Impact of a Dedicated Pleural Clinic on Indwelling Pleural Catheter Related Outcomes

A Retrospective Single Center Experience

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Background: **Recurrent pleural effusions are a major cause of morbidity and frequently lead to hospitalization. Indwelling pleural catheters (IPCs) are tunneled catheters that allow ambulatory intermittent drainage of pleural fluid without repeated thoracentesis. Despite the efficacy and safety of IPCs, data supporting postplacement follow-up is limited and variable. Our study aims to characterize the impact of a dedicated pleural clinic (PC) on patient outcomes as they relate to IPCs.**

Methods: **Patients who underwent IPC placement between 2015 and 2021 were included in this retrospective study. Differences in outcomes were analyzed between patients with an IPC placed and managed by Interventional Pulmonology (IP) through the PC and those placed by non-IP services (non-PC providers) before and after the PC implementation.**

Results: **In total, 371 patients received IPCs. Since the implementation of the PC, there was an increase in ambulatory IPC placement (31/133 pre-PC vs. 96/238 post-PC; $P = 0.001$). There were fewer admissions before IPC placement (18/103 vs. 43/133; $P = 0.01$), and fewer thoracenteses per patient (2.7 ± 2.5 in PC cohort vs. 4 ± 5.1 in non-PC cohort; $P < 0.01$). The frequency of pleurodesis was higher in the PC cohort (40/103 vs. 41/268; $P < 0.001$). A Fine and Gray competing risks model indicated higher likelihood of pleurodesis in the PC cohort (adjusted subhazard ratio 3.8, 95% CI: 2.5-5.87).**

Conclusion: **Our experience suggests that the implementation of a dedicated PC can lead to improved patient outcomes including fewer procedures and admissions before IPC placement, and increased rates of pleurodesis with IPC removal.**

Key Words: pleural effusion, indwelling pleural catheter, pleural clinic

(*J Bronchol Intervent Pulmonol* 2023;30:114–121)

Over 1.5 million malignant pleural effusions (MPE) and nonmalignant pleural effusions (NMPE) are diagnosed each year.[1,2] Leading causes of pleural effusions include congestive heart failure, parapneumonic effusions and MPE.[1] As the burden of pleural disease continues to rise globally, up to 15% of individuals diagnosed with cancer will develop an MPE.[3–5] Recurrent pleural effusions, both malignant and nonmalignant, are defined as pleural effusions that recur despite optimal therapy for the underlying etiology and are a major source of morbidity leading to chest pain, dyspnea, cachexia, and decreased activity.[6–8] Generally, the presence of a MPE portends a poor prognosis, with a median survival ranging from 1 to 13 months.[7] Though NMPE related mortality is less well described, recent literature suggests that NMPE carries a comparable mortality risk to MPE.[9–13] Although symptom burden remains high and life expectancy is limited, pleural effusion management remains a diagnostic challenge with variability in practices ranging from serial thoracenteses to more definitive therapies aimed at minimizing symptoms and preventing recurrence.[6]

Indwelling pleural catheters (IPCs) are tunneled catheters that are inserted into the pleural space allowing ambulatory intermittent drainage of pleural fluid.[14] In 1997, the PleurX catheter (CareFusion, Vernon Hills, IL) was approved by the US Food and Drug Administration for management of MPE, and in 2001 this license was extended to apply to NMPE.[15,16]

Received for publication May 1, 2022; accepted August 31, 2022.
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Disclosure: There is no conflict of interest or other disclosures.
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Supplemental Digital Content is available for this article. Direct URL citations are provided in the HTML and PDF versions of this article on the journal's website, www.bronchology.com.

