Summer 2004
SPECIAL ISSUE

healthpoints

ALL THE POSSIBILITIES OF MODERN MEDICINE

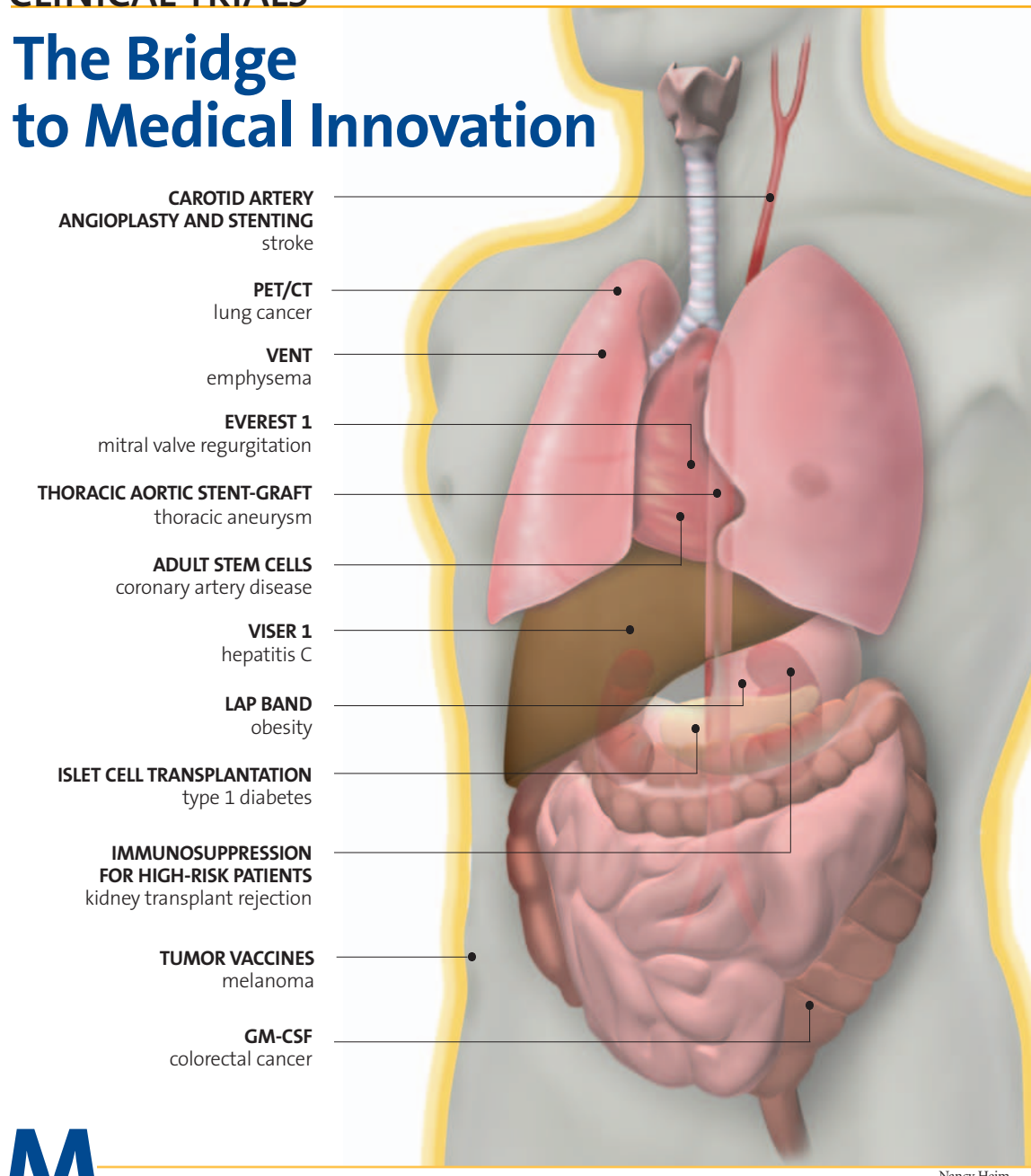
Columbia University Medical Center
Department of Surgery
NewYork-Presbyterian

"Our physician-scientists strive to help patients live longer fuller lives. Clinical trials lie at the heart of this effort. By collaborating across specialties and disciplines, we can test the possibilities of modern medicine and advance toward our ultimate goal of transforming years of hopeful research into long-term, successful treatments for our patients."

Eric A. Rose, MD
Morris and Rose Milstein/Johnson & Johnson Professor of Surgery
Chairman, Department of Surgery
Associate Dean for Translational Research, Columbia University Medical Center
Surgeon-in-Chief, NYPH/CUMC

CLINICAL TRIALS

The Bridge to Medical Innovation



Nancy Heim

Most people don't think about the origins of the drug they buy at the local pharmacy or the inspiration behind the medical procedure they undergo at their neighborhood hospital. Yet every pill, every diagnostic image, every surgical procedure—medical treatment in any shape or form—stems from a single source: *research.* Medical innovations start with the ideas and visions of committed scientists. Successful innovations then evolve over time—not weeks or months, but years—graduating through the different stages of development: *basic research, translational research, and clinical research.*

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"Basic research, done in labs, involves studying how cells work, how they talk to each other, how they know what to do, and what conditions and drugs make their functions more or less efficient. Here, scientists first test new treatments in animals to find out if they might be helpful or harmful to people," explains **Henry M. Spotnitz, MD,** *George H. Humphreys II Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Vice Chairman for Research and Information Systems* at the Department of Surgery.

