

Original Article

The Natural History and Treatment of Cardiac Implantable Electronic Device Associated Pneumothorax—A 10-Year Single-Centre Experience

Garry R. Thomas, MD, MSc,^a Sharath K. Kumar, MD,^a Suzette Turner, NP,^a
Fuad Moussa, MD, MSc, MMed,^{a,b} and Sheldon M. Singh, MD^{a,b}

^a *Schulich Heart Program, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada*

^b *Faculty of Medicine, University of Toronto, Toronto, Ontario, Canada*

ABSTRACT

Background: Pneumothorax is a common complication of cardiac implantable electronic device (CIED) procedures. There is a paucity of data on the natural history and management of a CIED-associated pneumothorax.

Methods: This is a single-centre retrospective study of all consecutive patients with a CIED-associated pneumothorax between March 2010 and March 2020. Pneumothorax size was determined on all chest x-rays after device implantation and before chest tube insertion (if placed). Changes in pneumothorax size on serial chest x-rays were reported. Clinical outcomes in patients with a severe-sized pneumothorax treated with a chest tube were compared with those treated conservatively.

Results: A total of 86 CIED-associated pneumothoraxes were identified, with 55 (63.9%) patients having a pneumothorax severe in size.

Pneumothorax is a well-known iatrogenic complication of cardiac implantable electronic device (CIED) procedures with a reported incidence of 0.7%–1.7%.^{1,2} A recent review of device implantation procedures in the United States demonstrated a rising frequency of a CIED-associated pneumothorax between 1998 and 2013 despite increased awareness and evolving vascular access techniques.² This complication will continue to persist given the increasing prevalence of risk factors (age >80, female gender, multilead device implantation) associated with CIED pneumothorax.^{1,2}

The consequences of a CIED-associated pneumothorax include pulmonary embolism and pneumonia, increased

RÉSUMÉ

Contexte : Le pneumothorax est une complication courante des interventions visant à mettre en place un dispositif cardiaque électronique implantable (DCEI). Il n'existe que très peu de données sur l'évolution naturelle et la prise en charge du pneumothorax lié à la pose d'un DCEI.

Méthodologie : Nous avons étudié rétrospectivement les cas de patients ayant présenté un pneumothorax lié à un DCEI et traités consécutivement dans un même centre entre mars 2010 et mars 2020. La taille du pneumothorax a été déterminée dans toutes les radiographies pulmonaires obtenues après la pose du DCEI et avant l'insertion d'un drain thoracique (le cas échéant). Les variations de la taille du pneumothorax mesurée sur les radiographies pulmonaires successives ont été rapportées. Les résultats cliniques observés chez les patients présentant un pneumothorax important traités par drainage

hospital length of stay and total hospital costs, and risk of death.² These complications are known to be higher in those who receive a chest tube for management. Despite this, there is a paucity of data on the natural history of a CIED-associated pneumothorax and limited guidance on management as it pertains to decision making on chest tube insertion. To address this gap in knowledge we report on the radiographic progression of a CIED-associated pneumothorax and clinical outcomes in patients with a severe-sized pneumothorax treated with and without chest tube drainage.

Methods

Study population

This is a single-centre retrospective cohort study conducted at Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada, which is a tertiary care academic institution. All patients undergoing implantation of a new or revision/upgrade to an existing transvenous cardiac device requiring the placement of a new transvenous lead at the institution between March 2010 and March 2020 were included in this single-

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Ethics Statement: Research ethics approval was provided by the Sunnybrook Health Sciences Centre research ethics board. The report adhered to the relevant ethical guidelines.

Corresponding author: Dr Sheldon M. Singh, Sunnybrook Health Sciences Centre, 2075 Bayview Ave, A222, Toronto, Ontario M4N 3M5, Canada. Tel.: +1-416-480-6100 x 83659; fax: +1-416-480-5707.

E-mail: sheldon.singh@sunnybrook.ca

See page 180 for disclosure information.

Thirty-seven patients with a severe pneumothorax received a chest tube, whereas 18 were managed conservatively. Chest tube use was associated with a higher rate of admission to hospital (100% vs 63%, $P = 0.02$) for patients undergoing outpatient procedure, longer length of stay (6.3 ± 3.9 vs 2.7 ± 2.9 days, $P = 0.04$), but fewer chest x-rays (1.9 ± 0.7 vs 4.1 ± 2.5 , $P = 0.002$).

