Real-World Clinical Characteristics of 112 Patients with Interstitial Lung Disease (ILD); Update from the Trio Health ILD Registry

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1. BACKGROUND AND AIM

The TRIO ILD registry consists primarily of patients with Idiopathic Pulmonary Fibrosis (IPF) and contains data reflecting current care trends and patient populations. Here we present baseline demographic and clinical assessments on 112 registry patients.

2. METHODS

TRIO-ILD registry is an observational, retrospective, and prospective registry. Demographic and clinical data are collected from 6 US tertiary care centers.

Registry inclusion: Patients >40 years old, diagnosed with ILD, receiving pirfenidone and/or nintedanib within 12 months prior to enrollment, and not in a clinical trial. The enrollment period was Jul 2019 to Sep 2020.

Gender, Age, and Physiology (GAP) scores were determined per Ley B et al. (2012) Ann Intern Med. 156(10):684 (doi: 10.7326/0003-4819-156-10-201205150-00004). Note that "unable to perform" for predicting DLCO was not captured and therefore not considered in the score calculation. GAP scores were converted into stages where 0-3 = stage I, 4-5 = stage II, and 6-8 = stage III. Stages are associated with estimated 2-year mortality of 10.9% (stage I), 29.9% (stage II), and 62.1% (stage III). See https://www.mdcalc.com/gap-index-idiopathic-pulmonary-fibrosis-ipf-mortality#evidence for details.

3. RESULTS

Demographic characteristics of the registry population and subsets by disease and by GAP stage are indicated in TABLE 1.

Most registry patients are male (70%, 78), white (80%, 88/110), and former smokers (71%, 77/109). At enrollment, median (range) age was 74 (52 to 92) years with 76% (84/111) >65 years old. 73 of 112 ILD patients have IPF with confirmation by CT scan (70%, 48/69), biopsy (26%, 18/69), or other (4%, 3/69). Family history of ILD or IPF was present in 14% (14/100).

At enrollment, 17% (19/109) of patients had FVC <50%, 33% (26/79) DLCO <36%, and 11% (12/105) 6-min walk distance (6MWD) <165 m. Most common comorbidities (TABLE 2) at enrollment were hypertension (54%, 60) and GERD (52%, 58).

GAP scores based on measures at enrollment were calculable for 78 of 112 patients; 27% (21) had stage I, 56% (44) stage II, 17% (13) stage III (TABLE 1, FIGURE 1).

Enrollment measures for 6MWD, FVC, and DLCO for the total population and within GAP stage subsets are provided in FIGURES 2-4. In comparison to patients with GAP stage I or II, a larger proportion of patients with GAP stage III had reduced 6MWD (6MWD <165m: 42% III v. 7% II or 10% I [FIGURE 2]), FVC (FVC <50%: 46% III v. 7% II or 5% I [FIGURE 3]), and DLCO (DLCO <36%, 85% III v. 27% II or 10% I [FIGURE 4]).

A greater proportion of patients with GAP stage III indicated use of supplemental oxygen (92% III v. 41% II or 43% I) with most (82%) receiving continuous oxygen therapy [FIGURE 5]. Similarly, pulmonary rehabilitation was more common in the GAP stage III group (67% III v. 50% II or 41% I); 25% of GAP stage III respondents with pulmonary rehabilitation were in rehabilitation at time of enrollment [FIGURE 6].

4. CONCLUSION

The TRIO ILD Registry contains an older population (median age 74) with a large proportion of current/former smokers (73%) and considerable proportions with severe functional impairment (11% with <165m 6MWD, 17% with FVC <50%, 33% with DLCO <36%); populations not well represented in clinical trials.

Ongoing data collection in this contemporary registry should provide insight into opportunities for care optimization in US clinical practice.

