

## **Study of Clinical, Radiological, and functional profile of interstitial lung disease: a prospective study in Western India**

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### Contributors

- 1. Dr Sourabh Jain**, MD Respiratory Medicine, Consultant, Department of Respiratory Medicine, Dr DY Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune, India 411018
- 2. Dr Vinay Sitaram Dharmadhikari**, MD Respiratory Medicine, Consultant, Department of Respiratory Medicine, Dr DY Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune 411018
- 3. Dr Nitin Sambhaji Gaikwad**, MD Respiratory Medicine, Professor, Department of Respiratory Medicine, Dr DY Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune, India 411018
- 4. Dr Ashwin Ramesh CB**, MD Respiratory Medicine, Senior Resident, Department of Respiratory Medicine, Dr DY Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune 411018

Department(s) and institution(s) , Department of Respiratory Medicine, Dr DY Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune 411018

Corresponding Author:

Name Dr Nitin Sambhaji Gaikwad, MD Respiratory Medicine, Professor

Address Department of Respiratory Medicine, Dr DY Patil Medical College, Hospital and Research Centre, Dr D Y Patil Vidyapeeth, Pimpri, Pune, India 411018

### **Abstract:**

Despite advances, little is known about the epidemiology of interstitial lung disease (ILD). The aim of this study was to understand Clinical, Radiological, and functional Profile of ILD patients attending tertiary care center in Pune, India.

Method: Prospective observational, study was conducted at Dr. D.Y. Patil Medical College, Hospital and Research, Pune. 50 known ILD patients, age 20 and above, who were attending OPD clinic and were willing to sign informed consent were recruited during July 2017 - September 2018. The information collected was age, gender, smoking habit, co-morbidities, symptoms, signs of ILD, auscultatory findings, area involved on auscultation, x-ray, CT scan and spirometer findings. Statistical analysis was done with mean, standard deviation, frequencies and percentages.

Results: Among 50 ILD patients, there was male dominance (58% vs 42%). Average age was 58.02 ±14.66 years. Most common symptoms were cough (100%) and dyspnea (94%). Most common radiological finding was reticular (54%) and nodular (52%). No patients showed sputum +ve for AFB. Infra- axillary and interscapular area involvement (each) was observed in 82% patients. Restrictive pattern was most common in spirometry (48%). CT scan showed presence of honeycombing pattern in 66% of patients. Diagnosis detected usual interstitial pneumonia (UIP) in 50% while non-specific interstitial pneumonia (NSIP) in 22% patients. UIP involved patients' lower lobe involvement (25 left and 24 right).

**Conclusion:** This pilot study has shown the profile of ILD patients from Pune, India. Larger epidemiological studies need to be conducted for assessment of burden of ILD.

**Key words** Interstitial lung disease, Epidemiology, Pulmonary fibrosis, India, Registry, hypersensitivity pneumonia

### Introduction:

Interstitial lung disease [ILD] is very complex disease having more than 100 groups of different conditions. Multidisciplinary team [clinicians, radiologists, pulmonologists] is required to diagnose ILD<sup>1</sup>. Globally, the incidence of ILD ranged from 1 to 31.5 per 100,000 person-years and prevalence ranged from 6.3 to 71 per 100,000 people<sup>2</sup>. Yet, there are few epidemiological studies describing the global burden of ILD<sup>2</sup>. There is geographic heterogeneity with ILD<sup>2</sup>. Data on ILD from developing countries is scarce and inconsistent<sup>3</sup>. Not much research has been done to understand the incidence and prevalence of ILDs from developing countries. Recently [July 2022], the very first study by Sahajal Dhooria described the incidence and prevalence of ILDs in northern India. For ILD, the estimated crude annual incidence and prevalence reported per 100,000 populations were 10.1–20.2, and 49.0–98.1 respectively<sup>4</sup>.

The registries from different countries show variable findings due to various reasons such as selection bias, study design, different diagnostic procedures, etc.<sup>5</sup>. The most common causes mentioned by the registries from three European countries are, sarcoidosis, idiopathic pulmonary fibrosis, hypersensitivity pneumonitis, interstitial lung diseases due to collagen vascular diseases and postinflammatory fibrosis<sup>5</sup>. In North America and Europe, idiopathic pulmonary fibrosis and sarcoidosis were the most dominant ILDs<sup>2</sup>. Hypersensitivity pneumonitis was higher in Asia, mainly in India (10.7–47.3%) and Pakistan (12.6%)<sup>2</sup>.