DOI: 10.1097/LBR.0000000000000901

As this time, IPCs are increasingly being used worldwide as the first-line management for MPE.[5,17–19] In Addition, IPCs have been suggested as an acceptable therapeutic option for the management of recurrent NMPE.[20] For both MPE and recurrent NMPE, IPCs have been shown to reduce hospitalizations, decrease length of stay relative to other interventions, and minimize effusion-related symptoms such as dyspnea.[14,17,19–24] IPCs are placed electively in the outpatient setting and facilitate outpatient management.[2,25] Depending on the disease state, IPCs may result in complete or partial resolution of the effusion or spontaneous pleurodesis and can remain in for several weeks to months.[19,20] Despite the efficacy and safety of IPCs, data supporting suitable postplacement follow-up and optimal frequency of drainage is variable, though data suggest that drainage frequency may affect rates of pleurodesis.[25–29] A modified Delphi consensus statement in 2020 called for the need for further studies related to IPC management.[2]

Since January 2018, our institution has implemented the pleural clinic (PC) as a subdivision of the Interventional Pulmonary (IP) practice to manage patients with pleural disease, including IPC placement and management for refractory effusions. Our study aims to characterize the impact of the implementation of a dedicated PC on patient-centered outcomes as they relate to IPCs.

PATIENTS AND METHODS

All patients who underwent IPC placement between January 2015 to January 2021 were included in this retrospective study. Data were collected by the electronic health record. For each patient, the first IPC placement was captured and subsequent IPCs in the same patient were excluded from the analysis. This study was approved by the institutional review board of the study institution. Individual informed consent was waived.

IPC placement was identified by current procedural terminology (CPT) code 32550. MPE was defined as a malignant effusion proven by cytology or a paramalignant effusion associated with a documented active malignancy and negative pleural cytology, and ICD-10 coding. Pleurodesis was identified with a documented catheter removal by current procedural terminology code 32552 and each patient with an IPC removal was independently reviewed by the authors (K.M. and Y.B.G) to exclude patients with catheter removal for alternative indications including infection, catheter malfunction or patient request. Emergency department (ED) visits and inpatient admissions for a respiratory related chief complaint 1 year before and 1 year after IPC placement were counted.

IPCs (PleurX, CareFusion, San Diego, CA) were either placed and followed by an interventional pulmonologist through the PC (the "PC cohort") or placed and followed by other non-IP specialties ("non-PC cohort") (Fig. 1). The PC was established in January 2018 and the pre-PC period is defined as dates between January 2015 and December 2017 where patients received IPCs with non-IP specialists and were not followed in the dedicated PC. For the non-PC cohort, patients were included for the entirety of the study period. The pre-PC patients were used as a subgroup of the non-PC cohort for comparison analyses, the "pre-PC cohort."

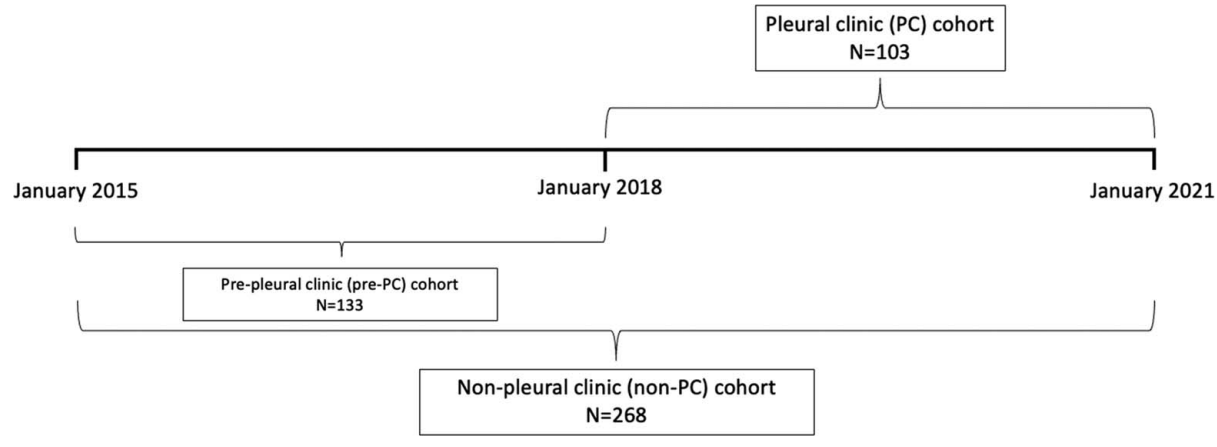

FIGURE 1. Summary of the 3 different patient cohorts included in the study. Number of patients in each cohort is noted. PC indicates pleural clinic.