"Then there's translational research, which involves deciding which basic science developments are most likely to be clinically useful and carrying out the intermediate steps. The process of identifying drugs, devices, or treatments that should be developed, funding and conducting the development, and putting the therapy in the hands of clinical investigators is the essence of translational research."

Clinical trials, also known as clinical research, are the furthest progression from the basic research lab. In clinical trials, scientists apply their discoveries to humans, testing new drugs, devices, or innovative therapies in selected patients.

What is a Clinical Trial?

This issue of *healthpoints* focuses on the clinical trial phase of the research process. Carefully conducted clinical trials are the safest way to evaluate potential medical treatments, assessing their effectiveness and potential risks. Only those treatments with the most promising laboratory results move from laboratory and animal studies into the clinical trial stage. Clinical trials are the bridge over which all new medical therapies must pass to become accepted practice—and the bridge is a long one. For patients, clinical trials can typically last for a few weeks or months. For scientists, they can continue on for years before a new therapy may see the light of day.

There are different types of clinical trials: treatment, prevention, diagnostic, screening, and quality-of-life trials—and the trials are conducted in progressive phases (I-IV). Once a clinical trial reaches the end of the bridge—proving its potential worth as a medical therapy—the Food and Drug Administration (FDA), a government agency, must officially approve the therapy for medical consumers.

For patients, participation in a clinical trial is voluntary. Common reasons for joining a clinical trial include: playing a more active role in your own health care; gaining access to innovative treatments before they become widely available; and helping others by contributing to advancements in medical research.

How do Clinical Trials Work?

To ensure that no one can influence the results of a study, clinical trials employ a range of specialized testing mechanisms intended to prevent bias and provide reliable results:

- **Prospective Trials**—Patients are identified and then followed over time.
- **Randomized Trials**—Patients are grouped by chance into (typically) a treatment group and a control group (also called a placebo group). The control group receives either the current standard treatment or a placebo—an inactive pill or liquid. The results of the control group are then compared with those of the treatment group.
- **Cross-over Trials**—Patients receive both the treatment and the placebo at different times, with careful monitoring of their responses to both approaches.
- **Double-blinded Trials**—Neither the patient nor the researcher knows if the patient is receiving the treatment or the placebo.

In addition, some clinical trials are called **open label studies**, because both the patient and the researcher know that the patient is receiving the treatment and not the placebo.

By federal regulation, every clinical trial in the United States must be approved and monitored by an Institutional Review Board (IRB), an independent committee of physicians, statisticians, community advocates, and others. The IRB is charged

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What are the Different Types of **CLINICAL TRIALS?**

TREATMENT TRIALS test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

PREVENTION TRIALS look for better ways to prevent a given disease in people who have never had that disease or to prevent a disease from returning. Preventative approaches include medicines, vaccines, vitamins, minerals, and lifestyle changes.

DIAGNOSTIC TRIALS are conducted to find better tests or procedures for diagnosing a particular disease or condition.

SCREENING TRIALS test the best way to detect certain diseases or health conditions.

QUALITY-OF-LIFE TRIALS (or supportive-care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

LAP BAND® Bringing Hope to More Overweight Americans

Obesity is the second largest cause of preventable death in the U.S. after smoking. Based on current trends, researchers predict obesity will become the number one cause by 2005, with the toll surpassing 500,000 deaths a year, rivaling the annual deaths from all forms of cancer combined. Despite efforts to reduce obesity, the incidence of this disease has been increasing over the past 20 years. While effective, obesity surgery has been reserved to date for patients at the highest risk—the most overweight. However, in a new clinical trial, physicians at Columbia are now taking a closer look at a different patient pool they believe could significantly benefit from weight loss surgery.

To define obesity, physicians typically use body mass index (BMI) units, which focus on weight changes in relation to height. An individual's BMI is calculated by dividing weight (in kilograms) by the square of the height (in meters). The diagnosis of obesity commences with a BMI of 30 or more, and morbid obesity with a BMI of 40 or more.

Currently in the U.S., one must have a BMI of 35-40 with co-morbidities (i.e. hypertension, diabetes, coronary artery disease, hyperlipidemia, osteoarthritis, sleep apnea, breathing problems, gall bladder disease, and psychological disorders like depression) or a BMI greater than 40 to qualify for obesity surgery. The Center for Obesity Surgery at Columbia University Medical Center is currently conducting a non-randomized, prospective study to determine the safety and effectiveness of Laparoscopic Adjustable Gastric Banding (LAGB), also known as LAP BAND®, in a less severely obese population who might not typically qualify for obesity surgery. The LAP BAND® is one of the least invasive obesity surgery procedures because neither the stomach nor intestine is cut. In this procedure, the surgeon places an adjustable silastic band around the upper part of the stomach to create a new small pouch above the band. The tightness of the banded opening

