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## I ANTI-HIV AGENTS

### A. Spanish doctors try switching therapy from month to month

#### Background

Highly active antiretroviral therapy (HAART) often has high adherence requirements and unpleasant side effects. Not surprisingly, some people with HIV/AIDS (PHAs) who use HAART consider taking drug holidays. However, during drug holidays, levels of the immune system's vital CD4+ cells often fall significantly. Moreover, it may take a minimum of one year of therapy before CD4+ counts rise to their pre-drug-holiday levels. Perhaps one way to help reduce drug side effects while also decreasing the risk of HIV becoming resistant to HAART is by cycling, or alternating, therapy. Under such a scheme, PHAs would take one combination of drugs for a month and a different combination the next month, switching between the two combinations from month to month. Researchers in Madrid, Spain, have been testing these alternating monthly cycles of therapy for one year and recently reported their results.

#### Study Details

Researchers enrolled 21 HIV positive subjects (gender unavailable), 17 of whom had previously experienced AIDS-related infections. Their profile was as follows:

- average CD4+ count – 102 cells
- average viral load – 26,000 copies

All subjects had been previously exposed to many anti-HIV drugs for an average of about 3.5 years before entering this study. Researchers created treatment

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## III SIDE EFFECTS

### A. Of power plants and energy shortages

#### Background

Inside nearly every person's cells are tiny kidney-bean-shaped bodies called mitochondria (Mt). Mitochondria act as tiny power plants. To do this, they "burn" sugar or fat with oxygen to produce energy. Mt need many nutrients to work properly, but the following are especially useful:

- L-carnitine
- B-complex vitamins
- co-enzyme Q<sub>10</sub>

Also, these miniature power plants won't work properly if they don't get *enough* of the right nutrients.

Mt can become damaged by certain drugs or groups of drugs, including:

- Tylenol (acetaminophen)
- alcohol
- anti-cancer medication
- nucleoside analogues (nukes)

Damaged Mt don't work properly and as a result don't produce enough energy for cells. This results in a power shortage, causing a cell to malfunction and even die. Malfunctioning Mt may be the underlying cause of some of the side effects experienced by PHAs who use nukes.

When Mt are not working properly they produce high levels of lactic acid. A buildup of lactic acid in the blood is called lactic acidosis, or lactic acidemia. Signs/symptoms of lactic acidosis can include:

- feeling tired/having a lack of energy
- nausea
- vomiting
- pain in the abdomen
- fatty, swollen liver

#### A rare side effect

Although higher-than-normal levels of lactic acid, or lactate, can have serious consequences, it is important to remember that severe lactic acidosis is rare. Indeed, several studies have found that less than 1% of PHAs develop this complication.

#### More on lactic acid

The body normally regulates the amount of lactic acid in the blood. But continuous and excessive

production of lactic acid could upset the body's ability to get rid of this substance. The source of excessive lactic acid production in PHAs is not clear. Some researchers think that the liver and kidneys, whose Mt may be damaged, normally help keep lactic acid levels within a safe range. Not surprisingly, many PHAs who have lactic acidosis have malfunctioning livers.

High levels of lactic acid may have an impact on other parts of the body. For instance, this complication often causes muscles to feel "tired." As well, researchers in Eastern Australia think that lactic acidosis may be linked to the development of thinner, weaker bones.

In this issue of *TreatmentUpdate*, we report on several research studies dealing with nuke side effects, such as the excessive production of lactic acid and its connection to bone problems.

### B. Nukes may be linked to hearing loss

The use of nukes — AZT, ABC (abacavir, Ziagen), ddI, d4T, 3TC, ddC — has been linked to various side effects, including the following:

- fatty, swollen livers
- swollen pancreas glands (pancreatitis)
- nerve damage in the hands/feet (peripheral neuropathy)

These complications occur because nukes can damage the energy-producing parts of a cell called mitochondria. When mitochondria are damaged, the cell experiences a power failure and gets injured. Prolonged power failures can cause the cell to die.

Some PHAs who use particular nukes such as ddC, ddI and d4T — the "d" drugs — have developed nerve damage in the hands and/or feet, a side effect called peripheral neuropathy. It therefore should come as no surprise that researchers now suspect that nukes may cause damage to people's sense of hearing — something that is heavily dependent on nerves.