All patients in the PC cohort had scheduled IPC teaching by ambulatory staff within a few days of IPC placement. During this teaching, patients received an IPC educational packet with a video link, and a phone call from the clinic to address any questions or concerns. Patients were instructed to drain their IPC with a negative pressure canister per regimen outlined with the clinician, typically thrice weekly (range daily to weekly). Outpatient drainage was performed by patients themselves or caregivers after detailed instruction with a clinic nurse or with a visiting nurse if available. Templated written instructions were provided for each patient (Supplemental Figure 1, Supplemental Digital Content 1, http://links.lww.com/LBR/A278), and publicly available patient information sheets.[30] A post-IPC placement visit protocol was instituted with initial follow up being 2 weeks after IPC placement for needs assessment and suture removal and an additional visit after 4 months to assess ongoing drainage requirements. Pleurodesis was assumed when pleural effusion drainage decreased to <50 ml over 3 consecutive drainages. Catheter removal took place if minimal residual fluid was noted on thoracic ultrasound.

For patients in the non-PC cohort, there was no documentation of a standardized or protocolized regimen regarding follow up intervals, frequency of drainage or teaching, and management was at the discretion of the referring provider.

Statistical Approach

Descriptive statistics were used to summarize categorical variables by frequencies and percentages and continuous variables by means and medians. Descriptive analysis between groups was performed using Welch t test and Fisher exact test for continuous and categorical data, respectively. Time to pleurodesis was analyzed with the Fine and Gray competing risks survival model, with competing risk being death, and described with a cumulative incidence curve, and subhazard ratio adjusted for age and Charlson Comorbidity Index. Time to death was analyzed with the Kaplan-Meier survival curve and Cox proportional hazard models as the interval in weeks between IPC insertion and death. For time-to-event analyses, hazard ratios (HRs) with adjustments for age and Charlson Comorbidity Index, and 95% CIs comparing the PC and non-PC groups are provided. Two-sided P-values <0.05 were considered statistically significant. STATA (version 16; StataCorp, College Station, TX) software was used for analysis.

RESULTS

Between January 2015 and January 2021, 371 patients underwent IPC placement. Of these IPCs, 27.8% (103/371) were placed and managed through the PC and 72.2% (268/371) were placed by non-PC providers. Before the implementation of the PC in January 2018, 35.8% of the IPCs (133/371) had been placed by non-PC providers. Baseline demographics at the time of IPC placement are shown in Table 1. Malignancy was documented in 84.1% of patients (312/371) (Supplemental Table 1, Supplemental Digital Content 2, http://links.lww.com/LBR/A279). Pleural cytology was positive for malignant cells in 42.6% of patients (158/371)

TABLE 1. Baseline Characteristics at Time of IPC Insertion

			Nonpleural Clinic		*P*	
	Total (N = 371)	Pleural Clinic (N = 103)	All (N = 268)	Pre-PC (N = 133)	All	Pre-PC
Age (y)	64.7 ± 15.3	68.2 ± 14.5	63.3 ± 15.4	64.7 ± 15.3	< 0.01	0.02
Sex					0.64	1
Male	202 (54.5)	54 (52.4)	148 (55.2)	69 (51.9)		
Female	169 (45.6)	49 (47.6)	120 (44.8)	64 (48.1)		
BMI, mean	24.2 ± 5.5 (N = 363)	23.9 ± 5.6 (N = 101)	24.3 ± 5.4 (N = 262)	23.5 ± 5.1 (N = 131)	0.54	0.64
Charlson Comorbidity Index, mean	8.8 ± 3.6	8.3 ± 7.6	8.9 ± 3.6	8.5 ± 3.1	0.12	0.69
Malignant cytology, yes	158 (42.6)	51 (50)	107 (39.9)	58 (43.6)	0.1	0.43
Extrapleural malignancy, yes	312 (84.1)	88 (85.4)	224 (83.6)	112 (84.2)	0.75	0.86
Benign effusion, yes	57 (15.4)	15 (14.6)	42 (15.7)	20 (15)	0.87	1

Data are presented as mean ± SD or number (%).
PC indicates Pleural clinic.

