Testing Leading to the Diagnosis of Idiopathic Pulmonary Fibrosis in Medicare Patients

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INTRODUCTION

- Idiopathic pulmonary fibrosis (IPF) is a deadly progressive fibrotic lung disease.[1]
- Establishing accurate diagnosis of IPF is challenging.
  - Median delay to diagnosis is 2.2 years.[2]
  - Delayed access to a tertiary care center and accurate diagnosis is associated with higher mortality rate in IPF, independent of disease severity.[2]
  - Recent advances make early treatment (and diagnosis) crucial, as treatment may slow disease progression.

OBJECTIVES

- Describe the pattern of diagnostic testing and pulmonologist visits, both proxies for respiratory symptoms, experienced by Medicare enrollees prior to receiving a claim-based diagnosis of IPF.

METHODS

Study Design and Data Source

- Retrospective cohort study of Medicare enrollees diagnosed with IPF in 2012.

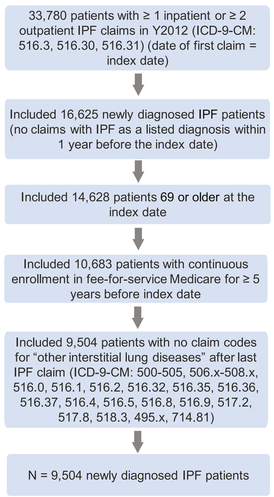
Patient Population

- Inclusion criteria are illustrated in Figure 1.

Study Measures

- Patient demographics, time to event and cumulative proportions of IPF patients receiving first respiratory test and first pulmonologist visit within 5 baseline years preceding IPF diagnosis.
  - Diagnostic tests included chest X-ray, chest computerized tomography [CT, including high-resolution chest CT (HRCT)][a], pulmonary function testing (e.g. spirometry), oxygen saturation, anti-nuclear antibodies (ANA)[b], six-minute walk test, arterial blood gas, fiberoptic bronchoscopy, lung biopsy, precipitin panel, and cardiopulmonary exercise testing.
- Distribution of CT scans per patient to show temporal patterns, such as repeated occurrence of tests before diagnosis and time frame of those tests.

Figure 1. Patient Population (N=9,504)



Statistical Analysis

- Descriptive statistics
- Kaplan-Meier curves showed proportions of first test/visit over time and time from test/visit until IPF diagnosis.

RESULTS

Demographics

- We identified 9,504 Medicare patients newly diagnosed with IPF in 2012.
- Mean (SD) age was 81.2 (6.4) years; 49.5% were female; and all geographic regions were represented in the sample **(Table 1)**.
- The majority of patients were White (94.1%) followed by Black (3.0%), then Hispanic, Asian, and other patients (2.9%) **(Table 1)**.

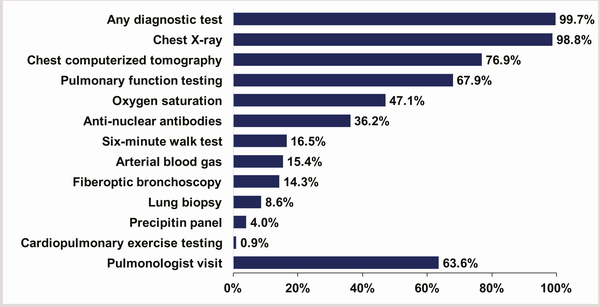
Table 1. Patient Demographics of Newly Diagnosed IPF Patients in Y2012 (N=9,504)

Age (y), mean (SD) [Median]	81.2 (6.4) [81]
Female, n (%)	4,708 (49.5)
Region, n (%)	
Midwest	2,485 (26.1)
Northeast	1,791 (18.8)
South	3,835 (40.4)
West	1,391 (14.6)
Other/Unknown	2 (0.0)
Race, n (%)	
White	8,948 (94.1)
Black	283 (3.0)
Hispanic	73 (0.8)
Asian	55 (0.6)
Other/Unknown	145 (1.5)

Frequency of Testing and Visit prior to IPF Diagnosis

- Nearly all patients (99.7%) had at least 1 test of interest in the 5 years leading to and including the date of diagnosis **(Figure 2)**.
- By the 4th year prior to diagnosis 14.7% had a chest CT and by the 3rd year prior, 25.0% had one **(Figure 3)**.
- By the time of diagnosis, three-quarters (76.9%) of patients had a chest CT **(Figure 2)**.
- About two-thirds (63.6%) of patients had at least 1 pulmonologist visit prior to an IPF diagnosis **(Figure 2)**.

