New Study Shows Cellular Therapy May Benefit ILD Patients

ILD is the acronym for interstitial lung disease and is the term used to define a broad category of chronic lung conditions that have similar symptoms. The common symptoms of interstitial lung diseases include lung tissue scarring, thickened lung tissues with limited elasticity, which is known as fibrosis, and eventually, respiratory failure. Interstitial lung diseases also have several causes in common, including smoking and inhalation of hazardous materials. Unfortunately, despite medical advances, interstitial lung diseases have no known cure. However, there are new studies that have produced data indicating that cellular therapy may have benefits for patients with interstitial lung diseases.

The Effects of Cellular Therapy on Interstitial Lung Diseases: A Study by the Lung Health Institute

One study by the Lung Health Institute took a look at the possibility that cellular therapy could benefit patients with interstitial lung diseases with encouraging results. Cellular therapy for the treatment of interstitial lung diseases involves taking autologous cells from a patient's bone marrow or blood, mixing these cells with platelet-rich plasma and inserting this combination into the body.

This particular study of cellular therapy involved 50 patients with various interstitial lung diseases, and of these patients, thirty-five patients had pulmonary fibrosis, which the most common of these conditions. Data was gathered from the patients taking part in the survey using a quality of life survey that was given before treatment, three months after treatment and six months after treatment.

The data gathered by the study was extremely positive. For instance, the study's data shows that six months after treatment 72% of the 50 patients reported an increase in quality of life. In addition, the data indicates that of the 35 pulmonary fibrosis patients in the study, more than 65% of them had an improved quality of life six months after their cellular therapy treatment.

The Lung Health Institute Is Leading the Way on Cellular Therapy

Research into the benefits of cellular therapy is ongoing, and more research is required. However, the studies that have been conducted by the Lung Health Institute indicate that cellular therapy has the potential to slow the progression of interstitial lung diseases and other lung conditions while also potentially improving the quality of life for many patients. For additional information about cellular therapy, contact one the Lung Health Institute's helpful and friendly patient coordinators today.

Autologous Cellular Therapy & its Effects on Interstitial Lung Disease.

THE PROBLEM WITH INTERSTITIAL LUNG DISEASES

Interstitial Lung Disease (ILD) is a progressive lung disorder that covers more than 150 biological processes and can lead to scarring within the lungs (pulmonary fibrosis) and respiratory failure. Although in most cases, it is not possible to determine the cause of ILD, in some cases the disease is brought about through smoking, exposure to hazardous materials or complications from other related illnesses. The group of disorders that make up ILD exhibit gradual fibrosis, leading to the destruction of the alveolar epithelium as well as the scarring of the interstitium and a diminished ability to oxygenate the blood. ILD is difficult to diagnose and even harder to treat, with a prevalence estimated at 42.7 per 100,000 persons.

Beginning with an inflammation within the bronchioles (air passageways), alveoli (tiny air sacs) or capillaries of the lungs (microscopic blood vessels), this inflammation can cause necrosis or apoptosis (cell death) of the alveolar epithelium and irreparable scarring of the lung tissue. In cases where there is no prior inflammation, ILD can also be sparked through epithelial injury and abnormal wound repair.

While many suggested medications are often nonspecific to the disease, these ineffectual medications frequently cause the disease to progress in spite of medical efforts to mitigate its advancement. This progression will ultimately lead to death. A common issue in addressing ILD is differentiating it from other more treatable diseases, in comparison to the more unpredictable idiopathic pulmonary fibrosis (IPF)—the most common ILD—which represents 45% of all ILD patients.

Of the diseases encompassed by ILD, IPF continues to be the most difficult to treat, with patients of the disease carrying a median survival of 2.5 to 5 years from the time of diagnosis.[4] Characterized as a chronic, progressive and fibrotic ILD, the prevalence of IPF is increasing, with current rates ranging from 14 to 43 people per 100,000 persons in the U.S.[4] As IPF is known to exhibit consistent and acute exacerbations, which work to further lung degeneration and increase the risk of mortality, it is crucial to address the progression of ILD immediately upon diagnosis.[3]

As ILD continue to contribute to frequent hospitalizations and increased mortality, in lieu of the limited efficacy of traditional treatment options, emerging treatments such as cellular therapy have come to the forefront in the treatment of lung disease symptoms and progression. With aims to address fibrosis directly, as well as the deteriorating effects of the autoimmune process on other organs, cellular therapy and the inherent healing properties it holds may be the most substantial form of treatment in managing ILD with few if any adverse effects. ■

