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Latest News in Blood Cancer Research

*Highlights from the
2009 Annual Meeting of the
American Society of Hematology*

Editor

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Learn about:

- Treatment advances in blood cancers
- Medications being developed
- Clinical trials
- Coping tips and support services



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Researchers continue to make important progress in treating blood cancers.

This special edition of the CancerCare Connect® booklet series presents cutting-edge research highlights from the 2009 Annual Meeting of the American Society of Hematology, which took place December 5–8 in New Orleans, Louisiana.

This guide includes information on advances in the treatment of blood cancers, a discussion of clinical trials, and tips on how to cope with a diagnosis of blood cancer.

Please note: Some of the treatments discussed are still in the very early stages of research and may not be available to the general public outside of a clinical trial.

The information contained in this booklet is intended for discussion with your doctor. He or she can let you know whether these research findings affect your treatment plan, and if a clinical trial is right for you.

Leukemia

Leukemia is the general term used to describe several different types of blood cancers. Each year, approximately 44,000 people in the United States are diagnosed with some form of leukemia. In this section, we discuss some promising results from clinical trials for people with the following types of leukemia:

- **chronic myelogenous leukemia (CML)**
- **chronic lymphoblastic leukemia (CLL)**

■ acute lymphoblastic leukemia (ALL)**■ acute myelogenous leukemia (AML)**

All of these forms of blood cancer affect various types of white blood cells, which are made by the bone marrow and help the body fight infections and other diseases. However, a major difference among these cancers is how they grow. The chronic forms of leukemia tend to grow slowly; the acute forms of leukemia grow more quickly.

TARGETED TREATMENT FOR CML PROVING BENEFICIAL OVER THE LONG TERM

When it was introduced in 2001, the drug imatinib (Gleevec) revolutionized the treatment of people with CML. A targeted treatment, imatinib attacks a specific cell mechanism thought to be important for cancer cell survival and growth. This specific targeting helps spare healthy tissues and causes less severe side effects. The first clinical trial took place nearly a decade ago, but researchers have continued to follow the patients who took part. They have reported that the benefits of taking imatinib can last as long as seven years. Most people in the clinical trial are still doing well, and many are in remission, meaning that current tests cannot detect any sign of cancer.



Most people who take imatinib must keep taking it indefinitely. However, in two recent studies, researchers found that remission continued even after imatinib treatment was stopped. This was especially true for male patients and those who had also received a drug called interferon. These studies show that some people may eventually be able to stop imatinib treatment. However, to be sure that further treatment is not needed, such people would have to have checkups and blood tests every one to two months.

ALTERNATIVES TO STANDARD CML TREATMENT

In the search for improved treatments for people with CML, researchers have found two possible alternatives to standard imatinib therapy: dasatinib (Sprycel) and nilotinib (Tasigna).

Dasatinib is a drug that has been used to treat certain types of leukemia, including CML and ALL. It has been approved by the U.S. Food and Drug Administration (FDA) to treat CML in adults whose cancer does not respond or no longer responds to imatinib. Because the medication worked well in such people, researchers hoped it would also benefit people as a first-line (first-time) treatment for CML.

Nearly 75 people with CML took part in a clinical trial. None of them had received earlier treatment for their cancer.

More than two years after treatment, nearly 80 percent of patients who received dasatinib had a major molecular response—that is, their bone marrow had begun to produce normal cells and, at least to some extent, started working properly. (Even though standard treatment with imatinib is effective, people who are taking it seldom have such a strong response.)

It's also important to note that patients responded quickly to dasatinib. Within three months of starting treatment with dasatinib, 80 percent had a complete cytogenetic response, meaning there was no longer any evidence of cancer in their bone marrow.

Results from a later stage of research with dasatinib are expected in 2010.

Nilotinib versus Imatinib

Nilotinib is a drug that belongs to the same family of medications as imatinib. A recent clinical trial compared these two drugs.