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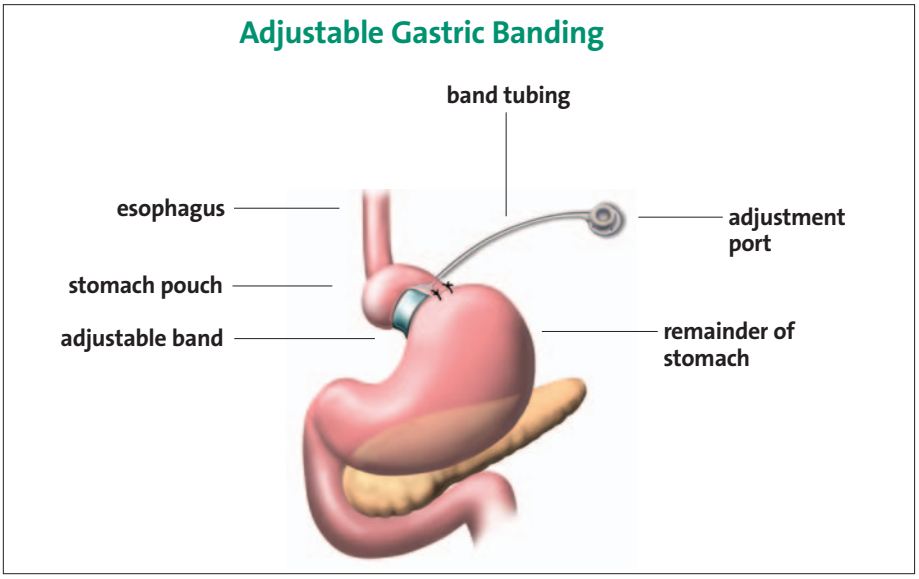
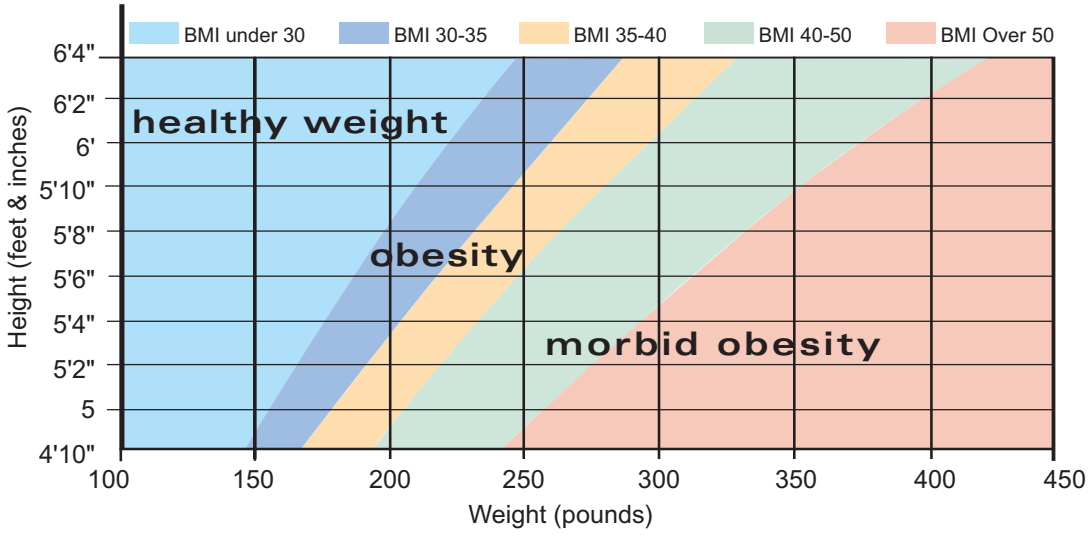


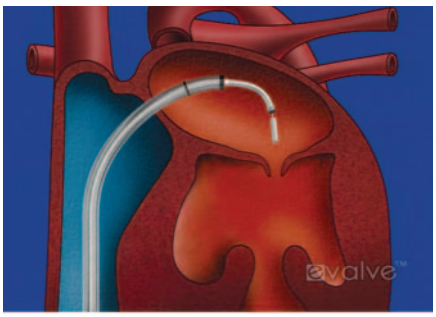
Illustration of laparoscopic placement of LAP BAND® around stomach.



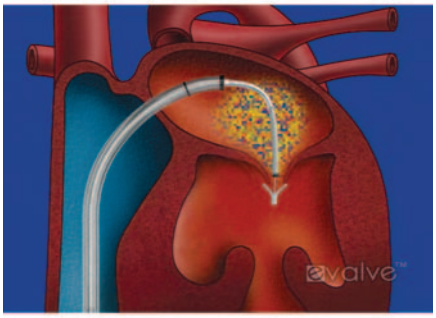
BMI is an indicator of optimal weight for health. To use the table, find the appropriate height in the left-hand column. Move across the row to the given weight. The intersection of the height and weight is the BMI.

Heart Surgery without the Heart Surgeon:
Evalve for Non-Invasive Mitral Valve Repair

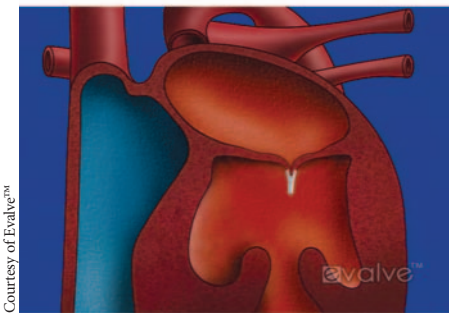
Researchers at Columbia University College of Physicians & Surgeons are conducting a Phase I clinical trial of the Evalve Cardiovascular Repair System (CVRS) for the treatment of mitral valve regurgitation, a common and potentially serious heart condition that may lead to arrhythmias or congestive heart failure. Initial results with the system have demonstrated that successful repair of the mitral valve is feasible using this less invasive approach, which takes the procedure out of the operating room and into the cardiac catheterization room. The clinical trial is called EVEREST I, or Endovascular Valve Edge-to-Edge Repair Study.



Accurate device position over valve before grasping valve leaflets.



Leaking of the heart valve before placing clip.



Courtesy of Evalve™

Procedure completed, clip in place, and leaking resolved.

