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Factors Influence Mortality in Interstitial Lung Disease in Central Chest Institute of Thailand Analyzed by the 2018 ATS/ERS/JRS/ALAT HRCT Classification Criteria

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Abstract

Background: Interstitial lung disease (ILD), has been recognized as a rare disease. Idiopathic interstitial pneumonia (IIP) is one group of ILD which classified after exclusion of specific causes. Among IIP, HRCT characteristics was mainly used for diagnosis recently classified by the 2018 ATS/ERS/JRS/ALAT as UIP, probable UIP, indeterminate UIP and alternative diagnosis. Idiopathic pulmonary fibrosis (IPF) which has radiological and histological terms as Usual interstitial pneumonia (UIP) is the most prevalent and associated with significant mortality in the world which have not much information in Thailand.

Objective—We aimed to study whether UIP is the most prevalent and associated with significant mortality or not and examine factors that affect mortality related to the high-resolution computed tomography (HRCT) patterns in patients with ILD by using HRCT pattern classification according to the latest guideline on idiopathic pulmonary fibrosis [1].

Methods— We analyzed the medical records of 201 consecutive patients diagnosed as having ILD in ILD clinic at Central Chest Institute of Thailand. The HRCT classifications were defined as UIP, probable UIP, indeterminate UIP and alternative diagnosis. To detect differences between groups, Fisher's exact test or Chi-square test was used as appropriate. Predictors of prognosis were determined using Cox regression models. Kaplan-Meier curves were generate and survival was compared among the four patterns using a log rank test for trend.

Results— One hundred four patients (53%) had HRCT findings classified as UIP, 34 (18%) as probable UIP, 12 (6%) as indeterminate UIP and 45 (23%) as alternative diagnosis. Thirty-one patients (72%) with UIP were died out of total 43 deaths in this clinic. Multivariate analysis showed that male patients was negative prognostic factors of mortality whereas 6MWT distance was protective prognostic factors of mortality.

Conclusion—Our results emphasize the increased prevalent in UIP patients significantly but increased mortality insignificantly compared with other groups. The impact on patient survival provides evidence that development of better strategies for the management of ILD could significantly lower the excess mortality of ILD patients.

Keywords – Factors, Mortality, Interstitial Lung Disease, ILD, Usual Interstitial Pneumonia, UIP, Central Chest Institute of Thailand, HRCT

Introduction

Interstitial Lung Disease (ILD), previously known as Diffuse Parenchymal Lung Disease (DPLD) has been recognized as a rare disease with bilateral parenchymal inflammation. Dry cough and shortness of breath are common symptoms found in patients together with progressively decline in lung function in some patients with fibrosis. Idiopathic interstitial pneumonia (IIP) is one group of ILD which classified after exclusion of specific causes such as rheumatic disease, drug and environmental exposure. Among IIP, Idiopathic pulmonary fibrosis (IPF) which has radiological and histological terms as Usual interstitial pneumonia (UIP) is the most prevalent and associated with significant mortality with 3-5 years survival [3-6] which have not much information in Thailand. Prevalence and incidence are less than those of asthma or COPD [17]. One of the reasons is that ILD diagnosis is sophisticated consuming time and resources, and also require multidisciplinary medical team discussion in order to make a correct diagnosis. Frequently we misdiagnosed and mishandled as pneumonia or congestive heart failure until fibrosis developed which led to reduced quality of life or even death.

There has been IPF diagnosis guidelines developing from An Official ATS/ERS/JRS/ALAT Statement 2011 [2] to present guidelines by "Guideline Diagnosis of Idiopathic Pulmonary Fibrosis: An Official ATS/ERS/JRS/ALAT Clinical Practice." recently updated in September 2018 [1]. In this guidelines, diagnosis has been made by combination between four radiological patterns and four histopathological patterns to make a diagnosis of IPF, IPF likely, indeterminate IPF and non-IPF which each group had different clinical characteristics and prognosis. Nevertheless, in real world practice radiological investigation by High-Resolution Computed Tomography (HRCT)-chest has been more available and less invasive whereas histopathological investigation has been less available and more invasive and also needs specialists.