More than 800 people who had been newly diagnosed with

CML participated in the trial. Nearly 550 were treated with nilotinib and nearly 300 with imatinib.

After 12 months of treatment, nilotinib appeared to be even more effective than imatinib. The bone marrow had begun to start working properly in twice as many people treated with nilotinib as those who were given imatinib (about 44 percent versus 22 percent). In about 80 percent of the people taking nilotinib, there was no longer any evidence of cancer in their bone marrow. For those taking imatinib, about 65 percent no longer showed any evidence of cancer in their bone marrow.

Based on these results, some researchers think that nilotinib may become the new standard of care for people with newly diagnosed CML, although further study is needed.

Omacetaxine for Imatinib-Resistant CML

Many people with CML respond well to treatment. But those who do not may have a mutation that makes their cancer resist drugs such as imatinib. A mutation is an abnormal

change in the genetic information of a cell. Sometimes these mutations have no effect at all, and other times they can be harmful.

For example, a small group of people with CML have a genetic mutation known as T315I. This mutation poses a challenge because even newer drugs such as dasatinib and nilotinib do not

seem to be effective against it. However, an older medication now called omacetaxine (Omapro) may be effective in this instance.

More than 80 people with CML took part in a very early-stage clinical trial to test omacetaxine. All of these patients did not respond or no longer responded to treatment with imatinib.

COPING TIP

Take an active role in your medical care.

Get a second opinion and consult with an expert in your type of blood cancer before choosing a treatment.

The best results with omacetaxine occurred in the 49 people who had chronic-phase CML. This type of leukemia is an early one, with less than 10 percent of blood cells not working properly. Two years after treatment, 80 percent of the 49 patients had survived. In the past, the average survival of people with a T315I mutation has been about a year and a half.

Future studies will test omacetaxine along with newer medications such as dasatinib and nilotinib.

POSSIBLE NEW STANDARD OF CARE FOR CLL

A three-drug combination known as FCR may become the new standard of care for people with CLL, the most common form of adult leukemia. The medications in this combination are fludarabine (Fludara and others), cyclophosphamide, and rituximab (Rituxan).

More than 800 people with CLL who had never received treatment for their cancer took part in a clinical trial. Some of the patients received FCR, and some received just fludarabine and cyclophosphamide (FC).

According to the results of this late-stage research, FCR helped more people to live longer than did FC. Three years after treatment, 87 percent of those treated with FCR were alive, compared with 83 percent of those treated with FC. Also, it took longer for the cancer to start growing again with FCR than with FC (an average of 52 months versus 33 months).

Researchers believe this is the first time such a clinical trial showed that a first-line treatment could lengthen the lives of people with CLL.

SECOND-LINE TREATMENT FOR ALL MAY BECOME FIRST CHOICE

Dasatinib was approved by the FDA in 2006 as a second-line treatment option for people with ALL that has not responded or no longer responds to other medications. However, based

on the results from an early-stage clinical trial, dasatinib may soon become a first-time option for people with what is known as Philadelphia chromosome-positive ALL, or Ph+ ALL.

The Ph chromosome carries a mutation that causes leukemia cells to grow uncontrollably. Like the similar drugs imatinib and nilotinib, dasatinib targets leukemia cells that carry this genetic change.



In this recent clinical trial, approximately 40 people with Ph+ ALL were treated with dasatinib. In more than 55 percent of these patients, blood counts (the level of blood cells) returned to normal. In nearly 80 percent, the ALL responded

after just one cycle with dasatinib. Thirteen months after this treatment, more than 70 percent of patients had survived.

NEW TREATMENT OPTIONS FOR PEOPLE AT RISK FOR AML

Myelodysplastic syndromes (MDS) are a group of conditions in which the bone marrow does not make enough healthy blood cells. Because MDS can increase the risk of developing leukemia, doctors sometimes refer to it as “pre-leukemia.” Recently, researchers have studied two different medications in people with MDS: romiplostim (Nplate) and clofarabine (Clolar).

