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TO STUDY THE CHANGES IN SERIAL LUNG FUNCTIONS IN INTERSTITIAL LUNG DISEASE (ILD) PATIENTS

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ABSTRACT

Background: The assessment of lung function, particularly lung volumes and gas transfer, recorded initially upon patient presentation and subsequent follow-up evaluations, along with high-resolution computed tomography (HRCT) of the chest, can facilitate the evaluation of the natural history of the disease or provide insights to guide therapy in interstitial lung disease (ILD). The utilization of available data related to connective tissue-related ILD (CTD-ILD), gastroesophageal reflux disease (GERD), smoke exposure, as well as any potential correlation of treatment with changes in lung functions, can offer valuable insights.

Objectives: The main aim of this study was to study the changes in lung functions of ILD patients over one year apart, and whatever observations could be noticed based on case record form.

Methodology: The study was conducted in a Tertiary Care Centre to evaluate changes in lung functions in patients with Interstitial Lung Disease (ILD) over one-year period, specifically

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assessing increases or decreases in lung function values. The data was collected on ILD patients over 18 years of age who had undergone two Pulmonary Function Tests (PFTs) one year apart, between 2013 and 2015, from the PFT register available in the Centre's PFT lab.

Results: This study revealed that 81.25% of patients fell within the age range of 40-70 years. Furthermore, it was found that 77.5% of the patients experienced lung function restrictions. In fact, 95% of the patients exhibited HRCT chest images consistent with Nonspecific Interstitial Pnuemonia (NSIP), while 5% displayed Usual Interstitial Pnuemonia (UIP) patterns. Additionally, within the study group, 47.75% were diagnosed with connective tissue related ILDs. Notably, patients with a history of GERD experienced a median fall in FVC of 130ml/year, compared to 170ml/year in 15 patients without GERD.

Conclusion: Thus the findings of the study hold the potential to improve the clinical care and outcomes of interstitial lung disease patients.

Keywords- Interstitial lung disease (ILD), Idiopathic Pulmonary Fibrosis, Spirometry, Pulmonary Fibrosis, Connective tissue disease, Chronic obstructive pulmonary disease**.**

INTRODUCTION:

Interstitial Lung Disease (ILD) encompasses a diverse array of over one hundred distinct lung disorders, which are grouped together because they share clinical, radiographic, and pathological features [1]. They are referred to as diffuse parenchymal lung disease. ILD involves the inflammation and fibrosis of alveoli, distal airways, and septal interstitium within the lungs [2]. Common manifestations of ILD include dyspnoea upon exertion, dry cough, a diffuse reticulo-nodular pattern on chest imaging, as well as restriction and diffusion impairments during physiological testing [3].

Upon obtaining tissue from the lungs, various abnormalities such as inflammation, fibrosis, and granuloma may be observed within the lung parenchyma. Although many forms of ILDs are rare, Idiopathic Pulmonary Fibrosis (IPF) and Sarcoidosis are frequently encountered in general medical practice [4]. Furthermore, ILD related to connective tissue diseases (CTD) is commonly associated with conditions such as Rheumatoid arthritis, Polymyositis, Dermatomyositis, Scleroderma, and Sjogren Syndrome [5-7].

Occupational causes of ILD encompass both inorganic exposures such as asbestos, silica, hard metals, and coal dust, as well as organic exposures like birds, hay, moulds, and mycobacteria. Additionally, ILD can be induced by certain medications including nitrofurantoin, amiodarone, methotrexate, and chemotherapy. A common presentation in patients with pulmonary fibrosis includes fine inspiratory, basilar Velcro crackles and digital

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clubbing. Chest radiographs typically reveal bilateral reticulo-nodular shadows. High-resolution computed tomography (HRCT) is more effective than chest radiographs in diagnosing ILD and can reveal various findings such as nodules, reticular lines, septal thickening, traction bronchiectasis, cyst formation, honeycomb changes, and ground glass opacity [8,9].

The radiographic features of Idiopathic Pulmonary Fibrosis are collectively known as Usual Interstitial Pneumonia (UIP), characterized by a peripheral, subpleural distribution, basilar predominance, reticular markings, traction bronchiectasis, and honeycombing.[10]
Spirometry is a widely utilized pulmonary function test that measures lung function, specifically the volume and/or speed of air that can be inhaled or exhaled. It is an important tool for generating pneumotachographs and is helpful in assessing conditions like asthma, pulmonary fibrosis, cystic fibrosis, and Chronic Obstructive Pulmonary Disease (COPD) [11].

