NEW STUDY REVEALS PROMISING TREATMENT FOR SCLERODERMA-RELATED INTERSTITIAL LUNG DISEASE

TWO-YEAR STUDY SHOWS MYCOPHENOLATE MOFITIL TO BE AS EFFECTIVE AS CYCLOPHOSPSHAMIDE

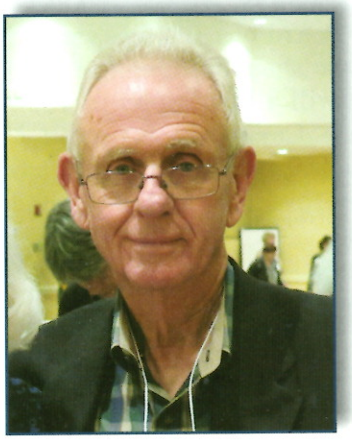
SAN FRANCISCO - Mycophenolate mofitil is as effective as cyclophosphamide in treating interstitial lung disease in people with scleroderma, according to new research findings presented in November 2015 at the American College of Rheumatology Annual Meeting in San Francisco.

Lung complications of scleroderma are potentially very serious. One particular complication is **interstitial lung disease**, which is characterized by progressive scarring of the lung tissue that eventually hinders a person's ability to breathe.

While there are few treatments identified to modify the course of scleroderma, researchers recently looked at mycophenolate mofitil (CellCept®) and cyclophosphamide (Cytoxan®) to determine if they could positively affect the outcomes of scleroderma patients who also have interstitial lung disease.

"For a sizeable fraction of people with scleroderma, scarring lung disease can be associated with a great deal of suffering and even with death," explains lead investigator in the study, **Philip Clements, MD, MPH**; professor emeritus, David Geffen School of Medicine at University of California, Los Angeles, [and featured speaker at the 2014 New England PES]. "We postulated that the interstitial lung disease seen in scleroderma was caused in part by inflammation. We therefore sought to decrease the inflammation with medications that have strong anti-inflammatory properties, namely cyclophosphamide and mycophenolate mofitil."

Dr. Clements's team followed 142 patients over the course of a two-year study to determine if oral cyclophosphamide or mycophenolate



Dr. Philip Clements

mofitil could impact forced vital capacity – a breathing test that measures the amount of air that can be exhaled from the lungs after taking a deep breath.

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The patients included in the study had all been diagnosed with scleroderma for fewer than seven years, suffered from moderate shortness of breath or difficulty breathing, had an initial forced vital capacity reading of 45 to 80 percent, and had high-resolution CT scan evidence of filling of the air spaces with scar and thickening of the lungs.

The researchers randomly placed each participant into one of two groups, and the participants did not know which group they were in. The first group received 2mg/kg cyclophosphamide by mouth daily for one year and then received placebo daily for the second year. The second group received up to 1,500mg of mycophenolate mofitil twice daily for two years.

At the beginning of the study, and every three months thereafter, each participant underwent a physical exam, which included the Modified Rodnan Skin Scoring, lung function tests, and a questionnaire that assessed their symptoms. With the exception of the mycophenolate mofitil group having higher Modified Rodnan Skin Scores, the two groups had similar characteristics at the beginning of the study.

At two years, both groups showed similar and significant improvements in forced vital capacity (lung function testing), breathlessness (breathing questionnaire), in skin thickening (modified Rodnan Skin Score), and in interstitial lung change on high resolution CT scan of the lungs ($p<0.05$).

While Dr. Clements notes that both of the drugs have serious potential side effects — and more studies are expected — he feels with careful monitoring, they can be used relatively safely for people with scleroderma-related lung disease.

"The most frequent cause of death among patients with scleroderma is interstitial lung disease. Since interstitial lung disease produces permanent damage predominantly in the first five-to-seven years of scleroderma, it is important that people with scleroderma get screened with lung function tests regularly every six months in those first five-to-seven years. If a patient's lung function declines, rheumatologists should consider treating him or her as early as possible with cyclophosphamide or mycophenolate mofitil to try to prevent further progressive lung scarring," concludes Dr. Clements.

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