Romiplostim

The drug romiplostim was tested in people with thrombocytopenia. Thrombocytopenia is a condition in which there is a lower-than-normal number of platelets in the blood. (Platelets are cells that help form blood clots and prevent bleeding.) People with MDS who are being treated with azacitidine (Vidaza) or decitabine (Dacogen) often

develop this side effect. Without enough platelets, the skin may bruise easily and wounds may bleed more than usual.

Romiplostim, which is designed to increase the number of platelets, was tested in a small clinical trial of nearly 30 people with MDS. Some patients received romiplostim. The rest received a placebo (a look-alike medication containing no active ingredient). About two-thirds of both of these groups also received four cycles of treatment with decitabine.

In another similar clinical trial of nearly 40 people with MDS, two-thirds of patients received romiplostim, and the others received placebo. In this study, some of the patients also received the targeted treatment lenalidomide (Revlimid).

COPING TIP

Reach out to experts for help in managing side effects.

Doctors can prevent and reduce symptoms such as fatigue, nausea, and anemia that are commonly experienced by people with blood cancers.

In both studies, people who were treated with romiplostim had increased platelet counts and fewer cases of bleeding. In the first study, those who received romiplostim needed fewer platelet transfusions as well. In the second study, romiplostim also made it possible for the patients to continue treatment with lenalidomide

without having to reduce the dose. That's important because taking the full dose of a drug increases a person's chances of being treated successfully.

Further study of romiplostim in people with MDS is planned.

Clofarabine

Clofarabine is another treatment in clinical trials for older adults with MDS or AML. This medication is already approved by the FDA to treat ALL that has relapsed or no longer responds to treatment. (A relapse is a return of cancer symptoms after a period of improvement.) Although clofarabine has been used intravenously (through a vein), a recent clinical trial tested an oral version of this drug.

Thirty-two people took part in this study. These patients all had MDS, which put them at a higher risk of developing leukemia. Seven of them received a low dose of clofarabine, 19 received an intermediate dose, and 6 received a higher dose.

Nearly half of the patients in the clinical trial (43 percent) had improved blood counts. Twenty-five percent had a complete hematologic response. This means that their blood counts returned to normal. Most of the responses occurred in the people who received the intermediate dose of clofarabine.

Lymphoma

Each year in the United States, about 72,000 people are diagnosed with some type of lymphoma. A little more than half of all blood cancers are lymphomas. This is a general term for a group of cancers that starts in the lymphocytes, a type of white blood cell that is an important part of our infection-fighting immune system.

Lymphomas are divided into two major categories. The largest group is called non-Hodgkin's lymphoma (NHL). There are more than 40 types of NHLs, and each has a different prognosis and treatment approach. For doctors to prescribe the most effective treatment, they must know the specific kind of NHL a person has. NHLs are grouped by how they look under the microscope, which—to a certain extent—predicts how fast the tumors would grow without treatment.

In this section, we focus on new treatment developments for:

- Slow-growing lymphomas such as follicular lymphoma (FL) and mantle cell lymphoma (MCL)
- A more aggressive lymphoma called diffuse large B-cell

lymphoma (DLBCL), which accounts for about two in five cases of NHL

- Lymphomas that do not respond or no longer respond to treatment
- Cutaneous T-cell lymphoma (CTCL), a type of NHL that begins in the skin as an itchy, red rash that can thicken or form a tumor

The main difference between NHL and Hodgkin’s lymphoma (HL) is the specific type of lymphocyte in the immune system each blood cancer involves—and that difference affects how they are treated.

ADDING NEWER MEDICATIONS TO CHEMOTHERAPY TO TREAT FL AND MCL

Doctors often add newer cancer drugs to standard chemotherapy to try to create even better treatments for people who have lymphoma. Two drugs—bendamustine (Treanda) and bortezomib (Velcade)—have been studied in recent clinical trials using this approach.