"From the patient's point of view, the Evalve technology allows a less invasive procedure with a virtually nonexistent recovery period. It's a major paradigm shift from surgery to a nonsurgical, endovascular approach," says **Hal Wasserman, MD,** *Associate Clinical Professor of Medicine* and *Associate Director* of the Interventional Cardiology Center, Columbia University College of Physicians & Surgeons. Dr. Wasserman is the principal investigator of the trial, along with **Allan Schwartz, MD,** *Harold Ames Hatch Professor of Medicine* and *Chief,* Division of Cardiology, Department of Medicine, Columbia University College of Physicians & Surgeons.

The mitral valve is a one-way valve that connects the left atrium and the left ventricle of the heart. With mitral valve regurgitation, the valve does not seal completely and blood leaks back into the left atrium. This reverse flow (regurgitation) can cause the heart to enlarge and the lungs to fill with fluid. Signs and symptoms may include an audible heart murmur, shortness of breath, and heart palpitations. Four million Americans are estimated to suffer from mitral valve regurgitation, with nearly 250,000 new cases diagnosed each year.

For most patients, traditional mitral valve repair requires them to endure a sternotomy (an incision in the center of the chest to access the heart), undergo cardiopulmonary bypass, and have their valve repaired or replaced with a tissue or mechanical substitute. They typically remain three to five days in the hospital and experience a lengthy recovery period at home.

With the Evalve system, a cardiologist guides a catheter, or thin tube, from the groin through the vascular system to the heart's mitral valve, using fluoroscopic and echocardiographic imaging to show the way. The Evalve repositionable clip, located on the tip of the catheter, is then placed near the center of the two valve leaflets, binding them together. The heart beats normally throughout the procedure. During the procedure, the cardiologist can test the clip's effectiveness in reducing regurgitation and can reposition it as needed.

Once a satisfactory placement is achieved, the clip is detached from the catheter and the catheter is removed. The patient remains under general anesthesia throughout the procedure and can return home within 24-48 hours. There is no surgical wound—just a Band-Aid where the catheter was inserted.

To qualify for the EVEREST I trial, individuals must:

- Have moderately-severe to severe mitral regurgitation with symptoms or with evidence of left ventricular dysfunction
- Qualify as a candidate for mitral valve surgery including cardiopulmonary bypass

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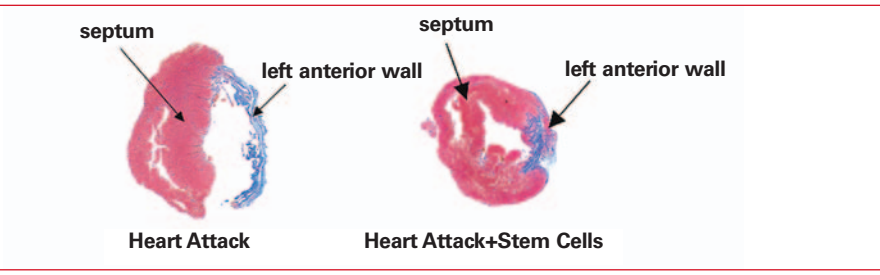
For more information about EVEREST I (IRB # AAAA3919), please contact Dr. Wasserman at 212-305-1581 or Dr. Schwartz at 212-305-5367.

Adult Stem Cells
and the Quest to Repair the Human Heart

Stem cells are cells that are capable of developing into other specialized cells required for organ or tissue functioning. Although adult stem cells lack the enormous versatility of embryonic stem cells, they may be easier to use clinically since they are already partially differentiated in the body. In addition, the use of adult stem cells does not confront the many ethical and legal questions associated with embryonic stem cell research. The therapeutic potential of adult stem cells is currently being put to test at NewYork-Presbyterian Hospital/Columbia University Medical Center.

Silviu Itescu, MD, *Director of Transplantation Immunology* for the Departments of Surgery and Medicine at NewYork-Presbyterian Hospital/Columbia University Medical Center has shown that if adult blood vessel stem cells, known as *angioblasts,* are injected into animals with damaged hearts, these cells find their way to the heart and create new blood vessels in the muscle wall to help repair itself. More recently, Dr. Itescu has also investigated whether a different type of adult stem cell, called a *mesenchymal precursor,* can regenerate cardiac muscles and arteries in animals.

Thanks to funding awarded by the NIH (National Institutes of Health), Dr. Itescu is initiating two clinical trials at Columbia to test both types of adult stem cells in human patients with heart disease. The initial trial—the first of its kind to receive FDA approval in the United States—evaluates the use of angioblasts in patients with ongoing symptoms of chest pain. The second trial will focus on patients with end-stage heart failure who have a left ventricular assist device (LVAD) implanted and will be performed in collaboration with **Eric A. Rose, MD**, *Chairman*, Columbia University Department of Surgery and *Surgeon-in-Chief,* Columbia University Medical Center. In this trial, angioblasts and mesenchymal precursors will be evaluated for their ability to help repair or regenerate the native hearts of these patients, so that ultimately, the LVAD might be removed.



The left hand panel demonstrates a representative rat heart that has undergone an experimental heart attack. The red depicts viable heart tissue and the blue represents dead heart tissue that has been replaced by scar. In contrast, in the panel on the right the animal has received stem cells, resulting in far less dead heart tissue and translating into improved heart function and a better prognosis for long-term survival.

Dr. Itescu anticipates that cell therapy will also be used in patients with acute myocardial infarction (heart attack). "In an acute heart attack, the blood supply to an area of the heart is blocked. Without blood, the tissue in that area dies and forms scars, preventing the heart from functioning as well as it did previously and causing future problems for the patient," explains Dr. Itescu. "Stem cell therapy should be complementary to angioplasty by helping to create new blood vessels that should enable heart muscle cells to stay alive and maintain muscle function after the heart attack."

The initial angioblast clinical trial is currently open and will run for the next two years. The second trial for LVAD patients is anticipated to commence in 2005.