TABLE 2. Procedures by Service

			Nonpleural Clinic		*P*	
	Total (N = 371)	Pleural Clinic (N = 103)	All (N = 268)	Pre-PC (N = 133)	All	Pre-PC
Location of IPC placement						
Inpatient	244 (65.8)	34 (33)	210 (78.4)	102 (79.7)	< 0.001	< 0.001
Outpatient	127 (34.2)	69 (67)	58 (21.6)	31 (23.3)		
Thoracentesis, average/patient						
Before IPC	3.7 ± 4.5(N = 275)	2.7 ± 2.5 (N = 81)	4 ± 5.1 (N = 194)	4.5 ± 6.1 (N = 98)	< 0.01	< 0.01
After IPC	2.3 ± 2.5 (N = 49)	1.6 ± 1.1 (N = 20)	2.8 ± 3.1 (N = 29)	2.8 ± 1.8 (N = 13)	0.06	0.05
Chest tube placement, average/patient						
Before IPC	1.1 ± 0.4 (N = 35)	1.1 ± 0.4 (N = 7)	1.1 ± 0.4 (N = 28)	1 (N = 11)	1	0.36
After IPC	1.1 ± 0.3 (N = 20)	1.1 ± 0.3 (N = 9)	1.1 ± 0.3 (N = 11)	1 (N = 4)	0.89	0.35

Data are presented as mean ± SD or number (%).
IPC indicates indwelling pleural catheter; PC, pleural clinic.

(Supplemental Table 2, Supplemental Digital Content 3, http://links.lww.com/LBR/A280). IPCs were placed for nonmalignant effusions in 15.4% of patients (57/371).

IPC placement occurred in the inpatient setting in 65.8% of patients (244/371) and in the outpatient setting in 34.2% of patients (127/371) (Table 2). The PC placed more IPCs on an outpatient basis than non-PC providers (67% [69/103] vs. 21.6% [58/268]; $P < 0.001$). There were fewer thoracenteses per patient before IPC placement in the PC group when compared with the non-PC group (2.7 ± 2.5 vs. 4 ± 5.1, respectively; $P < 0.01$). There was no difference in chest tube placement between the groups.

Since the implementation of the PC in January 2018, there was an increase in the overall proportion of IPC placement in the ambulatory setting (23.3% [31/133] before the implementation of the PC vs. 40.3% [96/238] after the implementation of the PC; $P = 0.001$). There were also fewer thoracenteses per patient before IPC placement when the PC cohort was compared with the pre-PC cohort (2.7 ± 2.5 vs. 4.5 ± 6.1, respectively; $P < 0.01$; Table 2).

Before the IPC placement, 7.6% of patients (28/371) had an ED visit, and 2.7% (10/371) had an ED visit after placement (Table 3). Before the IPC placement, 23.7% of patients (88/371) had a respiratory related admission and 10.5% of patients (39/371) were admitted after IPC placement. There were no differences in ED visits or admissions between the PC and non-PC cohorts.

At the end of the follow up period (January 1, 2021), 21.8% of patients (81/371) had achieved pleurodesis and 60.9% (226/371) had died (Table 4). Of the 94, the patients that had their IPC removed, 81 had their catheter removed for suspected pleurodesis. Of the remaining 13 patients, 6 were removed for documented or suspected infection, 3 were removed for pain, 2 were removed for frequent clotting, 1 was a temporary intra-op placement, and 1 was removed for patient safety related issues. Eight of the patients who achieved pleurodesis had talc poudrage during thoracoscopy, 5 of these in the PC cohort and 3 in the non-PC cohort. No patients received talc slurry. The frequency of pleurodesis was higher in the PC cohort (38.8% [40/103]) than in the non-PC cohort

TABLE 3. Hospital Encounters

			Nonpleural Clinic		*P*	
	Total (N = 371)	Pleural Clinic (N = 103)	All (N = 268)	Pre-PC (N = 133)	All	Pre-PC
ED visit, yes						
Before IPC	28 (7.6)	6 (5.8)	22 (8.2)	12 (9)	0.52	0.46
After IPC	10 (2.7)	1 (1)	9 (3.4)	6 (4.5)	0.3	0.14
Admission, yes						
Before IPC	88 (23.7)	18 (17.5)	70 (26.1)	43 (32.3)	0.1	0.01
After IPC	39 (10.5)	12 (11.7%)	27 (10.1)	14 (10.5)	0.7	0.84

Data are presented as mean ± SD or number (%).
IPC indicates indwelling pleural catheter; PC, pleural clinic.