The first new treatment combines bendamustine with rituximab. Researchers report that this combination may become the future standard of care for treating slow-growing lymphomas such as FL and MCL.

Rituximab is a monoclonal antibody that has been used to treat certain types of NHLs, such as DLBCL and FL. Often compared with guided missiles, monoclonal antibodies zero in on cancer cells whose surface has a “target molecule.” This molecule is an important key in the development of a cancer cell. Rituximab zeros in on and destroys lymphocytes that have a molecule called CD20 on their surface.

More than 500 people with FL, MCL, and other types of lymphomas took part in a German clinical trial, which is in a later stage of research. Half of these patients received

bendamustine and rituximab. The other half received the current standard of care called CHOP plus rituximab. CHOP is a combination of three chemotherapy drugs—cyclophosphamide, doxorubicin (Adriamycin and others), and vincristine (Oncovin and others)—plus a steroid called prednisone.

The cancer disappeared in more people treated with bendamustine and rituximab than in those treated with CHOP plus rituximab (40 percent versus 30 percent). Also, the time it took for the cancer to start growing again was longer with bendamustine and rituximab than with CHOP and rituximab (55 months versus 35 months).

COPING TIP

Be resourceful. Cancer can be a financial strain, but help is available. Organizations such as CancerCare® help cover costs such as transportation to treatment and co-pays.

As for side effects, there were fewer infections and higher blood counts with the bendamustine combination than with the CHOP

combination. Doctors also reported that bendamustine did not cause hair loss, which often is a problem with standard chemotherapy drugs.

HyperCVAD and R-CVAD

The second new treatment combines the targeted drug bortezomib with an intensive combination of anti-cancer medications known as hyperCVAD. A clinical trial of these medications was in an earlier phase of research than the study on bendamustine and rituximab.

These drugs are given in frequent small doses to reduce the side effects of this aggressive treatment.

The FDA has approved bortezomib for the treatment of people with MCL and multiple myeloma, a cancer of the plasma cells in bone marrow. (Plasma cells produce antibodies, which fight infection.)

Of the 76 people with MCL who took part in the clinical trial, 64 completed treatment with bortezomib and R-CVAD—hyperCVAD with rituximab. None of these patients had received treatment before for their cancer.

The cancer shrank in more than 95 percent of those treated, and it disappeared in 75 percent. Although researchers are encouraged by these early results, they want to follow these patients for a longer time to find out whether this new treatment can help extend their lives.

STANDARD OF CARE STILL THE FAVORED TREATMENT FOR DLBCL

Researchers wanted to find out whether a shortened treatment schedule of R-CHOP might be more effective in people with DLBCL than the standard treatment schedule.



More than 200 people older than age 65 who had DLBCL took part in the study. Half of the patients received the shorter treatment, taking the drugs every 14 days; the other half received the standard treatment, taking the drugs every 21 days.

To the surprise of many doctors, the shortened treatment seemed to be just as good as the standard treatment at shrinking the cancer. The cancer disappeared in 67 percent of those who received the shortened treatment schedule and in

75 percent of those who received the standard treatment schedule. There also did not seem to be a major difference between the two treatment schedules in terms of extending the lives of these people. However, there were fewer severe side effects with the standard treatment given every 21 days.

Therefore, at this time, the 21-day treatment with R-CHOP is still considered to be the standard of care for treatment of older people with DLBCL.

The Importance of Clinical Trials

The goal of clinical trials is to find better ways to treat, diagnose, and prevent cancer. Clinical trials that test new drugs or other treatments proceed in phases. Each phase has a different purpose and helps researchers answer different questions. If a new drug or treatment does not prove its worth in the early phases of testing, the research can be halted.

