Characterization of Elderly Patients Diagnosed with Idiopathic Pulmonary Fibrosis

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Background

Idiopathic pulmonary fibrosis (IPF) is a rare progressive and life-threating interstitial lung disease (ILD). Until recently, lung transplantation was the only treatment to impact prognosis in IPF patients. Recently approved pharmacotherapies for IPF are nintedanib and pirfenidone, both approved by the US Food and Drug Administration in October 2014. This study focuses on time prior to the marketing of pharmaceutical IPF treatments to provide background information about disease outcomes and comorbidities.

Objective

To characterize elderly patients newly diagnosed with IPF regarding demographics, healthcare resource utilization (HCRU), and clinical parameters.

To estimate prevalence and incidence rates (IRs) for a series of primary and secondary outcomes.

Data Source

Patients were drawn from a proprietary research database containing eligibility, pharmacy and medical claims from Optum's Medicare Advantage and Part D (MAPD) plan in the US. Occurrence and date of death was obtained from a linkage with the Social Security Administration Death Master File.

Methods

Study Design

- This was a non-interventional cohort study

Cohort Definition

- ≥ 1 medical claim with a diagnosis code of IPF between 01 January 2008 – 30 September 2014
- Age ≥ 65, medical and pharmacy benefits
- No claims for IPF or other ILD during the 12 month baseline period
- Follow-up continued until the earliest of: health plan disenrollment, death, a claim for another known cause of ILD, or end of the study period
- Subcohort with IPF diagnostic testing (surgical lung biopsy or high-resolution computed tomography)

Data Analysis

- Descriptive statistics of demographics, HCRU, and comorbidities prior to cohort entry
- Categorical variables presented as relative frequencies, while continuous variables presented as median and interquartile ranges (IQR)
- IRs calculated by dividing the number of patients with the outcome by the sum of all observation time-to-event or censoring, for the patients who did not have evidence of the condition during baseline
- All analyses conducted using SAS 9.4

Approvals

- This study was approved by the Western Institutional Review Board

Results

- Eligibility criteria were met by 4,716 patients; 53.4% had diagnostic testing
- Demographics and selected HCRU are shown in Table 1
- IRs for outcomes ranged from 1.0/1,000 person-years (pys, LT) to 374.3/1,000 pys (arterial hypertension) (Table 2)
- Baseline characteristics and IRs were similar for the IPF cohort and the subgroup with diagnostic testing

Table 1: Baseline Characteristics of IPF Patients, 01 January 2008 - 30 September 2014

	IPF Cohort (N = 4,716)		IPF Diagnostic Testing Subgroup (N = 2,518)	
	N	%	N	%
Age (years)				
65 - 74	1,683	35.7	981	39.0
75 - 84	2,633	55.8	1,366	54.2
85 +	400	8.5	171	6.8
Sex				
Male	2,374	50.3	1,319	52.4
Female	2,342	49.7	1,199	47.6
Geographic Area				
Northeast	821	17.4	467	18.5
Midwest	1,665	35.3	909	36.1
South	1,776	37.7	911	36.2
West	454	9.6	231	9.2
Cohort Entry Period				
2008 - 2009	970	20.6	525	20.8
2010 - 2011	1,401	29.7	731	29.0
2012 - 2014	2,345	49.7	1,262	50.1
Three or More Medications	3,910	82.9	2,115	84.0
Any Hospitalization (yes/no)	2,396	50.8	1,401	55.6
	Median	IQR	Median	IQR
Number of Physician Visits	12	8.0 – 19.0	14	9.0 – 21.0
Total Costs ($, US)	11,865	5,465 - 25,713	13,798	6,739 - 30,886

Results (Continued)

Table 2: Baseline Prevalence and Incidence Rates of Outcomes in IPF Patients, 01 January 2008 - 30 September 2014