Conclusion: An initial strategy of conservative management of a CIED-associated pneumothorax in select patients may be feasible and safe.

centre retrospective cohort study. During this time period, 10 staff physicians and over a dozen trainees implanted CIEDs. Access was achieved with a standard 14-gauge needle using the Seldinger technique. Micropuncture or vascular ultrasound was not used during this time period. Venography was at the discretion of the operator.

Procedures were generally planned as same-day procedures. All individuals received a chest x-ray within 4 hours after procedure. Patients with a CIED-associated pneumothorax were identified in the Sunnybrook Health Sciences Centre device database (Paceart Optima System, ver 1.8.269.0; Medtronic, Minneapolis, MN). An independent search of the Diagnostic Imaging database was also undertaken to ensure that all patients with radiographic documentation of a CIED-associated pneumothorax were identified during the study period. Patients were excluded if a pre-existing pneumothorax or a contralateral pneumothorax unrelated to vascular access was present. Chart review was performed to determine patient demographics, clinical characteristics, medication use, procedural details, and chest tube use. Research ethics approval was provided by the Sunnybrook Health Sciences Centre research ethics board.

Initial and changing pneumothorax size

Each chest x-ray subsequent to the pneumothorax diagnosis was reviewed by 2 investigators (G.R.T. and S.K.K.), and as per recommendations from the American College of Chest Physicians, the apical height of the pneumothorax was determined (see Fig. 1). A pneumothorax with an apical height ≥ 3 cm was deemed to be severe.³ Changes in pneumothorax size on subsequent chest x-rays were reported. All chest x-rays were analysed after implantation, and pneumothorax size reported before insertion of a chest tube.

Management of severe pneumothorax

The use of 100% fractional inspired oxygen to theoretically hasten pneumothorax resolution was not routinely performed given the conflicting data in the literature and the fact that it likely has no impact on large-sized pneumothoraxes.^{4,5} The need for and timing of subsequent chest x-rays, and the decision to place and subsequent management of a chest tube were at the discretion of the implanting physician in consultation with the Cardiac or Thoracic surgical service, with the chest tube size ranging from 12 to 16 French in diameter. The clinical characteristics, presence of symptoms (dyspnea, chest

thoracique ont été comparés à ceux de patients traités selon l'approche classique.

Résultats : Au total, 86 cas de pneumothorax liés à un DCEI ont été relevés; 55 patients (63,9 %) présentaient un pneumothorax important. De ce nombre, 37 patients ont subi un drainage thoracique, tandis que les 18 autres ont été pris en charge selon l'approche classique. Le recours à un drain thoracique a été associé à un taux d'admission à l'hôpital plus élevé (100 % vs 63 %; $p = 0,02$) dans le cas des interventions ambulatoires et à une hospitalisation plus longue ($6,3 \pm 3,9$ vs $2,7 \pm 2,9$ jours; $p = 0,04$), mais à un moins grand nombre de radiographies pulmonaires ($1,9 \pm 0,7$ vs $4,1 \pm 2,5$; $p = 0,002$).

Conclusion : Dans certains cas, il est possible et sûr d'avoir recours à une prise en charge initiale classique du pneumothorax lié à un DCEI.

pain, or hemoptysis) or change in vital signs, and outcomes including need for admission and hospital length of stay were determined for the subset of patients with a severe pneumothorax. Those receiving a chest tube were compared with those managed without a chest tube.

Statistical analysis

Continuous variables were expressed as mean \pm standard deviation and categorical variables reported as proportions. Descriptive statistics were used to describe patients with severe pneumothorax treated with a chest tube compared with those treated without a chest tube. We used Student's t -test for continuous variables (Excel, Microsoft Office, Redmond, WA) and the χ^2 test for categorical variables (SPSS: IBM Corp Released 2017, IBM SPSS Statistics for Windows, Version 25.0; IBM Corp, Armonk, NY). Because of the small sample size, multivariate analysis was not performed. A P value < 0.05 was deemed statistically significant.

Results

A total of 4492 CIED procedures requiring vascular access (including cephalic vein, axillary, or subclavian vein access) were performed at Sunnybrook Health Sciences Centre between March 2010 and March 2020. Of these, 86 (1.9%) were complicated by pneumothorax. Chest tube placement occurred in 42 (49%) of patients who sustained a pneumothorax. No patient in the study cohort experienced a tension pneumothorax, device-related infection, required thoracic surgery, or died.