Your doctor can guide you in making a decision about whether a clinical trial mentioned in this booklet may be right for you. You can also consult websites that list clinical trials to learn about other options you can discuss with your doctor. See page 24 for more information.

NEWER TREATMENT OPTIONS FOR RELAPSED LYMPHOMAS

As a rule, lymphomas that grow slowly respond well to standard treatments such as chemotherapy and radiation. But they tend to relapse, or come back, over time. Generally, these blood cancers respond again to similar or different treatments, but as time passes, the tumors can become resistant to treatment. So it's important to have additional treatment options available.

Brentuximab Vedotin

Two clinical trials show that the new drugs brentuximab vedotin (SGN-35) and SB1518 may be effective for some people with NHLs as well as HLs that relapse. However, it's important to remember that these results are from an early stage of research.

Brentuximab vedotin is a monoclonal antibody attached to a chemotherapy drug. It specifically targets and kills HL cells

while sparing normal cells in the body.

Approximately 35 people whose lymphoma had returned or no longer responded to treatment took part in a small clinical trial. Thirty-one of these patients had HL. All of the patients had already received an average of three chemotherapy treatments. They were given brentuximab vedotin weekly for three weeks as part of a 28-day treatment cycle.

In nearly half of the patients, the cancer shrank or disappeared after treatment with this new drug. The cancer disappeared in nearly one-third of the 35 patients. Although the results are early, researchers believe they are important enough to study this new treatment further in a major clinical trial.

A New Oral Cancer Drug

SB1518, a new oral cancer drug, showed promising results as well in a small study. Seventeen people who had relapsed HL or NHL took part in this clinical trial. All of these people had already received an average of five chemotherapy treatments for their lymphoma. SB1518 was given to them by mouth every day for eight weeks in different doses.

After eight weeks of treatment, the tumor shrank in three patients who received 300 milligrams of SB1518 and neither shrank nor grew in 11 other patients (nearly 75 percent). The most common side effects of SB1518 were diarrhea and constipation, each of which occurred in 40 percent of patients treated.

Researchers plan to study SB1518 in more people with lymphoma. It is hoped that future studies will show which types of lymphoma respond best to this new treatment.

NEW TREATMENTS FOR CTCL

Another lymphoma that may return and become resistant to treatment is CTCL. Now, researchers may have found two promising ways to treat people with this type of lymphoma.

The medications they are studying are pralatrexate (Folotyn) and belinostat (PXD101).

In the first clinical trial, which was in an early stage of research, 31 people with advanced CTCL received pralatrexate. For all of these people, previous treatments had either not worked or no longer worked.

Of the 31 patients in the study, the cancer disappeared in two people and shrank by at least 50 percent in nine people. The most common side effect of treatment with pralatrexate was mucositis (mouth sores), which occurred in more than 55 percent of those who received the drug. Doctors are now evaluating other people who have received this treatment.

COPING TIP

Acknowledge your emotions. It's perfectly normal to feel a wide range of emotions: anger, sadness, worry. Consider joining a CancerCare® support group online or on the phone. You can also get individual counseling free.

The second clinical trial studied belinostat in nearly 50 people with lymphoma that returned or no longer responded to treatment. Twenty of these patients had a fast-growing

NHL known as peripheral T-cell lymphoma (PTCL), and the others had CTCL.

Belinostat belongs to a new class of anti-cancer drugs known as histone deacetylase inhibitors. This type of medication causes a chemical change that stops tumor cells from multiplying.

The tumor either disappeared or shrank by at least 50 percent in four of the 29 people with CTCL who were treated with belinostat (14 percent). And the tumor either disappeared or shrank by at least 50 percent in five of the 20 people with PTCL (25 percent).

Researchers plan to study belinostat further in people with these subtypes of lymphoma.

Multiple Myeloma

Multiple myeloma (also known as myeloma or plasma cell myeloma) is a cancer of the plasma cells. Plasma cells, most of which are found in the bone marrow, are an important part of the immune system that helps fight infection and disease. Every year in the United States, approximately 20,000 people are diagnosed with multiple myeloma.

