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I ANTI-HIV AGENTS

A. Swiss study switching to efavirenz

Highly active antiretroviral therapy (HAART) has helped prolong survival in people with HIV/AIDS (PHAs). HAART regimens, particularly those containing protease inhibitors, can have a range of side effects, including nausea, vomiting and diarrhea, as well as food and water restrictions. In an effort to avoid these difficulties, some PHAs may replace or switch their protease inhibitor(s) with a non-nucleoside analogue (non-nuke), such as one of the following:

- delavirdine (rescriptor)
- efavirenz (Sustiva, Stocrin)
- nevirapine (Viramune)

Questions remain about what happens after PHAs make their switch, specifically:

- Will viral load continue to remain suppressed?
- Will PHAs be able to tolerate efavirenz-containing regimens?

To answer these questions, researchers in Switzerland conducted a study.

Study details

The researchers sorted and analysed medical records in their database, called the Swiss HIV Cohort. They collected data on the following groups of PHAs who had similar profiles:

- 184 switchers — these were PHAs who switched from protease-inhibitor-based regimens to efavirenz-based regimens
- 368 non-switchers — these were PHAs who continued to use protease inhibitors (PIs)

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The profile of the switchers was as follows:

- they had previously used the PIs indinavir (Crixivan) or nelfinavir (Viracept) or ritonavir (Norvir)
- they switched because of intolerance or toxicity caused by the PI
- they stopped using the PI once they switched to efavirenz
- 75% of subjects had been previously exposed to anti-HIV drugs for about 2.5 years before switching to efavirenz
- 30% female, 70% male
- an average of 503 CD4+ cells
- an average viral load of fewer than 400 copies

Results — viral load

After switching, those PHAs who had their viral load rise above the 1,000 copy mark were considered by their doctors to have had “virological failure.” The risk of PHAs developing virological failure after one year in each of the two study groups was as follows:

- switched to efavirenz – 9%
- remained on PIs – 27%

This difference was statistically significant; that is, not likely due to chance alone.

Results — CD4+ cell counts

There were no significant differences in CD4+ cell counts between switchers and non-switchers “at any time” during the study.

Efavirenz problems

Subjects who were injection-drug users (IDUs) were more likely than non-IDUs to stop using efavirenz, particularly during the first month after switching. For 73% of IDUs who did stop during this time, the reasons for doing so were “intolerance or side effects.”

When researchers analysed the rate at which subjects stopped using PIs, IDUs were no more likely to stop using PIs than other groups of PHAs.

The study authors concluded that data from this study suggests that replacing a PI with efavirenz can benefit treatment-experienced PHAs, particularly those who are not IDUs.

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B. Efavirenz helps get rid of Kaposi’s sarcoma (KS)

Kaposi’s sarcoma (KS) is a cancer that was common during the 1980s in HIV positive people. KS is likely caused by a sexually transmitted virus called HHV-8 (human herpes virus-8). This virus triggers the formation of lesions when the immune system is weakened by age or HIV infection. Although many anti-KS treatments are available, they do not cure this cancer because the underlying problem is one of weakened immunity.

When protease inhibitors (PIs) became available in the mid-1990s, there were many reports of KS skin lesions fading in people with HIV/AIDS (PHAs). More significantly, PI-based anti-HIV therapy helped PHAs recover from extensive KS lesions located inside the body in places such as the intestines, liver and lungs. Now, doctors in Genoa, Italy, have reported that a cocktail based on the non-nuke efavirenz (Sustiva, Stocrin) has helped a PHA recover from AIDS-related KS.

