similar pathogenesis as idiopathic pulmonary fibrosis.(2) Pirfenidone slows the decline in lung functions in idiopathic pulmonary fibrosis.(3) Therefore, pirfenidone may be efficacious in SSc-ILD.

Objectives: To compare the efficacy and safety of pirfenidone with placebo in SSc-ILD.

Methods: This was a double-blind, randomised, placebo controlled trial. We enrolled 34 consecutive subjects of SSc-ILD with forced vital capacity (FVC) >50% of predicted value and diffusing capacity of lung for carbon monoxide > 30% of predicted value. Subjects were randomly assigned in a ratio of 1:1 to receive either pirfenidone (n = 17) or placebo (n = 17) and followed up for 6 months. Pirfenidone was started at 600 mg/day and increased to 2400 mg/day over one month and continued for the trial period. Primary outcome was to compare the proportion of patients with stabilisation or improvement in lung functions (FVC). Secondary outcome was to compare the change in FVC, Mahler's dyspnea index, 6 minute walk distance (6MWD), modified Rodnan skin score (MRSS) and change in serum levels of tumour necrosis factor α (TNF- α) and tissue growth factor β (TGF- β) at the end of 6 months. Trial was registered with clinical trials registry of India (CTRI/2018/01/011449).

Results: By intention-to-treat analysis, 16 (94.1%) patients in treatment group showed stabilisation of lung function compared to 13 (76.5%) in control group (p = 0.335). The median change in FVC was -0.55% (IQR = -4.75% to 1.75%) and 1.0% (IQR = -8.5% to 5%) in the treatment and control groups respectively (p = 0.654). The median change in 6MWD was -15 (IQR = -42.5 - 13.75) meters and 0.0 (IQR = -50 - 30) meters in treatment and control groups respectively (p = 0.601). The median of focal scores for transitional dyspnea index in both the treatment and control groups were 3.0 (IQR = 0 - 3) (p = 0.838). Median change in MRSS was 0.0 (IQR = -2.0 - 1.0) and -1.0 (IQR = -4.0 - 0.0) in treatment and control groups (p = 0.828). Difference in TNF- α levels were -5.14 (IQR = -14.6 - 0.29) pg/ml in the treatment and -2.94 (IQR = -5.51 - -2.35) pg/ml control group (p = 0.918). Difference in TGF- β levels in the treatment and control groups were -186.73 (IQR = -731.43 - -64.6) pg/ml and 24.29 (IQR = -233.21 - 362.0) pg/ml respectively (p = 0.093). The mean tolerated dose of pirfenidone was 1700 $\pm$ 644 mg/day. Adverse events were mild, most common among them were gastrointestinal followed by skin rashes. Only one serious gastrointestinal adverse effect was documented.

Conclusion: We failed to demonstrate a beneficial effect of pirfenidone over placebo in stabilising FVC, functional status, or skin disease after 6 months of therapy. A larger study with longer follow up period may be further required.

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OP0244 EFFICACY AND SAFETY OF LOW-DOSE IL-2 IN PATIENTS WITH MULTIPLE MYOSITIS/ DERMATOMYOSITIS

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Background: Dermatomyositis (DM) and polymyositis (PM) are rare chronic inflammatory disorders with significant associated morbidity and mortality despite treatment [1, 2], characterized by subacute onset of proximal muscle weakness, elevated muscle enzymes, and inflammatory infiltrates on muscle biopsy. Although several hypotheses have been proposed for triggers of inflammation in the diseases [3], growing evidences have focused on the immune disorders [4]. However, the quantitative changes of lymphocyte subsets in DM/PM are unclear and whether low-dose IL-2 could rebalance the lymphocyte subsets and further benefit to remission disease activity of DM/PM patients is unknown.

Objectives: To investigate the quantitative status of peripheral blood lymphocyte subsets in the patients for the exploration of pathogenesis and evaluate the safety and efficacy of low-dose IL-2 therapy in patients with DM/PM.

Methods: From February 2016 to October 2018, total 147 patients with PM/DM and 128 gender and age matched healthy individuals were enrolled in this study. The absolute numbers of T, B, NK, CD4+T, CD8+T, Th1, Th2, Th17 and Treg cells in peripheral blood of these individuals were detected by flow cytometry combined with standard absolute counting beads. Patients in IL-2 group (n=31) were not only given traditional treatments, but injected subcutaneously human IL-2 (aldesleukin) at 50 WIU per day for a 5-day course. The demographic features, clinical manifestations and laboratory indicators were compared before and after the treatment.

Results: Patients with PM/DM had lower levels of Treg cells as well as T, CD4+T, CD8+T, Th1, Th2, and Th17 compared with those of the healthy controls (P < 0.05), which was correlated with disease activity (P < 0.05). After IL-2 administration, the absolute numbers of peripheral lymphocyte subsets in patients were significantly increased (P < 0.05), leading to a better remission compared with the patients received conventional therapy (P < 0.05).

Figure 1: Comparison of absolute numbers of peripheral lymphocyte subsets between patients with PM/DM (n=147) and healthy controls (n=128). All the lymphocytes subpopulations were analyzed by detected by flow cytometry combined with standard absolute counting beads. Data were presented as mean $\pm$ SD and statistical analysis was determined by two-tailed unpaired *t*-test. Patients had lower levels of T, NK, CD4+T, CD8+T, Th1, Th2, Th17 and Treg cells in PB compared with those of healthy controls. *P < 0.05, **P < 0.01, ***P < 0.001.

Figure 2: Changes of peripheral lymphocyte subsets after different treatments (n=31). Absolute numbers of T, CD4+T, CD8+T, Th1, Th2, Th17 and Treg cells in patients were significantly increased after treatment. *P < 0.05, **P < 0.01, ***P < 0.001.

Conclusion: The difference status of peripheral lymphocyte subsets, especially Tregs, between PM/DM patients and healthy individuals suggests that lymphocyte subsets may be involved in and play an important role in the pathogenesis of patients. Low-dose IL-2 can effectively increase the level of Treg cells as well as other lymphocytes to some degree and maintain the immunologic balance, which may help for PM/DM patients' symptoms remission without over-treatment and evaluated side effect. But long-term benefits of IL-2 therapy are required to further study.

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