ILDs are a broad, complex heterogeneous group of acute and chronic diffuse lung diseases of known and unknown causes<sup>5</sup>. Hence, it is hard to safely classify ILD patients<sup>6</sup>.

ILDs are Clinically Challenging<sup>7</sup>. The clinical profile of ILDs in India is sparse<sup>5</sup>. Besides, ILDs appear to be under-reported from India<sup>8</sup>. Lack of facilities, recognition for the disease may be some of the reasons. Singh *et al.* demonstrated the importance of a prospective registry for new-onset ILDs then pointed out the limitations as selection bias, under representation of geographic areas, resource poor setting etc<sup>9</sup>.

Hypersensitivity pneumonitis was the most common new-onset ILD in India<sup>4,5</sup>.

Indian ILD registry reports the diagnosis of HP as the leading ILD in India and it is associated with domestic environmental factors in the vast majority of patients<sup>9</sup>.

The challenges in diagnosing ILDs in India are confounded by ecological and cultural factors, lack of resources, and lack of standardized approach to diagnosis of ILD. From patient side it is linked with phobia, reluctance, hesitancy, especially when faced with the need for surgical lung biopsy. This leads to patients' reliance on the individual clinician's judgment<sup>9</sup>.

As mentioned diagnosis of ILD is challenging and it is because a large number of disorders fall into this category and many medical signs and symptoms can imitate ILD. To rule out these, some of the medical tests are necessary.

The first step in diagnosing ILD is Computerized tomography (CT) scan used in determining the extent of lung damage<sup>10</sup>. Spirometry or diffusion capacity are Pulmonary function tests, that shows how much air your lungs can hold, and how quickly you can move air out of your lungs. pulmonary

fibrosis can be definitively diagnosed only by examining a small amount of lung tissue (biopsy) in a laboratory<sup>10</sup>.

According to Mr. Ashok Gogiya, there are very few studies in India where spirometer test is carried out with the patients. He noticed with 30 ILD patients Restrictive pattern was present in majority of the patients in spirometry<sup>11</sup>.

Considering the complexity of the disease, and limitations with the researches conducted and reported till today, even a well-conducted single center study can add to the scientific knowledge of the disease. Based on the above studies, it is observed that the profile of ILD patients is studied only in few parts of India but not in Pune. Hence it was decided to study clinical, radiological and functional profile of patients of interstitial lung disease attending tertiary care center in Pune.

### **Method:**

This observational prospective single center study was conducted at D. Y. Patil Medical College, Hospital and Research center, Pune. The Respiratory Medicine OPD sees 1000 patients /month suffering from various pulmonary conditions such as COPD, Bronchitis, etc out of which 30 per month are diagnosed for ILD. Total 50ILD patients were diagnosed between year July 2017 and September 2018.

### **Inclusion criteria:**

- New patients with symptoms of progressive increasing dyspnea without any significant constitutional and endobronchial symptoms
- Known patients of ILD
- Patients with abnormal pulmonary function with evidence of restriction and impaired gas exchange
- Patient willing to give consent and willing to follow the study protocol

### **Exclusion criteria:**

- Patients who are unable to perform pulmonary test
- Contraindications to spirometry
- Patients who are having acute exacerbation of disease
- Patients having severe co morbidities
- HIV positive patients
- Patients who are not willing to give consent for the study

After securing Institutional Ethics committee approval to conduct the study, those patients who fulfill the inclusion criteria were recruited in the study. The purpose of the study was explained to the participants and was asked to sign the informed consent form (annexure I).

### **Data collection:**

The study recruited 50 patients. The recruited patients attending OPD with predominant symptoms and progressively increasing dyspnea were assisted to complete the data collection form (annexure II). This form was used to confirm and classify ILD.

Data was collected for demographics (age, gender), co morbidities (Hypertension, Diabetes and TB), smoking and Tobacco chewing habit, symptoms, signs, auscultatory findings, sputum status, X-ray and CT scan findings and spirometry test results. Spirometry (which test) is one of the most readily available and useful tests for pulmonary function. Patients were given 6MWT.

To understand the amount of oxygen and carbon dioxide in the blood, ABG test was conducted.

Hypersensitivity pneumonitis (HP) was diagnosed based on history of exposure to organic dust, radiological features combined with histological available evidence.