The problem in ILD clinic was we were faced with the breathless patients which had diffusely bilateral abnormal chest imaging together with variety of HRCT patterns. They had different survival. Some of them kept on admitting to the hospital and finally ended up with death, on the other hands some still looked stable and had longer survival. Thus we doubt what characters in both clinical characteristics and HRCT patterns that influenced the mortality. These led to this research to know whether only HRCT-chest patterns (UIP, probable UIP, indeterminate UIP and alternative diagnosis) can predict prognosis or not and what factors that influence mortality in ILD patients.

Materials and Methods

Study Design and Setting

This is a 3-year-observational-descriptive cross-sectional study. A retrospective medical record review study was conducted in the Central Chest Institute of Thailand, Nonthaburi, Thailand between Jan 2018 and Dec 2020 after ethical approval had been received from the Institutional Ethics Committee (CCIT-CRC-63-016).

Data Management

Central Chest Institute of Thailand is a tertiary hospital which become a pulmonary and cardiovascular center. We have pulmonary patients from walk-in patients, referral patients and consultation from cardiologist who previously diagnosed as congestive heart failure but clinical was not improved after treatment. All these patients were treated by pulmonologists in general chest clinic and basic investigation for ILD included HRCT-chest was sent to excluded other causes before sending them to ILD clinic. The inclusion criteria were more than 18 years old, diagnosed with

interstitial lung disease by pulmonologist, had been enrolled in ILD clinic. The exclusion criteria were patients who lost to follow-up over one year and misdiagnosed as other diseases after enrollment. All patients underwent through multidisciplinary team (radiologists, pulmonologists, thoracic vascular surgeons) discussion for radiological pattern classification and further management whether histopathological samples required or not. Medical record of ILD patients in paper during between Jan 2018 and Dec 2020 was manually reviewed and collected data in digital excel file. The following demographic and clinical characteristics were considered : age, gender, smoking status and pack-year of smoking, presenting symptoms (dyspnea, cough, asymptomatic), mMRC (Modified Medical Research Council) Dyspnea Scale, physical examination findings (%SpO2, clubbing, Velcro), related conditions (Connective Tissue Disease: CTD, Combined Pulmonary Fibrosis And Emphysema: CPFE, Pulmonary Hypertension: PHT), spirometry parameters (%FVC, %DLCO), six-minutes-walk test: 6MWT (distance, lowest SpO2, heart rate recovery at one minute of rest: HRR1), medication (corticosteroids, immunosuppressive agents, antifibrotic agents, GERD treatment, N-acetylcysteine), GAP score, du Bois score, death and hospitalization.

Data Analysis

Statistical analysis demographic data were summarized using descriptive statistics. Categorical variables were presented as frequency and percentage. Continuous variables were reported as mean ± standard deviation (SD) for normally distributed data, and median and interquartile range for non-normally distributed data. Comparisons of categorical variables among groups were performed using Chi-square test or Fisher's exact test. Continuous variables were compared using Student's t-test or Mann-Whiney U test. We investigate potential risk factors of mortality with each variable chosen for entry into univariate Cox regression analysis and performed multivariate Cox regression analysis with forward variable selection. Predictors of prognosis were determined using Cox regression models. Kaplan-Meier curves were generating and survival was compared among the four patterns using a log rank test for trend. IBM® SPSS® Statistics version 22 was used to perform all statistical analyses.

Results

Of the 201 ILD patients entered in ILD clinic in Central Chest Institute of Thailand during the study period, 6 data were excluded due to 3 repeated information, 3 misdiagnosed for tuberculosis and COPD (Figure 1). The remaining 195 patients were enrolled. The mean age was 68.5 ± 11.6 years at the diagnosis of ILD whereas UIP mean age (72.8±9.7 years) was significantly older than other groups (p<0.001). Ninety-eight patients (50.3%) were male. Near-

