The International AIDS Society Conference's Most Vital Findings

A roundup of POZ's reporting on studies presented at the Mexico City conference about HIV treatment, vaccines, PrEP and other concerns.

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The 10th International AIDS Society Conference on HIV Science (IAS 2019) in Mexico City provided thousands of conference goers with the cream of the crop of the latest major research findings regarding HIV. Below is a quick summary of POZ's reporting on the conference, including studies on experimental and approved antiretroviral (ARV) treatments, pre-exposure prophylaxis (PrEP), vaccine candidates, global concerns and hepatitis C virus (HCV) coinfection and liver disease.

To read more about any of the studies, click the hyperlinks. You can also visit POZ's IAS 2019 newsfeed by clicking here or on the #IAS2019 hashtag at the end of any conference article.

Experimental Treatment

A new analysis about the pair of Phase III trials—one for people starting treatment and the other for those switching from an oral regimen—that teed up ViiV Healthcare's application to the Food and Drug Administration (FDA) for approval of a long-acting injectable ARV regimen of cabotegravir and rilpivirine (sold in daily pill form as Edurant) found a high level of satisfaction among participants who received the monthly injection.

In aPhase IIb trial, Merck's islatravir (formerly MK-8591) proved safe and suppressed HIV at high rates regardless of the dose when the nucleoside reverse transcriptase translocation inhibitor (a new ARV class) was paired in a two-drug regimen with the recently approved Pifeltro (doravirine).

For those who have multidrug-resistant HIV and few remaining ARV options, ViiV's attachment inhibitor fostemsavir offers hope. Two years into a study in which the drug was combined with an optimized background ARV regimen (which for those with the most limited treatment options could include other experimental drugs), a majority of participants had achieved a fully suppressed viral load.

Further back in the pipeline, Gilead Sciences' injectable long-acting capsid inhibitor GS-6207

suppressed HIV well in a Phase Ib trial. The FDA has given the drug a breakthrough designation as a potential treatment for those with extensive experience with ARVs who have multidrug-resistant virus. A separate laboratory study indicated that low levels of the drug did not give rise to concerning viral resistance.

Approved Treatment

In a finding that could cut drug costs by 43%, a randomized study found that taking ARVs just four days per week rather than seven kept HIV fully suppressed among people who switched from a standard daily regimen.

Gilead's blockbuster single-tablet regimen Biktarvy (bictegravir/tenofovir alafenamide/emtricitabine) is currently approved only for those who are new to ARV treatment or who switch to the tablet when they have a fully suppressed viral load thanks to a different regimen. A Phase III trial found that Biktarvy suppresses HIV well among women and among those with drug-resistant virus—a finding that may lead to an approval for the tablet's use among those with drug resistance.

A pair of Phase III trialsfound that ViiV's two drug-regimen Dovato (dolutegravir/lamivudine) suppressed HIV well both among those starting their first ARV regimen and those who switched from a stable three- or four-drug regimen.

Gilead's tenofovir alafenamide (TAF), an updated version of one of the most important drugs in the HIV treatment armamentarium, tenofovir disoproxil fumarate (TDF), has resulted in reduced bone and kidney toxicity compared with TDF in recent trials. However, a new study presented in Mexico City found that kidney function test results improved only for those taking TAF rather than TDF if they began their time on TAF with subnormal kidney function.

A pair of studies assuaged recent concerns over the effects of dolutegravir (sold under the brand name Tivicay) on infants who are exposed to the ARV in the womb, indicating that the risk of neural tube defects in particular is very small. Consequently, the World Health Organization updated its ARV guidelines to recommend dolutegravir as a preferred first-line treatment for all adults and adolescents, including women who are or may become pregnant. The drug is included in Triumeq (dolutegravir/abacavir/lamivudine), Juluca (dolutegravir/rilpivirine) and Dovato.

PrEP

As the monthly ARV-infused vaginal ring awaits regulatory approval as a form of HIV prevention for

women, a study that served as a continuation of one of the major trials that support the ring's potential approval found that high proportions of participants adhered to the ring over time. Investigators estimated that the ring reduced the overall group's HIV acquisition rate by about 40%.

In a powerful example of PrEP's effect on a public-health level, a massive real-world study in Australia of nearly 10,000 men who have sex with men (MSM) who received Truvada as prevention and were followed for a cumulative 18,000 years saw only 16 new cases of the virus—a rate about 98% lower than that which researchers estimated would have occurred without PrEP.