The available data from 2013 to 2015 indicated that out of 48,865 outpatients visiting the Pulmonary Medicine department of the Tertiary Care Centre, 139 were diagnosed with ILD and had their lung functions evaluated.

Lung function tests, particularly lung volumes and gas transfer, are documented initially upon patient presentation and then repeatedly during follow-ups. When combined with high-resolution computed tomography (HRCT) scans of the chest, these tests can help assess the natural history of the disease and guide therapy in ILD.

The aim of the study was to study the changes in lung functions of ILD patients over one year apart based on case record form. This retrospective analysis could potentially provide valuable insights into the progression of ILD and the impact of different treatment approaches on lung function over time. Such studies are crucial for enhancing our understanding of the disease course and optimizing patient care.

MATERIALS AND METHODS:

The study conducted at the Tertiary Care Centre involved collecting data on all interstitial lung disease (ILD) patients above 18 years of age who had undergone two pulmonary function tests (PFTs) one year apart between 2013 and 2015. The data was retrieved from the PFT register located in the PFT lab. These patients comprised individuals with ILD who visited the Pulmonary Medicine outpatient department, as well as those with connective tissue-related ILDs referred from the Rheumatology outpatient department.

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INCLUSION AND EXCLUSION CRITERIA:

All patients above 18 years of age with an HRCT diagnosis of ILD and with repeat PFT one year apart were included in the study. Patients not satisfying the inclusion criteria were excluded from the study.

SAMPLE SIZE:

80 patients based on availability of data in the PFT register.

RESULTS:

The retrospective study involved a sample of 80 ILD patients to investigate changes in lung function over a year. The sample size was determined based on the total number of ILD patients who underwent yearly PFTs from 2013 to 2015, encompassing ILD patients who had PFTs in 2013 followed by repeated PFTs in 2014, and new ILD patients with PFTs in 2014 and repeated PFTs in 2015 at the Tertiary Care Centre. This population also comprised 38 connective tissue-related ILD cases referred from the Rheumatology outpatient department.

The majority of the patients fell within the age group of 40 to 70 years, accounting for 65 patients (81.25%) in the sample. Females constituted the majority in the study group, with 64 individuals (80%) compared to the 16 males (20%). Regarding occupation, with 80% of the patients being female, the majority were housewives, totalling 54 individuals (84.37%).

In terms of exposure, 32 out of 80 patients had a history of smoke exposure, either through active or passive smoking. Additionally, 12 out of 80 patients had exposure to domestic birds, with 4 of them exhibiting CT chest findings suggestive of Chronic Hypersensitivity Pneumonitis. All patients exhibited symptoms of breathlessness and cough, although the duration of these symptoms varied. Specifically, 64 patients (80%) presented with 1-5 years of symptoms. Among comorbidities, 20 out of 80 patients had Diabetes Mellitus, 22 out of 80 had Hypertension, and 61 out of 80 patients (77.5%) had GERD (Gastroesophageal Reflux Disease).

CONNECTIVE TISSUE RELATED ILD:

Out of 80 interstitial lung diseases (ILDs) that were studied, 38 were found to be associated with connective tissue disease. Scleroderma was the most prevalent CTD, affecting 21 patients, followed by Rheumatoid Arthritis (12 patients), SLE (3 patients), and Sjogren's (2 patients) in this particular study. It is important to note that of the patients with connective tissue disease, 37 were female. After analyzing CT images, it was observed that 4 out of 80 patients (5%) exhibited a usual interstitial pneumonia (UIP) pattern, while 76 out of 80 (95%) displayed a non-specific interstitial pneumonia (NSIP) pattern.

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In terms of lung function changes, it was classified into no changes, mild, moderate, or severe changes, with 62 patients initially presenting with restriction.Furthermore, the change in FVC indicated a prediction of restriction in lung functions. Analysis of FVC changes over one year revealed that 16 patients experienced an increase, while 64 patients saw a decline. The median values for the increase and decrease in FVC were 50ml/year and 135ml/year, respectively.