TABLE 4. Outcomes by Service

			Nonpleural Clinic		*P*	
	Total (N = 371)	Pleural Clinic (N = 103)	All (N = 268)	Pre-PC (N = 133)	All	Pre-PC
Pleurodesis, yes	81 (21.8)	40 (38.8)	41 (15.3)	18 (13.5)	< 0.001	< 0.001
Malignant	67	34	33	14	< 0.001	< 0.001
Benign	14	6	8	4	0.17	0.27
Time to pleurodesis (d)	90 (46-162) (N = 81)	89 (42-179.5) (N = 40)	91 (47-155) (N = 41)	82.5 (55-162) (N = 18)		
Malignant	90 (47-158)	86 (41-168)	97 (52-155)	82.5 (61-162)		
Benign	91 (43-212)	146.5 (43-261)	73 (41-151.5)	73 (45-217)		
Deceased, yes	226 (60.9)	59 (57.3)	167 (62.3)	80 (60.2)	0.41	0.69
Malignant	209	55	154	73	0.43	0.77
Benign	17	4	13	7	1	0.72
Time to death (d)	43 (16-152) (N = 226)	108 (33-322) (N = 59)	34 (14-109) (N = 167)	41 (16.5-127.5) (N = 80)		
Malignant	41 (15.5-141.5)	108 (32-322)	33 (13-96)	33 (15-112)		
Benign	108 (33-367)	292.5 (73-530)	108 (18-292)	292 (103-1312)		

Data are presented as mean ± SD or number (%) or median (interquartile range).
PC indicates Pleural clinic.

(15.3% [41/268]; adjusted HR 3.29, 95% CI: 2.12-5.12). After removing the patients who underwent talc poudrage, the frequency of pleurodesis remained higher in the PC group (35.7% [35/98] vs. 14.3% [38/265] in the non-PC group). The Fine and Gray competing risks model indicated higher likelihood of development of pleurodesis in the PC group than in the non-PC group (adjusted subhazard ratio 3.8, 95% CI: 2.5-5.87; $P < 0.001$; Fig. 2). The rate of death in the PC cohort was 57.3% (59/103) versus 62.3% (167/268) in the non-PC cohort (adjusted HR 1.01, 95% CI: 0.74-1.37). The median time to death after IPC placement in the entire cohort was 43 days (IQR 16-152). Compared with the non-PC cohort, the median time to death in the PC group was longer (108 d [IQR 33-322] vs. 34 d [IQR 14-109]). Kaplan-Meier curves for overall survival after date of IPC placement are shown in Figure 3.

DISCUSSION

The management of refractory symptomatic pleural effusions remains a complex clinical challenge. Although IPCs have emerged as an important tool in pleural effusion management, there remains a paucity of data regarding optimal follow up.[2,25] As improved pleural related outcomes have been reported when sub-specialist care is involved, PCs are increasingly being developed to provide specialist management of

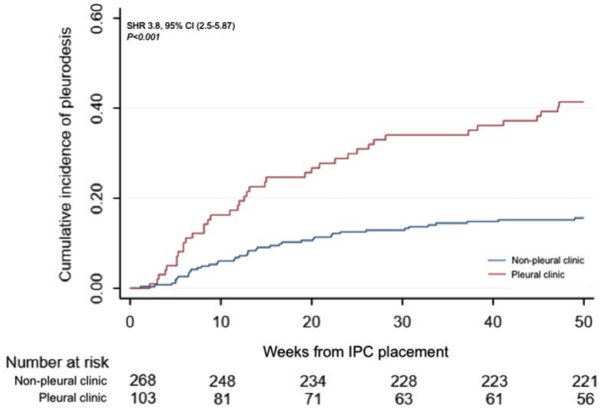

FIGURE 2. Cumulative incidence curve of pleurodesis success rate based on data estimated from Fine and Gray competing risks model. Number of patients at risk shown below. IPC indicates indwelling pleural catheter.