In an article that appeared in the June 1, 2001 issue of the journal *Clinical Infectious Diseases*, doctors in Denver, Colorado, reported on their investigation of hearing loss in three male PHAs. All subjects had experienced hearing loss before starting highly active antiretroviral therapy (HAART). This hearing loss occurred because of exposure to excessive noise. In the normal course of events, once people are no longer exposed to loud noise the loss of hearing stops — as was the case with all three subjects. However, shortly after they began taking anti-HIV medications, all three

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subjects reported ringing in the ears, or tinnitus, and their hearing loss resumed.

The doctors note that all three PHAs were between the ages of 47-53 years and would therefore have been at risk for developing hearing loss. As well, one PHA had low levels of vitamin B<sub>12</sub> in his blood and also used the drugs trazodone (Trazorel) and valproic acid (Depakene), all of which are factors associated with hearing loss. Nevertheless, when these PHAs started HAART, their hearing loss was striking. Furthermore, when two of the subjects stopped taking HAART, their hearing partly improved.

Among HAART-users, the following factors may increase the risk of hearing loss:

- older age
- pre-existing hearing damage

Clearly, further studies are needed to confirm this finding as well as to find safer therapies with fewer side effects for PHAs.

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### C. High levels of lactic acid in some users of HAART

#### Background

Symptoms of high levels of lactic acid are a rare complication of treatment with nukes. To find out more about this complication, researchers in Western Australia studied several hundred people with HIV who used HAART for about 1½ years.

#### Study details

Researchers enrolled 349 HIV positive subjects (15% female, 85% male) whose average age was about 42 years. About 69% of subjects were taking HAART. Technicians took blood samples for analysis on a regular basis.

#### Results — focus on five cases

In the researchers' lab, the normal range of lactic acid, or lactate, is 0.3 to 1.3 mmol/Litre. Over the course of the study, five subjects (2 female, 3 male) developed very high levels of lactic acid — greater than 5 mmol/

L — in their blood. Here is a description of these five cases:

1. One subject developed a form of cancer called non-Hodgkin's lymphoma with tumours that had spread to his liver. He was not taking anti-HIV drugs.

2. Another subject developed a viral infection (CMV, or cytomegalovirus) of the brain and also heart damage. He was not taking anti-HIV therapy.

3. The third male was taking anti-HIV therapy and was known to abuse alcohol. His high lactate levels may have been due to alcohol abuse or use of nukes. After his last bout of heavy drinking, he did not take his medication as directed and his lactate levels fell within the normal range.

4. One subject developed nausea and abdominal discomfort six months after she started a regimen of d4T and nelfinavir (Viracept). Her lactic acid levels were high — 6.4 mmol/L at the time she was diagnosed with lactic acidosis. Just one month before this diagnosis her lactic acid levels were only slightly above normal readings.

5. This woman had been taking a combination of d4T, 3TC and nelfinavir for one year when she suddenly developed severe tiredness, vomiting, abdominal pain and a swollen liver. Her lactate level at this point was 8.2 mmol/L. A review of her test results suggested that her lactate levels were nearly normal just one month prior to the appearance of her symptoms.

#### Results — changes in nuke therapy

During the study, another five subjects developed signs/symptoms (nausea, abdominal discomfort, abnormal liver enzyme levels, swollen liver) that suggested they had moderately high levels of lactic acid in the blood. Indeed, their lactic acid levels ranged between 2.8 to 4.1 mmol/L. Their doctors changed their treatment regimens by removing d4T (Zerit) and replacing it with either AZT or ABC (abacavir, Ziagen). As a result of this switch, their symptoms cleared.

#### High lactate levels linked to d4T

According to their analysis, researchers found that the 140 subjects who were using d4T had, on average, significantly higher lactate levels than the 101 subjects who were using AZT-containing regimens.