Eligibility criteria for the current trial include:

- Ongoing chest pain despite optimal medical and/or surgical therapy for coronary artery disease
- Males and females 18 years of age and older
- History of myocardial infarction more than six months earlier

"Ultimately, I hope that these clinical trials will enable conclusions to be made about the optimal type of adult stem cell for treating acute and chronic coronary artery disease and for repairing the damaged heart," says Dr. Itescu.

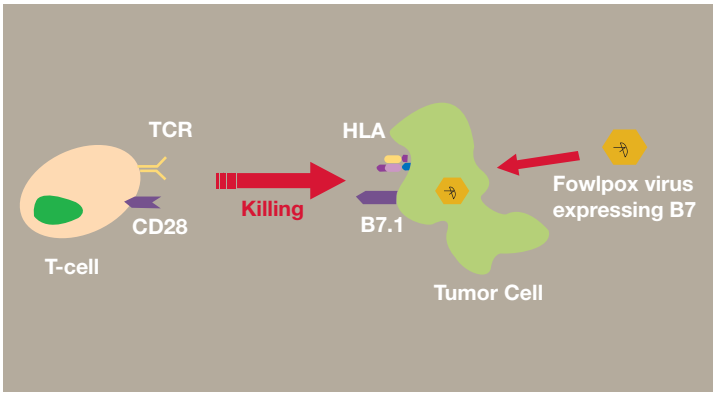
For more information about the stem cell clinical trials (IRB# 14577), please contact Dr. Itescu at 212-305-4354.

Tumor Vaccines

A Promising Weapon in the Fight Against Metastatic Melanoma

To date, physicians have struggled to successfully fight metastatic cancer, the spread of cancer beyond the original tumor site. Surgery, chemotherapy, and radiation therapy have failed to have a substantial impact on most metastatic solid tumors. Recently, the application of immunotherapy, or tumor vaccines, to the treatment of metastatic cancer has garnered much attention. The primary focus of immunotherapy is T-cell immunity. T-cells are white blood cells that fight infection and are involved in the destruction of tumor cells. Researchers believe that T-cells can recognize and possibly destroy tumors if they have been properly activated or stimulated against the tumor cells.

Physician-scientists at Columbia stand at the forefront of immunotherapy research, which could potentially revolutionize the treatment of metastatic melanoma. Melanoma is the most serious type of cancer of the skin. Each year in the United States, more than 53,600 people learn they have melanoma. "Several co-



Injecting a fowlpox virus encoding powerful immune enhancing genes (such as B7) results in effective tumor killing by local T cells.

investigators and I are currently leading a trial at Columbia to see if two particular tumor vaccines have the ability to create a strong immune response within patients—enabling their T-cells to react to the tumor cells and, hopefully, to fight back against the melanoma," says **Howard L. Kaufman, MD,** *Associate Professor of Clinical Surgery* at Columbia University College of Physicians & Surgeons and *Director of Tumor Immunotherapy* at NewYork-Presbyterian Hospital/Columbia University Medical Center.

The vaccines in the study, rF-B7.1 and rF-TRICOM, use two different, specially-constructed viruses that contain a gene or genes known to help activate T-cells. The viruses are based on the fowlpox virus, which causes disease in birds, but cannot replicate in human cells. Essentially, the altered virus is used as a delivery mechanism for the genes and provides danger signals that help to activate the immune system.

In laboratory models, T-cells activated with proteins made by the genes have been shown to destroy tumor cells. "Our understanding of T-cell biology is allowing us to develop more sophisticated and powerful vaccines for treating cancer patients. Although the approach has been effective in animal studies, the only way to determine the usefulness of the vaccine in patients is through clinical trials," says Dr. Kaufman.

For patients who enroll in the trial—which is only available at Columbia University Medical Center—Dr. Kaufman and his research team will evaluate any changes in the size of the tumor, study the immune responses to the vaccine, and assess any possible side effects. In addition to testing the effectiveness of the vaccines in fighting metastatic melanoma, the trial aims to determine the safest dosage levels. The 40 patients in the study will be randomized by a computer to receive either the rF-B7.1 vaccine or the rF-TRICOM vaccine.

Eligibility criteria for the trial include:

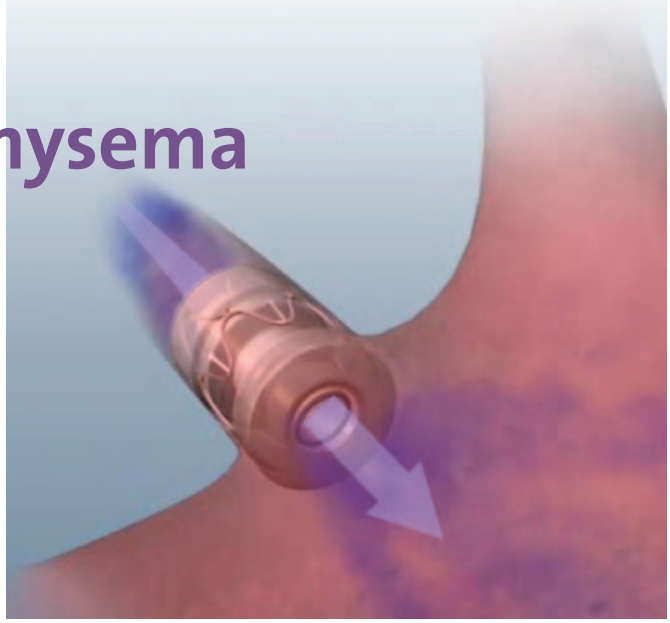
- Age greater than 18 years and not pregnant
- Metastatic melanoma
- Failed prior therapy for melanoma
- Completed all therapy at least four weeks prior
- Good overall medical condition
- Life expectancy at least three months
- Able to give informed consent
- No major medical problems, i.e., active autoimmune disorders, other types of cancer, or chronic infections
- No steroid use in the past four weeks

The tumor vaccine trial is being held in the Columbia Melanoma Center, which is led by national experts in medical oncology, surgical oncology, and tumor immunology, and serves as an active facility for conducting clinical studies. If the early findings appear promising, Dr. Kaufman and his colleagues plan to extend the trial to a larger group of patients at several medical centers across the country.

