site)
 - Chest X-ray if no air suctioned

Air suctioned or incomplete re-expansion on D4

No air suctioned, complete re-expansion

Failure: hospital admission

Chest tube drainage

- Suction
- Surgical referral on D6

Success
Device removed

Possible surgical referral

- Needle aspiration (including emergent if breathlessness)
- Chest tube drainage in cases of failure or breathlessness