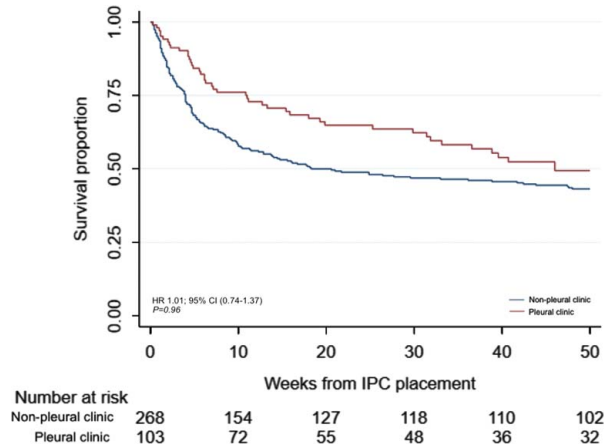

FIGURE 3. Kaplan Meier curve for overall survival after IPC placement. Number of patients at risk shown below. IPC indicates indwelling pleural catheter.

pleural disease through ambulatory care.[31,32] Our study sought to evaluate the impact of a dedicated PC on IPC related outcomes as they compare to non-specialist driven pleural care. To the best of our knowledge, this is the largest dataset analyzing a subset of patients followed in an IP dedicated PC with protocolized patient education and follow up.

In this cohort, there was a shift to ambulatory IPC placement after the implementation of the PC. In Addition, patients treated through the PC had fewer admissions before IPC placement compared with the pre-PC group. These findings are similar to that reported by Enríquez and colleagues,[32] who found that after the implementation of a pleural unit there was an increase in the number of procedures being done on an outpatient basis.[32] They also noted a decrease in readmissions for MPE from 9.3% to 2.9%, and a decrease in admission rates and length of stay for other pleural diseases, demonstrating a role for specialist pleural care.[32] Putnam and colleagues[21] described a reduction in hospitalizations, shorter duration of admissions (by as many as 7 d) and improved quality of life (QOL) when IPCs are placed on an outpatient basis. By shifting procedures to an elective ambulatory setting, patients avoid unnecessary hospital admissions. In Addition, ambulatory management of pleural effusions may reduce health care costs, as the cost for inpatient management of pleural effusions is up to 7.2 times higher than outpatient management.[33]

Aligning with guidelines, patients treated through the PC underwent fewer thoracenteses before IPC placement compared with the non-PC cohort.[29] Early IPC placement with fewer thoracenteses has been associated with reduced hospital length of stay and admission rates.[20,34] Serial thoracentesis may predispose patients to procedure related risks and pleural space organization. Ost and colleagues[35] quantitatively described this when they noted the strategy of repeat thoracentesis was associated with increased future procedures, complications, and ED visits in MPE when compared with early IPC placement. Furthermore, IPC related relief of symptoms is sustained and may enhance QOL when compared with the intermittent recurrence of dyspnea with interval thoracenteses. In NMPE, the REDUCE study found no differences in initial breathlessness for patients with refractory transudative effusions treated with serial thoracentesis versus IPC.[36] In a separate patient cohort of recurrent NMPE, serial thoracenteses lead to longer mean hospital stays (17.39 vs. 8.36 d) and an increased frequency of admissions when compared with the IPC group.[34] Taken together, these data support early discussion of IPC placement for patients with either NMPE or MPE related symptomatic refractory effusions.