Details

A 37-year-old man sought medical attention when KS lesions began to appear on his body over the course of six months. Technicians performed CAT scans of his abdomen, which revealed that KS lesions were also inside his body in the following places:

- lymph nodes
- lungs
- spleen

Blood tests found the following:

- CD4+ cell count – 30 cells
- viral load – 300,000 copies
- the presence of anti-HHV-8 antibodies

Although he was not taking anti-HIV drugs at the time, resistance testing revealed that his virus was resistant to indinavir (Crixivan) and nelfinavir (Viracept), so doctors prescribed the following combination of drugs:

- efavirenz
- AZT (Retrovir)
- 3TC (lamivudine, Epivir)

To prevent common AIDS-related bacterial infections he also received the following antibiotics:

- Bactrim/Septa
 - azithromycin (Zithromax)
-

Within two months of starting therapy, the man's CD4+ count rose to 305 cells. Five months after he began therapy, his viral load was below the 500 copy mark. A year after he sought medical attention, CAT-scans of his body revealed that his KS lesions had disappeared. As well, anti-HHV-8 antibodies could no longer be detected, suggesting that this virus had been contained.

Can nukes affect KS?

Recent work **in a lab** in London, England, using HHV-8, suggests that some nukes, such as AZT and d4T (stavudine, Zerit), may have anti-HHV-8 activity. In theory, the most that these drugs might be able to do in people is to temporarily impair the growth of new KS lesions but they would have no effect on pre-existing lesions. In the time before protease inhibitors, nukes by themselves did not have any significant impact on KS lesions in PHAs.

What likely happened in the case of the man reported by the Italian doctors is that potent suppression of HIV levels by all three drugs allowed his immune system to repair itself to the point where it was able to control and eventually destroy KS lesions.

The results reported by the Italian doctors are encouraging. Hopefully other researchers will confirm these promising findings and perhaps test the effect of another drug in the same class as efavirenz — nevirapine (Viramune) and delavirdine (Rescriptor) in PHAs with KS.

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II INFECTION FIGHTERS

A. Cidofovir and surgery for genital warts

A sexually transmitted virus called HPV (human papilloma virus) can cause warts to appear on or around the genitals and anus. Certain strains of HPV can also cause cervical and anal cancer. In HIV positive people, HPV-related warts can be troublesome. Although doctors can treat the warts — using liquid nitrogen, lasers, surgery — the warts usually recur because the underlying problem is one of weakened immunity.

Doctors in Milan, Italy, recently completed a study comparing the effects of different therapies on HPV-related warts in HIV positive subjects. The doctors found that a combination of surgery and treatment with the antiviral drug cidofovir (Vistide) was most useful in suppressing regrowth of warts.

Study details

Researchers recruited 74 subjects with the following profile:

- 28% female, 72% male
- average age – 33 years
- average CD4+ count – 265 cells
- average viral load – 35,000 copies
- 50 subjects were taking anti-HIV drugs

Warts were found in the following locations in the following proportions of subjects:

- on the penis – 51%
- around the anus – 21%
- around the vulva – 21%
- between the anus and genitals – 4%

Researchers randomly assigned subjects to receive one of the following three interventions:

- electro-surgery – burning of warts using a weak electrical current
- 1% cidofovir gel – this was applied to the warts five days weekly for up to six weeks
- electro-surgery and cidofovir – within a month of surgery, subjects applied cidofovir gel five days weekly for only two weeks to the affected area

Results — short-term

Not surprisingly, over the short-term, electro-surgery was more successful than cidofovir in removing warts.

Results — long-term

Of the 66 subjects whose warts cleared in the short-term, 47 returned to the study team for monitoring over the next six months. Warts reappeared in the following groups:

- electro-surgery alone – 74%
- cidofovir alone – 35%
- combined surgery followed by cidofovir – 27%

Recurrence of warts was not related to subjects' CD4+ counts. It is possible that a longer application of cidofovir — more than two weeks — following surgery may provide better suppression of warts. But this needs to be balanced with the potential for side effects, as between 32% and 42% of subjects who used cidofovir developed skin irritation. In three subjects the irritation was so severe that they had to stop using this drug.

REFERENCE

Orlando G, Fasolo MM, Beretta R, et al. Combined surgery and cidofovir is an effective treatment for genital warts in HIV-infected patients. *AIDS* 2002;16(3):447-450.

III SIDE EFFECTS

A. Viagra and grapefruit juice — not a good mix

The original formulation of the protease inhibitor saquinavir — Invirase — became available in North America around the mid-1990s. However, Invirase was poorly absorbed. The manufacturer suggested that taking Invirase with concentrated grapefruit juice would enhance the absorption of this drug. This effect occurs because grapefruit juice contains compounds that impair the activity of certain enzymes in the intestine — enzymes that help break down Invirase.

