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RESEARCH ARTICLE



Complications during chest tube drainage for iatrogenic pneumothorax

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ABSTRACT

Background: latrogenic pneumothorax is a common complication of diagnostic and therapeutic pulmonary procedures. New guidelines on primary spontaneous pneumothorax suggest ambulatory approaches may be suitable. However, guidance on iatrogenic pneumothorax occurring in patients with impaired lung function, increased age, comorbidity and frailty is lacking, and the safety profile of ambulatory management is not known. The objective was to study the safety of iatrogenic pneumothorax treated with chest tubes and to identify the risks of life-threatening events.

Methods: In a retrospective cohort of patients admitted and treated with an adhesive valveintegrated chest tube system, we recorded the incidence of complications. The primary outcome was the incidence of life-threatening events that required urgent medical action. Incidences of serious adverse events, adverse events, serious device-related events and whether outpatient ambulatory treatment would be safe were recorded based on the review of the medical charts. Results: In 97 patients, 6 (6%) life-threatening events occurred, including episodes of respiratory failure and an urgent need for new chest tube insertion. The event incidence was 21% in patients with pre-biopsy saturation below 95% and 1% in patients with saturation above 95%, p = 0.003, and greater if the lung had not expanded on the first radiograph, 25%, after insertion of the chest tube, than if the lung had fully expanded, 4%, or partially expanded, 2%, p = 0.009.

Conclusions: The incidence of life-threatening events during chest tube-treated iatrogenic pneumothorax is significant, but acceptable in patients without impaired lung function prior to the procedure and early response to treatment.

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KEYWORDS

Pneumothorax; Ambulatory management; Safety

Introduction

Pneumothorax occurs when air enters the thoracic cavity and alleviates the negative pressure relative to the atmospheric pressure, which is normally present in the pleural space. When pressure is annulated, the lung collapses due to elastic recoil properties of the lung. This may lead to respiratory failure due to a reduction in vital capacity, hypoventilation and shunting [1]. Pneumothorax may occur spontaneously due to lung rupture, traumatically as a result of penetrating or blunt chest trauma, or iatrogenic due to invasive medical procedures.

In respiratory medicine, a variety of commonly performed diagnostic and therapeutic procedures carry a risk of iatrogenic pneumothorax (IPX). For

example, biopsy is imperative to obtain cytological or histological material for diagnostic purposes. In the evaluation of suspected malignant lung lesions, the risk of IPX is approximately 25% in transthoracic computed tomography (CT)-guided biopsies [2]. Similar incidence of IPX is seen in endobronchial transbronchial cryo-biopsies, which are increasingly used in the diagnosis of interstitial lung diseases, and in transthoracic microwave ablative procedures (MWA), which are used for treating low T-stage primary lung tumours and metastases [3,4]. Although the incidence of IPX is lower after thoracentesis of pleural effusions and other ultrasound-guided transthoracic procedures, the high number of these procedures consequently results in many IPX.

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low-up [8,9].

Even though IPX is significantly more common than spontaneous pneumothorax, very limited evidence for IPX management exists. Current clinical practice is based on extrapolation from guidelines on spontaneous pneumothorax [5–7]. The recently updated BTS and ERS guidelines on spontaneous pneumothorax emphasise that treatment should be individualised. Several options are available, ranging from conservative management (no intervention), simple needle aspiration, admission with chest tube insertion or outpatient management with ambulatory devices containing one-way valves and outpatient fol-

Ambulatory chest tube for IPX could offer multiple advantages for patients and the healthcare service. Patients may prefer to avoid admission as this carries a risk of complicated infection and hospital resources are limited [10,11]. The efficacy of ambulatory devices for IPX after lung biopsy has been found to be very promising in two prospective [12,13] and one retrospective study [11]. However, tension pneumothorax due to chest tube dysfunction is a feared complication due to the rapid development of respiratory impairment that may require urgent medical attention [14]. Most patients with IPX are older than 50 years, have compromised lung function (COPD, emphysema, interstitial lung disease), are in poor general performance or nutritional status and may tolerate tube dysfunction poorly [15,16]. However, the injury to the lung in IPX may be smaller compared to that occurring in spontaneous pneumothorax, so the volume and duration of air leak may be shorter and easier to treat [17].