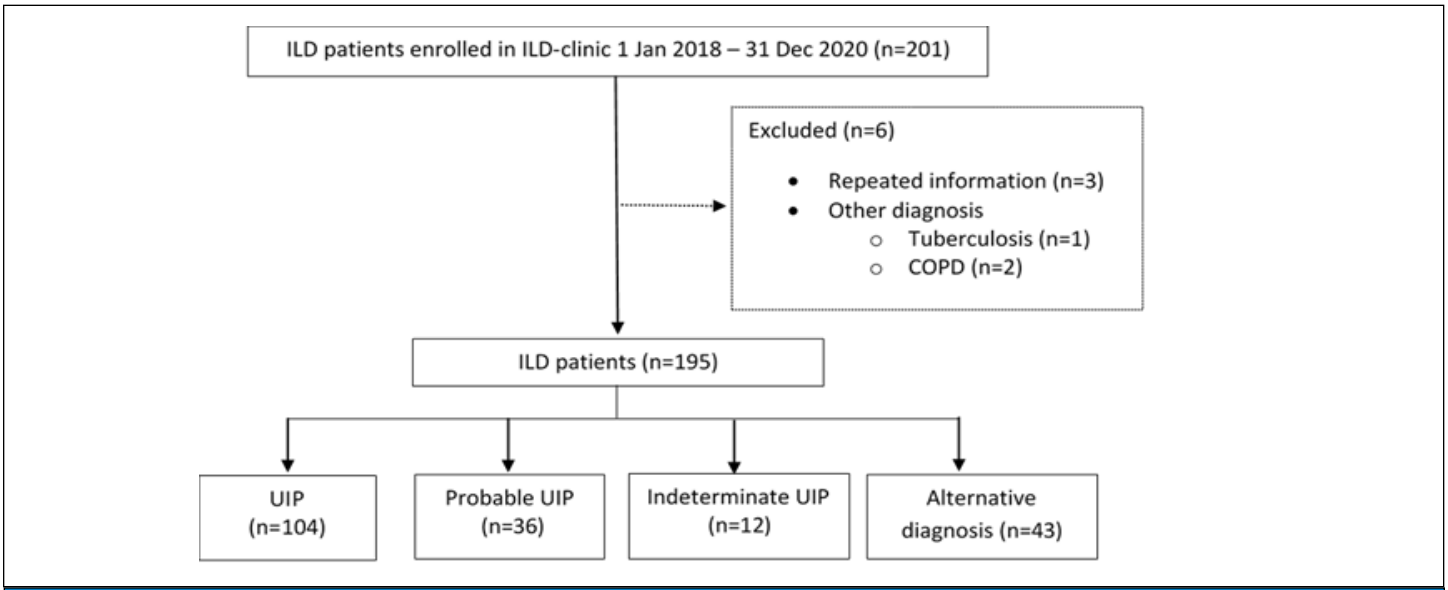

Figure 1: Flow Diagram of the patients enrolled in ILD clinic. ILD, interstitial lung disease; COPD, Chronic onstructive pulmonary disease; UIP, Usual interstital pneumonia.

ly half of the patients (N=93, 47.7%) had history of passive smoker with average smoking of 26.5 ± 19.4 pack-year. Almost all patients had symptoms (cough and dyspnea) at presentation. Only 3 patients in UIP group were asymptomatic while diagnosis was made from accidentally findings during cardiac investigation. Among patients with breathlessness symptoms self-reported degree of disability as mMRC scale 1 predominantly (N=84, 43.1%). Regarding physical examination findings, there were not significantly different in ambient-air oxygenation (mean±SD: 94.3±4.3%) and clubbing fingers (N=22 ,11.3%) in each group. Most of ILD patients were idiopathic at diagnosis point. Co-existing emphysema (called Combined Pulmonary Fibrosis with Emphysema : CPFE) and pulmonary hypertension (PHT) were almost 15 percent. Concerning about spirometry and 6WMT which are physiologic measurement standard tools used for follow-up showed that 34 (17.4%) patients and 61 (31.3%) patients could not achieve spirometry and 6MWT respectively. Among these patients who were unable to perform both procedures were mainly in UIP group. For patients who could complete spirometry, influential parameters such as %FVC and %DLCO were sequentially 66.8±18.8 % and 50.7±20.0%. While walking distance, lowest %SpO2 and HRR1 are meaningful 6MWT parameters were about 328.2±134.4 meters, 90.5±5.0% and 15.2±8.7 bpm respectively. There were not significantly different in medication used in each group except more N-acetylcysteine use in UIP group (N=72, 69.2%). GAP score and du Bois score are both accepted risk assessment system for IPF which are clinical prediction tools that estimates prognosis in patients. Average GAP score was 3.3±1.4, considerably more in UIP group (3.6±1.3) (p=0.034). While average du Bois score was 21.3±12.0 and not significantly different in each group (p=0.574). 84 patients (44.6%) ware hospitalized and more in UIP group (N=51,49%) not strikingly (p=0.476). Deaths from any causes occurred in 43 patients (22.1%) and more pronounced in UIP group (N=31,31%) outstandingly (p=0.013) (Table 1).