A few years later, doctors began to use another protease inhibitor, ritonavir (Norvir), in combination with Invirase. Ritonavir is much more effective than grapefruit juice at inhibiting enzymes in the intestine and liver. Examples of other drugs affected by grapefruit juice include the following:

- beta blockers – Cardizem (diltiazem)
- sedatives/sleeping pills – Halcion (triazolam), Versed (midazolam)

- transplant drug – cyclosporine (Neoral, Sandimmune)

Now it appears that grapefruit juice can also affect the absorption of the popular erectile dysfunction drug Viagra (Sildenafil). Because erectile dysfunction is common in some males with HIV/AIDS, we report on the interaction between grapefruit juice and Viagra.

Study details

Researchers in Köln, Germany, conducted a study using 24 healthy, HIV negative male subjects whose average age was 29 years. The men received a glass of grapefruit juice on an empty stomach and then one hour later another glass of grapefruit juice with Viagra 50 mg. Blood samples were collected over the next 24 hours. A week later the experiment was repeated with water being substituted for grapefruit juice.

Results

Researchers found that the absorption of Viagra increased by 23% when taken with grapefruit juice instead of water. Grapefruit juice also delayed the absorption of Viagra. This latter point is important because Viagra is supposed to be taken one hour before sex, and taking the drug with grapefruit juice may result in disappointment for some users of Viagra.

The grapefruit juice used in this study was white juice and supplied by Döhler-Euro Citrus NBI, GmbH. Other brands, types and doses of grapefruit juice may have different effects. The researchers suggest that the combination of Viagra and grapefruit juice be “avoided.”

Men who use protease inhibitors are usually prescribed less-than-normal doses of Viagra because protease inhibitors can raise levels of Viagra several times greater than normal, which can cause dangerous side effects. Therefore, men who use protease inhibitors and Viagra may wish to also avoid taking Viagra with grapefruit juice.

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-

B. Birth defect in baby born to efavirenz-user

The non-nuke efavirenz (Sustiva, Stocrin) is used as part of combination therapy by some people with HIV/AIDS (PHAs). Efavirenz can cause the following commonly experienced side effects:

- rash
- confusion
- dizziness
- difficulty concentrating
- drowsiness during the day
- difficulty falling asleep at night
- intense dreams and/or nightmares

These side effects are supposed to fade during the first four weeks of use.

Efavirenz can also have other effects. In one series of experiments, researchers gave monkeys efavirenz throughout pregnancy. They found that three of 20 (15%) of the monkeys had fetuses which had various defects. Based on these results, the use of efavirenz is not recommended for women who are pregnant.

Doctors in Rome, Italy, recently reported a case of an HIV positive woman who gave birth to a baby with birth defects. The woman had the following profile before she became pregnant:

- 34 years old
- 390 CD4+ cells
- a viral load of 7,600 copies

Doctors prescribed standard doses of the following drugs:

- AZT (Retrovir)
- d4T (stavudine, Zerit)
- efavirenz

The doctors also counselled her about the potential risks of this therapy in women of childbearing age and advised her about the use of “adequate” birth control. Sometime later, she noticed that her periods had stopped. After performing a pregnancy test, she found that she was pregnant.

On reporting her findings to her doctors, they switched her therapy to the following regimen which is considered to be less toxic to the fetus:

- 3TC (lamivudine, Epivir)
- d4T
- nelfinavir (Viracept)

Both before and during her pregnancy, the woman took the B-vitamin folic acid (folate). This vitamin can help reduce the risk of some birth defects. Nonetheless she gave birth to a baby with several defects:

- First, the baby had a large mass outside its body near the base of its spine, a condition called myelomeningocele.
- Second, the flow of fluid in the baby’s brain/spinal cord was blocked.

Ordinarily, babies with these problems can die, but thanks to surgery the myelomeningocele was removed and a shunt was placed in the brain to drain excess fluid. High-tech testing — called PCR — of the baby’s blood suggested that it was not infected with HIV.