With the present study, our objectives were to investigate the incidence and characteristics of adverse events in patients treated with chest tubes for iatrogenic pneumothorax and to identify risk factors for events that needed urgent medical attention.

Methods

Study design

The study was designed as a single-centre longitudinal observational retrospective cohort study. Reporting follows the Equator Network STROBE guidelines [18]. The study was approved by the relevant authorities (local ethics committee: 1-16-02-452-22 and Aarhus University Hospital administration) and followed national data protection regulations.

Setting

The study was performed in the Department of Respiratory Medicine and Allergy at Aarhus University Hospital, Denmark, which is a tertiary referral centre for approximately 1.3 million residents.

Participants

Patients with IPX following the standard post-intervention procedure (see below) who were treated with chest tube and admitted to the department were included. Patients who had more episodes of IPX due to repeated biopsy were excluded.

Standard procedure

According to local guidelines, patients are observed 2 h after transthoracic and endoscopic cryo-biopsy of the lung. Patients are discharged if deemed clinically well and if a posterior-anterior chest radiograph in maximal inspiration, taken 2 h after the procedure, evaluated independently by two reviewers (first: a resident doctor specializing in respiratory medicine; second: a consultant in respiratory medicine), demonstrates no pneumothorax. If a pneumothorax occurs, two scenarios can occur; if the IPX is less than 3 cm in the lateral mid-hilar and/or the upper distance from the lung to the chest wall and if the patient experiences minimal symptoms, a chest drain insertion is not indicated and the patient is admitted overnight for observation. Conversely, a chest tube insertion is indicated if the lung-chest wall distance is >3 cm, or if the patient has significant symptoms. A repeat chest radiograph is undertaken shortly after chest tube insertion and repeated the next day to monitor progression and reevaluate the need for chest tube insertion, tube removal, or continued admission. Patients managed conservatively are discharged if the size and symptoms of the pneumothorax have regressed.

Chest tubes are typically inserted into the 2nd or 3rd intercostal space at the midclavicular line unless chest radiographs or ultrasound suggest an atypical location of the pneumothorax. The standard chest tube system is a compact, adhesive and portable system with an integrated Heimlich valve and 13 French trocar-guided chest tube (Thora-Vent*, UreSil*, Arnhem, The Netherlands, EU). If IPX is detected immediately after a biopsy on a postprocedural CT scan performed in the Department of Radiology, an 8 French pigtail chest tube connected to an external Heimlich valve can be inserted if the standard chest tube system is not readily available.

Data collection

Demographic and clinical variables (age, sex, lung function tests, height, weight, pre-procedure oxygen



saturation, blood pressure, respiratory rate, heart rate, oxygen supply, medication use during admission and length of hospital stay) were extracted from the electronic patient system.

Patients' medical records were manually reviewed by a single investigator (BSJ) to collect data on study variables and outcomes. All adverse events were subsequently classified and described by two independent reviewers (BSJ and SHS).

The routine erect posterior-anterior chest radiograph 2 h after procedure and follow-up radiographs were reviewed by two independent reviewers (BSJ and SHS). Distance from the visceral pleura to the inner chest wall was recorded at the apical and hilar levels, along with the presence of lateral slip, the position of the tip of the tube (pointing up or downward) and the response to chest tube treatment (lung fully expanded, partially expanded or not expanded).

Outcomes

Primary outcome: incidence of life-threatening events that required urgent medical attention.

In the context of this study, this was defined as any event during the IPX-related admission requiring immediate medical action to save the patient's life due to chest tube failure or any other medical condition.

Secondary outcomes: a) Incidence rate of adverse events (AE), serious adverse events (SAE), adverse device events (ADE) and serious adverse device events (SADE) classified according to the European Commission [19], b) Rate of patients who could be treated safely out of hospital, defined as if the patient did not receive any treatment or medical intervention that was exclusively available in the hospital and c) Incidence and possible predictors of persistent air leak, defined as air leak continuing for more than 48 h.

