Changes in lung function and changes in patient-reported outcomes in patients with idiopathic pulmonary fibrosis (IPF)

IPF-PRO™ ILD-PRO™

Jamie L Todd,[1,2] Megan L Neely,[1,2] Anne S Hellkamp,[1,2] Daniel A Culver,[3] Justin M Oldham,[4] Peide Li,[5] Scott M Palmer[1,2] on behalf of the IPF-PRO Registry investigators

[1]Duke Clinical Research Institute, Durham, NC, USA; [2]Duke University Medical Center, Durham, NC, USA; [3]Cleveland Clinic, Cleveland, OH, USA; [4]Division of Pulmonary and Critical Care Medicine, University of Michigan, Ann Arbor, MI, USA; [5]Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA.

INTRODUCTION

- As IPF progresses, patients experience deterioration in lung function and health-related quality of life (HRQL).[1,2] However, the relationships between changes in lung function and meaningful differences in HRQL remain uncertain.
- Understanding the minimal important change to the patient (MICP) of clinical measures, *i.e.*, the smallest difference in a measure that is perceived as important by patients, is important to assist clinicians in the interpretation of changes in these measures.

AIM

- To assess relationships between changes in lung function and changes in HRQL, and to estimate MICPs in lung function measures, in patients with IPF.

METHODS

The IPF-PRO Registry

- The IPF-PRO Registry is a prospective observational registry of patients with IPF.[3] Patients with IPF that was diagnosed or confirmed at the enrolling center in the prior 6 months were enrolled at 46 US sites.
- Patients were followed prospectively, with data on lung function and HRQL collected as part of usual care.

Analyses

- HRQL was assessed using the St George's Respiratory Questionnaire (SGRQ)[4] total and activity domain scores and 12-item Short Form Survey (SF-12) questionnaire[5] physical component summary (PCS) score.
- As lung function measurements varied in frequency and timing, a joint model based on measurements and visit frequency was used to generate estimates for FVC % predicted and DLco % predicted for each patient for each day of follow-up. This provided estimates for the measures of lung function at the same time-points as the measures of HRQL.
- Correlations between FVC and DLco % predicted and each HRQL measure, and between changes in these measures from enrollment to 12 months and from 12 to 24 months, were assessed using Pearson correlation coefficients (r).
- MICPs for FVC and DLco % predicted were estimated using two anchor-based approaches:
  - Receiver operating characteristic (ROC) curves were constructed to identify thresholds of change in each lung function measure that best divided patients into those who had versus did not have a ≥5-unit increase (worsening) in SGRQ activity score and/or ≥5-unit decrease (worsening) in SF-12 PCS score.
  - A logistic regression approach was applied to classify patients into those who had versus did not have this degree of deterioration in one or both anchors.

CONCLUSIONS

- Among patients in the IPF-PRO Registry, changes in lung function were not closely related to changes in the SGRQ activity domain score or SF-12 PCS score over 12 months.
- No threshold of change in lung function reliably distinguished patients with versus without a meaningful concurrent deterioration in HRQL.
- These findings highlight the importance of assessing both lung function and HRQL in patients with IPF.

RESULTS

Baseline characteristics of analysis cohort (n=736)

Male	539 (73.2)
Age, years	70 (65, 75)
Ever smoker	494 (67.1)
FVC % predicted	73.9 (64.0, 85.5)
DLco % predicted	44.2 (35.3, 53.2)
SGRQ total score	36.7 (23.9, 49.9)
SGRQ activity score	53.6 (35.8, 71.0)
SF-12 PCS score	40.0 (33.0, 46.7)
Oxygen use at rest and with activity	96 (13.0)
Oxygen use with activity only	112 (15.2)

The analysis cohort included all patients with ≥1 value for the SGRQ activity score between 3 and 27 months after enrollment. Data are median (Q1, Q3) or n (%) of patients. Not all patients provided data for all variables.

Correlations (r) between FVC % predicted and patient-reported outcomes and between changes in these measures

	SGRQ activity score	SGRQ total score	SF-12 PCS score
At enrollment	−0.31	−0.29	0.26
At 12 months	−0.37	−0.38	0.28
At 24 months	−0.40	−0.37	0.30
Change from enrollment to 12 months	−0.28	0.08	0.20
Change from 12 to 24 months	−0.25	−0.35	0.35

Correlations (r) between DLco % predicted and patient-reported outcomes and between changes in these measures

	SGRQ activity score	SGRQ total score	SF-12 PCS score
At enrollment	−0.32	−0.29	0.24
At 12 months	−0.42	−0.39	0.29
At 24 months	−0.43	−0.38	0.33
Change from enrollment to 12 months	−0.15	0.11	0.06
Change from 12 to 24 months	−0.20	−0.24	0.23

