Treatments and Outcomes of Idiopathic Pulmonary Fibrosis in a Medicare Population Prior to Approval of Anti-fibrotic Therapies

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INTRODUCTION

- Idiopathic pulmonary fibrosis (IPF) is a progressive fibrotic lung disease associated with high mortality: incidence of 93.7 per 100,000 person-years (95% CI: 91.9 - 95.4) and median survival of 3.8 years (95% CI: 3.5 - 3.8).[1]
- Past treatment modalities aimed at minimizing inflammation or managing disease symptoms have failed to increase survival or improve quality of life in sizeable clinical trials.[2,3]
- Other commonly employed therapeutic recommendations are mainly supportive and include supplemental oxygen, pulmonary rehabilitation and management of associated conditions, in particular gastroesophageal acid reflux which has been associated with worsening of IPF.[4]
- A select minority of patients may be candidates for lung transplantation.[4]

OBJECTIVES

- To describe real-world treatment patterns and respiratory-related hospitalizations in Medicare patients with a claims-based diagnosis of IPF prior to the approval of anti-fibrotic treatments.

METHODS

Study Design and Data Source
- Retrospective cohort study of Medicare beneficiaries newly diagnosed with IPF in 2010.
- Data derived from the Medicare Research Identifiable Files (RIFs) containing demographic, enrollment, and health service claims data for all Medicare beneficiaries.
- Patients were followed for at least 1 year (unless death occurred) and up to 4 years after diagnosis.

Patient Population
- Inclusion criteria for identification of IPF patients, adapted from prior study[1] **(Figure 1)**.

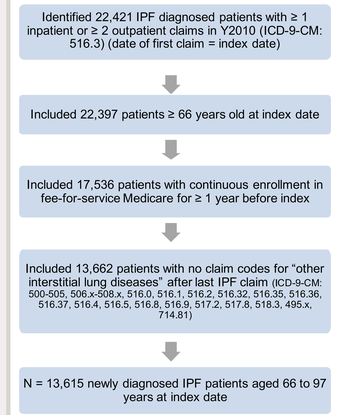
Study Measures
- Outcome measures:
  - Proportion of patients receiving IPF-related treatments during follow-up (1 year reported): pulmonary rehabilitation, oxygen therapy, acute corticosteroids (IV and IM), mechanical ventilation (MV; invasive and non-invasive), and lung transplant.
  - Proportion of patients with respiratory-related hospitalization during follow-up.
  - We also examined treatment and hospitalization frequencies during the year prior to diagnosis to assess potential empiric treatment.
  - Baseline characteristics included age, gender, geographic region, and race.

Statistical Analysis
- Descriptive statistics used to examine proportions of patients receiving treatments and respiratory-related hospitalizations and to assess baseline characteristics.
- Kaplan-Meier curves were generated to assess the probability of different therapies and outcomes over time.

RESULTS

Baseline Characteristics
- Identified 13,615 newly-diagnosed IPF patients with a qualifying claim.
- Median follow-up time was 2.8 years.
- Mean (SD) age was 78.9 (7.1) years; 49.7% were female **(Table 1)**.

Figure 1. Patient Selection



IPF-related Treatments
- By one year after receiving an IPF diagnosis, 69.7% of patients had pulmonary rehabilitation and 65.6% received oxygen therapy with the majority of these procedures occurring within the first year of diagnosis. 21.7% and 8.6% of patients received IV/IM corticosteroids and MV, respectively. Only 44 (0.3%) patients received a lung transplant during this period **(Figure 2)**.
- Prior to IPF diagnosis the rates of treatments were relatively similar: 58.1% had pulmonary rehabilitation and 51.9% had oxygen therapy, 25.0% IV/IM corticosteroids, 3.7% MV, and 0% lung transplant **(Figure 2)**.
- Use of pulmonary rehabilitation, oxygen therapy, and IV/IM corticosteroids increased significantly over 4 years of follow-up **(Figure 3)**, with median times until occurrence of 49, 36, and 1,236 days, respectively (median not reached for MV or lung transplant) **(Figure 3)**.