Data sources

Patients were identified in the electronic patient system, EPJ Midt, via the local Business Intelligence System, BI-data, by a search for a specific procedure code for insertion of a chest tube to treat pneumothorax, KGAA96. A filter was set to identify only patients admitted to the Department of Respiratory Medicine of Aarhus University Hospital. Data from May 2018 to May 2023 were extracted from the BI data system and imported into Stata, where data cleaning and organisation were performed. Data, including patient identifiers, were stored in a local file system that adheres to national data protection regulations.

Study size

A sample size was not calculated due to the descriptive and exploratory design of the study. National data regulations allow for data extraction over the past 5 years, and all relevant records in this time period were read.

Statistical methods

Variables were described by absolute numbers, means with standard variation, or medians with quartile ranges as appropriate for the parametric data distribution. This was assessed using histograms and quartilequartile plots. The unpaired Student's t-test or Fischer's exact test was performed to assess the difference between the variables according to the parametric data distribution.

Logistic regression analysis was performed for the primary outcome to find possible predicting baseline variables. The model was built a priori to include variables on sex, age, FEV1 (Forced Expiratory Volume in 1 s), oxygen saturation at baseline, apical distance from the lung to the chest wall prior to insertion of the chest tube and response to tube treatment at the first radiograph taken shortly after tube insertion. The variables were examined for distribution and classified if relevant. Univariate and multivariate values were estimated for the included variables. Sensitivity, specificity, positive and negative likelihood ratio and area-under-thecurve of receiver operating characteristic plots were calculated. To evaluate if ambulatory management would have been safe, the study population was grouped into two categories based on variables with significant differences and incidence was assessed in each of these groups.

Missing data were assumed to be missing at complete random, and no imputation was performed. All analyses were performed in Stata (STATA version 14.2; Stata Corp, Texas, US). A p-value of <0.05 was considered statistically significant.

Results

Participants

A total of 117 patients were treated with a chest drain for IPX. Ninety-seven patients were included in the study (see Figure 1 for the participant flow chart).

Descriptive data

Table 1 shows baseline clinical and demographic variables. Median admission time was 49 h (IQR 27-94), and

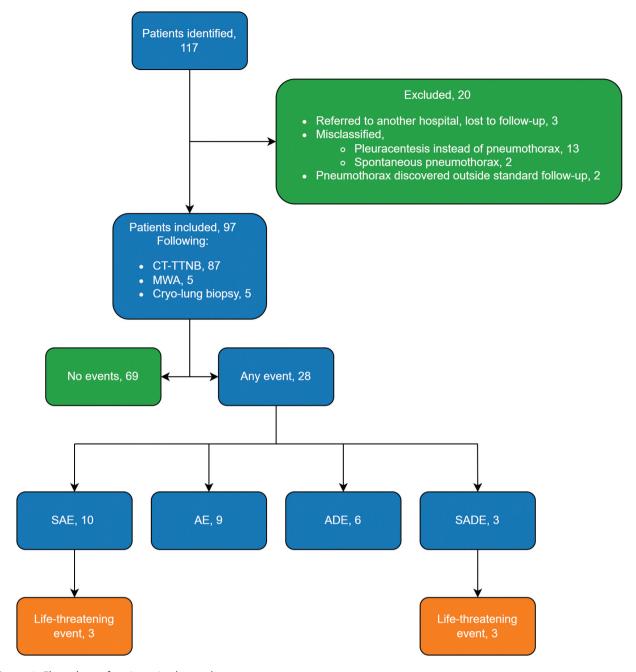


Figure 1. Flow chart of patients in the study.

CT-TTNB, Computed Tomography guided Trans Thoracic Needle Biopsy. MWA, Micro Wave Ablation. EBUS, Endo Bronchial Ultra Sound. SAE, Serious Adverse Event. AE, Adverse event. ADE, Adverse Device Event. SADE, Serious Adverse Device Event.

admission variables, including medication, management of chest tubes and response to treatment are listed in Supplementary Table S1 and Supplementary Figure S1. There were no discrepancies between the first and second chest X-ray reviewers in any of the patients.