Does efavirenz cause birth defects in people?

This report from the Italian doctors may well be the first case of a birth defect in a fetus accidentally exposed to efavirenz. It does **not** prove that efavirenz caused this type of birth defect, called a neural tube defect. The report does underscore the need for clear discussion and counselling by doctors about the potential risks and benefits of efavirenz to their HIV positive female patients who may become pregnant. If additional reports of neural tube defects in babies born to female users of efavirenz occur, then further and stronger precautions may be needed.

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C. Health Canada advises against kava

Health Canada is advising consumers not to use kava-kava (commonly called kava) or kava-containing products until it has completed a safety review of this herb. Kava and its extracts are commonly used to treat the following conditions:

- anxiety
 - nervousness
 - difficulty falling asleep
 - pain relief
 - muscle tension
-

Health Canada has issued this advisory because of reports of severe liver damage among kava users in Germany and Switzerland. In those countries, there have been at least 25 cases of adverse effects possibly related to kava usage. At least one person has required a liver transplant. It is noteworthy that in at least 18 of the 25 cases, kava users were also taking prescription and non-prescription medication with the potential to cause liver damage.

The situation elsewhere is as follows:

- UK — British Medicines Control Agency has asked stores in that country to temporarily stop selling kava
- Germany — kava-containing products have been withdrawn from sale
- United States — the Food and Drug Administration is currently investigating whether the use of kava is associated with liver problems

Kava has had a relatively good safety profile in Canada with no cases of liver toxicity being reported in this country. Health Canada advises consumers to “consult with their health care practitioner if they have experienced any adverse effects from taking products containing kava.” The following signs/symptoms may be associated with liver problems:

- jaundice (yellowing of the skin or whites of the eyes)
- brown urine
- nausea
- vomiting
- unusual tiredness
- weakness
- stomach or abdominal pain
- loss of appetite

Health care practitioners are being asked to report to regulatory authorities any cases of liver toxicity in association with kava-containing products, at the following toll-free numbers:

- Canada — 1.866.234.2345
- United States — 1.800.332.1088

For more information on this herb, see CATIE’s kava-kava Supplement Sheet at www.catie.ca/supple-e.nsf

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D. Nevirapine levels may predict toxicity

Although the non-nuke nevirapine (Viramune) is an effective part of combination anti-HIV regimens, it is associated with a number of side effects, including the following:

- rash
- fever
- ulcers in the mouth

As many as 17% of people exposed to this drug can develop a rash. In most cases, the rash is temporary. Nevirapine can also cause liver damage. Understanding how this happens is the focus of a research project in Madrid, Spain. The Spanish team suspects that nevirapine causes toxicity in two possible ways:

- The drug may cause the immune system to overreact and attack the skin and liver. This can be a problem in people with high CD4+ cell counts or in healthy people who have been exposed to HIV and wish to prevent infection by using nevirapine.
- A second way nevirapine might cause liver problems may be due to a toxic effect of the drug. To further understand this issue, researchers in Spain conducted a study.

Study details

Researchers, led by infectious disease expert Vincent Soriano, enrolled 70 HIV positive subjects, all of whom were using nevirapine as part of triple anti-HIV drug therapy. Nevirapine was taken in a dose of 200 mg twice daily for up to one year.

Results

In analysing the data, researchers divided subjects into two groups:

- 33 subjects who developed liver damage, detected by measuring levels of liver enzymes in their blood samples
- 47 subjects who did not develop any increases in liver enzyme levels during the study

Among the 33 subjects who developed liver damage, liver enzymes usually rose an average of six months after they began to use nevirapine. Levels of nevirapine in the blood of these subjects were, on average, significantly higher than in subjects without liver damage.

Hepatitis C

Another factor that played a role in liver damage was infection with hepatitis C virus (HCV). Those subjects co-infected with HCV were at increased risk for nevirapine-associated liver damage than subjects who were not co-infected with HCV. Indeed, those subjects who were HCV positive and who had high levels of nevirapine in their blood had a 92% chance of developing liver damage.

