Outpatient management of primary spontaneous pneumothorax: a prospective study

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ABSTRACT
We prospectively assessed the safety and cost saving of a small-bore drain based procedure, for outpatient management of first episodes of primary spontaneous pneumothorax (PSP).

Patients were managed by observation alone or insertion of an 8.5 F “pig-tail” drain connected to a one-way valve, according to size and clinical tolerance of the pneumothorax. All patients were re-assessed after 4 hours, on the first work day after discharge and on day 7. Patients still exhibiting air leak on day 4 underwent thoracoscopy. The primary end-point was complete lung reexpansion at day 7.

Sixty consecutive patients entered the study. Forty eight (80%) met the definition of large pneumothorax. The success rate was 83%. The 1-year recurrence rate was 17%. Thirty-six patients (60%) were discharged after 4 hours and 50% had full outpatient management. No severe complication was observed. The mean length of hospitalization was 2.3 ± 3.1 days. This policy resulted in about a 40% reduction in hospital stay related costs.

The present study supports the use of a single system combined with a well-defined management algorithm including safe discharge criteria, as an alternative to manual aspiration or chest tube drainage. This approach participates to health care cost-savings.

SHORT SENTENCE
Primary spontaneous pneumothorax can be managed outside hospital provided strict safety criteria are applied before discharge of the emergency room.
INTRODUCTION
The American College of Chest Physician (ACCP), the Belgian Society of Pulmonary diseases (BSP) and the British Thoracic Society (BTS) guidelines recommend the evacuation of air for large PSP and observation alone for the small ones (1)(2)(3). Evidence keeps on growing on the efficiency of observation alone for selected patients with PSP (4), and the idea of abandoning the conventional chest tube drainage (CTD) is now considered (5). Discrepancies remain about the definition of a « large PSP » and the procedures recommended to evacuate the air. While ACCP recommends the use of small-bore drain, the BTS and BSP recommend manual aspiration (MA) with a needle catheter as first step, followed by CTD in case of at least one unsuccessful MA attempt (1)(2). These new policies aim to manage a benign condition such as PSP easily and cost effective, while remaining safe. MA while being less invasive and more comfortable than the CTD, has an immediate success rate ranging from 50 to 68% (4)(6)(7)(8). Thus up to 50% of patients undergoing MA will end with CTD. Moreover, even in case of successful MA, an additional observation period of 3 to 6 hours in the emergency room (ER) is recommended (1). Therefore, although the quick and effective MA looks attractive, more than half of the patients end up hospitalized with CTD, after a total of 6 hours in the ER, cumulating procedure and observation time.
In order to simplify the management of PSP we conducted a study published in 2006 (9) evaluating a serial steps approach based on a small-bore catheter connected to a one-way valve. This approach was as safe and effective as CTD alone or combined with MA, with a shorter length of hospital stay (4) (6)(8)(7)(10)(11).
The present study was conducted in order to test whether our stepwise approach with a single system (9) also applies to the outpatient management of PSP in real-life conditions.
METHODS

Study design
The study aimed at assessing safety and effectiveness of outpatient management of PSP with a previously described procedure. This was an observational, prospective and non-controlled study. It was conducted in the Lille University Hospital, from July 2006 to January 2008. Each patient was managed according to our algorithm (Figure 1) and followed for 2 years after the PSP episode.

Patients and selection criteria
All consecutive patients, 16 years old or older, presenting with a first episode of PSP were eligible. To be enrolled, patients had to give an oral informed consent (from a parent or any advocate if age <18 years old). Exclusion criteria were as follows: previous ipsilateral episode of PSP, suspected or known underlying pulmonary disease, recent history of trauma, iatrogenic pneumothorax, and acute condition on admission.
A detailed information letter was given to each patient before inclusion. The study was approved by our institutional ethical committee.