For more information about the tumor vaccines clinical trial (IRB# 14535), please contact Dr. Kaufman at 212-342-0232.

Vent for Emphysema

A Minimally Invasive Approach to Breathing Easy



Courtesy of Emphasys Medical, Inc.™

The Emphasys Endobronchial Valve (EBV™) is designed to redirect airflow to healthier lung segments by blocking inhaled air to the diseased portion. Upon exhalation, trapped air is intended to be vented out (as shown in illustration), creating the potential for non-surgical bronchial lung volume reduction.

For patients with emphysema, a lung disease typically caused by cigarette smoking, the fundamental act of breathing becomes a battle. Approximately two million Americans are affected by emphysema, and the vast majority are over age 50. Emphysema occurs when damage to the air sacs affects the elasticity of the lungs, trapping air in the lungs and enlarging the chest wall. In lung volume reduction surgery (LVRS), those parts of the lung most affected by emphysema are surgically removed in order to improve the function of the rest of the lung. After LVRS, patients typically experience less shortness of breath and improved quality of life. In a new clinical trial, the Endobronchial Valve for Emphysema Palliation Trial (VENT), physician-scientists at Columbia are investigating the potential benefits of a less invasive approach to lung reduction.

The VENT trial builds upon the findings of the five-year, multi-center National Emphysema Treatment Trial (NETT), published in *The New England Journal of Medicine* in May 2003. This landmark study was administered by the National Institutes of Health (NIH) in cooperation with the Centers for Medicare and Medicaid Services (CMS) and was spearheaded at Columbia by **Mark E. Ginsburg, MD**, *Assistant Clinical Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Surgical Director* of The LeBuhn Center for Chest Disease and Respiratory Failure at NewYork-Presbyterian Hospital/Columbia University Medical Center, along with **Byron M. Thomashow, MD**, *Associate Professor of Clinical Medicine* at Columbia and *Medical Director* of The LeBuhn Center for Chest Disease and Respiratory Failure.

The objective of the NETT was to compare the best medical treatments available with LVRS in patients with severe emphysema. The study demonstrated that in select patients, LVRS significantly reduced both shortness of breath and mortality as compared to medical management alone. As a result of the NETT, the CMS approved coverage for bilateral LVRS in designated centers of excellence, such as Columbia.

Dr. Ginsburg and his co-investigator of the VENT trial, **Roger A. Maxfield, MD**, *Associate Clinical Professor of Medicine* at Columbia University College of Physicians & Surgeons, are now hoping to dig a bit deeper into LVRS and reveal the benefits of the new minimally invasive approach. "With the VENT study, we're testing if the Emphasys Endobronchial Valve (EBV™) procedure can be performed effectively through an airway. The EBV™ is an implantable device—it's essentially a one-way valve designed to allow trapped air to vent from the isolated lung segment during exhalation, while preventing air inflow during inhalation," explains Dr. Ginsburg.

"Right now lung reduction surgery is done as an open-chest operation, and it has fairly significant morbidity associated with it," he continues. "If we could take away the trauma of the procedure, we would gain a lot in terms of patient outcomes. The minimally invasive procedure could provide a much faster recovery time; the hope is that patients will stay in the hospital for less than 48 hours—versus an average stay of 9-10 days after open lung reduction. It would also be a less costly procedure."

VENT is a multi-center, randomized, prospective clinical trial designed to primarily study the safety and effectiveness of the EBV™ procedure. Of the 20 centers participating in the trial, Columbia is the only center based in the tri-state area. To be eligible for the trial, patients must have severe emphysema, with the worst damage prevalent in the upper lungs. All patients will be required to undergo pulmonary rehabilitation before and after surgery, and patients will be followed for 18 months after randomization.

"If our outcomes prove as promising as I suspect, then this would be another step forward beyond the NETT—and a major advancement for treating patients with severe emphysema," adds Dr. Ginsburg.

For more information about the VENT trial (IRB# AAAA0812), please contact Dr. Ginsburg at 212-305-1158.

Colorectal Cancer and GM-CSF

A Stronger Immune System for Less Recurrences

Colorectal cancer claims the lives of 60,000 Americans annually, with more than 140,000 new cases diagnosed each year. While surgical removal of tumors cures some patients, many go on to develop recurrences. "Conventional chemotherapy results in only modest improvements in survival, therefore, new treatment strategies are necessary," says **Richard L. Whelan, MD,** *Associate Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Chief* of the Section of Colon and Rectal Surgery at NewYork-Presbyterian Hospital/Columbia University Medical Center.

> **"It has been demonstrated in animal studies that stimulating the immune system with GM-CSF immediately before and after surgery prevents post-operative immunosuppression and significantly lowers the chances of tumor metastases forming. In a lung metastases model in mice, we reduced the rate of metastases by 60%. If we can even achieve a 5% reduction in humans, we are onto something."**

Dr. Whelan is leading the investigation of a drug that could reduce tumor recurrences in colorectal cancer patients, and subsequently—break new ground in the treatment of the disease.