The overall pleurodesis rate of 21.8% in our cohort is lower than that reported in the literature, with significantly higher rates of pleurodesis in our PC cohort (38.8%).[19] Muruganandan et al[27] and Wahidi et al[28] reported pleurodesis rates of 44% and 47%, respectively, when daily drainage regimens were used. Patients in the PC cohort were not routinely recommended to perform daily drainages and their drainage regimen was based on discussion with the patient. Typically, drainage regimens were initiated at thrice weekly and re-visited on follow up based on patient input. Detailed drainage regimens and instructions were documented in the chart and provided to the patient with additional educational material. In comparison, IPC drainage instructions for the non-PC cohort were inconsistently documented and management of the IPC was left to the referring provider. We suspect that the difference in pleurodesis rates between the PC and non-PC cohorts stems from several factors including early intervention before the development of nonreexpandable lung, and from clear management regimens communicated and taught to the patient. On average, time to pleurodesis was longer in all groups than that reported by the prior studies. Pleurodesis is a favorable side effect of IPC as the removal of the catheter liberates patients from the associated maintenance, infection risks, and costs.[37]

Median survival after IPC placement was 2.7 months in the PC cohort and 1.1 months in the non-PC cohort. These survival estimates are within the 1-to-13-month range reported for MPE, with a 1-year mortality for NMPE between 53% and –57%.[7,9–13] The difference in survival between the 2 cohorts may reflect earlier placement of IPC in the disease course for those treated by the PC clinic. It may also reflect any additional survival benefit obtained through early palliation of symptoms, as early utilization of palliative measures has been shown to improve QOL and even survival.[38]

Our findings suggest that protocolized drainage regimens with scheduled follow up in a dedicated PC may confer benefit through

decreased thoracenteses and increased rates of pleurodesis. Our post-IPC placement protocol includes an initial 2 week follow up visit to examine the insertion site and address post-placement issues. The 4-month visit assesses ongoing drainage needs. In review of the literature, scheduled follow up has varied. The AMPLE-1 study maintained follow up visits at 10 to 14 days, every 2 weeks for visits 2 to 4 and then every 4 weeks for visits 5 to 8.[26] The AMPLE-2 trial had follow-up at weeks 2 and 4 week, and thereafter monthly for 6 months by an unspecified clinic.[28] Overall, guidelines regarding postinsertion management are scarce and cite the paucity of data. In 2018, American Thoracic Society published weak recommendations regarding IPC placement for MPEs based on the available evidence and did not address postinsertion management.[29] In Addition, the American Association for Bronchoscopy and Interventional Pulmonology and The American Academy of Chest Physicians concluded that there was insufficient evidence based on the existing data to make recommendations regarding IPC postinsertion management.[2,25] This study provides real world data outside of the context of a clinical trial and supports the role of standardized post-IPC management and follow up.

This study has several limitations stemming from its single center, retrospective, and non-randomized design. The cohorts did not differ significantly by demographic factors though there is a possibility of unmeasured variables that may confound the relationship between PC and non-PC patient cohorts. Biases related to the increased frequency of IPCs placed in the inpatient setting by the non-PC cohort were unable to be accounted for. The single center nature of this study and center-specific practice patterns may limit generalizability to other populations. Given the single center nature, we were unable to include any outside hospital variables such as catheter removal at other sites or pleurodesis if not achieved locally, which may underestimate true rates of pleurodesis for both arms of this cohort. The relatively small number of events in each group may limit the ability to achieve statistical significance. In Addition, the teaching in the PC may lack interprovider standardization and patient ability to follow instructions (such as frequency of drainage) may vary and was not controlled for.

Despite the limitations, this study has several strengths. We studied a relatively large cohort of patients with both MPE and NMPE managed with IPC. Our study was designed as a comparative analysis utilizing a specific point in time when a dedicated PC was implemented. This allowed for a comparison of IPC related outcomes in the pre-PC and post-PC implementation periods of time. We demonstrated that the implementation of a dedicated PC run by IP providers can reduce admissions and achieve more frequent pleurodesis with IPC removal and thereby reduce IPC related burden to the patients while potentially providing a cost savings benefit.

In conclusion, this study provides a large single center retrospective analysis of pleural effusions managed with IPCs followed in a dedicated specialist PC. The data suggest that early involvement of dedicated specialists and routine follow up in a pleural clinic has a positive impact on pleural related outcomes, including lower rates of admissions with earlier IPC placement and higher rates of pleurodesis with catheter removal. Additional research is warranted on optimal post-IPC placement management.

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