Natural history of device-related pneumothorax

Figure 2 summarizes the natural history of device-related pneumothorax in the study cohort. The average time between the procedure and the initial chest x-ray was 3.3 ± 1.2 hours. The average apical height on the initial chest x-ray was noted to be 2.7 ± 2.2 cm. Thirty-five individuals (41% of the entire cohort or 63% of all individuals with a severe-sized pneumothorax during the follow-up period) had a pneumothorax that was classified as severe in size (4.9 ± 1.9 cm) on the initial chest x-ray performed immediately after procedure. The apical height in those deemed to have a nonsevere pneumothorax was 1.3 ± 0.7 cm ($P < 0.01$) on the initial chest x-ray.

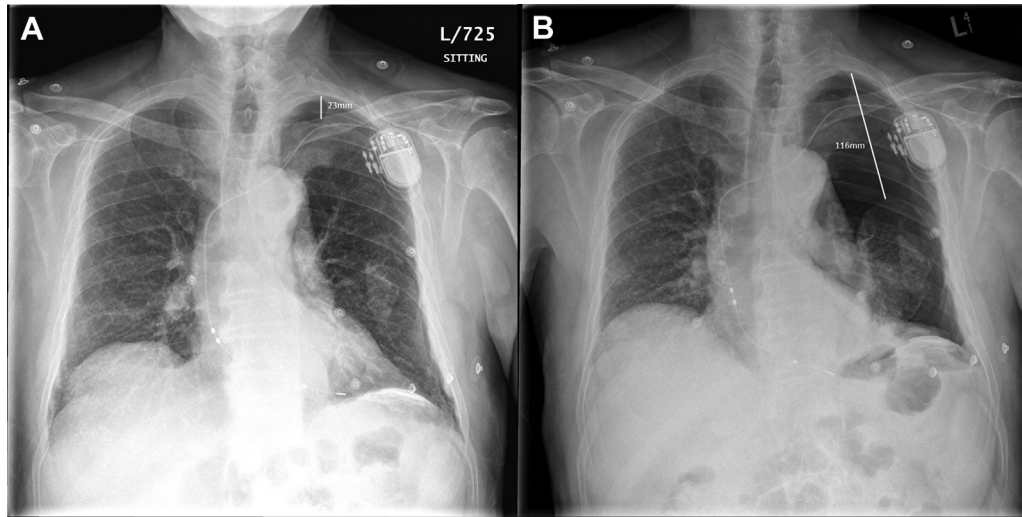


Figure 1. Determination of pneumothorax size. Apical height of the pneumothorax determined. Apical distance > 3 cm is considered severe as per the American College of Chest Physicians. **(A)** Initial chest x-ray in a patient with a nonsevere pneumothorax measuring 23 mm. **(B)** Repeat chest x-ray in the same patient 20 hours after the initial chest x-ray demonstrating progression to a severe pneumothorax with collapse of the lung.