Death from any cause occurred in 43 patients (22.1%) over a follow-up period of 3 years. Survival in UIP patients were lower than other groups insignificantly (log rank p=0.279) (Figure 2A). Patients with male gender, history of ex-smoker, shorter 6MWT distance, history of hospitalization and co-existing PHT had significantly worse survival than female gender, non-smoker, longer 6MWT distance, non-hospitalization and non-PHT (log rank p=0.001, p<0.001, p=0.006, p=0.007 and p=0.014 respectively) (Figure 2B, Figure 2C, Figure 2D, Figure 2E and Figure 2F). Predictors of prognosis were unable to analyze in separate groups of HRCT classification due to small population in each group. Even though only UIP group could be calculated but not any parameters were significant (data not shown). For all ILD patients, mortality demonstrated a trend toward univariate association with elderly, male, ex-smoker, CTD-related condition, PHT, hospitalization, GAP score and du Bois score significantly while baseline %SpO2 at ambient air, 6MWT distance and HRR1 were positive predictors of mortality by univariate analysis. Multivariate Cox proportional hazards analysis revealed male [hazard ratio (HR) 88.718; 95% CI 1.497 to 5256.501; p =0.031] to be negative prognostic factors of mortality whereas 6MWT distance [HR 0.986; 95% CI 0.973-0.999; p=0.041] to be positive prognostic factors

Discussion

This is the first study to talk about factors associated with mortality in ILD in Thailand. As one of the tertiary care centers in the country, this hospital receives referrals from all parts of the country. The patient population thus reflects a range of socioeconomic and cultural backgrounds. We identified male gender as factor that increased the hazard of mortality in ILD, while 6MWT distance was identified as having a protective effect on mortality. Inconsistent with previous report by *Sameer et al* that showed mortality was related to female gender (N=90, duration 2 years) [9]. One study about mortality in IPF (not ILD) by *Ali Bin Sarwar Zubairi et al* reported smoking, age greater than 60 years and hypoxemia to be associated with mortality which is similar with the present findings (N=239, duration 10 years) [8]. In this study there were 52 patients (26.7%) diagnosed as IPF in which died 14 patients (32.6%) of total death. Male gender was related to be associated with increased mortality could possibly clarified by more male included to this study than female.

Age at onset of symptom was about 64.35±12.05 years old while age at diagnosis was roughly 68.45±11.56 years old. Median time from symptom onset to current diagnosis was 3 months (range,