Primary outcome

The rate of patients who needed urgent life-saving medical treatment during admission for chest tube drained IPX, was 6% (6/97). Two patients had chest

tube dysfunction, probably due to obstruction of the lumen, and in one patient the tube dislocated away from the chest wall, both causing respiratory failure and the urgent need for insertion of a new chest tube. One patient had respiratory failure due to pulmonary embolism, one patient had respiratory depression related to morphine overdose and the cause of respiratory failure was not identified in one patient. There were no deaths related to these complications. The nature and classification of these events are shown in Table 2.

Table 1. Demographic and baseline clinical data.

Variable	Number (percentages) or mean (standard deviation)
Women, n (%)	51 (54%)
Age in years, mean (SD)	72 (9)
Height in centimetres, mean (SD)	168 (8)
Weight in kilograms, mean (SD)	71 (17)
FEV1 in litres/minute, mean (SD)	1.75 (0.7)
FEV1% of expected, mean (SD)	74 (27)
FVC in litres, mean (SD)	2.8 (0.8)
Oxygen saturation in %, mean (SD)	96 (6)
Heart rate in beats/minute, mean (SD)	76 (15)
Respiration rate in breaths/minute, mean (SD)	17 (3)
Systolic blood pressure in mmHg, mean (SD)	140 (21)
Diastolic blood pressure in mmHg, mean (SD)	77 (12)
Apical distance from lung to chest wall in millimetres, mean (SD)	38 (24)
Lateral distance from lung to chest wall at hilus in millimetres, mean (SD)	14 (14)
Complete lateral lung slip, n (%)	64 (76%)

Predictive value

The relationship between an emergency and life-saving event and the a priori selected variables (age, sex, FEV1, pre-procedure oxygen saturation, apical distance of pneumothorax, radiographic response) is shown in Figures 2 and 3. The incidence of emergency events was 21% (5/24) in patients with preprocedure saturation <95% and 1% (1/73) in patients with saturation >95%, p = 0.003. Likewise, the incidence of events was higher if the lung had not expanded on the first chest x-ray after insertion of the chest tube, 27% (4/15) than if the lung had fully, 5% (1/22), or partially expanded, 2% (1/55), p = 0.009. See Figure 3.

A univariate logistic regression showed that if the baseline oxygen saturation was below 95%, the odds ratio to have an event was 19 (95% CI 2.1-172), p = 0.009. The initial radiographic response was significant with an odds ratio of 7.6 (95% CI 0.8-76.9), p = 0.008. However, when adjusting for age, sex, FEV1, apical distance and radiographic response, none of the model variables reached the level of significance, listed in the Supplementary Table S2.

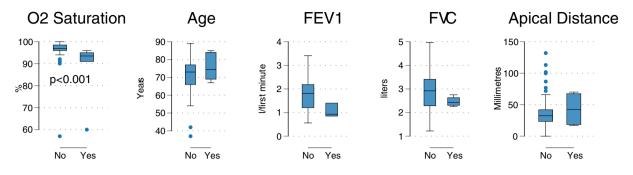
The AUC-ROC, Supplementary Figure S2, to predict an emergency and lifesaving event was 0.81 (95% CI 0.65–0.98), sensitivity 83%, specificity 79%, positive likelihood ratio 4 and negative likelihood ratio 0.2 using oxygen saturation before the biopsy with a cutoff point on 95%. Not having resolution in the chest radiograph follow-up after chest tube insertion showed AUC 0.74 (95% CI 0.47-1), sensitivity 67%, specificity 87%, positive likelihood ratio 5.2 and negative likelihood 0.4.

Table 2. Nature and classification of events that occurred during admission and treatment with an adhesive valve-integrated chest tube system for jatrogenic pneumothorax

