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I ANTI-HIV AGENTS

A. Drug holidays — an overview

Dealing with chronic health conditions is never an easy task both for patients and their doctors. Complex treatment regimens, large numbers of pills, side effects and drug interactions are just some of the challenges faced by people taking medications for these conditions. In high-income countries, many people with HIV/AIDS (PHAs) who have received highly active antiretroviral therapy (HAART) face these issues on a daily basis. Not surprisingly, some of these PHAs tire of taking HAART day after day, for many years. As a result, there is much interest in the idea of possibly taking a break from treatment regimens. Such breaks are commonly referred to as “drug holidays” or structured treatment interruptions (STIs).

Concerns about studies

Most of the studies on drug holidays have been small, not well designed and sometimes short. Despite these shortcomings, some useful information has been collected. Larger and longer trials are either planned or underway, but their results will not be available for another two to three years. Until then, it's clear that drug holidays are not the best way to manage HIV/AIDS. This is because CD4+ counts decrease (sometimes rapidly) and the amount of HIV (viral load) that is produced increases. There may also be less obvious damage to the immune system that resumes when therapy is stopped. Together, these changes increase the risk of developing life-threatening infections. Ironically, in seeking to get away from the demands and stresses of treatment regimens, PHAs on drug holidays require more frequent visits to the clinic to have blood taken for CD4+ and viral load monitoring.

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Another issue raised by drug holidays is that of HIV developing resistance against therapy. This issue arises because not all drugs leave the body at the same time. Some drugs, such as efavirenz (Sustiva) and nevirapine (Viramune), remain in circulation at lower levels for a few days than other drugs such as, say, AZT. Some doctors are concerned that during the time of low efavirenz or nevirapine levels it may be easier for HIV to build up resistance to these drugs. Resistance to one member of this class of drugs, called NNRTIs (non-nucleoside reverse transcriptase inhibitors), usually means that a person also is resistant to the other NNRTIs.

Very early HIV infection

If any good immunologic news for drug holidays exists, it has come from people in the very early stages of HIV infection. In these cases, people have received treatment to suppress HIV levels, and then, once suppressed for several months, they take a supervised drug holiday. Overall, results from a small number of subjects suggest a theoretical benefit — possibly better control of HIV by the immune system. However, there is no proof that this strategy delays the decline of the immune system or prolongs survival. Finally, application of this type of intervention is not usually practical because the average person doesn't know exactly when they were exposed to HIV.

Chronic infection

Perhaps the people most interested in a drug holiday are those PHAs who have been HIV positive for many years and have been taking HAART for a long time. Unfortunately, the immunologic results of drug holidays in these people are not impressive. All in all, while on a drug holiday, it is clear that their immune systems have not learned how to control HIV. Indeed, results from the largest trial to date (the SSITT study), with more than 100 subjects, have shown no overall benefit. Interestingly, test-tube studies found that the ability of subjects' immune systems to attack HIV increased during the study. However, this improvement did not result in significantly lowered viral loads while off therapy.

Heavily treatment-experienced PHAs

In PHAs who have been exposed to several treatment regimens, HIV usually develops resistance to therapy. In these people, despite changing therapies, viral load continues to rise while CD4+ counts fall. Doctors sometimes interrupt therapy for a few months, usually between different regimens. This is done to reduce the pressure on HIV to mutate and decrease its level

of resistance. During the break, HIV that is drug resistant tends to be harder to find in blood samples. Once therapy resumes, drug-resistant virus eventually re-emerges.

As many questions about interrupting or stopping HAART remain unanswered, researchers around the world are planning or starting large studies to compare the effect of different drug holiday strategies. Some trials call for fixed periods of on/off therapy (for example, one week on/one week off), while others are more flexible and resuming therapy often depends on CD4+ and viral load levels. Below are short summaries of some of these studies.

