Early Treatment Reduces Serious Illnesses by 40% in HPTN 052

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Starting antiretroviral (ARV) therapy once a CD4 count falls below 550 was associated with a 40 percent reduction in the risk of serious illness, but not deaths, in HPTN 052, according to researchers summarizing the second set of major findings from the study at the 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention in Rome.

Immediate treatment was not, however, associated with a reduction in death rates, and the bulk of the serious illnesses averted by early therapy were caused by extrapulmonary tuberculosis—Mycobacterium tuberculosis infections spreading from the lungs to other parts of the body. The results may have important implications in countries where treatment is typically delayed and where complications such as extrapulmonary tuberculosis are common.

HPTN 052, conducted by the HIV Prevention Trials Network, is among the first prospective clinical trials to confirm not only a significant reduction in the risk that people living with the virus and taking ARVs would transmit HIV to their negative partners, but also the significant clinical benefits among those taking therapy earlier than is recommended in many countries.

As Beatriz Grinsztejn, MD, of the Oswaldo Cruz Foundation in Rio de Janeiro, and Mina Hosseinipour, MD, of the University of North Carolina at Chapel Hill, explained in separate presentations, HPTN 052 enrolled 1,763 sexually active, HIV-serodiscordant couples. All but one of the study couples were heterosexual male and female couples.

All of the HIV-positive participants had to have a CD4 count between 350 and 550 upon entering the study. After the study began, 886 HIV-positive participants were randomized to start ARV therapy right away (the immediate treatment group), whereas 877 waited until their CD4s dropped to 250 or they developed an AIDS-related illness (the delayed treatment group).

Overall, 278 couples were enrolled at sites in the Americas, notably the United States (2 couples) and Brazil (276 couples); 954 couples were enrolled in Africa, and 531 were enrolled in Asia.

Roughly half of all HIV-positive partners in the study were men. The average age upon entering the study was 32. Average CD4 counts were relatively high among the HIV-positive partners in the immediate and delayed treatment groups: 442 and 428, respectively.

About 21 percent of the people living with HIV assigned to the deferred treatment arm eventually

went on to start treatment, typically within three and a half years of entering the study, usually because of a drop in their CD4 counts.

Viral load responses were excellent among those who used ARV treatment in the study, with 90 percent of those in the immediate therapy group and 93 percent of those in the deferred therapy group reporting undetectable viral loads after a year of treatment.

The researchers were on the watch for several health complications among the HIV-positive individuals in the study: A World Health Organization stage 4 event (major AIDS-related complications, including extrapulmonary tuberculosis, or a disease related to the infection that spreads beyond the lungs), pulmonary tuberculosis, severe bacterial infection or death.

At least one of these health complications was documented in 105 HIV-positive study volunteers, 40 of whom were in the immediate treatment group and 65 of whom were in the delayed treatment group. These numbers translated into a 40 percent reduction in serious illnesses among those starting treatment earlier compared with those starting later.

Rates of extrapulmonary tuberculosis—which can affect many organs and tissues outside the lungs—were the biggest difference in the two groups. It was diagnosed in three people living with HIV in the immediate treatment group, compared with 17 of those in the deferred treatment group.

Conversely, rates of pulmonary tuberculosis—disease restricted to the lungs—were similar in both groups. Fourteen cases were documented in the immediate treatment group, compared with 16 cases in the deferred treatment group, with no statistically significant difference between the two.

Extrapulmonary tuberculosis tended to occur at higher CD4 counts. Among the three HIV-positive individuals in the immediate treatment group, the average CD4 count when extrapulmonary tuberculosis was diagnosed was 443 cells, whereas the average CD4 count was 342 among the 17 patients with extrapulmonary tuberculosis in the deferred treatment group. Pulmonary TB, however, appeared just as likely to be diagnosed in those with lower CD4 counts (295 cells) and higher CD4 counts (521 cells).

Also of interest, there was a trend toward more bacterial infections among those in the immediate treatment group (19 cases), compared with those in the deferred treatment group (13 cases). Rates of bacterial pneumonia were distributed equally between the two groups, whereas sepsis appeared to be more common among those in the immediate treatment group.

Death rates were similar between the two groups, with most deaths attributed to causes that didn’t have anything to do with HIV.

Not surprisingly, adverse side effects—likely because of ARV therapy—were more common among people in the immediate treatment group compared with those in the deferred treatment group. However, there was no difference in rates of severe side effects.

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