Procedures and protocol
Each patient underwent baseline assessment including: past history data collection, clinical examination and postero-anterior chest X-ray. The pneumothorax was classified as small or large according to the BSP guidelines (2), i.e.: a large pneumothorax is one with lung dehiscence over the whole height of the lateral chest wall. All the patients then went through the following 4 steps (Figure 1): 1) initial management: pleural drainage or observation; 2) 4th hour clinical and radiological reevaluation; 3) hospital discharge or hospitalization in the pulmonary ward; 4) follow-up. “Discharge safety criteria” included: 1) patient in stable condition; 2) time to reach the hospital from patient’s home < 1h by any transport means; 3) patient not living alone; 4) patient able to understand and implement instructions given in case of problem and 5) time of discharge < 8PM. This latter criterion was chosen since, in a realistic approach, it seemed not reasonable to discharge a patient at night, within minutes of pneumothorax treatment.

Initial management in the ER
Patients with a small PSP had simple clinical observation, whereas those with a large PSP or breathlessness underwent pleural drainage. The procedure was performed at bedside, under
local anesthesia, by the attending emergency physician. We used a 8.5F Fuhrman catheter with a Heimlich valve (references C-PPD-850 and C-CASP-A-FORD; COOK critical care, Bloomington, IN, USA). The catheter was inserted in the 2nd or 3rd anterior intercostal space on the mid-clavicular line, the patient lying in semi-recumbent position, following the Seldinger technique. It was then attached to the one-way valve. Folded sterile gauze was set as a pillow under the catheter to avoid kinking (Figure 2). Step one pain killers were given as needed. Oxygen was administered only for correction of arterial hypoxemia, if present.

4th hour (H4) reevaluation
Each patient had a clinical evaluation and a postero-anterior chest X-rays (CXR). Patients with a small pneumothorax who showed clinical and radiological stability and who fulfilled all 5 discharge criteria were discharged with an appointment with the pulmonologist in the outpatient clinic on the next work day. Here again, in a realistic approach, we considered the “next work day” as closer to real world management of a benign condition such as PSP than a strict “24h follow-up” which would take place in the middle of a week-end when the outpatient clinic is closed. Patients undergoing pleural drainage (large pneumothorax), whose CXR showed complete or almost complete lung re-expansion (i.e. only a very small of < 10 mm rim of apical air) and who fulfilled all 5 discharge safety criteria, had their catheter withdrawn without previous clamping and with no additional CXR. They were then discharged with an appointment in the outpatient clinic on the next work day. Those who showed incomplete lung re-expansion and fulfilled all 5 discharge safety criteria were discharged with their pleural catheter kept on the valve and an appointment in the outpatient clinic on the next workday. Recommendations regarding the use of step one pain killers were given before discharge. Any patient who did not fit one of the discharge criteria and especially criteria number 5, stayed in the ER and was reevaluated on the next morning. In patients with a pleural catheter, the catheter was connected to a four-chamber device for suction, in case of acute dyspnea.

Day-1 (D1) reevaluation (first work day after ER admission)
Patients were clinically and radiologically reevaluated as done at H4. For the patients who stayed overnight in the ER this reevaluation took place there on the morning following their admission. For those who were discharged at H4 the D1 reevaluation took place in the outpatient clinic, either on the morning following their ER admission for patients who were
discharged from Sunday to Thursday, or on the next workday for those who were discharged on another day.

Patients who had their catheter in place and showed complete or nearly complete lung re-expansion underwent catheter withdrawal without clamping and additional CXR and were given a new appointment on day 7. Those with persisting pneumothorax were admitted to the pulmonary ward and the valve was replaced by a four-chamber water seal device, with a – 10 to – 20 cm H₂O suction applied for 24 to 48 hours.

Those who had no tube at D1 and showed persisting lung re-expansion were given a new appointment on day 7. Those who showed early relapse of their pneumothorax had a new pleural catheter inserted which was connected to a four-chamber water seal device with suction applied for 24 to 48 hours.

After 24 to 48 hours, if the CXR confirmed the lung re-expansion, suction was stopped provided air leak was absent and the drain was kept on water seal device (acting as a one-way valve) for 24 additional hours. It was then withdrawn in case of success. If not, the drainage was maintained under suction, for a maximum of 48 h. Patients with persisting air leak or pneumothorax at day 4 underwent chest CT and were proposed and video-assisted thoracoscopy (VATS) for definitive treatment. For such patients, the day 7 visit was cancelled and they were considered as failure.