Treatment Overview

SUMMARY OF PROCESS

The Lung Health Institute (LHI) provides treatment by harvesting autologous cells (hematopoietic cells and mesenchymal cells—otherwise known as pericytes) by withdrawing bone marrow or peripheral blood. These harvested autologous cells are isolated and along with platelet-rich plasma, are then reintroduced into the body through the peripheral venous system which ultimately enters into the pulmonary vasculature (vessels of the lungs) where cells are trapped in the microcirculation (the pulmonary trap). ■

METHODOLOGY

Individuals diagnosed with ILD were tracked by the Lung Health Institute to measure the effects of treatment via either the venous harvest protocol or bone marrow harvest protocol on their Quality of Life.

Quality of Life Survey (QLS) & Quality Improvement Score (QIS)

Patients with progressive ILD will typically experience intermittent periods of decline in their respiratory health in which they may see a steady decrease in their quality of life. Given this development, a patient's Quality of Life Score is frequently used to define additional therapeutic effects, with regulatory authorities frequently encouraging their use as primary or secondary outcomes.[8]

On quality of life testing, data was collected through the implementation of the Clinical COPD Questionnaire (CCQ) based survey[5]. The survey measured the patient's self-assessed quality of life on a 0-6 scale, with adverse quality of life correlated in ascending numerical order. It was implemented in three stages: pre-treatment, 3-months post-treatment and 6-months post-treatment. The survey measured two distinct outcomes: the QLS score, which measured the patient's self-assessed quality of life score, with a higher score signifying a worse quality of life. And the QIS, a percentage-based measurement determining the proportion of patients within the sample that experienced QLS score improvements. ■

DEMOGRAPHICS

Over the duration of six months, the results of 50 patients treated for ILD through venous and bone marrow based therapies were tracked by the Lung Health Institute in order to measure changes in quality of life.

Of the 50 patients treated for ILD* by the Lung Health Institute, 31 were male (62%) while 19 were female (38%). Ages of those treated range from 50-89 years old with an average age of 71 for ILD (Figure 1.1)*.

Of the 35 patients treated for Pulmonary Fibrosis (PF) by the Lung Health Institute, 23 were male (66%) while 12 were female (34%). Ages of those treated ranged from 50-87 with an average age of 74 for PF (Figure 1.2). ■

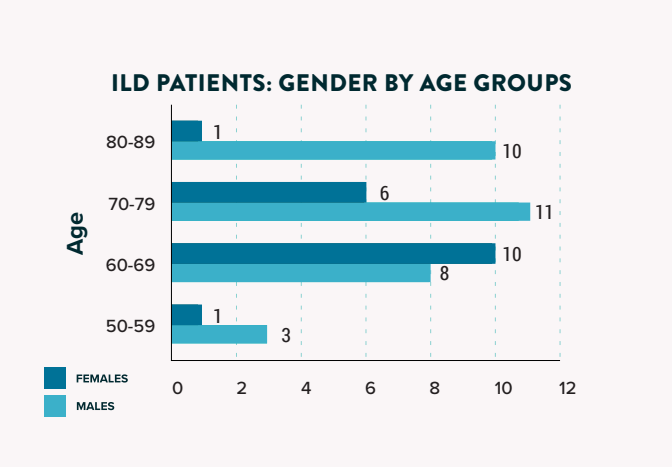

Figure 1.1 - Patient Demographics (ILD)

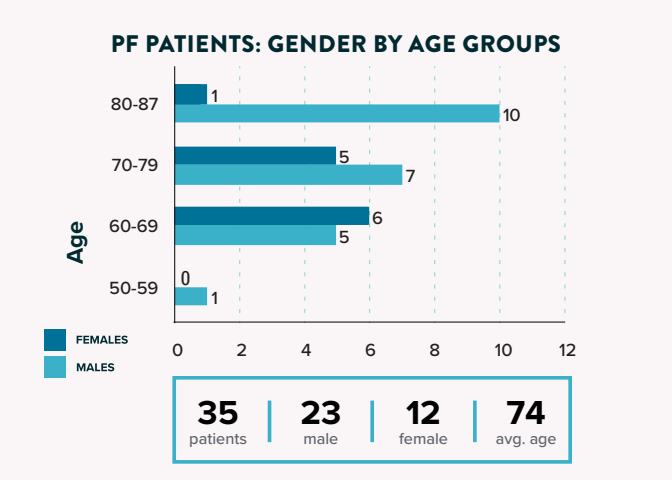

Figure 1.2 - Patient Demographics (PF)

