Longer Antiviral Treatment Prevents Lung Transplant Complications

June 15 2010

(PhysOrg.com) -- Extending the course of treatment to prevent a common virus after lung transplantation dramatically reduces infection rates and possibly the risk of the body rejecting the new lungs, according to research from Duke University Medical Center.

The most prevalent opportunistic infection in lung transplant recipients is cytomegalovirus (CMV), a virus that often has mild effects but can be life threatening for organ transplant recipients. The standard preventative therapy for lung transplant patients is treatment with up to three months of valganciclovir. But even with this therapy, the majority of lung transplant recipients develop CMV infections within a year of their transplant.

The Duke researchers wanted to test the safety and efficacy of extended treatment.

“We found that 12 months of oral valganciclovir (Valcyte, manufactured by Roche) was extremely effective and led to a dramatic reduction in the rate of CMV infection and disease,“ said Scott Palmer, MD, MHS, scientific director of the Lung Transplant Program at Duke. “We also showed that there was no increased or added toxicity with the extended course of treatment.”

“In addition, the study examined viral resistance mutations and demonstrated that extended therapy did not lead to increased drug resistance, a potential concern with longer courses of treatment,” Palmer

added.

Palmer and his colleagues conducted a double-blind, placebo-controlled, randomized study at 11 centers in the United States. They compared the effect of extending the standard three-month therapy for preventing CMV to 12 months. The results are published in the June 15 issue of the Annals of Internal Medicine.

The study was comprised of 136 participants who completed three months of oral valganciclovir and then 66 received an additional nine months of placebo and 70 received an additional nine months of oral valganciclovir.

CMV infection was present in 64 percent of the short-course group compared to 10 percent of the extended-course group. CMV disease, or pneumonia caused by CMV virus, occurred in 32 percent of the short-course group and was reduced to 4 percent in the extended-course group.

“Preventing CMV is important because it can directly lead to pneumonia or a viral syndrome, but CMV prevention is even more important because we think CMV is a risk factor for chronic long-term rejection,” Palmer said.

In February, Palmer and his colleagues published research in the *American Journal of Respiratory Critical Care Medicine* that showed CMV in a patient’s transplanted lungs significantly increases the risk for rejection and leads to worse survival.

“It’s not good enough to say we have drugs to treat CMV, we have to prevent our patients from ever getting CMV,” Palmer said.

Currently, only 50 percent of lung transplant patients survive five years after transplant, according to Palmer.

“If we want to improve patient outcomes and make them more comparable to other organs, we have to reduce these infections and the complications that come with them,” he said.

Palmer and his team conducted their research based on the idea that there is a critical period after transplant when patients are at high risk of developing CMV.

“It looks like three months is too short, and if we stop the therapy then, the patients will still be at risk. But, maybe 12 months is enough for most patients.”

Palmer and his team also evaluated the patients six months after the treatment ended to ensure they had not just delayed the onset of CMV disease. They found that CMV disease remained extremely low in the 12-18 month window.

“Twelve months of the drug valganciclovir appears to be effective in preventing CMV disease and is not associated with any increased risks or complications. So, I believe most physicians will switch to the extended therapy.”

Provided by Duke University