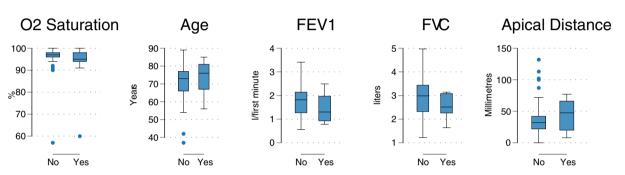
		Classification			
Case	Event	Emergency event requiring urgent treatment	Ambulatory management possible	SADE	SAE
1	Accidental self-removal of chest tube system leading to respiratory failure and insertion of surgical chest tube.	Yes	No	Yes	No
2	Dysfunction of chest tube leading to respiratory failure and insertion of surgical chest tube.	Yes	No	Yes	No
3	Dysfunction of chest tube leading to respiratory failure and insertion of surgical chest tube.	Yes	No	Yes	No
4	Respiratory failure. Surgical chest tube inserted. No effect. CT-angiography with bilateral pulmonary embolism.	Yes	No	No	Yes
5	Repeated incidents of respiratory failure and need for high-flow oxygen therapy.	Yes	No	No	Yes
6	Morphine overdose leading to respiratory depression needing observation in intensive care.	Yes	No	No	Yes
7	Recurrence of pneumothorax after chest tube removal leading to reinsertion.	No	Yes	No	Yes
8	Recurrence of pneumothorax after chest tube removal leading to reinsertion.	No	Yes	No	Yes
9	Progression of pneumothorax whilst functional chest tube leading to surgical chest tube insertion.	No	Yes	No	Yes
10	Progression of pneumothorax whilst functional chest tube leading to surgical chest tube insertion.	No	Yes	No	Yes
11	Respiratory failure with need for nasal oxygen	No	No	No	Yes
12	Acute exacerbation of COPD requiring antibiotic, bronchodilators, and oral steroids.	No	No	No	Yes
13	Morphine overdose without respiratory depression	No	No	No	Yes
14	Chest pain and respiratory distress just after chest tube insertion. Resolved quickly.	No	No	No	No
	Total	6/97	9/97	3/97	10/97
	Incidence rate	(6%)	(9%)	(3%)	(10%)

SAE: Serious Adverse Event. SADE: Serious Adverse Device Event.

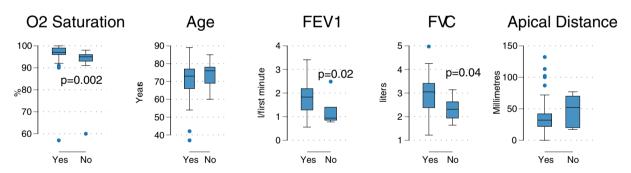
Emergency Event



SAE + SADE



Ambulatory Treatment Possible



Persistent Air-leak

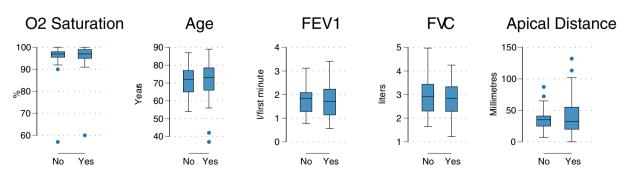


Figure 2. Medians of oxygen saturation (O2 SATS), age, forced expiratory volume in one second (FEV1), forced vital capacity (FVC) and for distance from the top of the lungs to the chest wall shown for the primary outcome (emergency events) and secondary outcomes on combined serious adverse events (SAE) and serious adverse device effects (SADE), and if ambulatory treatment was judged possible by chart reviewers.

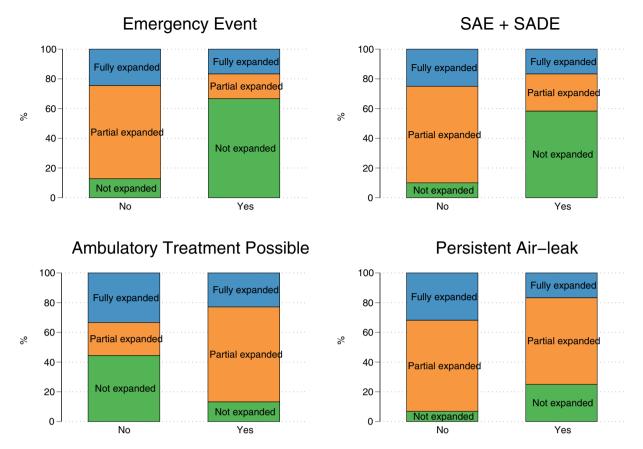


Figure 3. The risk of acute life-threatening emergency event and serious adverse events (SAE) plus serious device-related events (SADE) was significantly higher if the lung had not expanded on the chest radiograph after chest tube insertion.