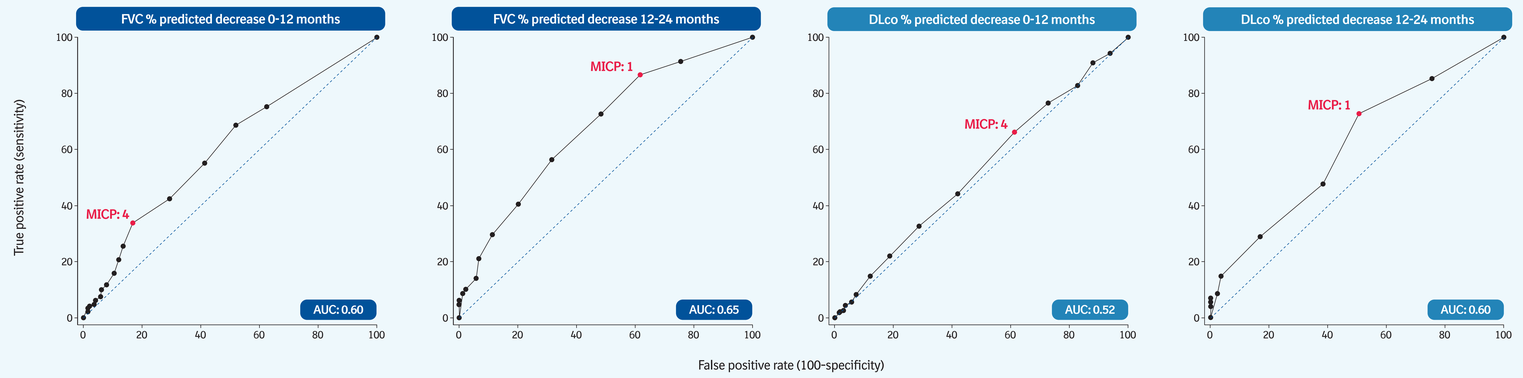
Estimated MICP for FVC % predicted

	Enrollment to 12 months	12 to 24 months
ROC curve	−4	−1
Logistic regression	−3	−3

Estimated MICP for DLco % predicted

	Enrollment to 12 months	12 to 24 months
ROC curve	−4	−1
Logistic regression	−5	−2

ROC curves for changes in FVC and DLco % predicted and deterioration in anchors (SGRQ activity score and/or SF-12 PCS score) during the same period



The area under the curve (AUC) indicates the ability of the predictor to discriminate between the outcomes. An AUC of 1 indicates perfect discrimination and an AUC of 0.5 indicates that the predictor is no better than a random guess. A random guess would yield a point along the blue dashed line. Red dots indicate the value selected as the MICP.

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IPF-PRO Registry enrolling centers: Albany Medical Center, Albany, NY; Baylor College of Medicine, Houston, TX; Baylor University Medical Center at Dallas, Dallas, TX; Cleveland Clinic, Cleveland, OH; Columbia University Medical Center/New York Presbyterian Hospital, New York, NY; Duke University Medical Center, Durham, NC; Froedtert & The Medical College of Wisconsin Community Physicians, Milwaukee, WI; Houston Methodist Lung Center, Houston, TX; Lahey Clinic, Burlington, MA; Loyola University Health System, Maywood, IL; Lynchburg Pulmonary Associates, Lynchburg, VA; Medical University of South Carolina, Charleston, SC; National Jewish Health, Denver, CO; NYU Medical Center, New York, NY; Piedmont Healthcare, Austell, GA; Pulmonary Associates of Stamford, Stamford, CT; PulmonIx LLC, Greensboro, NC; Renovatio Clinical, The Woodlands, TX; Salem Chest and Southeastern Clinical Research Center, Winston Salem, NC; South Miami Hospital, South Miami, FL; St. Joseph's Hospital, Phoenix, AZ; Stanford University, Stanford, CA; Temple University, Philadelphia, PA; The Oregon Clinic, Portland, OR; Tulane University, New Orleans, LA; UNC Chapel Hill, Chapel Hill, NC; University of Alabama at Birmingham, Birmingham, AL; University of California, Davis, Sacramento, CA; University of California Los Angeles, Los Angeles, CA; University of Chicago, Chicago, IL; University of Cincinnati Medical Center, Cincinnati, OH; University of Louisville, Louisville, KY; University of Miami, Miami, FL; University of Michigan, Ann Arbor, MI; University of Minnesota, Minneapolis, MN; University of Pennsylvania, Philadelphia, PA; University of Pittsburgh, Pittsburgh, PA; University of Virginia, Charlottesville, VA; UT Southwestern Medical Center, Dallas, TX; Vanderbilt University Medical Center, Nashville, TN; Vermont Lung Center, Colchester, VT; Wake Forest University, Winston Salem, NC; Washington University. St. Louis, MO; Weill Cornell Medical College, New York, NY; Wilmington Health and PMG Research, Wilmington, NC; Yale School of Medicine, New Haven, CT.

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