Table 1: Characteristics of ILD patients in ILD clinic

Characteristics	All patients	UIP	Probable UIP	Indeterminate UIP	Alternative diagnosis	P value
No. of patients	195	104	36	12	43	-
Age, mean±SD	68.5±11.6	72.8±9.7	66.1±9.5	61.3±9.6	62.0±13.4	<0.001*
Male,N [%]	98 [50.3]	62 [59.6]	15 [41.7]	6 [50]	15 [34.9]	0.032*
Ex-smoker,N [%]	93 [47.7]	60 [57.7]	14 [38.9]	4 [33.3]	15 [34.9]	0.028*
-Pack-year,mean±SD (n=93)	26.5±19.4	26.2±21.3	26.6±15.6	38.8±8.5	24.5±16.2	0.627
Presentation symptoms						
-Dyspnea,N [%]	166 [85.1]	87 [83.7]	30 [83.3]	12 [100]	37 [86.0]	0.495
-Cough, N [%]	163 [83.6]	86 [82.7]	31 [86.1]	10 [83.3]	36 [83.7]	0.973
-Asymptomatic,N [%]	3 [1.5]	3 [2.9]	0 [0]	0 [0]	0 [0]	0.652F
mMRC, N [%]						
0	7 [3.6]	1 [1]	4 [11]	1 [8.3]	1 [2.3]	0.019F*
1	84 [43.1]	39 [37.5]	19 [52.8]	6 [50]	20 46.5]	0.370
2	55 [28.2]	33 [31.7]	10 [27.8]	2 [16.7]	10 [23.3]	0.583
3	40 [20.5]	25 [24.0]	3 [8.3]	3 [25]	9 [20.9]	0.239
4	9 [4.6]	6 [5.8]	0 [0]	0 [0]	3 [7.0]	0.464F
Physical examination						
-%SpO2 (Room air),mean±SD (n=195)	94.3±4.3	94.1±4.3	95.2±4.0	95.0±3.8	93.8±4.4	0.405
-Clubbing,N [%]	22 [11.3]	16 [15.4]	1 [2.8]	2 [16.7]	3 [7]	0.114F
-Velcro,N [%]	133 [68.2]	85 [81.7]	23 [63.9]	5 [41.7]	20 [46.5]	<0.001*
CTD-related ILD						
-Idiopathic,N [%]	80 [41.0]	48 [46.2]	16 [44.4]	3 [25]	13 [30.2]	0.199
-IPAF,N [%]	63 [32.3]	35 [33.7]	9 [25]	4 [33.3]	15 [34.9]	0.777
-CTD,N [%]	49 [25.1]	21 [20.2]	11 [30.6]	5 [41.7]	12 [27.9]	0.280
-Others,N [%]	3 [1.5]	0 [0]	0 [0]	0 [0]	3 [7.0]	0.041F*
CPFE-related ILD,N [%]	26 [13.3]	20 [19.2]	2 [5.6]	0 [0]	4 [9.3]	0.076F
PHT-related ILD,N [%]	28 [14.4]	19 [18.3]	4 [11.1]	1 [8.3]	4 [9.3]	0.415
Spirometry						
-Unable to perform,N [%]	34 [17.4]	20 [19.2]	5 [13.9]	0 [0]	9 [20.9]	0.328
-%FVC,mean±SD (n=160)	66.8±18.8	67.7±18.6	72.3±20.8	64.1±18.0	60.8±16.7	0.089
-%DLCO,mean±SD (n=126)	50.7±20.0	49.5±19.3	52.6±21.8	71.9±17.9	45.9±18.0	0.010*
6MWT						
-Unable to perform,N [%]	61 [31.3]	36 [34.6]	7 [19.4]	1 [8.3]	17 [39.5]	0.066
-Distance in metre,mean±SD (n=134)	328.2±134.4	298.8±121.8	364.9±134.1	365.6±196.5	359.7±104.8	0.044*
-Lowest %SpO2,mean±SD (n=134)	90.5±5.0	89.9±4.8	91.2±4.8	90.0±6.8	91.6±5.0	0.443
-HRR1,mean±SD (n=134)	15.2±8.7	14.2±7.6	14.8±8.4	17.6±11.2	17.3±10.4	0.350
Medication,N [%]						
-Corticosteroids	56 [28.7]	28 [26.9]	8 [22.2]	3 [25.0]	17 [39.5]	0.328
-Immunosuppressive agents	44 [22.6]	22 [21.2]	7 [19.4]	2 [16.7]	13 [30.2]	0.571