- **OPTIMA** — taking place in Canada, the UK and U.S. This study is also known as CTN 167. In this trial, researchers will examine which treatment strategies are best once first and second regimens have failed. Subjects may receive combinations of four or five drugs and will also take drug holidays. Researchers hope to enroll 1,700 subjects over three years. For more information about this study, contact the Canadian HIV Trials Network at 1.800.661.4664.
- **SMART** — supported by the U.S. National Institutes of Health and the CPCRA, this American study will use on/off schedules guided by CD4+ cell counts. Researchers hope to enroll thousands of subjects. This trial is expected to last for between seven and 10 years.
- **STACCATO** — this study is taking place in Australia, Switzerland and Thailand. In it, researchers will compare three strategies: one week on/one week off therapy; continuous therapy; and stopping therapy when the CD4+ count is above the 350 cell mark and resuming therapy when it is below that figure. Researchers plan to enroll 600 subjects and monitor them for two years.

It is great that researchers are finally studying drug holidays in such a serious way. Even though results of trying to “teach” the immune system to contain HIV through drug holidays have been largely disappointing, these breaks from treatment offer another kind hope: simply giving PHAs a break from drugs and their side effects in order to enhance quality of life.

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B. Here's a story about a drug holiday

Over the past two years, guidelines for starting HAART have become gradually more cautious by suggesting that treatment be initiated later (lower CD4+ counts) rather than earlier (higher CD4+ counts) in the course of HIV disease. Before this change in guidelines, some PHAs began therapy at CD4+ counts that are higher than the presently recommended starting point (for the latest HIV/AIDS treatment guidelines, go to <http://hivatis.org/trtgdlns.html>). As a result of early therapy, these PHAs may have had huge increases in CD4+ counts. Some American PHAs who found themselves in this position decided to embark on a closely supervised drug holiday. We now report on this study.

Study details

Doctors collected data on 72 subjects with the following profile:

- 24 women, 48 men
- average age – 35 years
- average pre-HAART CD4+ count – 285 cells
- average pre-HAART viral load – 26,000 copies

Before starting their drug holiday, subjects had their viral load suppressed with HAART for an average of six months. All subjects stopped taking HAART for at least three months; the average length of time off HAART was 11 months.

Results — CD4+ cell counts

- At the time subjects interrupted therapy, the average CD4+ count was 554 cells.
- Three months after stopping therapy, the average count had fallen to about 400 cells.
- Eleven months after stopping therapy, the count had fallen further, to an average of 300 CD4+ cells. (This is about the level of their CD4+ count when they originally started taking HAART.)

Those subjects who interrupted therapy when their CD4+ counts were greater than 350 cells “tended to lose cells faster than those who stopped

therapy when their CD4+ count was below the 350 cell level.” Another factor that affected the decline in CD4+ counts was age — CD4+ counts declined faster in older PHAs than in their younger counterparts.

Life-threatening conditions

Four subjects whose CD4+ counts fell to fewer than 200 cells while off therapy developed the following complications:

- AIDS-related wasting – 1 person
- blood poisoning due to bacterial infection – 1 person
- PCP (*Pneumocystis carinii* pneumonia) – 2 people

According to the doctors' article, in PHAs whose viral load was suppressed with treatment, supervised drug holidays appear to be safe so long as CD4+ counts remain above the 200 cell mark.

Intermittent therapy

One of the strategies pursued in treatment interruption studies is intermittent therapy. They can be one week on therapy/one week off, or the periods may be longer. The results of this study have implications for intermittent therapy studies. If, as this study has found, the factor that best predicts the loss of CD4+ cells while off therapy is the number of cells gained during therapy, then perhaps the best time to initiate drug holidays are when CD4+ cell counts are high. In this way, the loss of cells while off therapy may be minimized.

The doctors acknowledge that their report probably reflects a “best-case scenario.” By that they mean that only subjects who were able to discontinue therapy for at least three months were included in this study. Those subjects who had “large” decreases in CD4+ counts would have had to quickly resume therapy. The results of this study may not apply to PHAs with a different profile.

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II TOXICITY

A. Milk thistle and indinavir

Background and summary

In North America, some people with HIV/AIDS (PHAs) use vitamins, supplements and herbs to complement their drug-based therapy. One complementary therapy that is popular is the herb milk thistle. Traditionally, this herb has been used for the treatment of liver disorders such as jaundice (yellowing of the skin and whites of the eyes). Recent laboratory research on cells suggests that milk thistle extracts may be useful in helping the liver and kidneys recover from damage caused by certain drugs and alcohol.