Statistical test used: In addition to basic statistics like mean, standard deviation, frequency, percentages, Pair t test was used to check if there was significant reduction in

- i) Diffusion capacity of carbon monoxide and
- ii) O<sub>2</sub> saturation after 6 minute walk among ILD patients

#### Results:

Total of 302 subjects were enrolled. The cohort demonstrated a female preponderance, having 185 females (61.3%), compared to 117 (38.7%) males. The mean age $\pm$ SD was 59.52 $\pm$  12.84 years, ranging widely from 9 to 87 years. Males were significantly older than females having mean age $\pm$ SD of 63.5 $\pm$  10.7 years in contrast to 56.9  $\pm$  13.4 years in females ( $p < 0.01$ ).

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The cohort of 50 patients demonstrated male dominance having 29(58%) men compared to 21 (42%) women. The mean $\pm$  std was 58.02  $\pm$  14.66 ranging from 20 to 83 years. The mean age of men was higher than females (59.23 vs 56.63, however, the difference was not statistically significant).

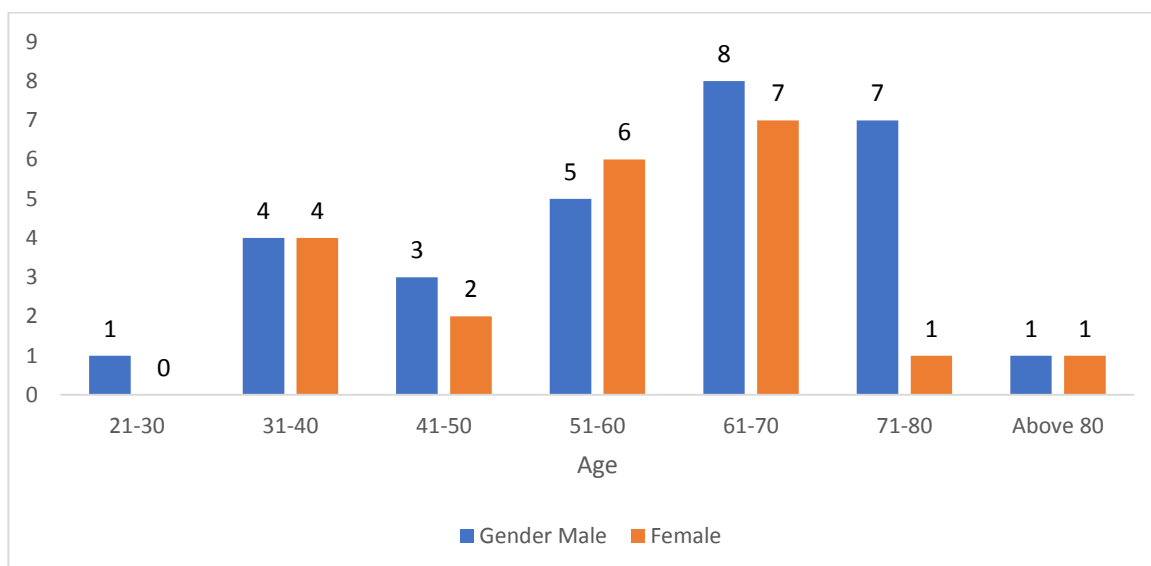


Figure 1 shows Bar diagram shows Age by gender wise distribution of study sample.[Y axis shows frequency].

Only 18% patients smoked and 22% patients chewed tobacco.

More patients had Hypertension 9(18%) compared to TB 7(14) and diabetes 6 (12%).

Symptoms: Cough was most common symptom among study sample and it was present in all 50 (100%) patients. Dyspnea was 2<sup>nd</sup> most common symptom present in 47 (94%) of the patients. Loss of appetite, wheezing was present in 33 (66%) and 30 (60%) of the patients. Few patients were having, fever, weight loss, joint pain, palpitation etc.

