

AIDS patients with serious complications benefit from early retroviral use, study shows

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HIV-positive patients who don't seek medical attention until they have a serious AIDS-related condition can reduce their risk of death or other complications by half if they get antiretroviral treatment early on, according to a new multicenter trial led by researchers at the Stanford University School of Medicine.

The study results could lead to widespread changes in treatment for HIV patients, particularly those diagnosed at an advanced stage, experts say.

"Even in San Francisco, one of the first epicenters of HIV in the United States, we still find that many people present late in the course of their illness with an opportunistic infection," said Mitch Katz, MD, San Francisco's director of health, who was not involved in the study. "This study shows that it is life-saving to treat those persons with antiretroviral drugs while they are still in the hospital. The results of this study will change practices throughout the world."

Some 60,000 to 70,000 newly HIV-infected individuals are identified every year in the United States, according to recently revised figures from the federal Centers for Disease Control and Prevention. A growing number of these patients, particularly minorities, youth, injection-drug users and those in poor rural areas, are being diagnosed late in the disease process when they've already developed life-threatening conditions, said Andrew Zolopa, MD, associate professor of infectious diseases and geographic medicine at Stanford and first author of the study. When these patients come for treatment of these complications,

doctors are often reluctant to give them anti-AIDS drugs at the same time, fearing the two therapies could interfere with one another.

"A lot of people wait, thinking, 'Let's get the patient out of acute crisis, and then we'll deal with the underlying HIV infection later,'" said Zolopa. "But that answer is wrong. If we're more aggressive with HIV drugs, we can reduce AIDS-related complications and death by 50 percent. It's a substantial clinical benefit."

The study was conducted by the AIDS Clinical Trials Group, the world's largest clinical trial organization. Results will be published May 18 in the online journal *PLoS-ONE*.

William Powderly, MD, dean of medicine at the University College Dublin School of Medicine, said the study addresses one of the last, longstanding unknowns in the management of AIDS.

"Clinicians have long grappled with the question of whether or not early treatment with antiviral drugs will help people who come to the hospital with advanced infections, such as pneumonia," said Powderly, the study's senior author. "The answer is clearly yes. Early antiviral treatment for [HIV](#) improves the clinical outcome, including the likelihood of surviving in the next few months. It probably does so by improving the immune system and therefore adds to the ability to resist these infections."

The study findings, presented in abstract form at an earlier scientific meeting, are already starting to change clinical practices. The International AIDS Society, the CDC and the British AIDS Society all have adopted guidelines that recommend that early antiretroviral treatment be considered in patients with an opportunistic infection, Zolopa noted.

The study involved 262 patients at 39 sites across the United States,

from Puerto Rico to Seattle. An additional 20 patients were enrolled in a hospital in Johannesburg, South Africa. Eighty-five percent of the patients were men whose median age was 28. They were an ethnically diverse group: 37 percent were black, 36 percent Hispanic, 23 percent white and 5 percent Asian.

The patients all had one or more opportunistic infection, with the most common ones being pneumocystis jirovecii pneumonia, cryptococcal meningitis and serious bacterial infections. Patients with tuberculosis were excluded from the study because it was unclear what the optimal antiviral treatment was for these patients, Zolopa said.

The patients, who were enrolled between May 2003 and August 2006, were separated into two groups: those who got antiretroviral treatment early and those for whom this treatment was delayed until their opportunistic infections had been dealt with. The patients were all offered [antiretroviral drugs](#) free of charge. The drugs for the study were supplied by Abbott Laboratories (lopinavir/ritonavir), Gilead Sciences (tenofovir and emtricitabine) and Bristol-Myers Squibb (stavudine).

The patients in the early intervention arm of the study were treated with ARVs within an average of 12 days, while those in the deferred group received the treatment within an average of 45 days after the start of treatment for the opportunistic infection. Among the patients treated early, there were 20 (14.2 percent) who died or developed another significant AIDS-related complication. That compared with 34 patients (24.1 percent) in the deferred group who died or suffered a new complication.

In addition, the patients in the early treatment group saw a much swifter recovery of their immune systems. The early group patients saw their T-cell counts, a measure of the immune cells destroyed by the AIDS virus, increase to more than 100 within four weeks. In the deferred treatment

group, it took 12 weeks for the patients' T cells to reach that same level, the researchers reported.

"I was quite impressed at how rapidly these T cells could rise in these patients," Zolopa said. "By starting ARVs early you can effectively reduce the window of vulnerability where another AIDS-related complication could develop."

Zolopa said there was no difference between the two sets of patients in their adherence to their prescribed regimens. One concern in treating patients with ARVs soon after being diagnosed with AIDS is that they might not stick to their treatments and could then develop drug resistance. But adherence did not prove to be an issue, he noted.

"Starting the therapies early didn't scare people off," he said.

According to Zolopa, the study results probably provide some guidance for patients in developing countries, though each country would have to determine its own strategy for initiating ARVs in patients with advanced [AIDS](#).

"These results do have important implications across the globe," he said.

Although the study did not include patients with tuberculosis, the most common AIDS-related complication among patients in sub-Saharan Africa, early ARV treatment has been shown in other, more recent studies to be of value in those patients with TB, Powderly said.

Zolopa said implementing the study findings could entail some logistical challenges, as hospitals will have to develop interdisciplinary teams, including pulmonary specialists, emergency physicians, pharmacists and others, in coordinating early [treatment](#) for these critically ill [patients](#) as they come into the system.

Source: Stanford University Medical Center ([news](#) : [web](#))

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