Day 7 visit
This took place in the outpatient clinic and intended to confirm the recovery. A clinical evaluation and a CXR were performed. Information and instructions were given to the patient about relapses (symptoms, management…) and their prevention.

Endpoints and statistics
Primary endpoint was the success rate of PSP management at day 7, defined as the percentage of patients with a complete or almost complete persistent, lung re-expansion on the CXR. Secondary endpoints were: the percentage of subjects with full outpatient management, the mean length of hospital stay, the mean cost of management (mean length of hospitalization stay multiplied by the one-day hospitalization fees for medical unit in a French public hospital), the 2-year actuarial recurrence rate (defined as the proportion of patient presenting with a first ipsilateral relapse within the 2 years following the first episode), the side-effects and the complications of medical procedures. Qualitative data are provided as percentages of the population, demographics and other quantitative data as mean or median ± standard
deviation (SD). The time-depending data were expressed using Kaplan-Meyer method. The Wilcoxon and the Fisher statistical tests analyzed the quantitative data and qualitative values, respectively. A p value less than 0.05 was deemed statistically significant.
RESULTS

Patients (table 1)

Sixty consecutive patients entered the study and all were followed for at least 2 years. Main characteristics of patients and pneumothoraces are displayed in Table 1. Eighty percent were smokers, 91% were men and the body mass index (BMI) was < 21.5 kg/m² for more than 50% of subjects. Forty-eight (80%) met the definition of large PTX and 12 (20%) met the definition of small PSP. Among patients with a large PTX, only 2 had a < 2 cm rim of air between the lung margin and the chest wall at the level of the hilum. Thus 96% of patients classified as having a large pneumothorax satisfy the BTS criteria for “large pneumothorax” (3). Small and large PSP did not differ in terms of age or cigarette consumption (data not shown).

H4 reevaluation (figure 3 & 4)

All patients with a small PSP (n=12) were treated conservatively (none of them complained of breathlessness) and were discharged at H4 without further complication. They had a persistent complete or almost complete lung re-expansion at D7.

All patients with a large PSP (n=48) had pleural drainage with the 8.5 F “pig-tail” pleural catheter connected to the one-way valve. More than 25 different practitioners inserted the pleural catheters, only 5 of them being respiratory physicians. Nine patients showed lung reexpansion on H4 reevaluation and were discharged after having their catheter withdrawn. Fifteen were discharged with their pleural catheter kept on valve since showing incomplete lung re-expansion and fulfilling all 5 discharge safety criteria. Two patients with a large pneumothorax required suction applied to the pleural catheter within the first 4 hours of observation because of acute dyspnea and increase in pneumothorax size. Twenty-two additional patients with a large PSP did not fulfill the 5 discharge criteria and stayed overnight. Thus 36 patients (12 small PSP + 24 large PSP) out of the 60 patients (60%) were discharged early (H4).

D1 reevaluation (first work day after ER admission) to D7 reevaluation (figure 3 & 4)

Among the 36 early discharged patients 6 were readmitted one (n=4), two (n=1) and 3 days (n=1) after discharge since the first reevaluation as outpatient showed insufficient lung reexpansion or very early relapse. None of them presented acutely when reassessed at D1. These patients had their pleural catheter placed under suction as per protocol.
Among the 24 patients staying overnight, 14 required additional suction, as per protocol because their D1 reevaluation did not show lung reexpansion. Twenty could eventually be discharged after having their pleural catheter withdrawn at day one (n=8), day 2 (n=2), day 3 (n=7) and day 4 (n=3) respectively. Step one pain killers were sufficient in all but 6 patients who had their pleural catheter placed under suction and needed step 2 antalgics. Only 2 patients whose pleural catheters were under suction required supplemental oxygen because of transient hypoxemia.