A concern with herbal supplements is that they may interact with medications — by either raising or lowering levels of medications used to treat HIV/AIDS and other conditions. Interactions can occur because many drugs are processed by enzymes in the liver. Herbs and drugs can speed up or slow down the activity of these enzymes, raising or lowering drug levels. If an interaction raises drug levels, new or intensified side effects may occur. Similarly, if drug levels are lowered, the effectiveness of treatments will also be reduced. In the case of therapies for HIV/AIDS, this could lead to the development of drug-resistant HIV and reduced treatment options in the future.

This concern is not just a theory. The plant St. John's wort, often used for managing anxiety and mild depression, can interact with many drugs, including two classes used for the treatment of HIV/AIDS:

- protease inhibitors (PIs)
- non-nucleoside reverse transcriptase inhibitors (non-nukes or NNRTIs)

In laboratory experiments with cells, researchers found that extracts from milk thistle significantly reduced the activity of certain liver enzymes — specifically those used to process PIs and non-nukes. In theory, these extracts could raise levels of PIs and non-nukes in the blood. To find out if this was the case in people, researchers at the National Institutes of Health in Bethesda, Maryland, conducted a small study. They found that, overall, milk thistle reduced levels of the PI indinavir (Crixivan) in the blood by about 9%. They also found that just before it was time to take the next dose of indinavir, in subjects using indinavir and milk thistle, blood levels of this drug fell 25% lower than they normally should. The

implications of these findings are discussed later in this report.

Study details

Researchers enrolled 10 healthy, HIV negative subjects (four females, six males) whose average age was 35 years. At different times over a period of six weeks, subjects received the following regimens:

- indinavir 800 mg every 8 hours on an empty stomach
- indinavir and milk thistle
- milk thistle only

The brand of milk thistle used in the study was Thisilyn, made by Nature's Way. This product contained 80% silymarin — one of the compounds responsible for the herb's beneficial effect. Subjects received 175 mg three times daily with meals.

A note about drug levels

The highest level a drug reaches in the blood is called the "peak" and the lowest level the "trough." The level of a drug in the blood usually reaches the trough level when it's time to take the next scheduled dose. If viral resistance is to develop, it often occurs when drug levels are at their lowest — the trough.

Results — indinavir and milk thistle

Overall, the total amount of indinavir that entered the blood was decreased by only 9% with the use of milk thistle. Perhaps more significant were the changes in trough levels of indinavir. Levels of this drug are at their lowest just before it's time to take the next dose — eight hours after the last dose was taken. Milk thistle lowered indinavir trough levels by about 25% compared to their levels when indinavir was taken alone. This change was statistically significant, that is, not likely due to chance alone. In one subject, trough levels decreased by about 60%.

Results — side effects

Milk thistle was "generally well tolerated"; subjects using indinavir reported "an odd taste in their mouth" and nausea.

Why these results?

That milk thistle interacted with indinavir to cause a decrease in that drug's level in the blood of people is surprising because experiments with cells suggested the opposite. The reasons for this difference may be due to the following:

- not using identical ingredients in both sets of studies (test-tube and people)
-

- using a concentration of substances in the lab that is much higher than that used in people
- experiments based solely on what's happening in a test tube don't always reflect the complexity of the organs and systems found in a body

Milk thistle and HIV/AIDS drugs

A decrease of 25% in trough levels may be a concern for some people who are using only one protease inhibitor in their HIV drug combination. However, in North America and perhaps the European Union, more doctors are increasingly prescribing indinavir along with another PI, ritonavir (Norvir). This is because ritonavir increases or boosts the level of indinavir in the blood and maintains this level for prolonged periods. As a result, ritonavir-indinavir need only be taken twice daily. Similarly, ritonavir is used to boost other PIs including the following:

- amprenavir (Agenerase)
- lopinavir (in Kaletra)
- saquinavir (Fortovase or Invirase)

When taken with ritonavir, because it is such a powerful booster, indinavir levels are not likely to be significantly affected by the dose of milk thistle used in this study.

The effect of milk thistle on unboosted protease inhibitors and non-nukes, until studied, is not clear.