"Typically, before patients come in for colorectal surgery, we just give them antibiotics and then we perform the surgery. It's naïve to think that we cannot somehow improve their ability to respond to the operation," reports Dr. Whelan.

The strategy behind the clinical trial is to stimulate the patient's immune system before and after surgery with the drug Cytokine Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF,) in the hopes of avoiding post-operative immune suppression. Major surgery has been shown to result in a period of immunosuppression which, in turn, has been associated with increased post-operative tumor growth. Dr. Whelan believes a total of seven daily injections of GM-CSF will prevent the immune suppression that occurs after surgery and might even augment the patient's immune function during the perioperative period. Ultimately, the approach may lower the chances that a tumor recurrence will develop.

"It has been demonstrated in animal studies that stimulating the immune system with GM-CSF immediately before and after surgery prevents post-operative immunosuppression and significantly lowers the chances of tumor metastases forming," says Dr. Whelan. "In a lung metastases model in mice, we reduced the rate of metastases by 60%. If we can even achieve a 5% reduction in humans, we are onto something."

Eligibility criteria for the trial include:

- Primary colon or rectal cancer
- A functioning immune system as determined by a DTH skin test (similar to the tuberculosis skin test)
- Age 18 years or older

Immunosuppressed patients are not eligible.

Since this is a randomized trial, half of the patients (the control group) will receive saline injections and the other half will receive the actual drug. Co-investigators in the trial are **Kenneth A. Forde, MD**, *José M. Ferrer Professor of Clinical Surgery* at Columbia University College of Physicians & Surgeons, **Tracey D. Arnell, MD,** *Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons, and **Irena Kirman, MD, PhD,** *Associate Research Scientist* at Columbia University College of Physicians & Surgeons.

"Our goal in this phase I trial is to show that the drug is well tolerated and also to test the function of the circulating lymphocytes and other white blood cells to see if the drug has had an effect," says Dr. Whelan. "So far, the results are promising. If things continue to go well, we're hoping the drug company or the NIH would be willing to sponsor a larger multi-center trial that could involve 1000 patients or more. If we can show that GM-CSF can consistently decrease the tumor recurrence rate and increase the survival rate over the long-run, then this type of treatment would be made available to all colorectal cancer patients who are to undergo surgical resection."

For more information on the GM-CSF trial (IRB# 14319), please contact Dr. Whelan at 212-342-1155.

PATIENT PROFILE

My Experience in a Clinical Trial…

JOHN SMITH, a 50-year-old Senior Occupational Therapist, participated in Dr. Richard Whelan's GM-CSF clinical trial for colon cancer in July 2003. He shares his candid thoughts about the experience with *healthpoints.*

HP: How did you find out about the GM-CSF clinical trial?

JS: I had turned 50 and my primary care physician recommended I have a colonoscopy. I got the results back to find out I had stage I colon cancer and would need to undergo surgery. I had been to another surgeon first, and then decided to go to Dr. Whelan for a second opinion. I had gone to Dr. Whelan to find out more information about laparoscopic colorectal surgery, and by chance found out that he was conducting a clinical trial that could help boost my immune system. I didn't go looking for a clinical trial; I went looking for the best doctor for me and I found a clinical trial in the process.

HP: Had you ever participated in a clinical trial before? What was your motivating factor for participating in this trial?

JS: No, I hadn't. Dr. Whelan carefully explained the trial to me and provided me with very specific literature on the study, so I knew what I was getting into. He introduced me to his research team as well—he was very thorough, which really impressed me. The trial offered me an opportunity to boost my immune system and potentially reduce the tumor recurrence rate. I thought it could be beneficial and wanted to give it a try. I was also aware of Dr. Whelan's reputation. I had done some research on him and had read about his work. His extensive experience and his bedside manner were truly the motivating factors for me, more than anything else. In addition, I realized this could benefit not just me, but other people one day. Although the study was blind to me, because it was randomized, I still wanted to contribute to it.

HP: Did you have any initial fears or concerns about participating in the clinical trial?

JS: Sure, there are always possible side effects that one might be concerned about. But I asked a lot of questions and thought the risks were low. In the end, I definitely thought there were more advantages to the trial than disadvantages. I didn't really see a downside to it. The truth is, I didn't really have any fears around the trial—there were enough other real fears on my mind that dealt with the cancer itself.

HP: In brief, what did the trial entail?

JS: Initially, I had to have some skin tests to see what my baseline immune reaction was. There were three sets of skin tests total—baseline, pre-surgery, and then post-surgery. Basically, the trial entailed receiving injections of the drug GM-CSF before and after surgery, in the hopes of boosting my immune system. And this was done in a very accommodating manner; the research team came to my home before surgery to give me the injections. They did this because it was more convenient for me. They really treated me with care and respect.

HP: Did you experience any side effects or adverse reactions during the trial?

JS: None.

HP: How long did the clinical trial take?

JS: From the time I had the skin tests until the surgery was over, totaled probably three weeks. I am no longer in the trial. Post-surgery there was follow-up for a couple months, but that's it. I have to have a CAT scan and a colonoscopy this summer—a full year after the trial, so we can keep a close eye on things.

HP: What is the status of your health now?

JS: The surgery went very well. Dr. Whelan removed the tumor. My CAT scan this summer will be able to provide more information. As for the trial, since it was a blind study to me, there is not much I can definitively say. However, I personally believe I got the drug since my post-surgery skin test immune response was so large. I do know it boosted my confidence because I thought my immune system was being boosted. And that helped me maintain a positive attitude throughout the process.