Characteristics	All patients	UIP	Probable UIP	Indeterminate UIP	Alternative diagnosis	P value
-Antifibrotic agents	13 [6.7]	11 [10.6]	1 [2.8]	0 [0]	1 [2.3]	0.226F
-GERD treatment	97 [49.7]	57 [54.8]	15 [41.7]	5 [41.7]	20 [46.5]	0.475
-N-acetylcysteine	108 [55.4]	72 [69.2]	18 [50.0]	4 [33.3]	14 [32.6]	<0.001*
Total death,N [%]	43 [22.1]	31 [31.0]	2 [5.9]	1 [8.3]	9 [22.0]	0.013*
Hospitalization,N [%]	87 [44.6]	51 [49.0]	13 [36.1]	4 [33.3]	19 [44.2]	0.476
GAP score,mean±SD (n=125)	3.3±1.4	3.6±1.3	3.0±1.5	2.3±1.5	3.1±1.5	0.034*
GAP stage, N [%]						
1 (0-3)	72 [57.6]	31 [47.0]	17 [73.9]	6 [75.0]	18 [64.3]	0.077F
2 (4-5)	46 [36.8]	31 [47.0]	5 [21.7]	2 [25.0]	8 [28.6]	0.091
3 (6-8)	7 [5.6]	4 [6.1]	1 [4.3]	0 [0]	2 [7.1]	1.000F
du Bois score,mean±SD (n=89)	21.3±12.0	21.5±12.7	24.3±12.2	20.2±13.9	17.9±7.9	0.574

*significant; F,Fisher's Exact Test; ILD, interstitial lung disease; UIP, usual interstitial pneumonia; mMRC, modified Medical Research Counsil dyspnea scale; CTD, connective tissue disease; IPAF, interstitial pneumonia with autoimmune features; CPFE, combined pulmonary fibrosis with emphysema; PHT,pulmonary hypertension; FVC, forced vital capacity; FEV1, forced expiratory volume in 1 second; 6MWT,six-minute walk test; DLCO, diffusing capacity of the lung for carbon monoxide; SpO2, oxygen saturation; HRR1, heart rate recovery at one minute of rest; SD, standard deviation; GERD, gastroesophageal reflux disease; GAP, gender, age and physiology; du Bois score, score determines 1-year mortality by Dr. Roland du Bois

0-72 months) (data not shown) which was shorter duration than previous study in INTENSITY Survey (median 7 months, range 0-252 months) [7]. This revealed that the medical services in Thailand were quite enough to make most necessary investigation available and enough for patients in need. The possible explanation included almost all Thai people could access the treatment rights by supported medical expenses by Civil Servant Medical Benefit Scheme: SCMBS, Social Security Scheme: SSS and Universal health-care Coverage Scheme: UC. Many studies reported average time from diagnosis to death of interstitial lung disease was about 2-3 years [10,14] to be associated with present finding that was approximately 23 months (data not shown).

Concerning about 6MWT distance which happened to be a significant factor effecting on mortality, the average distance was 328.2±134.4 meters. Many studies have shown that mean walk distance was 487 meters (range 271- 689) in *Chetta, A., Aiello,et al* study (N=40) [15]. The mean walk distance was 433 meters (range 96- 681) in *Jacqueline A. Chang, et al* finding (N=50) [16]. The possible explanations for the lower mean walk distance in this study were more 6MWT-capable patients (N=134) and main UIP patients included. The average distance was lowest at 298.8±121.8 meters in UIP group. We scheduled spirometry and 6MWT program in every 6 months in order to closely monitor our patients. In addition, patients who unable to perform these procedures were 34 patients (17.4%) and 61 patients (31.3%) in spirometry and 6MWT respectively, especially those were more in UIP groups [(20 patients (19.2%) for spirometry and 36 patients (34.6%) for 6MWT]. The patients who were able to perform 6MWT showed better survival than those who could not. (log rank p=0.036).