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III TESTING

A. Some factors affecting survival in HIV positive women

Background

In high-income countries, the use of highly active antiretroviral therapy (HAART) has greatly decreased deaths and illness due to AIDS. However, the benefits of HAART have not been as dramatic in some HIV positive women as they have been in HIV positive men. The reasons for this difference are not clear, but perhaps they involve issues around access to care and treatment.

Researchers in the United States conducted a study to examine the causes of death in HIV positive women. To do this, they examined information in death certificates. This information was collected from a large group of women, most of whom were HIV positive and some who were at high risk of becoming positive. The study took place between 1994 and 2000, and during that time the researchers found that 18% of the women died. A large minority of these deaths was from causes apparently unrelated to AIDS. The study authors concluded that in order to decrease death rates further, HIV positive women need to have care that increases its focus on conditions such as "hepatitis C, depression, drug and tobacco use."

Study details

Researchers recruited 2,059 HIV positive women between October 1994 and November 1995 for this study. Data up to April 2000 was collected and analysed. The profile of the women who enrolled in the study was as follows:

- average age – 36 years
- racial breakdown – 56% black, 23% Latina, 22% white
- average income – \$4,500 U.S. per year
- 66% reported abuse or domestic violence in their past
- average CD4+ count – 330 cells
- average viral load – 22,000 copies

There were also 569 women who were HIV negative when they entered the study but our report focuses mostly on the HIV positive women.

Results — HAART and survival

The women did not use combination therapy with a protease inhibitor or non-nuke until the

early part of 1996. This point is noteworthy because deaths due to AIDS began to decline significantly in that year. Among the women, AIDS-related deaths declined by an average of 31% each year of the study. In contrast, deaths unrelated to AIDS remained stable throughout the study.

Overall survival

By the end of the study, the number of deaths in the following groups were:

- HIV positive – 451 women
- HIV negative – 17 women

The researchers calculated that the rate of death was seven-fold greater among HIV positive women when compared to those without HIV.

Causes of death — AIDS

Among HIV positive women, AIDS-related complications were responsible for 71% of deaths. The common causes of death were as follows:

- life-threatening infections – 40%
- blood poisoning from bacterial infections – 10%
- AIDS-related cancers – 6%
- unspecified AIDS – 31%
- unspecified pneumonia – 8%

Non-AIDS-related causes of death

A large minority of deaths (91 women) was due to causes other than AIDS, including the following:

- liver disease – 21%
- drug overdose – 18%
- cancers not listed in the definition of AIDS – 13%
- murder/suicide/accidents – 11%
- cardiovascular disease – 11%

Non-AIDS-defining cancers that occurred were as follows:

- lung cancer – 3 women
- throat cancer – 2 women
- blood/bone cancers – 2 women
- brain cancer – 1 woman
- colon cancer – 1 woman
- ovarian cancer – 1 woman
- stomach cancer – 1 woman

Focus on individual factors

On average, women who died from complications due to AIDS usually had a higher average viral load (220,000 copies) than women who survived (14,000 copies) or even women who died from causes unrelated to AIDS (55,000 copies). On

average, HIV positive women who died from causes other than AIDS had the following factors in common:

- higher viral load
- symptoms of depression
- previously used injection drugs

All in all, the researchers found that women who died from causes other than AIDS were “extremely vulnerable.” The researchers noted that 75% of these women experienced depression, and more than 80% used injection drugs.

If deaths due to factors other than AIDS are to be reduced in this population, HIV positive women need to be assessed for depressive illness and drug use, and they also need to have these conditions effectively managed. As well, screening for and treatment of hepatitis C virus infection should be incorporated into their health care. Because other studies have also found that HIV positive women experience a high level of domestic violence, programs that address this issue are needed as well.

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IV ANTI-CANCER AGENTS

A. A new treatment for Kaposi's sarcoma?

Infection with the virus HHV-8 (human herpes virus-8) can cause a disease called Kaposi's sarcoma (KS). Signs of this disease are the growth of KS lesions on the skin; as well, lesions can merge, particularly inside the body, around lymphatic vessels. This can cause fluid build-up, swelling and pain. In some cases, particularly when KS affects important organs such as the lungs, it can become life threatening.