TABLE 1 — PATIENT DEMOGRAPHICS AT ENROLLMENT

Characteristic	All Patients (n=112)	by Diagnosis		by GAP Stage			
		IPF (n=73)	Other ILD (n=39)	Stage I (n=21)	Stage II (n=44)	Stage III (n=13)	Not calculable (n=34)
Age; median (range)	74 (52,92)	72 (52,92)	76 (57,91)	69 (57,90)	74 (52,91)	75 (69,88)	73 (52,92)
Age; N (%)							
≤60	4/111 (4%)	3/72 (4%)	1 (3%)	2 (10%)			2/33 (6%)
61-65	23/111 (21%)	17/72 (24%)	6 (15%)	8 (38%)	11 (25%)		4/33 (12%)
>65	84/111 (76%)	52/72 (72%)	32 (82%)	11 (52%)	33 (75%)	13 (100%)	27/33 (82%)
Gender							
Female	34 (30%)	20 (27%)	14 (36%)	13 (62%)	10 (23%)		11 (32%)
Male	78 (70%)	53 (73%)	25 (64%)	8 (38%)	34 (77%)	13 (100%)	23 (68%)
Race							
White	88/110 (80%)	56/71 (79%)	32 (82%)	17 (81%)	36 (82%)	10/12 (83%)	25/33 (76%)
Black	6/110 (5%)	3/71 (4%)	3 (8%)	2 (10%)	2 (5%)		2/33 (6%)
Asian	6/110 (5%)	4/71 (6%)	2 (5%)	1 (5%)		2/12 (17%)	3/33 (9%)
Hispanic	5/110 (5%)	3/71 (4%)	2 (5%)	1 (5%)	2 (5%)		2/33 (6%)
Other Race	5/110 (5%)	5/71 (7%)			4 (9%)		1/33 (3%)
BMI							
Underweight (<18.5)	2/111 (2%)	1/72 (1%)	1 (3%)		1/43 (2%)		1 (3%)
Normal (18.5-24.9)	31/111 (28%)	18/72 (25%)	13 (33%)	3 (14%)	8/43 (19%)	3 (23%)	17 (50%)
Overweight (25-29.9)	47/111 (42%)	32/72 (44%)	15 (38%)	8 (38%)	23/43 (53%)	7 (54%)	9 (26%)
Obese (≥30)	31/111 (28%)	21/72 (29%)	10 (26%)	10 (48%)	11/43 (26%)	3 (23%)	7 (21%)
Smoking Status							
Current	3/109 (3%)	3/72 (4%)			2 (5%)		1/31 (3%)
Former	77/109 (71%)	49/72 (68%)	28/37 (76%)	16 (76%)	32 (73%)	8 (62%)	21/31 (68%)
Never	29/109 (27%)	20/72 (28%)	9/37 (24%)	5 (24%)	10 (23%)	5 (38%)	9/31 (29%)
Diagnostic Confirmation							
Biopsy	24/102 (24%)	18/69 (26%)	6/33 (18%)	4 (19%)	11/43 (26%)	2/12 (17%)	7/26 (27%)
CT Scan	75/102 (74%)	48/69 (70%)	27/33 (82%)	17 (81%)	31/43 (72%)	9/12 (75%)	18/26 (69%)
Other	3/102 (3%)	3/69 (4%)			1/43 (2%)	1/12 (8%)	1/26 (4%)
Family History of IPF/ILD	14/100 (14%)	11/65 (17%)	3/35 (9%)	1 (5%)	7/40 (18%)	2 (15%)	4/26 (15%)
Measures; N (%)							
FVC <50%	19/109 (17%)	13/72 (18%)	6/37 (16%)	1 (5%)	3 (7%)	6 (46%)	9/31 (29%)
DLCO <36%	26/79 (33%)	14/45 (31%)	12/34 (35%)	2 (10%)	12 (27%)	11 (85%)	NA
6MWD <165m	12/105 (11%)	7/70 (10%)	5/35 (14%)	2 (10%)	3/42 (7%)	5/12 (42%)	2/30 (7%)
Measures; median (IQR)							
GAP	4 (3,5)	4 (4,5)	4 (3,5)	3 (2,3)	4 (4,5)		NA
FVC	67.0 (54.0,87.0)	64.5 (53.0,79.6)	72.0 (58.0,90.6)	92.0 (75.5,99.2)	69.5 (58.0,81.8)	50.0 (40.3,62.0)	63.0 (49.0,73.0)
DLCO	43.1 (34.0,51.6)	44.0 (34.0,51.0)	43.0 (35.0,52.5)	56.0 (49.0,66.0)	43.0 (35.0,48.0)	30.0 (24.6,34.0)	NA
6MWD	330 (250,421)	342 (274,433)	288 (202,394)	330 (285,411)	322 (274,425)	247 (126,259)	375 (277,439)
Platelets	233 (180,256)	225 (180,248)	238 (185,278)	248 (220,263)	224 (183,255)	213 (167,250)	203 (173,247)
AST	22 (17,27)	21 (17,26)	24 (17,29)	18 (16,25)	23 (19,31)	19 (16,24)	23 (18,26)
ALT	18 (13,27)	18 (13,28)	18 (12,26)	18 (11,19)	19 (14,30)	17 (12,23)	15 (12,26)
eGFR	61 (56,76)	61 (59,61)	70 (54,84)	61 (59,72)	61 (58,82)	62 (53,75)	61 (54,61)