#### Lactate levels

On average, each subject in the study had his or her lactate levels measured about four times. Only five subjects had lactate levels that rose above the 5 mmol/

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L mark. Remember that the normal range for lactate in this study was 0.3 to 1.3 mmol/L. At some point in the study, the remaining subjects had lactate levels that were as follows:

- 65% had lactate levels greater than 1.5 mmol/L
- 18% had lactate levels greater than 2.5 mmol/L
- 6% had lactate levels greater than 3.5 mmol/L

Factors not significantly associated with higher-than-normal levels of lactate included:

- age
- gender
- having AIDS
- length of HIV infection
- low CD4+ cell counts
- high viral load
- having hepatitis B or C infection
- length of prior AZT use in current d4T users
- use of protease inhibitors
- use of non-nukes

### Predicting who will get lactic acidosis

One of the findings of this study is that regular measurement of lactate levels — taken every one to three months — was not useful in predicting which subjects would develop symptoms of lactic acidosis. This difficulty arises because lactic acid/lactate levels can often remain low or only mildly elevated until just before symptoms of lactic acidosis appear.

### The good news

Another finding from this study is that many PHAs can tolerate mildly elevated lactate levels without developing symptoms of lactic acidosis. As well, in this study, only two subjects developed symptoms of severe lactic acidosis. If caught in the early stages, symptoms of mild lactic acidosis may clear up by replacing d4T with another nuke.

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## D. Australian study links nukes, lactic acid to bone loss

### Background and summary

Reports of thinning bones and damage to the hips and other joints in users of HAART have increased alarmingly in the past two years. Researchers are struggling to find possible causes of this problem and now it appears that a team in Sydney, Australia, has come up with what may be the underlying cause for this vexing side effect. In reviewing data on 221 HIV positive male subjects, researchers found that having high levels of the waste product lactic acid, or lactate, was linked to the development of thinner, more porous bones, a condition called osteoporosis. The risk of osteoporosis developing in study subjects was 50% higher than in the average HIV negative, healthy Australian male.

Since high levels of lactic acid — a condition called lactic acidosis — have previously been linked to the use of nukes, these drugs may play a critical role in the loss of bone. Readers should be aware that there are likely other factors involved in the loss of bone in PHAs who were not in this study (for a list of risk factors for bone loss, see the next story).

### Why do bones shrink?

It is important to note that bones are living tissue. Bone cells therefore need energy just like other cells in the body. The Australian researchers think that the energy-producing parts of bone cells — mitochondria — get damaged by the use of nukes. Damaged cells in the bone and elsewhere in the body produce high levels of lactic acid. To neutralize this acid, the body uses calcium. If it is not getting enough calcium from food, the body may take calcium from bones. Over the long term, this loss of calcium from bones could lead to osteoporosis.

### Study details

Researchers analysed data collected from 221 male HIV positive subjects who were divided into the following groups:

- 32 subjects not taking anti-HIV treatment who did not have lipodystrophy (body-shape changes)
- 14 subjects who used nukes and who had lipodystrophy
- 28 subjects who used nukes and who did not have lipodystrophy
- 103 subjects who used protease inhibitors and nukes and who had lipodystrophy
- 44 subjects who used protease inhibitors and nukes and who did not have lipodystrophy

All subjects received special X-ray scans, called DEXA (dual-energy X-ray absorptiometry), of their bodies as well as various blood tests. DEXA scans are particularly useful when trying to find out the thickness of bones. High levels of lactic acid were defined as any readings greater than 2.0 mmol/Litre. The basic profile of subjects at the start of the study was as follows:

- average age – 43 years
- average CD4+ count – 485 cells
- average viral load – about 1,500 copies
- average length of HIV infection – 7½ years
- 20% of subjects had AIDS
- 52% had lipodystrophy
- 20% had high levels of lactic acid in their blood
- 14% had symptoms of lactic acidosis

### Results — thinning bones

According to the results of the DEXA scans, a total of 51 subjects, or 23%, had bones that had shrunk. The subjects were grouped in the following manner:

- 44 had lost calcium and other minerals in their bones
- 7 had lost so many minerals that their bones were thin and porous

Loss of calcium and other minerals from the bone occurred in the following groups of people:

- 2 subjects who had never used anti-HIV drugs
- 11 subjects who had used nukes
- 36 subjects who had used nukes and protease inhibitors

When the researchers compared data from HIV negative, healthy Australian men, the proportion of HIV positive subjects with thinning bones was 50% higher.