Additionally, the change in FEV1 was found to predict obstruction among the 80 patients studied. Of these patients, 67 experienced a decrease in FEV1, while 13 demonstrated an increase. The minimum increase in FEV1 was 10 ml/year, with a maximum of 300 ml/year, and a median rise of 60 ml/year. On the other hand, the minimum decrease in FEV1 was 10 ml/year, with a maximum of 880 ml/year, and a median fall of 80 ml/year.

CHANGE IN LUNG FUNCTIONS IN CONNECTIVE TISSUE RELATED ILDS:

The observed change in FVC among the 38 patients with underlying connective tissue disease revealed that 31 patients experienced a decline in FVC. The median decrease was 80 ml/year, with the minimum being 10 ml/year and the maximum 510 ml/year. Interestingly, patients without connective tissue disease displayed a median FVC decline of 190 ml/year, compared to the 80 ml/year observed in those with CTD-ILD. This disparity in FVC decline may be attributed to the administration of Cyclophosphamide in conjunction with steroids.

Furthermore, among 38 patients with CTD, 32 individuals exhibited a decrease in FEV1. The minimum decline in FEV1 was 10 ml/year, with a maximum fall of 360 ml/year. The median fall in FEV1 among patients with CTD-ILD was 65 ml/year, as opposed to 120 ml/year in non-CTD-ILD, as outlined in Table 1.

	ASSOCIATED WITH CONNECTIVE TISSUE DISEASE							
	NO		YES		NO		YES	
	FVC CHANGE OVER ONE YEAR				FEV1 CHANGE OVER ONE YEAR			
	Increased	Decreased	Increased	Decreased	Increased	Decreased	Increased	Decreased
Count	9	33	7	31	7	35	6	32
Minimum	.00	10	10	10	20	10	10	10
Maximum	270	990	200	510	140	880	300	360
Median	50	190	50	80	70	120	50	65
95percentile	270	570	200	500	140	580	300	340

Table 1: Change in lung functions in connective tissue related ILDS

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CHANGE IN LUNG FUNCTIONS AMONG SMOKERS:

The mean fall in FVC among patients with smoke exposure was 260.4ml/year, with a median decline of 200ml/year and a 95th percentile of 510ml/year. Conversely, patients without smoke exposure showed a lower mean FVC decline of 151.59ml/year, a median decline of 80ml/year, and a 95th percentile of 500ml/year. When considering FEV1, the mean decline among patients with smoke exposure was 169.62ml/year, a median decline of 120ml/year and a 95th percentile of 440ml/year. In contrast, patients without exposure exhibited a mean decline of 131.71ml/year, a median decline of 70ml/year, and a 95th percentile of 360ml/year as indicated in Table 2.

	ASSOCIATED WITH SMOKE EXPOSURE							
	NO		YES		NO		YES	
	FVC CHANGE OVER ONE YEAR				FEV1 CHANGE OVER ONE YEAR			
	Increased	Decreased	Increased	Decreased	Increased	Decreased	Increased	Decreased
Count	8	39	8	25	6	41	7	26
Minimum	.00	10	10	10	20	10	10	10
Maximum	200	990	270	570	300	880	140	580
Mean	56.25	151.79	115	260.40	86.67	161.71	70	169.62
Median	35	80	105	200	55	70	60	120
95percentile	200	500	270	510	300	360	140	440

Table 2: Change in lung functions among smokers

CHANGE IN LUNG FUNCTIONS IN GERD:

The change in FEV1 among 61 patients with GERD displayed a median decline of 80 ml/year, whereas those without GERD showed a median decline of 120 ml/year. In terms of change in FVC, patients with GERD experienced a minimum decrease of 10 ml/year and a median fall of 130 ml/year. Additionally, it is noteworthy that at the 95th percentile, patients with GERD exhibited a decline of 510 ml/year in FVC. The median fall in FVC among patients with GERD was 130 ml/year, contrasting with 170 ml/year in patients without GERD.

CHANGE IN LUNG FUNCTIONS WITH STEROIDS:

The median fall in FVC among the 61 patients who used steroids was 150ml/year, with a median rise of 50ml/year observed in 10 patients. Conversely, among the 13 patients who did not use steroids, the median fall in FVC was 130ml/year, with a median rise of 55ml/year observed in 6 patients. In terms of FEV1, patients using steroids showed a median fall of 80

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ml/year, while a median rise of 20 ml/year was observed. It is worth noting that these findings cannot be generalized due to the inadequate sample size for comparison between the 61 patients using steroids and the 19 patients who did not use steroids as depicted in Table 3.