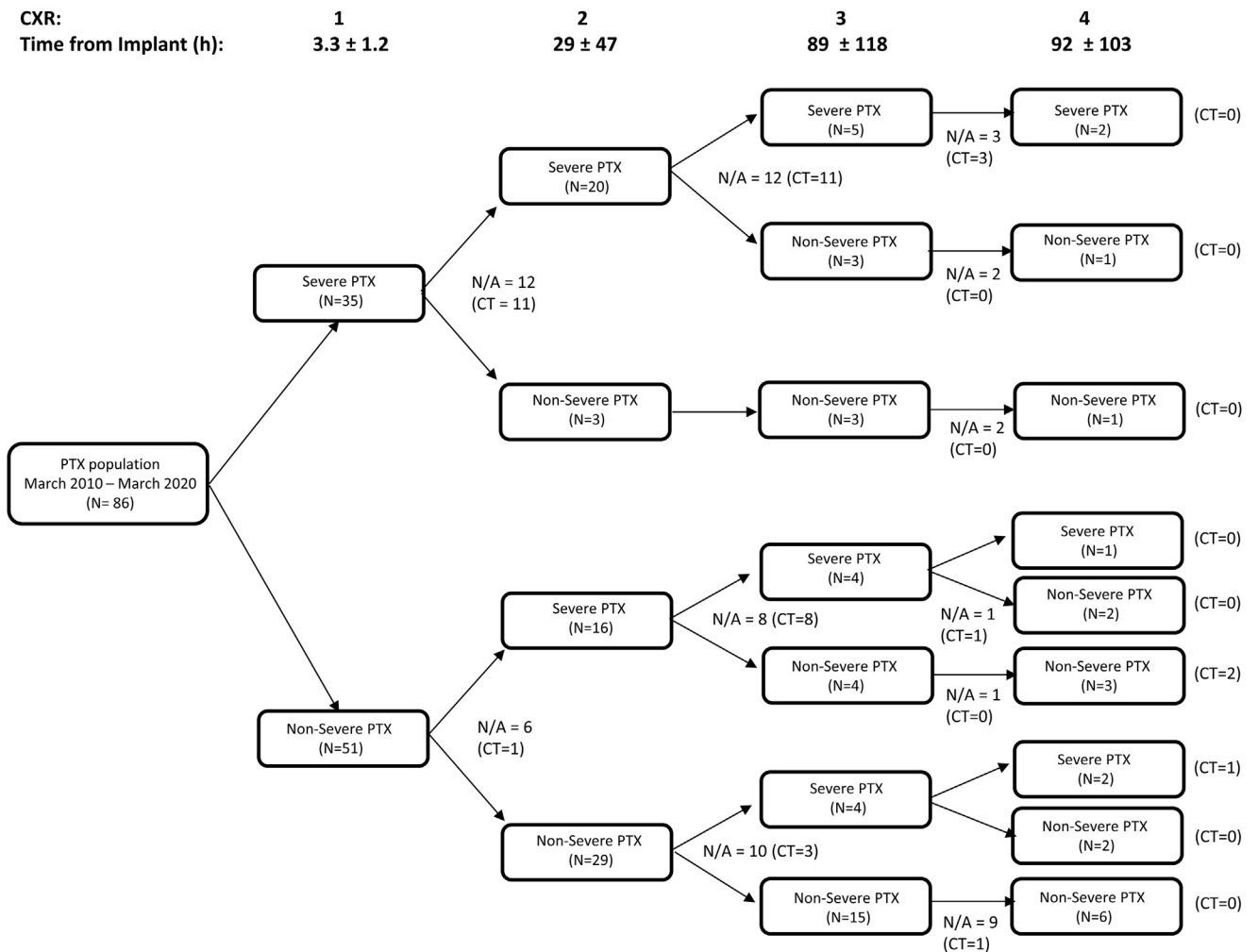


Figure 2. Trajectory of patients with a pneumothorax. N/A means subsequent chest x-ray data not available either due to subsequent chest tube placement or no further chest x-rays were performed. Those receiving a chest tube (CT) after the completed x-ray are indicated. CXR, chest x-ray; PTX, pneumothorax.

Table 1. Clinical characteristics of patients with severe pneumothorax

	Chest tube (N = 37)	Conservative (N = 18)	P value
Demographics and clinical characteristics			
Age, mean ± SD	80 ± 10	78 ± 10	0.55
Female, n (%)	11 (30)	7 (39)	0.55
Hypertension, n (%)	26 (70)	11 (61)	0.55
Diabetes, n (%)	7 (19)	2 (11)	0.70
Any respiratory disease, n (%)	3 (8)	2 (11)	1.00
Medication use			
Dual antiplatelet, n (%)	1 (3)	0 (0)	1.00
Oral anticoagulation, n (%)	3 (8)	5 (28)	0.1
Procedure details			
Single-lead device, n (%)	15 (40)	7 (40)	1.00
Dual- or triple-lead device, n (%)	22 (60)	10 (57)	1.00
Upgrade, n (%)	0 (0)	1 (6)	0.33
Defibrillator, n (%)	13 (35)	11 (61)	0.09
Venogram, n (%)	13 (35)	4 (22)	0.37
Pneumothorax characteristics			
Apical height on first chest x-ray (mm), mean ± SD	3.8 ± 2.6	3.3 ± 1.6	0.41
Maximal apical height (mm), mean ± SD	6.1 ± 2.7	4.3 ± 1.1	0.01
Symptoms or change in vital signs, n (%)*	7 (30)	2 (17)	0.43

SD, standard deviation.

*The presence of symptoms (dyspnea, chest pain, and hemoptysis) or change in vital signs was able to be determined for 23 of 37 patients receiving a chest tube and 12 of 18 not receiving a chest tube.

A second chest x-ray was performed in 68 (79%) patients 29 ± 47 hours after the procedure was completed. Clinically important reclassification of pneumothorax severity (ie, severe becoming nonsevere or nonsevere becoming severe) occurred in 19 (28%) patients.