**Primary endpoint**
Fifty patients (12 small PSP + 38 large PSP) fulfilled the definition of success (83% success rate). Ten (large PSP) failed to reexpand their lung or had air leak more than 4 days after ER admission and thus underwent thoracoscopy. No significant clinical nor radiological difference was observed between success and failure groups (table 2).

**Secondary endpoints (table 3)**
Two patients developed a procedure related complication. One presented an a vacuo reexpansion pulmonary edema 2 hours after suction was applied to his drain. This complication resolved spontaneously and the patient was discharged at day 3. One showed a small pleural effusion on the D7 follow-up, 4 days after drain withdrawal, and had 800 ml of blood tingled fluid evacuated in the outpatient clinic.

Thirty patients (50%) were fully managed as outpatients (12 small PSP + 18 large PSP), 6 needed to be readmitted, and 24 had a single course hospital stay. The mean length of hospital stay was 2.3 ± 2.5 days (range 4h to 12 days). The mean drainage duration was 2.3 ± 3.1 days (range 0 to 12 days). Twenty patients needed suction, including the 10 who finally underwent a thoracoscopy. Thus, 2/3 of the 60 patients did not need any connection to wall suction, and could walk around during the whole time course of their pneumothorax management.

Within the first year, an ipsilateral relapse occurred in 4 out of 12 patients with a small PSP (1, 4, 5 and 9 months) and 6 out of 48 patients with a large PSP (3 weeks n=1; 1 month n=1; 1.5 month n=2; 3 months n=1 and 12 months n=1) after discharge. Two years recurrence rate was 16.7%. Relapses appeared to be significantly associated with young age (p = 0.015), with 8/10 occurring among patients aged < 25; and small PSP (p = 0.04), with 4/12 in small PSP vs 6/48 in large PSP.
The cost of the device is 107 € (65 € for the Fuhrman drain and 42 € for the Heimlich valve). Considering hospitalization fees in a pulmonary department (1194 € per day), the mean cost of management was 2710 € per patient.
DISCUSSION

In this study conducted in real life conditions, nearly two third of patients suffering a 1st episode of PSP could be discharged after 4 hours in the ER. Management of pneumothorax needed some wall suction in only one third of the patients. The short-term success rate was remarkably high (83%) and the two-year actuarial recurrence rate was low (16.7%).

Demographic characteristics of our study population agree with common findings in PSP, confirming that this disease usually occurs at rest in tall and thin young smoking males. (1)(12)(6)(8)(7)(9)(13)(14). The 20% proportion of small PSP is close to our previous findings (9) and is less than those reported in the literature. This might be related to differences in defining the size of a pneumothorax. ACCP guidelines especially consider a PTX as large, when the distance from apex to cupola is ≥ 3 cm (1) whatever the dehiscence on the axillary line. BTS guidelines in contrast consider a PTX as large, when there is a ≥ 2 cm rim of air between the lung margin and the chest wall at the level of the hilum (3, 12). In the present study 96% of the patients classified having a large PTX satisfied the BTS criteria. Interestingly, none of our patient classified having a small PTX required drainage because of breathlessness. Our one week success rate is close to the success rates reported in the literature with standard chest tubes (6)(8)(7)(11) and with the 85% success rate that we previously reported with a similar technical approach but with a 100% hospitalisation policy (9). BTS and SBP guidelines recommend manual aspiration (MA) as first step for patients with a large PSP, followed by CTD in case of at least one unsuccessful MA attempt (12)(2). This allows approximately 50% of the patients with a large PTX to be discharged after MA followed by 3 to 6 hours observation in the ER. We previously showed that, in patients with a 1st episode of PTX, provided a well-defined serial steps approach is used, the single small catheter/Heimlich valve system could safely replace 1st step MA but also subsequent CTD, avoiding prolonged ER observation, subsequent hospitalisation and unnecessary additional discomfort related to secondary tube thoracostomy, in those patients who fail MA (9). As previously shown for MA (6) the size of the PTX on admission did not influence the success or the failure of our single small catheter/Heimlich valve approach.