Four connective tissue disorders were observed among ILD patients. Two of them had joint pain and two did not have joint pain.

| Variables                     | No (%)            |
|-------------------------------|-------------------|
| Age (years)                   |                   |
| Mean $\pm$ std                | 58.02 $\pm$ 14.67 |
| Range                         | 20 - 83           |
| Gender                        |                   |
| Male                          | 29 (59)           |
| Female                        | 21 (42)           |
| Smoking                       |                   |
| Yes                           | 9 (18)            |
| No                            | 41 (82)           |
| Tobacco chewing               |                   |
| Yes                           | 11(22)            |
| No                            | 39(78)            |
| Co morbidities                |                   |
| DM                            | 6 (12)            |
| HTN                           | 9 (18)            |
| TB                            | 7 (14)            |
| Signs                         |                   |
| Pallor                        | 10 (20)           |
| Pedal edema                   | 8(16)             |
| Clubbing                      | 21 (42)           |
| Lymphadenopathy               | 2 (4)             |
| Cyanosis                      | 2(4)              |
| Auscultatory                  |                   |
| Crepitations                  | 47 (94)           |
| Wheeze                        | 09 (18)           |
| Reduced breath sound          | 05 (10)           |
| Normal vesicular breath sound | 03 (6)            |
| Area involved in Auscultatory |                   |
| IAA                           | 42 (82)           |
| IFSA                          | 41 (82)           |
| ISA                           | 31 (62)           |
| SSA                           | 13 (26)           |
| Sputum status                 |                   |

|              |          |
|--------------|----------|
| AFB Negative | 50 (100) |
| CRP Positive | 2 (4)    |
| Negative     | 48 (98)  |
| RF Positive  | 01 (2)   |
| Negative     | 49(98)   |

Table 1 shows Demographic and Clinical characteristics of ILD patients

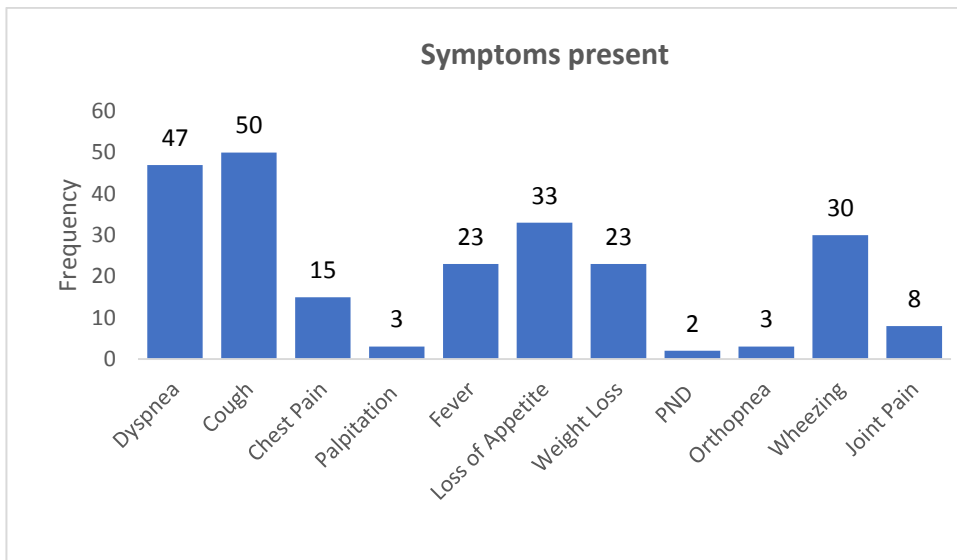


Figure 2 :Bar diagram showing symptoms present among study sample

Signs: The most common sign present among interstitial lung disease patients was clubbing 21 (42%). Pallor and pedal edema was present in 10 (20%) and 8 (16%) of patients respectively. Cyanosis and lymphadenopathy were present in few patients.

The most common auscultatory finding was crepitation and it was present in 47 (94%) of the patients. On auscultation findings, infra axillary area involvement was observed in 42 (82%) while infra scapular area involvement was in 41 (82%) of the patients. 31 (62%) and 13 (26%) patients showed inter scapular and sub scapular area involvement respectively.

In our sample, none of the patients had sputum positive for AFB. C Reactive was positive in 2 (4%) and Rheumatoid factor was present in 1 (2%) patient.

X-ray findings 1[A multiple response question]: Reticular and Nodular was the most common pattern found on X-ray chest PA view. It was present in 27(54%) and 26(52%) of patients. Inhomogeneous opacities and cystic changes were present in 14 (28%) and 6(12%) respectively.