Secondary outcomes

Adverse events

For secondary outcomes, the chart reviewers identified serious adverse events, SAE, in 10% (10/97) of the patients and 3% (3/97) had a serious device-related adverse event, SADE. Adverse events, AE, rate was 9% (9/97), device-related adverse events, ADA, rate was 6% (6/97) and in 71% (69/97) of the patients no AE was found. The rate, nature and classification of SAEs and SADEs are listed in detail in Table 2.

Patient review during admission

During admission, 41% (40/97) of patients had unplanned contact with a nurse and 42% (41/97) with a doctor, while 11% (11/97) had only planned contacts only as assessed from the patient notes retrieved by reviewers.

Persistent air leak

Persistent air leak for more than 48 h was present in 54% (52/97) of the patients. Only a lack of lung expansion on chest X-ray predicted incidence of persistent air leak on both univariate (OR 7 (95% CI 1.5–32.5,

p = 0.01)) and multivariable analysis (OR 12.3 (95% CI 1.2–123.2, p = 0.03)), see Supplementary Table S2. The incidence of persistent air leaks after MWA was 80% (4/5), which was higher than the incidence after CT-TTNB of 51% (44/87), p = 0.36. Additionally, there was a tendency for a longer admission time in the MWA group, as seen in Supplementary Table S1, p = 0.42.

Procedure causing the life-threatening event

On review of the procedures leading to pneumothorax, emergency and lifesaving treatment was needed in 5.8% (5/87) of patients who had pneumothorax after CT-TTNB. The incidence of such an event was 20% (1/5) in patients who had MWA of metastasis in the lung, p = 0.29. In a univariate logistic regression analysis, the odds ratio for having an SAE was 4.6 (95% CI 0.7–30.7, p = 0.12) for patients following MWA compared to the other procedures. The OR was 17.8 (95% CI 0.4–839, p = 0.13) when adjusted for FEV1, oxygen saturation, age, sex and radiological response. The OR for persistent air leak was 3.9 (95% CI 0.4–36.4, p = 0.23) for patients with MWA compared to the other procedures.

Possible ambulatory outpatient management

A detailed review of the patient charts demonstrated that in 90% of the patients (n = 87/97), no treatment or medical intervention that is exclusively available in the hospital was provided. The population was divided into two groups based on the significant variables from the primary outcome univariate logistic regression with cut-points on FEV1 ≤1 L/min>, pre-procedure oxygen saturation ≤95%> and full or partial lung expansion vs. no expansion at the first chest radiograph. Thus, the group that had pre-procedure oxygen saturation >95%, FEV1 >1 L/min, and full or partial radiographic response may have been eligible for ambulatory outpatient management. In this group of patients, comprising 44% (43/97), no emergency or life-saving event was noted. Conversely, all six emergency and life-saving events were found in the sub-population that would have been hospitalized irrespectively due to these underlying patient characteristics, difference: p = 0.007. See Supplementary Table S3 for details.

Discussion

This retrospective cohort study aimed to assess the incidence and characteristics of complications arising from IPX treatment by chest tube as well as to understand if outpatient management could be a potential alternative treatment for stable patients.

Firstly, the primary findings indicate a notable incidence of events that require urgent medical intervention and would have been life-threatening if occurring outside of a hospital, making ambulatory management unsafe. Secondly, this study identifies variables that predict such events and suggests that in a subgroup of patients who had good lung function prior to the procedure (oxygen saturation above 95% and FEV1 above 1 l/min) and who had an early lung expansion, the incidence rate of these events was acceptably low to allow ambulatory treatment.

The concept of outpatient management has gained prominence as a viable treatment option for spontaneous pneumothorax, and the idea of extending this to IPX is certainly intriguing and should be explored. Nevertheless, the safety of ambulatory chest tube management represents a paramount concern that deserves to be evaluated before clinical implementation. According to our dataset, the overall incidence of events that require immediate medical attention and could potentially pose a life-threatening risk if they occurred outside the hospital was unacceptably high. However, it is noteworthy that the incidence of SAE, 10%, falls within the range reported in other relevant studies. Hallifax et al. report a 12% incidence of SAE for ambulatory care in a trial on primary spontaneous pneumothorax [20]. These include cases that would have been classified as life-threatening in our study. In a recent update of the British Thoracic Society guidelines on pleural diseases, a recommendation for ambulatory management for patients with spontaneous pneumothorax was reached based on the data from this trial [8].