Interestingly we could confirm that, provided strict discharge safety criteria are applied, portable small-caliber catheter and Heimlich valve can be used in ambulatory care management (15).
In terms of quality of life, this approach which allowed full ambulatory management of 50% of the patients can be considered as an improvement when compared to the more conservative CTD approach which would have led up to 80% of the patients in a hospital ward, with their chest connected to a tube and a vacuum bottle. From a health cost point of view, reduction of hospital stay is also important to be considered. If one takes into account the average usual 4 days hospital stay of a patient undergoing CTD for a pneumothorax (6)(8), the cost saving of the H4 discharge in the 24 patients with a large PTX was estimated more than 114,000 €, even though 6 of them required a short readmission. If one considers only the patients who usually are hospitalized (large pneumothoraces), saving hospital stay in 18 patients (fully managed as outpatients) out of a total of 48 patients makes a 38 percent reduction in hospital stay related costs.

PSP is a common problem affecting young and healthy people. Given the age and sex-adjusted incidence of PSP (16)(17), health care facilities serving a catchment population of 1M inhabitants are expected to treat 125 PSP every year (18)(19). In terms of quality of life and health costs saving, all efforts must be made to manage these young and otherwise healthy people ambulatory. MA is recommended as a first step by several guidelines (12)(2) but conservatism of doctors and drawbacks inherent to the MA technique hinder the wide implementation of the technique. The present study support the use of a single system (portable small-bore catheter connected to a one-way valve) combined with a well-defined management algorithm including appropriate discharge safety criteria, as an alternative to MA. Despite significant limitations (small sample size, lack of a randomized controlled intervention trial, single center experience, applicable to patients living near to the hospital,..) this study should prompt further improvement in management of pneumothorax, including controlled prospective studies comparing MA, the “gold standard” approach, to catheter + valve + immediate “back home” in patients with large pneumothoraces.
References


### Table 1: Patients (n=60) characteristics at baseline.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>25.6 ± 6.5</td>
<td>16 - 48</td>
</tr>
<tr>
<td>Sex (M/W)</td>
<td>55/5</td>
<td>-</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>20.6 ± 2.1</td>
<td>17.3 - 25.0</td>
</tr>
<tr>
<td>Smoking status (yes/no)</td>
<td>48/12</td>
<td>-</td>
</tr>
<tr>
<td>Pack-years in smokers</td>
<td>9</td>
<td>2 - 30</td>
</tr>
<tr>
<td>Comorbidities, number</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Time to diagnosis (days)</td>
<td>1.2 ± 2.9</td>
<td>0.5 - 21</td>
</tr>
<tr>
<td>First symptom (pain/dyspnea)</td>
<td>49/23</td>
<td>-</td>
</tr>
<tr>
<td>First symptom (rest/effort)</td>
<td>48/12</td>
<td>-</td>
</tr>
<tr>
<td>Pneumothorax side (Right/Left)</td>
<td>31/29</td>
<td>-</td>
</tr>
<tr>
<td>Pneumothorax size (large/small)</td>
<td>48/12</td>
<td>-</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SD, number, and ranges. For time to diagnosis (Dg), 0.5 day is any delay from 0 to 12h. M= men, W= women, BMI= body mass index.

### Table 2: Comparison of patients: “success of treatment” group vs “failure of treatment” group

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Success (n = 50)</th>
<th>Failure (n = 10)</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>25.0 ± 6.6</td>
<td>28.8 ± 4.9</td>
<td>p = 0.19</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>45/5</td>
<td>10/0</td>
<td>Not valid</td>
</tr>
<tr>
<td>Smokers (%)</td>
<td>80.8</td>
<td>80.0</td>
<td>p = 0.22</td>
</tr>
<tr>
<td>Pack-years in smokers</td>
<td>7.4 ± 7.0</td>
<td>8.5 ± 5.1</td>
<td>p &gt; 0.50</td>
</tr>
<tr>
<td>First symptom (pain/dyspnea)</td>
<td>41/12</td>
<td>8/2</td>
<td>p = 0.41</td>
</tr>
<tr>
<td>First symptom (rest/effort)</td>
<td>39/8</td>
<td>7/1</td>
<td>Not valid</td>
</tr>
<tr>
<td>Time to diagnosis (days)</td>
<td>1.3 ± 3.2</td>
<td>0.6 ± 0.3</td>
<td>p &gt; 0.30</td>
</tr>
<tr>
<td>Size of PTX (small/large)</td>
<td>12/38</td>
<td>0/10</td>
<td>p = 0.18</td>
</tr>
<tr>
<td>Side of PTX (Left/right)</td>
<td>24/26</td>
<td>5/5</td>
<td>p = 1</td>
</tr>
</tbody>
</table>

