

# Researchers study prevention of blood clots in cancer patients

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As more individuals with cancer are being treated as outpatients, the University of Rochester Medical Center is working on an emerging problem: how to prevent the life-threatening blood clots that can accompany some newer cancer drugs.

A team of researchers, awarded \$3 million this month by the National Heart, Lung and Blood Institute, is seeking to change the current standard of care by conducting a landmark clinical trial. They will test whether the drug dalteparin, a low-molecule-weight heparin available in a once-daily injection, can prevent pulmonary embolism or other forms of venous thromboembolism (VTE) in patients receiving chemotherapy on an outpatient basis.

The team includes Principal Investigator Charles W. Francis, M.D., professor of Medicine in Hematology/Oncology at the University's James P. Wilmot Cancer Center, and URMCo co-investigators Alok A. Khorana, M.D., associate professor of Medicine in Hematology/Oncology, and Mark B. Taubman, M.D., chair of the Department of Medicine and a member of the Aab Cardiovascular Research Institute. Duke University is a research partner as well.

Until recently, physicians had no way to identify which cancer patients might be at higher risk for the clots. But the Rochester group designed a risk model that was published in the journal, *Blood*. Then, based on input from the Rochester experts, the American Society of Clinical Oncology in 2007 issued its first set of guidelines for clinicians on clot

prevention for cancer patients. The next step is to demonstrate that clots can be prevented among those identified as higher risk.

"Venous thromboembolism is one of the leading complications in cancer patients and is the second leading cause of death," Francis said. "We expect that the results of this trial will show the way in preventing these problems and improving care for patients with cancer."

When blood clots develop in the deep veins of the leg or thigh, they can block blood flow and cause pain. In more serious cases, the clot breaks loose and travels to the lungs where it blocks arteries and can be fatal. Being hospitalized or confined to bed rest are risk factors, but clots can also develop in more active people.

Hospitalized patients routinely are given drugs such as dalteparin to prevent or treat the clots as soon as they develop. In the outpatient setting, however, the protocol for cancer treatment does not include using a drug such as Dalteparin for prevention of clots.

"The difficulty for outpatients is that not everyone who has a blood clot is symptomatic," Khorana said. "And in some cases when they do have symptoms of a clot in the lungs, the patient will complain of chest pains, shortness of breath, fatigue or a cough, which can be confused with cancer symptoms."

The Acting United States Attorney General Steven K. Galson, M.D., M.P.H., issued a "call to action" on Sept. 15, 2008, to reduce the number of cases of deep vein thrombosis and pulmonary embolism by urging people to learn more about the condition. The government estimates that up to 600,000 Americans each year suffer from dangerous clots, and that number is expected to rise as the baby-boomer population ages.

Scientists also believe the incidence may be growing with the use of a

newer class of cancer therapies called anti-angiogenesis drugs, such as Avastin. Although these newer drugs have less toxicity than chemotherapy, some are associated with higher rates of VTE.

In addition, the properties of some tumors may promote clots. Cancer-associated VTE leads to interruption of therapy, hospitalizations and increased risk of death.

To better understand the biological components of VTE risk in cancers, the Rochester group, led by Taubman, will also study whether elevated levels of tissue factor (TF) in plasma is a predictor of blood clots in cancer patients. Tissue factor is a protein in platelets that plays a vital role in how coagulation occurs and the promotion of blood clots. They will test the TF hypothesis using blood samples and biopsy specimens from patients who enroll in the Dalteparin clinical trial, and from a control group of patients identified as having a low risk of clots.

For years Taubman has been investigating the role of tissue factor in heart disease. But more recently he discovered data that shows certain cancers are also associated with elevated levels of TF, particularly pancreatic cancer. TF levels also tend to be higher in prostate cancer patients who survive for years.

The reasons for increased TF are not completely understood, but scientists do know that as cancer cells grow and die, they dump TF into the bloodstream. Chemotherapy also contributes to more TF entering the bloodstream as the cancer cells die off.

"This grant puts us in the forefront nationally of this growing field of inquiry," Taubman said. "I am confident that we will be the ones to answer the questions about cancer-associated tissue factor and whether anti-coagulant therapy has an effect of the risk of blood clots in cancer patients."

Source: University of Rochester

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