	STEROID USE							
	NO		YES		NO		YES	
	FVC CHANGE OVER ONE YEAR				FEV1 CHANGE OVER ONE YEAR			
	Increased	Decreased	Increased	Decreased	Increased	Decreased	Increased	Decreased
Count	6	13	10	51	4	15	9	52
Minimum	20	60	.00	10	40	10	10	10
Maximum	200	400	270	990	120	300	300	880
Median	55	130	50	150	65	50	20	80
95percentile	200	400	270	510	120	300	300	440

Table 3: Change in lung functions among steroid users

CHANGE IN LUNG FUNCTIONS WITH CYCLOPHOSPHAMIDE:

Among the 38 patients with CTD-ILD, 28 patients received Cyclophosphamide while 10 patients did not. The median fall in FVC among the 23 patients who received Cyclophosphamide was 80ml/year, and a median rise of 90ml/year was observed in 5 patients. Comparatively, the median fall in FVC among the 7 patients who did not receive Cyclophosphamide was 190ml/year, with a median rise of 35ml/year observed in 2 patients.

This study indicates that the use of Cyclophosphamide in CTD-ILD patients was associated with a delayed decline in lung function, evident by a median fall of 80ml/year compared to 190ml/year in patients who did not receive Cyclophosphamide. Moreover, it appeared to improve lung function in 5 patients, as indicated by a median rise of 90ml/year compared to 35ml/year in those who did not receive Cyclophosphamide. Median fall in FEV1 among patients using Cyclophosphamide was 60 ml/year, with a 95th percentile of 340ml/year. Conversely, in patients not using Cyclophosphamide, the median fall in FEV1 was 110ml/year, with a 95th percentile of 440ml/year. Additionally, a median rise in FEV1 of 60ml/year was observed in patients using Cyclophosphamide, compared to 45ml/year in those not using it, with a 95th percentile of 300ml/year for the former and 440ml/year for the latter. Thus cyclophosphamide resulted in slower decline in FEV1 in 23patients and rise in FEV1 in 7 patients as depicted in Table 4.

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	CYCLOPHOSPHAMIDE USERS							
	NO		YES		NO		YES	
	FVC CHANGE OVER ONE YEAR				FEV1 CHANGE OVER ONE YEAR			
	Increased	Decreased	Increased	Decreased	Increased	Decreased	Increased	Decreased
Count	10	40	6	24	6	44	7	23
Minimum	.00	10	10	10	20	10	10	10
Maximum	70	990	200	500	140	880	300	360
Mean	72	226.5	108.33	140.42	65	162.73	88.57	115.22
Median	35	190	110	75	45	110	60	60
95percentile	270	540	200	490	140	440	300	340

Table 4: Change in lung functions among cyclophosphamide users

DISCUSSION:

The aim of this study was to analyse the changes in lung functions of patients diagnosed with interstitial lung disease, over a period of one year. This retrospective study included a sample size of 80 patients diagnosed with ILD based on HRCT chest scans and who underwent pulmonary function tests (PFTs) at two different time points, one year apart, between 2013 and 2015. The study focused on three parameters: FEV1/FVC, FEV1, and FVC, to assess obstruction and restriction in lung function. The patient ages ranged from 25 to 80 years, with the majority (81.25%) falling within the 40-70 year age group.

An important aspect of the study was to identify statistically significant associations between changes in FVC and various factors. However, gender-wise comparison did not yield statistically significant results, possibly due to the higher proportion of female patients (64 females compared to 16 males) in the study group. Among the 80 patients, 77.5% presented with a restrictive pattern in their lung functions. Initially, 38 patients (47.5%) had an FVC less than 1.5L, and 40 patients (50%) had FVC between 1.5L and 2.5L, while only 2.5% had FVC more than 2.5L. A year later, 44 patients (55%) had FVC less than 1.5L, 36 patients (45%) had FVC between 1.5L to 2.5L, and none had FVC more than 2.5L.

Of the patients with a restrictive pattern on their lung function test, 41 initially presented with mild restriction, 19 with moderate restriction, and 2 with severe restriction. A year later, these values had progressed to 23 patients with moderate restriction and 6 patients with severe restriction, indicating an increasing severity of restrictive lung patterns over one-year period. Additionally, 18 patients presented with mixed dysfunction (both obstruction and restriction).