Data are expressed as mean ± SD, percentages and numbers. M= male, F= female, PTX = pneumothorax.
Table 3: Summary of the results for the study end-points

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Success rate at day 7</td>
<td>50 (83.3%)</td>
</tr>
<tr>
<td>Part or full outpatient management</td>
<td>30 (50%)</td>
</tr>
<tr>
<td>Mean length of hospitalization stay</td>
<td>2.3 ± 2.5 days</td>
</tr>
<tr>
<td>Mean cost of management per episode</td>
<td>2710.36 Euros</td>
</tr>
<tr>
<td>Two years recurrence rate</td>
<td>10 (16.7%)</td>
</tr>
<tr>
<td>Complications rate</td>
<td>2 (3.3%)</td>
</tr>
</tbody>
</table>
Figure 1: Management algorithm of primary spontaneous pneumothorax (PSP).

Success = complete or nearly complete lung re-expansion; Failure = persisting lung dehiscence on CXR or air leak on suction water seal device, without worsening; Worsening = increase of PTX size on CXR or clinical deterioration; * suction at -10 to -20cmH2O, could be applied at any time if poor clinical tolerance; **stability= for small PTX only, ***discharge only if all discharge criteria present; PSP = primary spontaneous pneumothorax; PTX = pneumothorax; CXR = chest X-ray; VATS = video-assisted thoracoscopy.
Figure 2: A Fuhrman pleural drain inserted in the left 3rd intercostal space, attached to a Heimlich one-way valve, for PSP treatment. Folded sterile gauze was set as a pillow under the catheter to avoid kinking. An adhesive transparent bandage was applied, while additional adhesive tapes secured the valve on the skin.
Figure 3: Flow diagram for the progress through the management and outcome

First episode of PSP
n=60

Small PSP
n=12 (20%)

Observation alone
n=12

Success
n=12 (100%)
Day 1  n=4
Day 2  n=1
Day 3  n=1
Day 7  n=6

Follow-up
n=12
One-year relapses
n=4 (33.3%)

Large PSP/ dyspnea
n=48 (80%)

Small-bore catheter + Heimlich valve
n=48

Success
n=38 (79.2%)
Hour 4  n=9
Day 1  n=8
Day 2  n=14
Day 3  n=4
Day 4  n=1
Day 7  n=2

Follow-up
n=38
One-year relapses
n=6 (15.8%)

Failure
n=10 (20.8%)
Persistent air leak: n=6
Early relapse: n=4
Day 1  n=1
Day 2  n=1
Day 3  n=1
Day 4  n=1

Video-assisted thoracoscopy, n=10

One-year relapses
n=0

Figure 3: Flow diagram for the progress through the management and outcome
Figure 4: Flow diagram representing patient’s admissions and discharges along the study period.

- PSP enrolled, n=60
  - H4: Discharged, n=36 (60%)
    - 12 small (all without tube)
    - 24 large (5 without tube, 15 with tube + one-way valve)
  - Hospitalized, n=24 (40%)
    - All large

- D1: Re-hospitalized, n=4 all large
  - Discharged, n=8

- D2: Re-hospitalized, n=1 large
  - Discharged, n=2

- D3: Re-hospitalized, n=1 large
  - Discharged, n=7

- D4

- D7: Fully outpatient, n=30 (50%)
  - 12 small + 18 large
    - Success, n=30
    - Failure, n=10
  - Hospitalized ≥ 1 night, n=30 (50%)
    - All large
    - Suction applied, n=20

Figure 4: Flow diagram representing patient’s admissions and discharges along the study period.