The majority of those initially classified as severe in size remained severe (20 of 23; 87%), with 35% of these patients having a stable or decrease in pneumothorax size noted on the repeat chest x-ray. The average pneumothorax size on the second chest x-ray in this subgroup was 4.7 ± 2.3 cm, corresponding to a change of 0.5 ± 0.8 cm when compared with the initial chest x-ray (*P* = 0.34).

An increase in apical height on the second chest x-ray occurred in 71% (32 of 45) of patients with a non-severe-sized pneumothorax on the initial chest x-ray. The average pneumothorax size on second chest x-ray was 2.9 ± 2.7 cm, reflecting a 1.7 ± 2.6 cm change when compared with the initial chest x-ray (*P* < 0.01). Thirty-six percent (16 of 45) of individuals with a non-severe-sized pneumothorax on initial

Table 2. Clinical outcomes

	Chest tube (N = 37)	Conservative (N = 18)	P value
Admission to hospital, n (%)*	16 (100)	7 (64)	0.02
Length of stay (d), mean ± SD*	6.3 ± 3.9	2.7 ± 2.9	0.04
Total chest x-rays (n), mean ± SD	2.0 ± 1.0	4.3 ± 2.1	0.002

SD, standard deviation.

*Outpatient procedures occurred in 16 receiving a chest tube and 11 conservatively managed.

chest x-ray were reclassified as severe on the second chest x-ray.

In patients where a chest tube was not inserted, the pneumothorax stabilized or decreased in size as noted on a subsequent chest x-ray (on average the 1.2 ± 0.3 chest x-ray), which was performed approximately 57 ± 80 hours after the device implantation (or 41 ± 81 hours after the initial chest x-ray where the severe pneumothorax was diagnosed).

Management of nonsevere pneumothoraxes

Nonsevere pneumothoraxes occurred in 31 (36%) of individuals within this cohort, all but 5 who were treated conservatively without complications. Five patients received chest tubes—the first patient had a history of breast cancer and pneumothorax in an atypical location (base of the lungs) associated with pain, the second had a history of a prior lobectomy, the third had severe chronic obstructive pulmonary disease, and the fourth and fifth had no comorbidity or symptoms, but whose chest x-rays were likely interpreted as “severe” in size by the operator. Three of these 5 patients with nonsevere pneumothoraxes had documented symptoms of shortness of breath and the need for supplemental oxygen in response to documented desaturations.

Management of severe pneumothoraxes

Severe-sized pneumothoraxes occurred in 55 (64%) individuals within this cohort, 37 of whom received a chest tube. Table 1 compares the clinical characteristics of those who did and did not receive a chest tube. Those receiving a chest tube had on average a larger maximum pneumothorax size (6.1 ± 2.7 vs 4.3 ± 1.1 cm; *P* = 0.01). No patient receiving conservative management had a pneumothorax >6 cm in apical height. Symptoms or changes in vital signs were ascertained in 35 of the 55 individuals with a severe pneumothorax, with the majority of patients being asymptomatic (71%), with similar frequencies in the group that did and did not receive a chest tube (Table 1).

Of the 46 of patients undergoing an elective outpatient device implantation who sustained a pneumothorax, 27 (58%) were admitted to hospital. Table 2 summarizes the clinical outcome of patients with severe-sized pneumothoraxes treated with and without a chest tube. All outpatients with a severe pneumothorax who received a chest tube were admitted to hospital, whereas 64% treated conservatively were admitted to hospital (*P* = 0.02). For those admitted, length of stay was greater with a chest tube than without (6.3 ± 3.9 days vs 2.7 ± 2.9 days, *P* = 0.04). Patients treated conservatively received more chest x-rays compared with those receiving a chest tube (4.1 ± 2.5 vs 1.9 ± 0.7, *P* = 0.02). A nonsignificant trend towards greater use of chest tubes to manage severe pneumothorax was observed when patients received a CIED during an existing inpatient admission compared with those receiving a CIED as an outpatient procedure (75% vs 59.3%, *P* = 0.26).

Device function

No change in device pacing threshold was reported in patients with a severe-sized pneumothorax. Of note, 54% (13 of 24) patients with implantable cardiac defibrillators who sustained a severe-sized pneumothorax had chest tube

insertion. No ventricular arrhythmias requiring defibrillation was noted in the group of implantable cardiac defibrillator patients with a pneumothorax who did not receive chest tube drainage.