On the flip side of such an equation, a real-world San Francisco study of nearly 1,000 PrEP users found that the HIV acquisition rate seen among those who had stopped taking Truvada for prevention was some eight times greater than the rate while the cohort members were on PrEP.

In a new analysis of the Phase III trial that the FDA is considering as it weighs approval for Gilead's Descovy (tenofovir alafenamide/emtricitabine) as PrEP, researchers found evidence suggesting that HIV-protective drug levels were achieved faster and lasted longer among those taking Descovy compared with those randomized to receive Truvada as prevention.

Gilead's assertion at the conference that Descovy actually has a higher efficacy as PrEP over Truvada was met with skepticism. While it is true that fewer people contracted HIV in the Descovy arm of the study, this number was not statistically significantly different from that seen in the Truvada arm—meaning that the difference may have been driven by chance.

Years into the future, Merck's islatravir could be a major game changer in the PrEP field, considering findings from a three-month Phase I study of a matchstick-sized implant infused with the drug. The implant gave rise to drug levels found to be protective against a simian form of HIV in a previous monkey study. Such high levels persisted long enough to provide a projected year of continuous protection.

During the conference, the World Health Organization endorsed the on-demand, or 2-1-1, PrEP dosing regimen, thanks to research based in France. An update of this research was presented at the conference, adding more weight to the conclusion that the dosing protocol is highly effective at preventing HIV acquisition. Those using the 2-1-1 regimen should take a double dose of Truvada two to 24 hours before expected sex; then, if sex occurs, they should take an additional dose 24 hours after the double dose and one last dose 24 hours after that.

Vaccines

Starting this fall, a third major HIV vaccine efficacy trial, called Mosaico, will launch among MSM and transgender and gender-nonconforming individuals in more than 50 sites in the United States, Mexico, South America and Europe. The vaccine, which is given in four injections over a 12-month period, is similar to the one already being investigated among women in sub-Saharan Africa in the Imbokodo trial.

A pair of earlier-stage trials,APPROACH and ASCENT, that investigated the vaccine regimens that were ultimately advanced to Mosaico and Imbokodo buttressed hope that that these vaccines will prove substantially protective against HIV. These studies found that the vaccine candidates prompted a strong immune response, one that could likely persist for years.

Global Concerns

The Joint United Nations Programme on HIV/AIDS (UNAIDS) updated its estimates of the state of the global HIV epidemic, reporting that recent advancements in reducing the spread of the virus are slowing down just as global funding has declined for the first time and that progress is uneven. The direction of the epidemic is particular cause for concern in three regions, including Eastern Europe and Central Asia, the Middle East and North Africa, and Western and Central Africa.

A separate study found that HIV is rising in Latin America, a trend that has been driven solely by increasing acquisition rates among young men.

On the bright side, researchers found that providing PrEP on the same day that at-risk MSM and trans women visit a clinic is feasible in Latin America.

Coinciding with the conference, three major studies that each analyzed the effects of broad-based programs to scale up HIV testing and treatment of the virus were published in The New England Journal of Medicine. Collectively, they found that such efforts reduced the annual rate of new infections by about 30%. A mathematical modeling study based on one of these studies, called PopArt, was presented at the conference and projected that the program it assessed would cut the annual HIV rate in half by 2030 and was also cost effective.

Liver Disease

Among young adults who were born with HIV and hepatitis C virus (HCV), direct-acting antiviral (DAA) treatment is highly effective, a Spanish study found. However, by the time the young people studied were treated for hep C, many of them already had advanced liver disease—a finding that stressed the importance of earlier DAA treatment for this group.

Concerning findings out of Europe indicated that of those people with HIV who were cured of HCV in an ongoing cohort study, 13% have been reinfected with the latter virus in recent years.

A study of people with HIV who did not have viral hepatitis identified various biomarkers that could identify non-alcoholic fatty liver disease (NAFLD) and rule out advanced fibrosis.

Heart Disease

A randomized controlled trial found that among those people with HIV who had a moderate long-term risk of cardiovascular disease, taking the statin Crestor (rosuvastatin) did not slow plaque buildup in their arteries. This held true despite the fact that, as expected, those taking Crestor rather than a placebo experienced a decline in cholesterol.