Figure 2. Cumulative Proportions of Patients Receiving First Diagnostic Test and First Pulmonologist Visit during the 5 Years[a] prior to IPF Diagnosis (N=9,504)



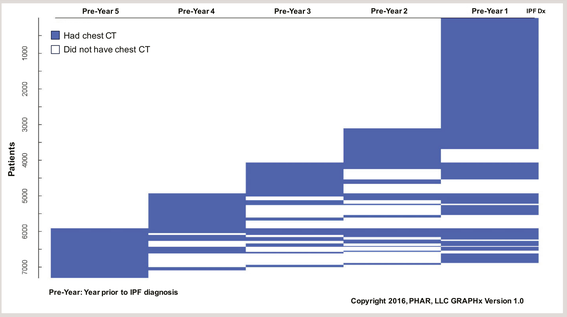
Time from Testing and Visit to IPF Diagnosis

- Only chest X-rays, chest CTs, pulmonary function tests, and pulmonologist visits were received by >50% of IPF patients in the 5 years pre-diagnosis **(Figure 2)**.
- This median was reached earliest for chest X-rays (47 months before diagnosis), followed by chest CTs (6.9 months), and pulmonary function tests (5.4 months) indicating a lag between most testing and diagnosis **(Figure 4)**.
- Use of all studied tests and visits to the pulmonologist increased immediately prior to diagnosis **(Figure 4)**.
- Sensitivity analysis of rates and timing of tests/visits among IPF patients who received a chest CT showed similar results (results not shown).

Distribution of Chest CTs

- Among the 7,306 patients who received a chest CT, some had a single scan while others had multiple scans prior to diagnosis. Multiple scans occurred both continuously from year to year and following yearly gaps. **(Figure 3)**.

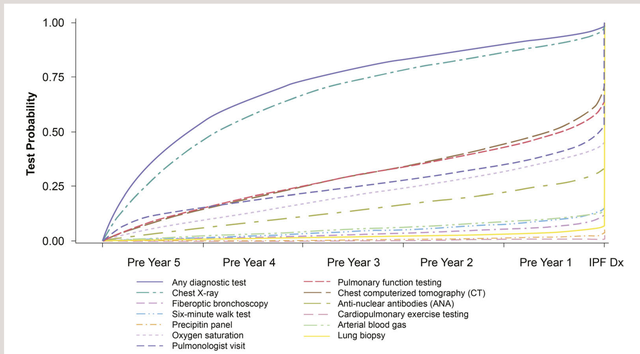
Figure 3. Distribution of Chest CT Prior to IPF Diagnosis, by Patient (N=7,306)



LIMITATIONS

- Claims-based diagnosis of IPF may not capture all patients with IPF and could be improved by requiring receipt of a chest CT as part of the IPF diagnostic criteria.
- Due to changes in classification and diagnosis codes, some interstitial lung diseases may be inaccurately classified; however, prior studies have used the proposed codes and algorithms to identify IPF cases based on claims data.
- There is no specific procedure code for HRCT of the chest.
- This study was limited to fee-for-service Medicare enrollees 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.

Figure 4. Time from First Diagnostic Test and First Pulmonologist Visit to IPF Diagnosis (N=9,504)



CONCLUSIONS

- Results confirm many tests are performed in the 5 years prior to establishing a diagnosis of IPF. Most, but not all, patients had a pulmonologist visit prior to diagnosis.
- Not all patients with a claims-based IPF diagnosis received recommended testing prior to their diagnosis.
- Chest CT is recommended as a crucial test in the initial evaluation of suspected IPF[1], yet only about three-fourths of patients received a chest CT.
- The majority of initial pulmonologist visits occurred more than a year before the first IPF diagnosis, suggesting an opportunity for earlier diagnosis.
- More work is needed to understand whether our findings reflect a lack of knowledge among clinicians about what to do when respiratory symptoms present or a lack of urgency to establish a diagnosis in the absence of more effective treatments. Further research should focus on diagnostic testing and visits among centers of excellence to determine whether results vary.
- In the United States, as of 2012, there were no approved treatments for IPF.
- **Opportunities may exist for earlier diagnosis, potentially leading to earlier treatment and improved patient outcomes.**

REFERENCES

1 Raghu G, et al. *Lancet Respir Med*. 2014 Jul;2(7):566-72.
2 Lamas, et al. *Am J Respir Crit Care Med*. 2011;184(7):842-847.

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[a] Procedure codes for high-resolution and routine CT are the same. [b] Includes ANA, Rheumatoid Factor, DNA (DS) Antibodies, Sm and Sm/RNP Antibodies, Scleroderma Antibodies (SCLA-70), and Sjögren's Antibodies (SSA, SSB).

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