### Factors linked to bone loss

Subjects who lost bone mass during the study were more likely than others to have the following:

- lactic acid levels greater than 2 mmol/L
- lower muscle mass
- older age
- longer use of d4T

### Factors not linked to bone loss

The researchers found that the following factors were **not** associated with the loss of bone in this study:

- smoking tobacco
- exercise
- the type of protease inhibitor used

- the type of non-nuke used
- levels of fatty substances — cholesterol and triglycerides — in the blood

### What's next?

The findings reported by the Australian researchers are certainly important because they help narrow the focus on the possible drug-related causes of osteoporosis in HAART users. These findings need confirmation because doctors don't know if switching nukes, particularly from d4T to other nukes, will reduce the risk of developing thinning bones.

The research team also suggests that regular testing for lactic acid levels should be considered only in PHAs who use nukes who also have fractures, osteoporosis or other risk factors for bone disease.

The people who may be at high risk for osteoporosis include PHAs with the following factors:

- women who have gone through menopause
- men with lower-than-normal levels of testosterone
- little physical exercise or excessive bed rest
- low levels of calcium in the diet
- use of corticosteroids

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## E. Bone damage — more than just nukes involved

The Australian study that uncovered a link between high levels of lactic acid and bone damage in PHAs (see previous story) is perhaps not surprising. Last year, researchers in Spain found that people with hepatitis C virus infection (who were HIV negative) who used a combination of the anti-hepatitis-C nuke ribavirin with interferon-alpha had an increased risk of developing thinning bones compared to other people with hepatitis C who used interferon only.

The common link between the HIV positive and HIV negative groups of people is the use of a group of drugs called nukes. These drugs damage the energy-producing parts of a cell, called mitochondria, and appear to cause the liver to produce higher-than-normal levels of lactic acid, or lactate.

Although both the Australian and Spanish results need to be confirmed by other researchers, it is important to note that there are other factors associated with

bone loss. Some of these factors likely play a role in the bone health of PHAs. These factors can include the following:

### Medical conditions

- diabetes
- kidney dysfunction
- thyroid dysfunction
- liver damage
- pancreatitis
- less-than-normal levels of testosterone (men)
- less-than-normal levels of estrogen (women)

### Nutritional issues

- poor eating habits
- not eating enough calcium and magnesium-rich food
- not getting enough vitamin D

### Lifestyle

- excessive bed rest
- no regular weight-lifting exercise

### Drugs

- alcohol abuse
- corticosteroid use

### Protecting bones

Researchers are not sure about the best way to protect the bones of HAART users. A first step might be to develop a regimen of nutrients that nourish and protect mitochondria:

- vitamins C and E
- L-carnitine
- co-enzyme Q<sub>10</sub>
- B-complex vitamins

Another step may be to take supplements of bone-building nutrients such as calcium and vitamin D<sub>3</sub>. To help maintain bone health, the dose of calcium recommended by the American Institute of Medicine for “older adults” is between 1,000 to 1,500 mg per day. The best dose of vitamin D<sub>3</sub> for adults with osteoporosis is not clear but is probably somewhere between 400 to 1,000 international units per day. Readers should note that there appear to be factors other than nuke-related bone damage which need further study.

### Protease inhibitors and non-nukes

Even though the Australian researchers mentioned in the previous report on lactic acidosis and bones found little or no connection between thinning bones and protease inhibitors (PIs) or non-nukes, other researchers may have found such a link. A research team in the U.S. has found that in lab experiments PIs and non-nukes impair the liver’s ability to convert vitamin D to its useful or “activated” form, vitamin D<sub>3</sub>. Without sufficient amounts of active vitamin D, the body may be unable to absorb and retain enough calcium to build and maintain strong bones.

PIs may also interfere with the growth and development of cells in the bone marrow that eventually turn into bone-building cells.

It is also possible that HAART may upset certain chemical signals, such as TNF, used by both the immune system and bone cells. This can have the effect of unnecessarily prolonging the life of specialized cells whose function is to tear down bones. Further study of the drugs that make up HAART and their impact on bone health needs to be done.

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