Many options for the treatment of KS are available, from standard chemotherapy drugs to vitamin A-type creams (Panretin, alitretinoin). Recently, liposomal forms of chemotherapy such as Caelyx (liposomal doxorubicin) and Daunoxome (liposomal daunorubicin) have become available. These are supposed to be more active than their original formulations. However, none of these drugs cures KS.

What allows KS to flourish is a weakened immune system. The use of highly active antiretroviral therapy (HAART) has helped to reverse the course of KS in many PHAs who respond to therapy. However, in some PHAs, HAART alone may not be sufficient for managing KS. Researchers at several clinics across the U.S. have recently published the results of a clinical trial of the drug paclitaxel (Paxene, Taxol) in the treatment of PHAs with KS. This drug seems to be useful but, like all chemotherapy, can have serious side effects.

Study details

Researchers enrolled 107 HIV positive subjects who had the following profile when they began the study:

- 100% male
- average age – 38 years
- average CD4+ count – 41 cells
- 81% had 25 or more KS lesions
- 36% had KS in their lungs or gastrointestinal tract
- 52% had fluid build-up or swelling
- 82% had previously experienced a life-threatening illness or had the following signs/symptoms when they entered the study — fevers, night sweats, unintentional weight loss, fatigue
- at least 8% of subjects had previously received chemotherapy for KS
- about 44% were using a protease inhibitor (PI) as part of their treatment

The brand of paclitaxel used in this study was Paxene. The drug was given intravenously every two weeks at a dose of 100 mg per square metre of skin over the course of three hours. Taking the following drugs before each dose of Paxene helped to reduce hypersensitivity reactions:

- Decadron (dexamethasone) – 10 to 20 mg
- Tagamet (cimetidine) – 300 mg
- Gravol (diphenhydramine) – 50 mg

If subjects developed blood/bone marrow, liver or kidney toxicity, the next dose of Paxene could be either delayed or reduced to 75 mg/m².

Results — Response to therapy

Responses to Paxene were as follows:

- In four subjects, all lesions and associated complications cleared for at least four weeks.

- In 56 subjects, some lesions shrank or disappeared as did signs/symptoms such as swelling, fluid build-up and pain.
- Overall, 56% of subjects showed some form of positive response to therapy while 46% did not.
- Response to therapy was promising both in subjects with internal and external KS lesions.
- Similarly, response to therapy was not different in subjects who had more than 200 CD4+ cells from those with fewer cells.
- On average, subjects took about six weeks to respond significantly to therapy and this response lasted for about nine months.
- Half the subjects remained alive two years after entering this study.

Effect of protease inhibitors

While use of PIs did not affect the response to Paxene, it did appear to do the following:

- delay the spread of new lesions
- prolong the length of Paxene's anti-cancer effect
- prolonged survival

Side effects

Although Paxene had benefits, it caused a range of side effects in the following proportion of subjects:

- diarrhea – 67%
- fever – 66%
- weakness – 65%
- hair loss – 62%
- nausea – 48%
- rash – 47%
- headache – 34%

Perhaps the most dangerous side effect was Paxene's impact on the bone marrow. Sixty-five percent of subjects developed less-than-normal levels of the infection-fighting white blood cells called neutrophils. In 44% of these subjects, the decrease was severe, while in 54% it was life threatening. Not surprisingly, four subjects died from Paxene-related side effects.

Infections

During chemotherapy, about 53% of all subjects developed AIDS-related infections. The most common were as follows:

- CMV (cytomegalovirus) eye infections – 12%
 - PCP (*Pneumocystis carinii* pneumonia) – 6%
 - MAC (*Mycobacterium avium* complex) – 3%
 - fungal infection of the brain – 2%
-

Despite the side effects associated with Paxene, on some measures quality of life improved, probably because lesions disappeared from the faces of subjects and pain was decreased because swelling was reduced.

In this study, Paxene had significant anti-KS activity in a population of severely affected and ill subjects. Exposure to many previous types of chemotherapy did not result in any apparent cross-resistance to Paxene. The drug did cause significant side effects, as is common with many chemotherapy regimens. PHAs exposed to Paxene require careful monitoring. Paxene is now being tested in the U.S. as an initial treatment for KS. Paclitaxel is licensed in North America as a treatment for breast, lung and ovarian cancers.

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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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