TABLE 2 — COMORBIDITIES AT ENROLLMENT (≥5% OF POPULATION)

Characteristic	All Patients (n=112)	by Diagnosis		by GAP Stage			
		IPF (n=73)	Other ILD (n=39)	Stage I (n=21)	Stage II (n=44)	Stage III (n=13)	Not calculable (n=34)
Hypertension	60 (54%)	39 (53%)	21 (54%)	9 (43%)	26 (59%)	9 (69%)	16 (47%)
GERD	58 (52%)	38 (52%)	20 (51%)	7 (33%)	28 (64%)	7 (54%)	16 (47%)
Obstructive sleep apnea	32 (29%)	23 (32%)	9 (23%)	8 (38%)	12 (27%)	3 (23%)	9 (26%)
CVD	27 (24%)	22 (30%)	5 (13%)	6 (29%)	7 (16%)	3 (23%)	11 (32%)
CAD	26 (23%)	16 (22%)	10 (26%)	4 (19%)	7 (16%)	6 (46%)	9 (26%)
Type II Diabetes	23 (21%)	17 (24%)	6 (15%)	7 (33%)	6 (14%)	5 (38%)	5 (15%)
COPD/Emphysema	21 (19%)	13 (18%)	8 (21%)	6 (29%)	8 (18%)	2 (15%)	5 (15%)
Depression	13 (12%)	10 (14%)	3 (8%)	5 (24%)	2 (5%)	1 (8%)	5 (15%)
Thyroid Disease	12 (11%)	7 (10%)	5 (13%)	4 (19%)	4 (9%)	1 (8%)	3 (9%)
Renal Insufficiency	11 (10%)	5 (7%)	6 (15%)	2 (10%)	4 (9%)	2 (15%)	3 (9%)
CTD	10 (9%)	6 (8%)	4 (10%)	2 (10%)	3 (7%)	0 (0%)	5 (15%)
Valvular Heart Disease	10 (9%)	7 (10%)	3 (8%)	1 (5%)	5 (11%)	1 (8%)	3 (9%)
Heart Failure (Diastolic)	9 (9%)	3 (4%)	6 (17%)	1 (5%)	4 (9%)	1 (8%)	3 (10%)
Cancer	10 (9%)	3 (4%)	7 (18%)	3 (14%)	4 (9%)	0 (0%)	3 (9%)
Asthma	6 (5%)	5 (7%)	1 (3%)	1 (5%)	3 (7%)	0 (0%)	2 (6%)

FIGURE 2 — PATIENT DISTRIBUTIONS BY GAP STAGE AND 6MWD

FIGURE 3 — PATIENT DISTRIBUTIONS BY GAP STAGE AND FVC

FIGURE 4 — PATIENT DISTRIBUTIONS BY GAP STAGE AND DLCO

FIGURE 5 — DISTRIBUTIONS BY GAP STAGE AND SUPPLEMENTAL O2

FIGURE 1 — PATIENT DISTRIBUTION BY GAP SCORE AT ENROLLMENT (N=78)

FIGURE 6 — DISTRIBUTIONS BY GAP STAGE AND PULMONARY REHAB HISTORY