Discussion

Our work highlights several important features of CIED-associated pneumothoraxes. First, the majority of CIED-associated pneumothoraxes are classified as severe in size. Second, a nontrivial proportion of patients with an initial non-severe-sized pneumothorax subsequently become severe in size highlighting the value of a repeat chest x-ray. Third, conservative management of severe CIED-associated pneumothoraxes may be possible in select patients.

As device implantations continue to increase, worldwide CIED-associated pneumothorax will persist. Although this complication may be almost eliminated with the use of cephalic vein cutdown, this approach requires specific surgical skills and may not be feasible in all patients.⁶ Prior work has described the risks for a CIED-associated pneumothorax, as well as consequences of treatment with a chest tube.^{1,2} However, there is currently no specific guidance on the management of a CIED-associated pneumothorax with current recommendations derived from literature on spontaneous or traumatic pneumothorax. Furthermore, variation exists in guidelines and consensus statements, including the definition of what constitutes a severe pneumothorax.⁷ Knowledge of the appropriate treatment of this condition is important given the consequences of chest tube insertion.⁸

In response to the heterogeneity of management strategies, a recent multicentre, open-label, randomized trial was undertaken to evaluate an initial conservative strategy vs invasive (with chest tube) management of patients with primary spontaneous pneumothorax.⁹ Despite this study being performed in a younger cohort with a different mechanism of pneumothorax, the findings are important and complement our work. First, radiographic and symptom resolution of pneumothorax occurs in conservatively managed patients, with similar times to symptom resolution but prolonged time to radiographic resolution in those treated conservatively. Second, adverse events were 3.32 times higher in those treated with a chest tube, primarily related to chest tube insertion. Third, hospital length of stay and time off work were longer in those receiving a chest tube. The study highlighted that a strategy of initial conservative management was noninferior to interventional management and could save 85% of pneumothorax patients from an invasive intervention. Further work to ensure that a conservative approach may be applicable to patients receiving CIEDs is needed particularly as CIED patients may be older with other comorbidities including respiratory comorbidities and, as seen in our work, the majority are asymptomatic or minimally symptomatic despite the presence of a severe-sized pneumothorax. In addition, it is important to ensure that this strategy may be applied to patients with implantable cardiac defibrillators given the known increase in defibrillation threshold in the setting of pneumothorax.¹⁰

If an intervention is deemed appropriate, there is also lack of consensus as to the best approach to achieve drainage.¹¹ At our centre, the decision for chest tube insertion was largely

based on consultant preference, with the chest tube size typically 12-16 French in diameter. A recent single-centre observational study evaluated a strategy of drainage with fine needle aspiration.¹² This approach was successful in over half of patients and resulted in decreased length of hospital stay. This approach is recommended by the British Thoracic Society for early management of a spontaneous pneumothorax or small secondary pneumothorax; however, it is not strongly endorsed by other society guidelines.¹³

Our work highlights the role of serial chest x-rays in delineating the natural history of a CIED-associated pneumothorax. We observed a wide range of sizes and rates of pneumothorax progression. An early repeat chest x-ray is important but may be particularly important in patients with an initial non-severe-sized pneumothorax on the initial chest x-ray. Specifically, 1 in 3 patients with an initially nonsevere pneumothorax were reclassified as severe on the repeat chest x-ray. Repeat chest x-ray may be influential on decision making in the absence of symptoms of pneumothorax.

Our study has several limitations. First, this was a retrospective analysis with a small sample size from a single centre. Second, there was no prespecified approach (based on radiographic findings and symptoms) to manage CIED-associated pneumothorax during this time period, which is consistent with the absence of guidelines on managing this condition during this time period. Third, symptoms and hemodynamic compromise were not uniformly documented in all patients, which may have prevented us from determining clinical factors that may have influenced patient management—an important consideration as most patients were asymptomatic. Our work is valuable as it is the first systematic report of the natural history of a rare complication that will inevitably continue to occur, and highlights the need to determine appropriate management strategies for this complication. We suggest further multicentre, and if possible randomized, studies to evaluate conservative vs invasive management, including the study of chest tube vs needle aspiration, for CIED-associated pneumothorax.

Conclusions

CIED-associated pneumothorax is frequently severe in size. Conservative management is associated with shorter hospital length of stay and may be a reasonable approach in select patients with CIED-associated pneumothorax.

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Disclosures

The authors have no conflicts of interest to disclose.

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