Results

INTERSTITIAL LUNG DISEASE (ILD) PATIENTS			
Quality of Life (QOL)	Average Score*	Data Size	% Improvement
Pre-Treatment	3.2	50	-
3 Month Post-Treatment	2.3	50	27.8%
6 Month Post-Treatment	2.5	50	22.7%

Figure 1.4 - Lung Health Institute ILD Outcomes Data

During the three to six-month period after treatment, patients saw a natural decline in their progress. QLS scores dropping from 27.8% to 22.7%, the QIS from 80% to 72%, while statistically significant improvement within the QIS dropped from 70% to 58% after six months.

Over the course of the study, 80% of all patients found that their Quality of Life Improvement score (QIS) had improved (figure 1.3), while 70% of patients found statistically significant improvement overall. Among those whose quality of life increased, the average improvement was 27.8% within three months of treatment (figure 1.4)*. ■

*Within this metric, the QIS denotes general improvement within the CCQ score, while statistically significant improvement is marked by a.4 or greater improvement within this score.

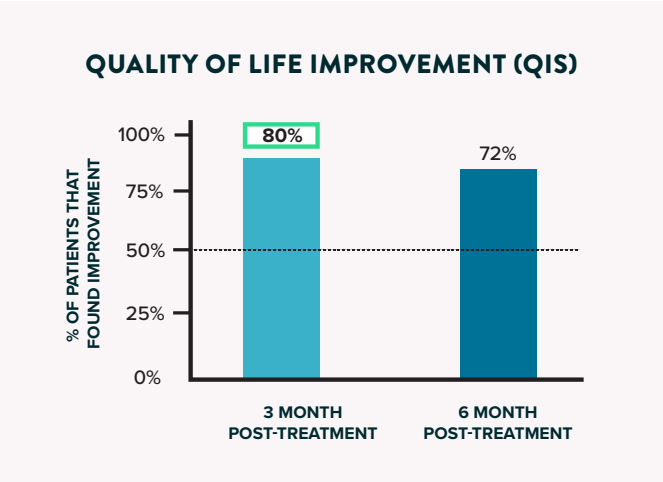

Figure 1.3 - Lung Health Institute QIS for ILD

Results

PULMONARY FIBROSIS (PF) PATIENTS			
Quality of Life (QOL)	Average Score*	Data Size	% Improvement
Pre-Treatment	3.3	35	-
3 Month Post-Treatment	2.4	35	26.9%
6 Month Post-Treatment	2.7	35	19.0%

Figure 1.6 - Lung Health Institute PF Outcomes Data

During the three to six-month period after treatment, patients saw a natural decline in their progress. QLS scores dropping from 26.9% to 19%, the QIS from 80% to 65.7%, while statistically significant improvement within the QIS dropped from 68.6% to 57.1% after six months.

Over the course of the study, 80.0%% of all patients found that their Quality of Life Improvement score (QIS) had improved within three months of treatment (figure 1.5) while 68.6% of patients found statistically significant improvement overall. While patients saw an average increase of 26.9% to their Quality of Life (QLS) score within three months of treatment (figure 1.6). ■