Indeed, it is crucial to acknowledge that the two study populations, i.e. patients with IPX and those with primary spontaneous pneumothorax, exhibit differences in terms of lung function, age, overall health status and frailty. It is plausible that an adverse event could manifest more rapidly and severely in patients who are older, have multiple comorbidities, have reduced lung function and are undergoing diagnostic or therapeutic procedures for severe lung diseases compared to younger and otherwise healthy individuals.

Recent guidelines concerning the management of pneumothorax have emphasised the importance of tailoring treatment strategies based on the presentation of symptoms and the clinical condition of the patient [8,9]. In accordance with this paradigm, our study aimed to identify parameters that allow the identification of candidates for ambulatory chest tube treatment. Results indicate that by excluding patients with low pre-procedure oxygen saturation or poor early response to chest tube insertion from being eligible for ambulatory management, the overall risk of experiencing a severe life-threatening event is at an acceptable level.

In the future, the imminent implementation of lung cancer screening programmes in many European countries may result in a higher rate of lung lesions referred for CT-TTNB procedures, potentially leading to an increase in the incidence of pneumothorax cases [21]. These trends highlight the importance of proactive planning and research to address the evolving landscape of IPX management. The use of endoscopic biopsy techniques that have a lower risk of IPX is emerging but has not yet been established in many centres [22]. At the same time, the use of endoscopic procedures with a high risk of pneumothorax, such as transbronchial cryobiopsy or placement of endobronchial valves, is increasing [23,24].

Both the limitations and strengths of our study should be acknowledged. First, our data were retrospectively obtained from a single hospital, and while this institution performs a substantial volume of procedures annually, it is important to recognise that the management of IPX in this hospital is predominantly rooted in tradition rather than guided by robust empirical evidence, given the scarcity of such data. As



a result, IPX management may differ significantly in other hospitals, and the findings of our study may not be readily generalisable to settings with different treatment traditions. Second, according to the collected data, it appears that ambulatory chest tube management was a feasible option for many patients. However, considering the retrospective design of our study in which data were extracted from patient files, this number must be interpreted with caution, as multiple factors that were not listed in the medical journal can hinder outpatient treatment. Not needing in-hospital treatment may not necessarily mean that outpatient treatment is feasible. Third, the relatively low total number of events observed in our study can potentially lead to overestimation or underestimation of variables in the prediction model. On a positive note, our study benefitted from a patient identification process that relied on a coding system, facilitating the accurate extraction of data with minimal misclassifications. This improves the validity of our data. Fourth, according to local standard, all chest X-rays were read by two independent and skilled pulmonologists. The practice of reading chest radiographs may differ among hospitals. Furthermore, all chest radiographs were obtained in full inspiration, and although expiratory chest radiographs have not been shown to increase diagnostic yield, they can be used in other centres [25]. Finally, our data do not answer the question of conservative management in IPX, which is increasingly used in spontaneous pneumothorax, as only patients who had a chest tube inserted were included in the study population [25]. Finally, our data does not answer the question of conservative management in IPX, which is being increasingly used in spontaneous pneumothorax, since only patients who had a chest tube inserted were included in the study population.

In perspective, our data suggest that patients with pneumothorax after MWA, with low oxygen saturation or poor resolution after chest tube insertion are at high risk for events that are incompatible with ambulatory treatment due to safety risks. In other patients, the incidence of events was significantly low and these may be considered candidates for ambulatory IPX treatment. However, future prospective randomised trials must confirm this before a conclusion can be drawn. Furthermore, before implementing ambulatory IPX management, a 24-h service must be available that effectively treats chest tube problems and acute adverse events. Even in hospitals that provide a dedicated pleural service, a case of pneumothorax that occurs outside of hours will likely be admitted to the emergency department, where familiarity with chest tube complications may be limited.

In conclusion, this study found that the incidence of severe complications of IPX treated with the chest tube is too high to recommend ambulatory treatment to all patients but acceptably low in selected patients with preserved lung function and early response to chest tube treatment.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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