In this section, we discuss clinical trials studying treatments for this type of cancer.

FIRST-LINE COMBINATION TREATMENTS

Combination treatments that include the targeted drug bortezomib are one of the most exciting developments in multiple myeloma. Researchers believe that bortezomib combinations may be an effective way to make multiple myeloma shrink or disappear. They also believe such treatments may improve the results of stem cell transplants, helping to extend the lives of more people with multiple myeloma.

Bortezomib has been approved by the FDA for treating people whose multiple myeloma has not responded to other anti-cancer drugs. Because bortezomib has been effective for these patients, researchers have now begun to give bortezomib combinations to people with newly diagnosed multiple myeloma. In several early clinical trials, the following treatment combinations have shown promise when used as first-line options.

- VMP: bortezomib, melphalan (Alkeran), and prednisone
- VTP: bortezomib, thalidomide (Thalomid), and prednisone

VMP may be a new standard of care for people with multiple myeloma who are being treated for the first time, according to the results of a clinical trial that included 250 people with newly diagnosed multiple myeloma. One-third of these patients were older than 75.

Some of these patients received six cycles of VMP. The others received six cycles of VTP. Then, all of the patients continued to be treated with bortezomib and either thalidomide or prednisone for two years.

At the end of the two years, nearly 88 percent of all patients treated with VMP or VTP were still alive. After the primary treatment, the cancer completely disappeared in 23 percent of all patients. After two years of continued treatment, the cancer completely disappeared in 42 percent of all patients.

Although both combination treatments effectively shrank multiple myeloma, VMP seemed to be easier for these older patients to tolerate than VTP. And although there were no severe heart complications with VMP, eight percent of the people treated with VTP developed severe heart problems.

Based on these late-stage results, VMP seems to be a beneficial choice for older people with multiple myeloma who are being treated for the first time. Also, the use of continued treatment—called maintenance therapy—for this blood cancer is an appealing approach that deserves further study.



VMPT: VMP Plus Thalidomide

More than 500 people took part in this later-stage clinical trial. About half of the patients were treated with VMPT along with bortezomib and thalidomide maintenance therapy. The others were treated with just VMP and were given no maintenance therapy.

In this study, VMPT seemed to be more effective at shrinking the cancer than VMP. Multiple myeloma disappeared in more patients treated with VMPT than in those treated with

VMP (34 percent versus 21 percent). Also, nearly two years after treatment, the cancer had not continued to grow in 70 percent of the VMPT-treated patients, compared with only 58 percent of the VMP-treated patients.

Researchers believe that this was the first time a four-drug combination treatment followed by maintenance therapy was more effective than VMP alone in treating multiple myeloma.

RVD: Lenalidomide, Bortezomib, and Dexamethasone

In the past few years, lenalidomide has been approved in combination with other drugs to treat people with multiple myeloma that does not or no longer responds to other treatment. Considered a breakthrough medication for multiple myeloma, lenalidomide seems to work in a number of ways, in part by helping a person's immune system fight the growth of cancer.

COPING TIP

Develop good communication with your health care team.

Prepare a list of questions before your appointments; it's one way to make sure all your concerns are addressed.

Researchers are now trying to find out whether using lenalidomide in combination with other drugs is also an effective way to treat people with newly diagnosed multiple myeloma. A very early-stage clinical trial seems to indicate that it is effective in these people as well.

RVD was given to 35 people with newly diagnosed multiple myeloma.

The cancer shrank in all of the patients treated with RVD. The cancer completely or almost completely disappeared in more than half of the patients.

After treatment with RVD, eight patients (more than 30 percent) went on to have an autologous stem cell transplant. (Taking RVD does not remove the option of having a transplant.) This is a procedure in which blood-forming stem cells are removed, stored, and later given back to the patient. The hope is that the stem cells will mature into

healthy bone marrow cells and help replenish red and white blood cells more quickly.