The present study had some limitations. Firstly, there was not represent to general Thai population due to case selection into referral center. (Central Chest institute of Thailand is a tertiary hospital specialized in pulmonary and cardiovascular diseases). Secondlly, there was less CTD-related ILD patients due to no rheumatologist in this institute. Referral cases automatically excluded known-co-existing rheumatologic disease and/or rheumatologist-containing institute transfer for patients' most benefits after thorough investigation was made for CTD-related ILD. This problem partially solved by monthly online conference together with tele-consultation with rheumatologist from Mahidol university, Ramathibodi hospital. And lastly, some parameters could not be performed especially in last one year of study according to COVID-19 outbreak. Despite limitations, the present study is one of the very first study in Thailand that aimed to investigate factors

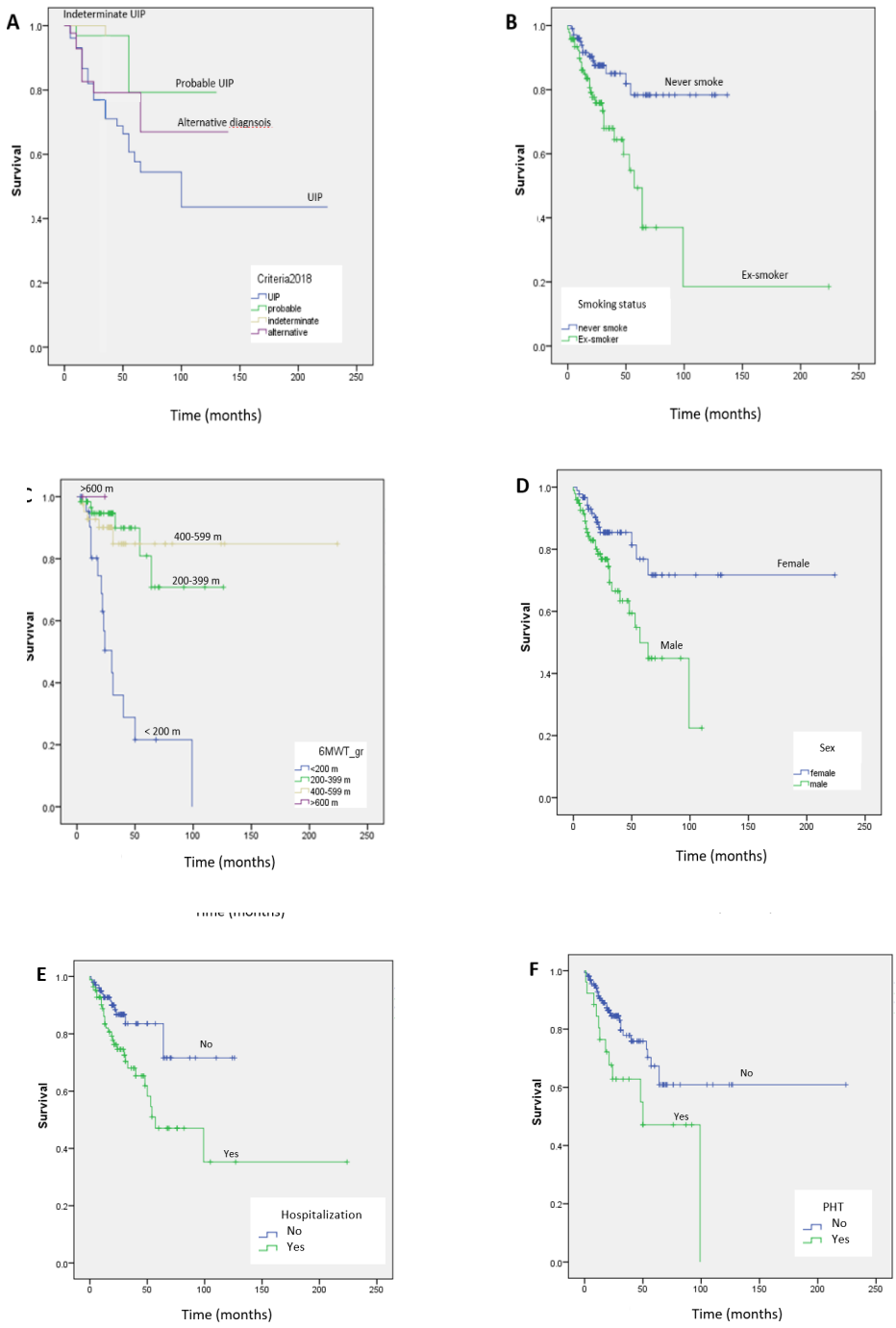

Figure 2: Kaplan-Meier survival curves of all-cause mortality. (A) There were no significant differences in survival between patients with UIP, probable UIP, indeterminate UIP and alternative diagnosis (p=0.279); (B) the patients with history of ex-smoker showed poorer survival than non-smoker (p=0.001); (C) the patients with longer in 6MWT distance showed better survival than those with shorter distance (p<0.001); (D) male patients reveals significantly worse survival than female patients (p=0.006); (E) non-hospitalized patients lived longer than hospitalized patients strikingly (p=0.007); (F) co-existing PHT associated with shorter survival than those without PHT (p=0.014).

Table 2: Analyses of predictors of mortality in patients with ILD

Characteristics	Univariate Cox regression		Multivariate Cox regression	
	Crude HR (95% CI)	P value	Adjusted HR (95% CI)	P value
Age	1.040 (1.007-1.075)	0.019*	0.980 (0.872-1.102)	0.735
Male	2.315 (1.130-4.741)	0.022*	88.718(1.497-5256.501)	0.031*
Ex-smoker	2.740 (1.336-5.618)	0.006*	0.373(0.023-6.003)	0.486
%SpO2(Room air)	0.840 (0.773-0.913)	<0.001*	0.792(0.468-1.340)	0.385
Clubbing	0.493 (0.139-1.755)	0.275	-	-
