Pediatric Viramune May Still Work as Treatment in Kids Exposed at Birth

July 22, 2009 By Tim Horn

Infants exposed to single-dose Viramune (nevirapine) monotherapy at the time of delivery—potentially resulting in rapid resistance to the drug if HIV infection does occur—may still benefit from a Viramune-based treatment regimen, according to an important finding reported Monday, July 20, at the Fifth International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention in Cape Town.

Viramune monotherapy to prevent mother-to-child HIV transmission at the time of delivery is widely used in resource-poor nations. Typically, a single dose of Viramune is given to the pregnant woman at the onset of labor, with a single dose given to the infant immediately after birth. While this approach has been proved effective, it carries a substantial risk—the high possibility of rapid resistance to Viramune and, with it, a lower likelihood of benefiting from this drug as treatment if needed.

Based on this assumption, treatment guidelines in place in many resource-poor areas recommend starting HIV-positive infants exposed to Viramune monotherapy at birth on a protease inhibitor–based drug combination to ensure effectiveness.

The new data from the NEVEREST study, reported at IAS by Ashraf Coovadia, MD, from the University of the Witwatersrand Coronation Hospital in Johannesburg and his colleagues, may help open the playing field for nevirapine-exposed HIV-positive children, especially those unable to tolerate—or afford—protease inhibitor–based therapy.

NEVEREST enrolled 195 children born with HIV, all of whom had been exposed to single-dose Viramune at birth. They were immediately started on a regimen consisting of Kaletra (lopinavir/ritonavir) plus Zerit (stavudine) and Epivir (lamivudine). Provided that their protease inhibitor–based regimen kept their viral load below 400 copies for at least three months, the children were then allotted to either remain on Kaletra/Zerit/Epivir or to switch their Kaletra for Viramune.

According to Coovadia, about 56 percent of children who switched to Viramune had viral loads below 50 copies a year later. In the Kaletra group, only 42 percent had undetectable viral loads at the end of the 52-week observation period. This difference was statistically significant, meaning it was too great to have occurred by chance.

Allowing for one transient viral load elevation during the yearlong follow-up period, 73 percent of those in both the Kaletra and Viramune groups had HIV levels below 50 copies at week 52.

Conversely, more children who remained on the Kaletra-based regimen (98 percent), compared with those who switched to Viramune-based therapy (80 percent), maintained viral loads below 1,000 copies. Though a viral load below 50 copies remains the most desirable outcome and is usually the strongest indicator of treatment effectiveness in clinical trials, the below 1,000 copies comparison prompted Coovadia's group to conclude that the poorer Kaletra showing in the below 50 copies comparison was likely a result of poor adherence and not differences in treatment effectiveness, per se.

Not surprisingly, not having a non-nucleoside reverse transcriptase inhibitor (NNRTI) mutation before beginning treatment was a key factor associated with virologic success upon switching to Viramune. Among children without an NNRTI mutation, 88 percent maintained viral loads below 1,000 copies. As for those with HIV containing a key NNRTI mutation, about 55 percent maintained viral loads below 1,000 copies—a surprisingly high rate of effectiveness in the setting of high-level resistance to nevirapine.

Average CD4 percentages—the standard measure of immune system function in young HIV-positive children—were higher among those who switched to Viramune (33.2 percent) compared with those who remained on Kaletra (30 percent).

Also of note, CD4 percentages were more likely to drop in those who remained on Kaletra compared with those who switched to Viramune. Declines of at least 10 percent were documented in 16.3 percent of those continuing Kaletra-based therapy, versus 3.2 percent of those switching to the Viramune-inclusive regimen.

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