Further studies of RVD and RVD-based combinations are either planned or ongoing.

NEWER TREATMENT COMBINATIONS FOR RELAPSED MULTIPLE MYELOMA

Two drug combinations have shown impressive results in clinical trials of people with multiple myeloma that did not respond or no longer responds to treatment:

Bortezomib and Tamsirolimus (Torisel)

Tamsirolimus is a drug that has been approved by the FDA to treat advanced kidney cancer. According to the results of a recent clinical trial, the combination of bortezomib and tamsirolimus may prove to be an effective way to treat multiple myeloma that resists other treatments.

Nearly 40 patients were treated once a week with bortezomib and tamsirolimus. In 25 percent of the 31 patients evaluated so far, the multiple myeloma decreased by at least 50 percent. In 10 percent of these patients, the cancer completely or nearly disappeared.

None of the evaluated patients experienced any symptoms of nerve damage from being treated with bortezomib and tamsirolimus. Bortezomib treatment can have some nervous system side effects, but they are usually mild and reversible. Researchers believe the weekly treatment does not affect the nervous system as much as a twice-weekly treatment.

Lenalidomide, Elotuzumab, and Dexamethasone

This combination appears to be effective for people with multiple myeloma that has returned (relapsed). Like many of the targeted treatments discussed in this booklet, elotuzumab (HuLuc63) is a monoclonal antibody. These

medications zero in on and destroy cancer cells that have a certain target on their surface.

So far, 28 patients have received this combination treatment. The cancer shrank or disappeared after treatment in more than 80 percent of the 23 patients evaluated so far. Results were even better in patients who had not already been treated with lenalidomide before this study. The cancer shrank or disappeared in 95 percent of those patients.

Based on these promising early results, the combination of lenalidomide, elotuzumab, and dexamethasone will be studied further in a larger study in 2010. It's important to remember that these studies are in a very early stage of research and need to be confirmed in larger clinical trials with more patients.

Supportive Care

Many people being treated for cancer also receive supportive care. This type of medical care prevents or reduces the symptoms of cancer itself, as well as the side effects caused by cancer treatment. In this section, we discuss two side effects about which researchers are learning new information, which will help develop effective treatments.

NEW DRUGS MAY REPLACE OLDER TREATMENT FOR BLOOD CLOTS

A clinical trial on two new blood-thinning drugs, dabigatran etexilate and rivaroxaban (BAY 59-7939), suggests that there is now an easier and better way to treat potentially dangerous blood clots, which can result from chemotherapy.

Chemotherapy can create blood clots that travel through the body's bloodstream, sometimes blocking the flow of blood in veins or arteries. When a clot blocks the flow of blood in a vein, the condition is called venous thromboembolism (VTE). Such clots can be life-threatening if they block the flow of blood to the lungs.

The standard treatment of VTE is a medication called warfarin (Coumadin and others). Warfarin belongs to a class of drugs called anticoagulants, which thin the blood to prevent clots.

Although warfarin is one of the most widely prescribed drugs in the world, patients who use it often need to have a number of blood tests so that their doctor can adjust the amount of medication and find the ideal dose. As a result, doctors have looked for a better and easier way to treat VTE.

Dabigatran

Dabigatran was tested in a large clinical trial of more than 2,500 people. Half of them received dabigatran, and the others received warfarin.

After six months of treatment, the results were generally the same in both groups and, in some cases, were better for dabigatran. Both dabigatran and warfarin were effective in preventing VTE and in reducing the risk of bleeding.

Unlike warfarin, dabigatran is an oral blood thinner that is given in a fixed dose. Therefore, it does not require repeated blood tests as warfarin does, which is very appealing to both doctors and patients.