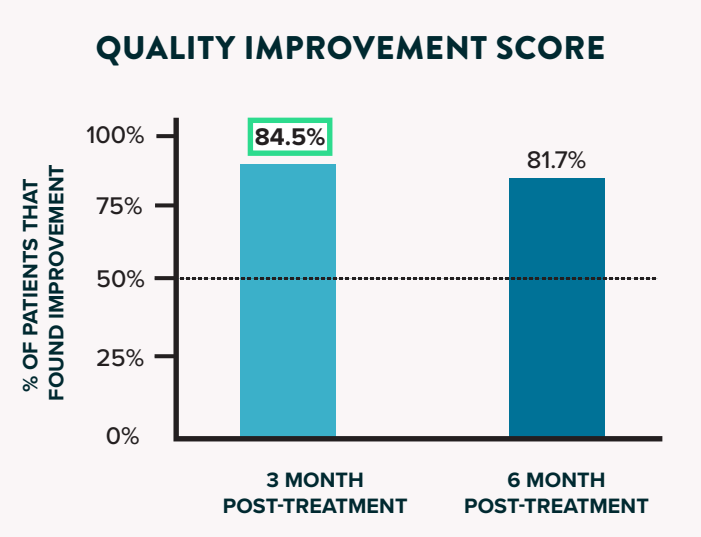

Figure 1.5 - Lung Health Institute QIS for PF score

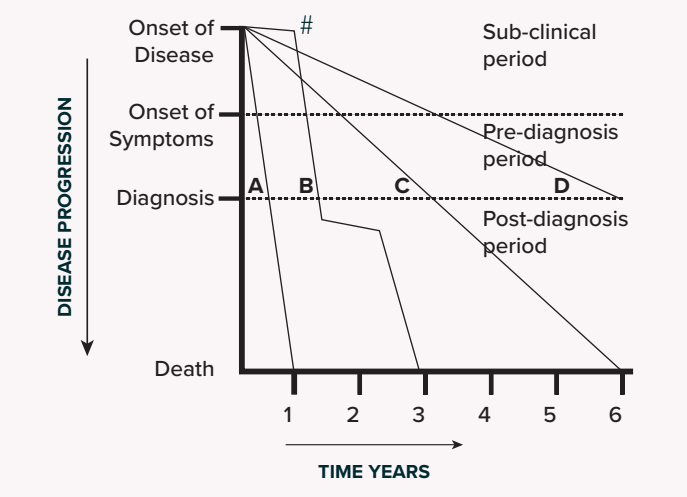

Figure 1.7 - Maher's IPF decline

In Maher's findings of natural lung function decline for idiopathic pulmonary fibrosis, the model shows that patient survival rate can be improved through appropriate and early intervention (figure 1.7).[6] Though quitting smoking will mitigate the harmful effects of cigarette smoke, unlike cellular treatment, no evidence has shown that quitting smoking alone can increase pulmonary function. It remains to be seen if better quality of life will translate to longevity, but if one examines what factors allow for improved quality of life such as improvement in oxygen use, exercise tolerance, medication use, visits to the hospital and reduction in disease flare ups then one can see that quality of life improves in association with clinical improvement. ■

Conclusion

Through the data collected by the Lung Health Institute, development of methodologies for this form of treatment are taking place with other entities in the medical community quickly following suit. Through the infusion of autologous cells derived from the patient's own body, cellular therapy minimizes the chance of rejection to the highest degree, may promote healing and quality of life with adverse side effects virtually eliminated.

Although more studies using a greater number of patients are needed to further examine objective parameters such as PFTs, exercise tests, oxygen, medication use and hospital visits, larger sample sizes will also help determine if one protocol is more beneficial than others. With deeper research, utilizing economic analysis along with longer-term follow up will answer questions on patient selection, the benefits of repeated treatments and a possible reduction in healthcare costs for ILD treatment.

The field of Cellular Therapy and Regenerative Medicine is rapidly advancing and providing effective treatments for diseases in many areas of medicine. The Lung Health Institutes strives to provide the latest in safe, effective therapy for chronic lung disease and maintain a leadership role in the clinical application of these technologies.

Although cellular therapy has shown substantive progress in treating chronic lung disease, it is not a cure. Cellular therapy cannot serve to grow new lung tissue, but can only work to stop or slow the progression of the disease itself. As with any form of treatment, the intended benefits of cellular therapy are not universal and not every patient will respond equally to treatment. In the case of those who see progress in their condition, it may be gradually eroded by the degenerative nature of lung disease, ultimately requiring additional booster treatments to maintain the same effects.

In a landscape of scarce options and rising costs, the Lung Health Institute believes that cellular therapy is the future of treatment for those suffering from ILD and other lung diseases. Although data is limited at this stage, we are proud to champion this form of treatment while sharing our findings.

In accordance with the most up-to-date draft guidelines and exemptions set forth by the Food and Drug Administration on the use of human cells, tissues and cellular and tissue-based products, the Lung Health Institute has continued to practice safe and effective treatment within full compliance of current industry mandates and regulations. ■

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