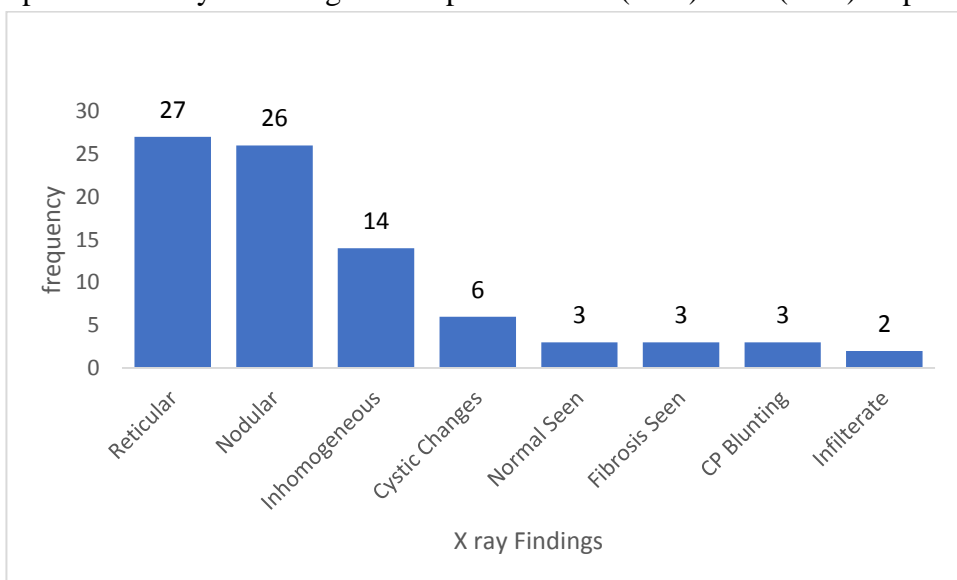


Figure 3a X ray findings among study subjects

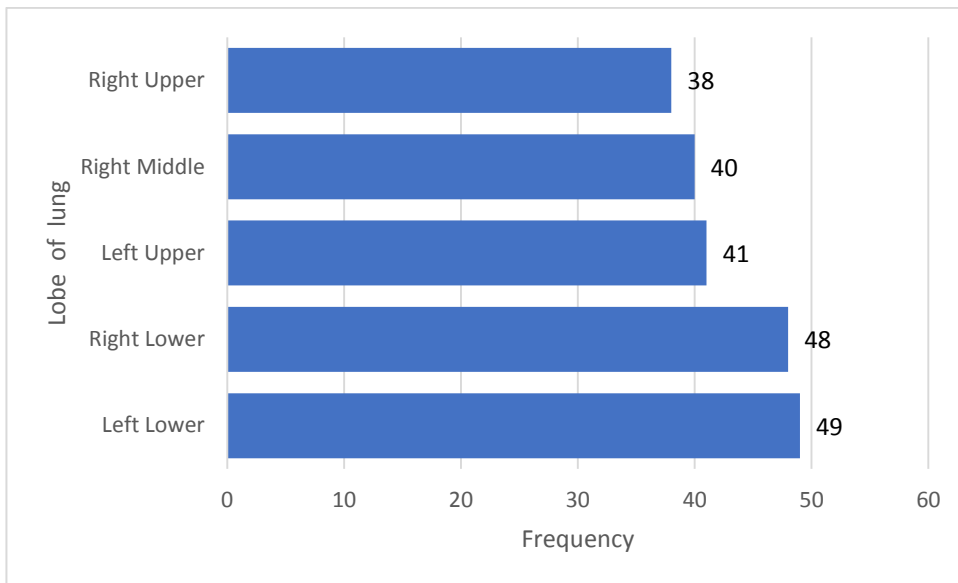


Figure 3b Lung involvement in CT score

Lobe involvement in CT scan: CT scan is important while diagnosing ILD. All 25 (50% of total patients) UIP subjects, patients had left lower lobe involvement while 24 (48% of total) had right lower lobe involvement. This suggests UIP involves lower lobes of lung.

CT scan findings 2: Figure 4 shows that honeycombing pattern was the most common finding with 33 (66%) of patients. 14 out of 25 UIP patients were having honeycombing. The 2<sup>nd</sup> most common finding among ILD patients was interstitial thickening. Bronchiectasis (either cystic or traction or both) was present in 22 (44%) patients of ILDs. Ground Glass Opacity (GGO) was observed in 19 (38%) of ILD patients. GGO was present in 7 patients out of 11 NSIP patients. Opacities, either reticular, modular or both were present in 9 (18%) of the patients. Cystic changes, emphysema, random nodule, lymph node enlargement were also observed.

The spirometry results showed that mean FVC, FEV1, and FEV1/FVC ratio in Normal was higher than restrictive and mixed (obstructive + restrictive) [Table not shown or do you want to include in appendix?]

