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

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Rationale: As IPF progresses, patients experience deterioration in lung function and health-related quality of life (HRQL). We used data from the IPF-PRO Registry to assess relationships between changes in physiologic measures and changes in patient-reported outcomes (PROs).

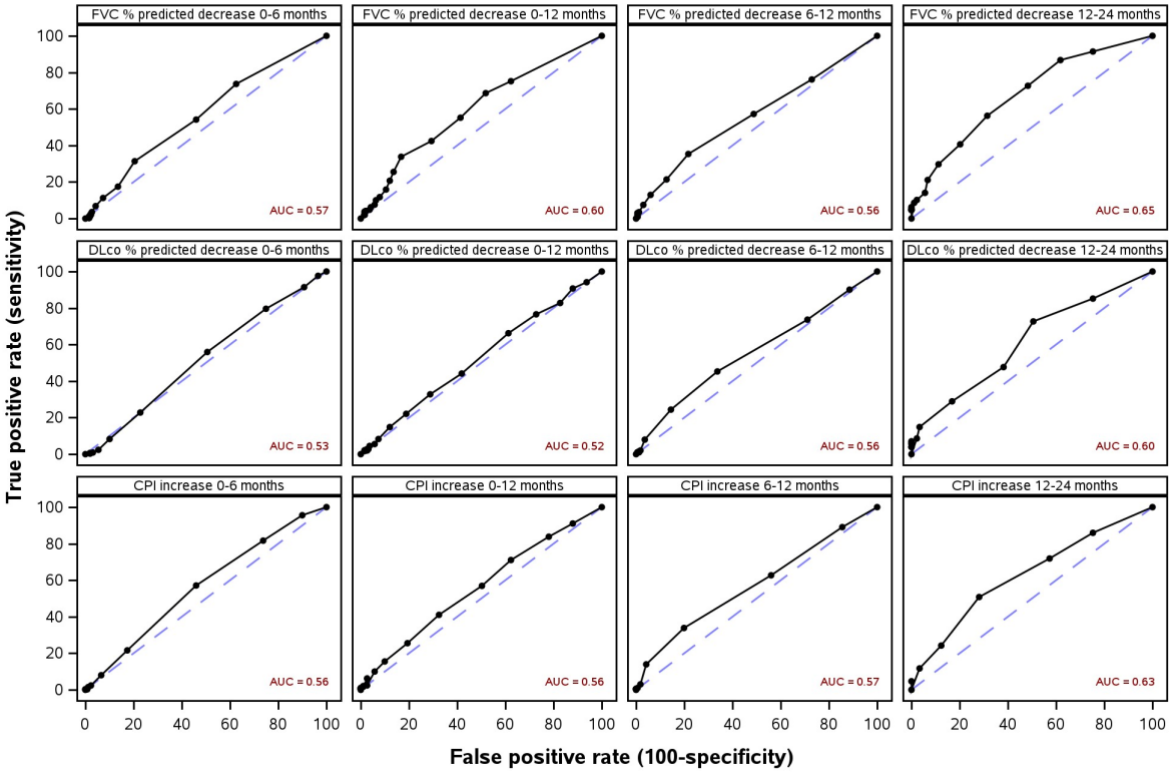
Methods: The IPF-PRO Registry enrolled patients with IPF that was diagnosed or confirmed at the enrolling center in the previous 6 months. FVC and DLco were measured as part of the patient's usual care. The composite physiologic index (CPI) was calculated based on % predicted values for FVC, DLco and FEV_1. A joint model provided estimates for these physiologic measures during follow-up. Receiving operating characteristic (ROC) curves were constructed for each measure to identify the value that best divided patients who had versus did not have a deterioration in PROs (*i.e.,* a worsening of ≥5 points in the St George's Respiratory Questionnaire (SGRQ) activity domain score and/or worsening of ≥5 points in the 12-item short form survey (SF-12) physical component summary [PCS]) score from enrollment to 6 months, enrollment to 12 months, 6 to 12 months, 12 to 24 months. Correlations between changes in physiologic measures and changes in PROs over the same interval were assessed using Pearson correlation coefficients (r).

Results: The analysis cohort included 736 patients. At enrollment, estimated median (Q1, Q3) FVC % predicted was 73.7 (63.5, 84.6), DLco % predicted was 43.5 (36.5, 52.3) and CPI was 50.2 (43.6, 56.3). ROC curves indicated that none of these measures discriminated patients who had versus did not have deterioration in the PROs; area under the curve (AUC) values ranged from 0.52 to 0.65 (Figure). From enrollment to 6 months, enrollment to 12 months, 6 to 12 months and 12 to 24 months, respectively, correlations between changes in FVC % predicted and changes in the PROs were 0.16, 0.29, 0.16 and 0.30, correlations

between changes in DLco % predicted and changes in the PROs were −0.003, 0.14, 0.08 and 0.24, and correlations between changes in CPI and changes in the PROs were −0.07, −0.22, −0.12 and −0.30.

Conclusion: Among patients in the IPF-PRO Registry, changes in physiologic measures were not closely related to changes in the SGRQ activity domain score or SF-12 PCS over 6 to 12-month periods. No cut-off threshold for changes in physiologic measures reliably distinguished patients with a larger deterioration in lung function and meaningful decline in HRQL from those who did not have a meaningful decline in HRQL.

Figure. Receiver operating characteristic (ROC) curves for change in FVC % predicted, DLco % predicted and CPI and deterioration in SGRQ activity domain and/or SF-12 PCS score of ≥5 points during the same period.



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