With these results, researchers now believe that dabigatran may be a possible replacement for warfarin as a treatment for VTE. Dabigatran has been approved for treatment or prevention of VTE in 40 countries throughout the world. Although dabigatran has not yet been approved for use in the United States, many doctors think it will be approved sometime in 2010.



Rivaroxaban for VTE

The drug rivaroxaban is similar to dabigatran in many ways. As an oral blood thinner with a fixed dose, rivaroxaban also does not require repeated blood tests or dose adjustments. And, unlike warfarin, it does not require any changes in diet.

Nearly 1,200 people took part in a clinical trial studying rivaroxaban. These patients had previously experienced a VTE and had already taken blood-thinning medications.

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Doctors wanted to find out whether they would benefit from continued medication to prevent VTEs. About half of them were treated with the new drug, and the others were given a placebo.

The risk of a return of VTE was reduced by 82 percent in

patients on rivaroxaban compared with those on placebo. Researchers called this result “dramatic.”

Rivaroxaban was also able to reduce a return of VTE without raising the risk of severe bleeding or damage to the liver.

Like dabigatran, rivaroxaban has been approved for treatment of VTE in several countries but not yet in the United States. Researchers have also directly compared rivaroxaban with warfarin, and they hope to have these results later in 2010.

PROMISING OPTION FOR PREVENTING A COMPLICATION OF STEM CELL TRANSPLANTATION

Although doctors do not have an effective way to prevent or treat a life-threatening side effect of stem cell transplantation known as veno-occlusive disease (VOD), a new drug called defibrotide appears to reduce the risk of this condition in children who have had a transplant.

As described earlier in this booklet, stem cell transplant (SCT) is a procedure in which blood-forming stem cells are removed from a patient's bone marrow and stored. When the stem cells are on reserve, doctors give the patient high doses of chemotherapy to destroy his or her remaining cancerous bone marrow. Later, these reserved cells are given back to the patient. The hope is that these stem cells will mature into healthy bone marrow cells and help replenish red and white blood cells more quickly.

After SCT, some young people may experience VOD, in which some of the small veins of the liver are blocked. People who develop VOD may gain weight from retaining fluid, may have an enlarged liver, and may experience higher levels of bilirubin in the blood. (Bilirubin is a substance that is formed when the red blood cells break down.)

More than 350 children under the age of 18 took part in a clinical trial of defibrotide. All of these children were thought to be at high risk of VOD.

Half of them received defibrotide for 30 days after SCT, and the other half did not.

The results of this later-stage research showed that children were 40 percent less likely to develop VOD if they were given defibrotide after receiving a transplant. Only 12 percent of the patients who were on defibrotide developed VOD, whereas 20 percent of the patients who were not on defibrotide developed VOD.

Researchers say they may eventually consider defibrotide the standard for prevention and treatment of VOD.



Resources

■ GENERAL

CancerCare

1-800-813-HOPE (4673)

www.cancercares.org

American Cancer Society

1-800-227-2345

www.cancer.org

Cancer.Net

Patient information from the American Society of Clinical Oncology

www.cancer.net

National Cancer Institute

1-800-422-6237

www.cancer.gov

■ BLOOD CANCER ORGANIZATIONS

The Leukemia & Lymphoma Society

1-800-955-4572

www.lls.org

Lymphoma Research Foundation

1-800-500-9976

www.lymphoma.org

International Myeloma Foundation

1-800-452-2873

www.myeloma.org

Multiple Myeloma Research Foundation

1-203-229-0464

www.multiplemyeloma.org

National Bone Marrow Transplant Link

1-800-546-5268

www.nbmtlink.org

National Marrow Donor Program

1-800-627-7692

www.marrows.org

■ CLINICAL TRIALS WEBSITES

Coalition of Cancer Cooperative Groups

www.CancerTrialsHelp.org

National Cancer Institute

www.cancer.gov/clinicaltrials



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All people depicted in the photographs in this booklet are models and are used for illustrative purposes only.

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