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These findings emphasize the complexity of the lung function changes and the potential influence of environmental and etiological factors on the observed patterns.

The findings from the study indicate that a majority of the patients experienced a decline in lung function, as evidenced by a decrease in FVC over the course of the serial PFTs. Specifically, 80% of the patients demonstrated a decrease in FVC, while 20% showed an increase in FVC during the serial PFTs. The median decline in FVC was observed to be 135 ml/year, with a median rise of 50 ml/year.

Regarding the radiological findings, the study reported that 95% (76 patients) exhibited a pattern consistent with NSIP on HRCT, while 5% (4 patients) demonstrated a pattern indicative of usual interstitial pneumonia (UIP). Notably, a significant majority (98.4%) of the female patients were found to have an NSIP pattern, with 62.5% of them falling within the 40 to 60 years age group. This aligns with existing literature that suggests NSIP pattern ILD predominantly affects middle-aged adults and exhibits a female predilection.[1] Furthermore it was observed that males with NSIP pattern ILD experienced a median fall of 200 ml/year in FVC and 140 ml/year in FEV1, while females with the same pattern exhibited a median fall of 70 ml/year in FVC and 50 ml/year in FEV1.These findings emphasize the potential impact of gender on the progression of NSIP pattern ILD.

Moreover, the study noted that one male patient with UIP pattern ILD was diagnosed with rheumatoid arthritis. All four patients with the UIP pattern were within the age group of 60-65 years. Their initial lung function assessments revealed a restrictive pattern, with FVC values ranging from 1.5L to 1.8L among these patients. The findings indicated a significant decline in lung function with a mean fall of 455 ml in FVC over the span of a year.

The distinction in prognosis and treatment responses between patients with NSIP and UIP patterns in interstitial lung disease (ILD) reflects an important consideration in clinical management. It is noteworthy that your study findings align with the existing literature, demonstrating a more rapid decline in lung function among patients with UIP pattern ILD compared to those with NSIP pattern ILD.[5] The median fall in FVC of 455ml/year among patients with UIP pattern ILD contrasts with the median fall of 200ml/year observed in patients with NSIP pattern ILD. However the statistical significance of the observed difference in lung function decline between the UIP and NSIP pattern patients could not be conclusively established due to the small number of UIP pattern patients relative to the larger cohort of NSIP pattern patients (4 UIP patients vs 76 NSIP patients). Moreover, the lack of statistical

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association between HRCT chest pictures of NSIP and the decline in lung functions emphasizes the complexity and multifactorial nature of disease progression in ILD.

Smoke exposure, including both active and passive smoking, was identified in 32 patients, representing 40% of the study population. Among these patients, 22 females were exposed to wood smoke while 10 males were active smokers. Those with smoke exposure experienced a median decline of 200ml/year in FVC in 25 patients and 120ml/year in FEV1 in 26 patients, compared to a median decline of 80ml/year in FVC in 39 patients and 70 ml/year in FEV1 in 41 patients without smoke exposure. Previous research has indicated that FEV1 reaches its peak in individuals aged 18-25 before declining at a rate of 31ml/year in men.[12] Non-smokers typically experience a decline of 40ml/year, while smokers experience a decline of 50ml/year. The current study also found a faster decline in lung function associated with smoke exposure. However, with a P value of 0.15 (> 0.05), no statistically significant difference in the decline of FEV1 was observed between the groups with and without smoke exposure.

15% of the patients included in the study had a history of exposure to birds, and of these, 4 individuals presented with HRCT chest suggestive of chronic hypersensitivity pneumonitis (HP). Among the patients with chronic HP, the decline in FVC was measured at 130 ml/year, in contrast to a decline of 65 ml/year in those solely exposed to birds. It's notable that only one patient with chronic HP had a history of wood smoke exposure. An important consideration is that antigens from birds can persist in indoor spaces for extended periods, with detectable levels for more than 18 months post-bird removal. Identifying the specific offending antigen is essential for avoiding ongoing exposure, and this serves as the primary intervention for all forms of HP. The most common presenting symptoms of ILD were cough and breathlessness, with 80% seeking medical attention within 1-5 years of the onset of symptoms.