Primary Outcomes	Prevalence (%)	IR[1,2,3]	95% CI
Acute Respiratory Worsening of Unknown Cause	2.7	19.0	15.6 - 22.8
Pulmonary Hypertension	4.6	46.0	40.6 - 51.9
Pulmonary Arterial Hypertension	0.2	2.2	1.2 - 3.7
Lung Transplantation (LT)	0.2	1.0	0.4 - 2.2
Lung Cancer	16.1	26.0	21.7 - 30.9
Acute Myocardial Infarction	2.7	34.4	29.8 - 39.5
All-Cause Mortality	n/a	180.4	169.8 - 191.5
Secondary Outcomes			
Gastrointestinal (GI) Perforation	0.2	5.0	3.4 - 7.2
Chronic Renal Failure/Insufficiency	26.5	152.9	141.2 - 165.2
Hemorrhagic Diathesis or Coagulopathy	2.5	23.4	19.6 - 27.7
Venous Thrombosis	6.4	47.5	41.9 - 53.6
Pulmonary Embolism	3.3	25.0	21.1 - 29.5
Stroke	3.8	33.2	28.6 - 38.3
Cardiac Arrhythmia	34.2	178.1	164.5 - 192.4
Congestive Heart Failure	31.7	162.4	150.0 - 175.4
Ischemic Heart Disease	40.4	154.5	141.2 - 168.8
Arterial Hypertension	76.3	374.3	338.6 - 412.8
Neutropenia	0.8	9.3	7.0 - 12.1
Pneumonia	9.2	72.2	65.1 - 79.8
Sepsis	5.2	62.0	55.7 - 68.9
Chronic obstructive pulmonary disease	51.5	247.1	227.8 - 267.5
Gastroesophageal reflux disease	28.0	154.5	142.0 - 167.8
Type 2 Diabetes Mellitus	32.5	59.3	51.9 - 67.4
Obstructive sleep apnea	8.1	33.0	28.3 - 38.3
Bronchitis	40.5	243.9	226.2 - 262.7
Upper Respiratory Tract Infection	9.6	67.9	60.9 - 75.6
Pulmonary Rehabilitation	1.6	22.5	18.8 - 26.7
Acute Coronary Syndrome	3.1	24.4	20.5 - 28.9
Angina Pectoris	5.4	27.5	23.3 - 32.2
Bleeding	12.0	115.6	106.1 - 125.7
Major GI Bleeding (Upper)	1.6	15.2	12.2 - 18.7
Major GI Bleeding (Lower)	6.6	58.4	52.1 - 65.3
Hemorrhage of the Rectum or Anus	2.5	22.6	18.9 - 26.9
Blood in Stool	2.7	29.0	24.7 - 33.7
Epistaxis	2.5	25.2	21.3 - 29.7
Hemorrhoids	2.2	19.9	16.4 - 23.9
Hemorrhoidal Bleeding	0.6	5.2	3.6 - 7.4
Intracranial Hemorrhage	0.8	9.8	7.4 - 12.7
Acute Pancreatitis	1.0	6.3	4.4 - 8.6
Hepatic Failure	0.3	3.7	2.3 - 5.6
Acute Renal Failure	13.0	97.5	89.2 - 106.4
Depression (Major depressive disorder only)	12.2	80.2	72.5 - 88.5
Depression (Major depressive disorder and other)	13.7	86.9	78.8 - 95.7

Abbreviations: Incidence Rate per 1,000 person-years: IR; Confidence Interval: CI

[1]The median follow-up time was 0.8 years

[2]Occurrence of one outcome did not preclude the occurrence of another

[3]Among patients without the condition during baseline

Discussion

- IPF patients aged 65 years and above have high morbidity and mortality
- The observed occurrences of pulmonary and extra pulmonary conditions in this cohort are within the range of other published findings, despite potential differences in study populations, data sources and outcome definitions[1,2]
- Strengths include:
  - The Optum-MAPD contains millions of lives, allowing for broader investigations of drug use patterns and rare diseases and outcomes
  - Some of the outcomes in this study have only rarely been assessed in IPF populations, and other outcomes, such as hepatic failure, acute pancreatitis, acute renal failure, and bleeding, are being assessed for the first time
- Limitations include:
  - Study was conducted in an automated medical and prescription claims database which was not created for research purposes
  - Some outcomes may not require medical attention and are not well captured in medical claims, which potentially leads to underestimation

[1]Raghu G, Amatto VC, Behr J, Stowasser S. Comorbidities in idiopathic pulmonary fibrosis patients: a systematic literature review. Eur Respir J. 2015;46(4):1113-30.

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