Respiratory-related Hospitalizations
- 28.0% of patients had at least 1 respiratory-related hospitalization during the 1 year after diagnosis **(Figure 2)**.
- In the year prior to diagnosis 19.7% of patients had such hospitalization.
- Hospitalizations increased during the entire follow-up period with the 25th percentile time to hospitalization = 232 days (median not reached) **(Figure 3)**.

Table 1. Demographic Characteristics of IPF Patients

Age in years, mean (SD)	78.9 (7.1)
Male, n (%)	6,847 (50.3)
Region, n (%)	
South	5,238 (38.5)
Midwest	3,499 (25.7)
Northeast	2,559 (18.8)
West	2,311 (17.0)
Other/Unknown	8 (0.1)

Figure 2. Frequencies of IPF-related Treatments and Respiratory-related Hospitalizations before and after IPF Diagnosis

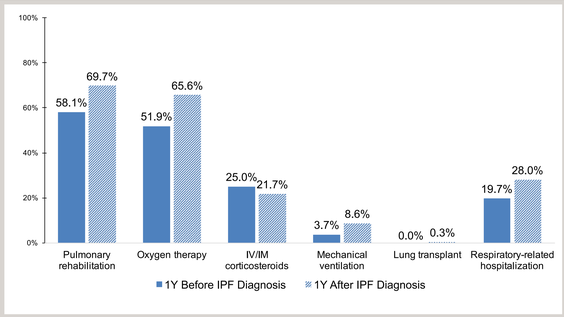
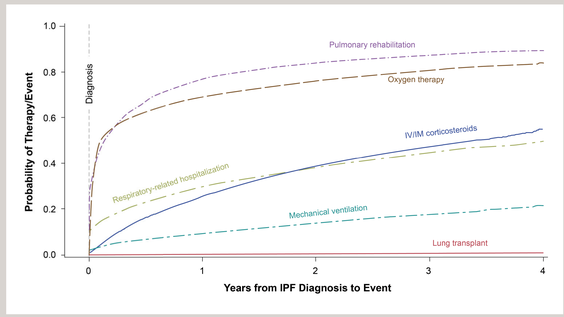


Figure 3. Probabilities of IPF-related Treatments and Hospitalizations after Diagnosis



LIMITATIONS

- Claims-based diagnoses of IPF may not capture all patients with IPF and could be improved by requiring receipt of chest CT as part of the IPF diagnostic criteria.
- Due to changes in interstitial lung disease (ILD) classification and related diagnosis codes, some ILDs may be inaccurately classified; however, prior studies have used the proposed ICD-9-CM codes and algorithms to identify IPF cases based on administrative claims data.
- This study was limited to fee-for-service Medicare beneficiaries and thus may not be generalizable to other types of insurance and age groups. However, patients 70 and older represent the largest proportion of IPF cases.
- These data come from the period before the introduction of FDA-approved anti-fibrotic agents; thus, treatment patterns may have changed since.

CONCLUSIONS

- For many patients, empiric treatment and acute care begin prior to establishing an IPF diagnosis, presumably to alleviate symptoms or comorbid conditions. Care before and after diagnosis was remarkably similar, which may simply reflect the lack of effective anti-fibrotic therapy at the time of this study.
- The majority of Medicare patients with IPF receive supportive treatments such as pulmonary rehabilitation or oxygen therapy.
  - Despite not being recommended by treatment guidelines, IV/IM corticosteroid use was relatively common. A minority of Medicare enrollees received a lung transplant, the only curative treatment option for IPF, although this may reflect the small proportion of older patients (i.e. > 65 years) among lung transplant recipients.[5,6]
- As clinicians become comfortable using newly approved anti-fibrotic agents, one might expect an increasing urgency to establish a diagnosis of IPF, and more dramatic differences before and after the diagnosis is made.

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