Velcro	0.795 (0.386-1.635)	0.533	-	-
CTD-related				
Idiopathic	1.553 (0.783-3.080)	0.207	-	-
IPAF	0.821 (0.400-1.688)	0.592	-	-
CTD	2.923 (1.074-7.955)	0.036*	0.817(0.032-20.886)	0.903
CPFE-related	1.279 (0.498-3.283)	0.609	-	-
PHT-related	3.594 (1.514-8.536)	0.004*	1.291(0.076-21.989)	0.860
%FVC	0.985 (0.963-1.007)	0.169	-	-
%DLCO	0.989 (0.964-1.015)	0.404	-	-
6MWT Distance	0.992 (0.989-0.996)	<0.001*	0.986(0.973-0.999)	0.041*
Lowest %SpO2 in 6MWT	0.931 (0.853-1.015)	0.104	-	-
HRR1 in 6MWT	0.875 (0.809-0.945)	0.001*	0.837(.695-1.009)	0.062
Hospitalization	3.352 (1.630-6.893)	0.001*	7.247(0.638-82.336)	0.110
GAP score	1.597 (1.097-2.325)	0.015*	0.189(0.028-1.251)	0.084
du Bois score	1.054 (1.008-1.103)	0.021*	1.099(0.969-1.246)	0.140

*significant; Crude HR, Crude hazard ratio; 95% CI,95% confident interval; ILD, interstitial lung disease; CTD, connective tissue disease; IPAF, interstitial pneumonia with autoimmune features; CPFE, combined pulmonary fibrosis with emphysema; PHT, pulmonary hypertension; FVC, forced vital capacity; 6MWT,six-minute walk test; DLCO, diffusing capacity of the lung for carbon monoxide; SpO2, oxygen saturation; HRR1, heart rate recovery at one minute of rest; GAP, gender, age and physiology; du Bois score, score determines 1-year mortality by Dr. Roland du Bois.

associated with mortality in ILD patients.

Conclusion

In patients with ILD, patients who classified as UIP by HRCT have increased prevalent substantially compared with probable UIP, indeterminate UIP and alternative diagnosis. The results showed increased mortality in UIP more than any groups but not significantly. Male and 6MWT distance significant related to mortality strikingly. The results of present study highlight the need to develop a strategy to improve awareness process by significant parameter in this study to improve quality of life in ILD patients.

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Conflicts of interest

The author declares no conflict of interest, and no financial support from the companies that produce and/or distribute the drugs, devices, or materials described in the present report.

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