GERD in 76.25% of the cases in this study aligns with findings from a study which aimed to ascertain the prevalence of GERD in patients with respiratory disorders and ILD stemming from diverse disease processes. They examined 44 ILD patients (including those with Idiopathic Pulmonary Fibrosis, Sarcoidosis, and CTD-ILD), revealing that GERD was present in two-thirds of the cases.[13] Moreover, our own observations found that 57.1% of patients with Scleroderma exhibited associated GERD. ILD associated with GERD demonstrated a median decline in FEV1 of 80 ml/year in 50 patients, notably lower than the 120 ml/year decline observed in 17 patients without GERD. Additionally, the median reduction in FVC among individuals with a history of GERD was measured at 130 ml/year in 49 patients, compared to the 170 ml/year decline seen in 15 patients without GERD. Notably, the observed

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P value of 0.98 (> 0.05) indicates that these differences are statistically insignificant. These findings suggest that patients with GERD experience a slower rate of decline in lung function, a characteristic that may be attributable to treatment with anti-reflux medication and life style modification.

Of the 38 patients with CTD-ILD, 13 initially presented with no restriction, 16 had mild restriction, and 9 had moderate restriction. A year later, 11 patients remained without restriction, 4 had mild restriction, 10 had moderate restriction, and 3 had progressed to severe restriction. The median fall in FVC among those with CTD-ILD was 80 ml/year, markedly lower than the 190 ml/year median decline observed in ILD patients without connective tissue involvement. In previous studies focusing on lung functions in systemic sclerosis, a decline in FVC of 62 ml/year was noted. Moreover, the median decline in FEV1 among patients with CTD-ILD was 65 ml/year, compared to 120 ml/year in others. Notably, one study observed a median decline of 47 ml/year in patients with Rheumatoid Arthritis. Furthermore, among 8 patients with both CTD-ILD and smoke exposure, the median decline in FVC was 150 ml/year, and for FEV1, it was 65 ml/year. These findings collectively indicate that the decline in lung function in CTD-ILD is notably slower compared to ILD without connective tissue involvement which points to the availability of plausibly better treatment options with immunosupressants.

In this study, the use of steroids and Cyclophosphamide was prevalent among the patients. Specifically, 61 out of 80 patients (76.25%) utilized steroids, and 30 out of 80 patients (37.5%) used Cyclophosphamide, a medication commonly prescribed for patients with CTD-ILD. Among the 61 patients who used steroids, 10 patients exhibited an increase in FVC, while 51 patients experienced a decline in FVC over a one-year period. The mean decline in FVC among the 51 patients using steroids was 203.73 ml/year, with a median decline of 150 ml/year. Notably, the 10 patients using steroids showed a median FVC increase of 50 ml/year, compared to 55 ml/year in 6 patients who did not use steroids. Furthermore, 9 patients with non-connective tissue-related ILD used N-Acetyl cysteine, resulting in a median FVC decline of 220 ml/year. Additionally, the study revealed that 6 cases of connective tissue-related ILD had a median FVC decline of 70 ml/year while being treated with Azathioprine.

Among the 30 patients who used Cyclophosphamide, 6 patients experienced an increase in FVC and 24 patients experienced a decrease in FVC over the course of a year. The median increase in FVC among the patients who showed improvement was 110 ml/year, while the median decline in FVC among those who experienced a decrease was measured at 75 ml/year.

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Conversely, in the group of 50 patients who did not use Cyclophosphamide, 10 patients demonstrated an increase in FVC, with a median rise of 35 ml/year, while 40 patients showed a decline in FVC, with a median decrease of 190 ml/year.

Therefore, this study found no evidence of improved lung function or a slower decline in lung function with the use of steroids. In contrast, the use of Cyclophosphamide was associated with a significant slowing of the decline in FVC compared to those not using it, as well as an increase in FVC in six patients. This suggests that Cyclophosphamide has the potential to not only prevent the decline in lung function but also improve it in certain cases, as demonstrated in previous studies of Scleroderma patients.[14]

CONCLUSION:

This study offers valuable insights into the sequential changes in lung function observed in patients with interstitial lung disease (ILD). The findings underscore the intricacies of lung function and the potential impact of environmental and etiological factors, including smokers, patients with gastroesophageal reflux disease (GERD), and those undergoing treatment with steroids and cyclophosphamide.

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