Therapeutic drug monitoring for nevirapine levels, particularly in PHAs co-infected with HCV, may help alert doctors as to which of their patients are at risk for long-term nevirapine-associated liver problems.

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E. Comparing liver toxicity between efavirenz and nevirapine

The use of highly active antiretroviral therapy (HAART) has greatly reduced AIDS-related death rates in North America, Western Europe and Australia. Yet HAART users can experience a range of side effects, including varying degrees of liver damage. Indeed, between 6% and 30% of people with HIV/AIDS can develop increased levels of liver enzymes in the blood — suggestive of liver damage — once they begin to use HAART. This problem occurs because HAART drugs often affect the liver, interfering with how this organ works.

It is possible that some drugs used in HAART regimens affect the liver more than others. To begin studying this, researchers in Baltimore, Maryland, compared the effect that two commonly used anti-HIV drugs — the non-nucleoside analogues (non-nukes) efavirenz (Sustiva, Stocrin) and nevirapine (Viramune) — have on the liver.

Study details

Between 1996 and 2001, researchers enrolled 568 HIV positive subjects who were prescribed combination anti-HIV therapy containing either nevirapine (256 subjects) or efavirenz (312 subjects). The subjects had the following profile:

- 71% male, 29% female
- an average CD4+ count of 150 cells
- an average viral load of 45,000 copies

Researchers divided subjects into two basic groups based on the drugs they used — nevirapine or efavirenz — and monitored them for an average of about 10 months.

Liver enzyme levels

Before starting their study medications, in general, researchers found that there were no differences in liver enzyme levels between the two groups of subjects. However, subjects co-infected with hepatitis C virus (HCV) had significantly higher liver enzyme levels than subjects who were not co-infected with HCV.

Results

After subjects entered the study and began using HAART, levels of liver enzymes in the blood remained near normal levels in the following proportion of subjects in each group:

- efavirenz users – 51%
- nevirapine users – 20%

This difference was statistically significant; that is, not likely due to chance alone.

Researchers detected severe liver toxicity — which they defined as liver enzyme levels greater than 3.5 times the upper limit of normal — in the following proportion of subjects:

- efavirenz – 8%
- nevirapine – 16%

This difference was also significant.

Hepatitis C

The researchers found that severe liver toxicity was most commonly detected in HCV co-infected subjects receiving nevirapine or efavirenz in combination with a protease inhibitor.

Nevirapine hypersensitivity

In a very small proportion of nevirapine users, a hypersensitivity reaction — fever, rash — can occur. In this study, hypersensitivity reaction occurred in only one male user of nevirapine.

Unrelated factors

Researchers found that the following factors were not related to developing severe liver damage:

- race
 - gender
 - age
 - viral load
 - use of AZT, d4T (Zerit, stavudine) or ddI (Videx)
-

Deaths due to complications of liver damage

Three HCV positive subjects who received nevirapine and protease inhibitors required hospitalization because of complications from liver damage. Two of these subjects died. Among HCV positive subjects who received efavirenz and protease inhibitors, one required hospitalization and later died from complications due to liver damage. Overall, death occurred in the following proportion of subjects in each group:

- nevirapine – 23%
- efavirenz – 11%

Key points

- It is important to bear in mind that that the majority of subjects in this study did not develop severe liver damage.
- The risk of developing severe liver damage was twice as high among subjects co-infected with hepatitis-causing viruses.
- 70% of cases of severe liver damage occurred among subjects who were co-infected with HBV (hepatitis B virus) or HCV.
- Subjects who used protease inhibitors in addition to efavirenz or nevirapine were twice as likely to develop serious liver toxicity as subjects who did not use protease inhibitors.

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Sulkowski MS, Thomas DL, Mehta SH, et al. Hepatotoxicity associated with nevirapine or efavirenz-containing antiretroviral therapy: role of hepatitis C and B infections. *Hepatology* 2002;35:182-189.

Disclaimer

Decisions about particular medical treatments should *always* be made in consultation with a qualified medical practitioner knowledgeable about HIV-related illness and the treatments in question.

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Credits

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