The restrictive pattern was most common on spirometry followed by mixed (obstructive + restrictive) in 21 (42%) of patients and normal in 5 (10%) patients.

Base line and post SPO2 score was measured. The mean and standard deviation for these two readings was  $95.24 \pm 0.433$  and  $88.20 \pm 0.948$ . Paired t test showed significant ( $P < .0001$ ) reduction in O2 saturation after 6 minute walk of ILD patients.

### Diagnosis:

The process of achieving a diagnosis in a patient with ILD requires close communication between clinician, radiologist and pathologist

Usual Interstitial Pneumonia (UIP) was most common diagnosis that was present in 25 (50%) of subjects. Non-Specific Interstitial Pneumonia (NSIP). It was present in 11 (22%) patients of patients.



Cryptogenic Organizing Pneumonia (COP) was present in 6 (12%). Hypersensitivity pneumonitis (HP), IPF, LAM and sarcoidosis were also present in small numbers.

Gender wise, out of 26 (or 50%) UPI patients, 50% were men and women each. Out of 11 NSIP patients, 6 (54.54%) were men and 5 (45.6%) were women.

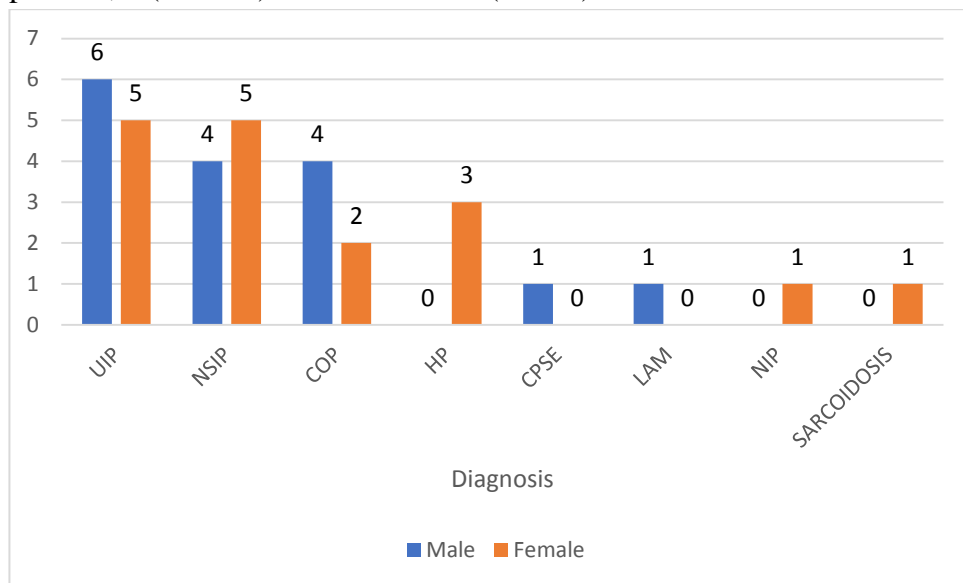


Figure 4: Gender wise distribution of diagnosis [Y axis shows frequency]

Diffusing capacity of lungs for carbon monoxide

Diffusing capacity of carbon monoxide [DLCO] was tested for ILD patients. DLCO and DLCO predicted mean and standard deviation was  $18.49 \pm 1.39$  and  $24.30 \pm 0.345$ .

By using paired t test, it was found that there was a significant ( $p = .0001$ ) difference between DLCO corrected and DLCO predicted. It showed significant reduction in diffusion capacity of carbon monoxide among ILD patients.

Mean  $\pm$  std of ABG readings are showed in the Table below.

| ABG readings   | PH              | PO2               | PCO2             | HCO3             | SO2             |
|----------------|-----------------|-------------------|------------------|------------------|-----------------|
| Mean $\pm$ std | $7.44 \pm .079$ | $74.57 \pm 23.74$ | $36.12 \pm 6.02$ | $23.73 \pm 4.56$ | $92.27 \pm 6.9$ |

Table 2 shows Arterial Blood Gas( ABG) readings.

Pulmonary Hypertension (PH) was found in only 12 (24%) patients. Out of 12, seven had mild and 2 each had moderate and severe pulmonary hypertension and one had very severe PH.

PFTs can't analyze a particular ILD and can't recognize active lung inflammation versus fibrosis, however are basically important in assessment of respiratory side effects, reviewing of severity of disease and its progression and also response to the treatment given.

A diffuse abnormal x ray is the abnormal finding that cautions the doctor to the likelihood of ILD. The presence of honeycombing as predominance of CT scan finding is highly specific for UIP while predominant ground glass opacity is specific for NSIP.

DLCO is one of the most valuable measurements to provide information about gas exchange.

## Discussion

This single center study from Pune, Western India demonstrated that UPI was most frequent among ILD patients. The results of our study are compared with results from other studies and discussed below.

### Age and gender

Mean age of study sample was  $58.02 \pm 14.06$ . Various studies show ILD typically occurs, after 50 years of age<sup>4,5,12</sup>. Few other studies have reported average age to be < 50 years also<sup>11,13</sup>.

Male predominance was noticed among our ILD patients in agreement with the result mentioned in ILD registries from three European countries<sup>14</sup>. This is however

Discordant with Dr. Ramana's study<sup>7</sup>, Saudi Arabia<sup>12</sup> and a study from Sri Lanka where female predominance is observed<sup>15</sup>.

### Symptoms and sign

Our results highlighted that cough was the most common symptom followed by dyspnea among all the 50 subjects and 47 subjects respectively. These two were complaints seen in many studies<sup>8,14,16,17</sup>. Their proportion was slightly different, but still both contributed as most common symptom in comparison with wheezing, pain in joint and chest, loss of weight etc.

Clubbing was most common sign found in this study among 21 (42%) study patients. It was 2<sup>nd</sup> most common in comparison with V. Das, Unnati Desai, Jyotsna Joshi et al<sup>16</sup> where inspiratory Velcro snap was more common and Ashok Gagiya, Suthar Hemang N et al<sup>11</sup> where crepitations were more prevalent (63.27%).

### Chest x ray

Regular and nodular pattern were commonly presented on X ray chest PA view while honeycombing on CT scan. This result is parallel to the result indicated by previously mentioned studies<sup>11,13</sup>.

### Chest CT scan

Honeycombing pattern was present in 33(66%) of patients. 14 out of 25 patients of UIP were having honeycombing. The second common finding observed was Interstitial thickening in ILD patients in this study. Ground glass opacity (GGO) appearance was observed in 19(38%) of ILD subjects and it was present in 7 patients out of 11 NSIP patients. Studies<sup>7,13,16,17,18</sup> suggest that GGO honeycombing and interstitial fibrosis were common CT scan finding among ILD subjects. Diagnosis of NSIP based on uniform, bilateral, ground glass opacity and UPI on honeycombing was also proposed by Elliot TL, Lynch DA et al<sup>19</sup> and Lynch DA, Travis WD et al<sup>20</sup>.

### Spirometry

Spirometry showed restrictive pattern in 48% subjects. This result is similar to the result shown by Dr. Raman's study in Vishakhapatnam<sup>7</sup>. Mixed (obstructive + restrictive) pattern was observed in 42% subjects. There was significant decline in diffusion capacity of carbon monoxide and O<sub>2</sub> saturation in 6 minute walk test among 50 subjects. Similar result was observed with study by Rajkumar et al<sup>13</sup> among NSIP.

Diffusing capacity of lungs for carbon monoxide (DLCO)

Mean of predicted DLCO was 24.30% which was lower than Raj Kumar et al<sup>13</sup> in which it was 50.56%. In ILD diffusion capacity for carbon monoxide decreases and it was significant decrease than predicted value in this study.

Dhooria's and Sheetu Sing's study reports sarcoidosis and pulmonary hypertension (HP) are the highest burden in India<sup>(4,5)</sup>. Our study found little less than one-fourth (24%) patients were detected with HP. This percentage is higher than 6.3% from Saudi Arabia<sup>11</sup> and 17.7% hypersensitivity pneumonitis (HP) reported in a registry from Pakistan<sup>21</sup>.

Usual interstitial pneumonia (UPI) was most common diagnosis present in half (50%) and Non-specific pneumonia (NSIP) was present in 22% patients

### Limitation

Sample size for the study was small.

It was a single center study

### Conclusion

We have tried to understand the profile of ILD patients in Pune, Western India. ILD is a fatal disease with a poor prognosis. India is a diverse country where epidemiology of ILD is less known. Henceforward awareness and screening will be the need of the day. This will help with a better understanding of the geographic patterns of disease prevalence and identifying clusters of ILD subtypes.

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