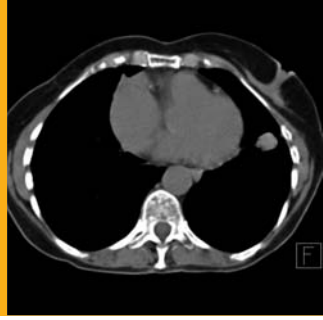
HP: Was the clinical trial a unique experience for you in any way?

JS: It was unique in that it kind of gave me a special status. I feel the trial fostered a stronger doctor-patient relationship in some way. Also, I think the trial shifted the focus from the cancer to something positive—my immune system being boosted. It served as a positive distraction for me, and as an added hope in some form.

HP: What advice would you give to someone who is considering participating in a clinical trial?

JS: I would say really learn what the trial is about first, and ask all the questions you have so that you are more comfortable with your decision. There is a great chance that it might be beneficial to yourself and others—and that makes it well worth investigating and participating in.

PET/CT
Fusing Views for More Targeted Medicine

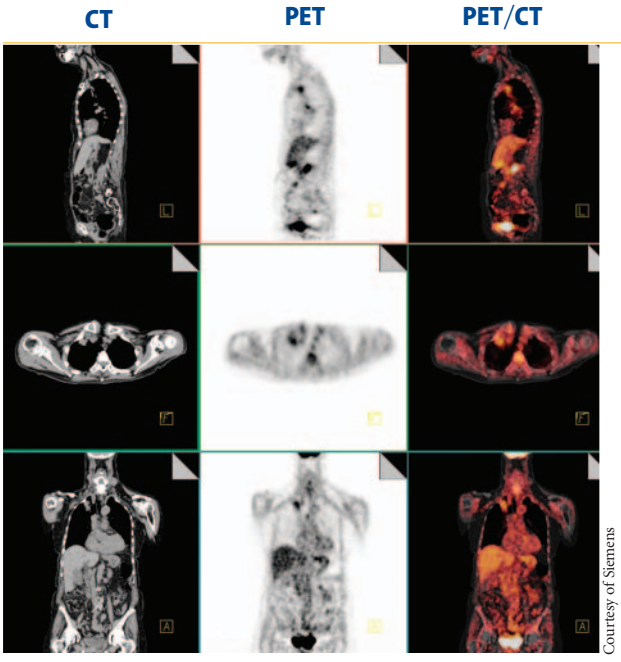


From the invention of the X-ray in 1895 to the plethora of medical imaging technologies available today, many of the advances of modern medicine stem from our ability to see inside the human body. A dual-purpose imaging device, PET/CT provides the next leap forward in medical imaging by offering researchers and physicians alike the ability to view the body in two different ways at once.

PET/CT is literally the combination of PET (positron emission tomography) and CT (computed tomography) imaging techniques within a single scanner. The individual scans, which are taken virtually simultaneously, can be presented separately or as a single, overlapping, or "fused" image. The two techniques present different types of information about the human body: *PET shows metabolic or chemical activity in the body; CT shows the body's anatomical structures.* For example, a PET scan would highlight a tumor's increased glucose consumption, while a CT scan would reveal its physical mass.

PET/CT & Research

Richard M. Gewanter, MD, *Clinical Instructor of Radiation Oncology* at Columbia University College of Physicians & Surgeons, is conducting a clinical trial to investigate the benefits of PET/CT for targeted, dose-escalated radiation therapy in individuals with unresectable (inoperable), non-small cell lung cancer that has not spread beyond the lungs. Currently, such patients typically receive radiotherapy, chemotherapy, or a combination of both approaches. Those with locally advanced disease have a five-year survival rate of 10-20%. Using PET/CT to visualize tumors, Dr. Gewanter hopes to better tailor the radiation field while increasing the dosage level within that field—thereby improving survival rates.



Courtesy of Siemens

"PET/CT should be the baseline of diagnostic care for many oncology patients since it has the potential to substantially impact treatment plans."

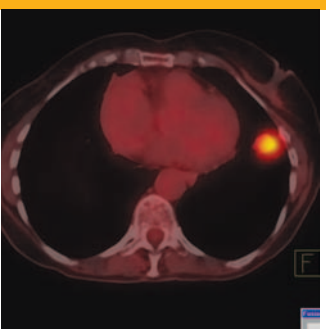
"The success of radiation therapy relies on knowing exactly where the tumor is in 3D space within the body and its relationship to the surrounding structures of the body," explains Dr. Gewanter. "Traditionally, treatment planning for these patients has been based on CT alone. In many cases, CT is limited in its ability to tell us the exact dimensions of the tumor and which parts of an abnormality are biologically active. PET, on the other hand, has the advantage of giving us the information we need about biological activity, but it lacks the necessary image resolution and spatial information. Combining the best of both modalities into one image should optimize our ability to deliver treatments."

Individuals who enroll in Dr. Gewanter's clinical trial will receive an initial, or baseline, PET/CT scan and a follow-up scan partway through treatment. Physicians will use the follow-up scan to monitor the patient's response to the radiation therapy and to determine whether to adjust the radiation field or boost the dosage within that field. The goal is to increase the effectiveness of the therapy on the tumor site, while reducing the damage to surrounding healthy tissue. Dr. Gewanter plans to enroll around 10 participants in the pilot study and will expand the study population if initial results prove favorable. Eligibility requirements include:

- Non small-cell carcinoma of the lung, unresectable & locally advanced
- Good performance status for tolerating aggressive radiation therapy, including adequate pulmonary function
- No prior radiation therapy and a limit of one previous cycle of chemotherapy

The CT image *(left)* shows a mass in the right lung. The combined PET/CT image *(below)* reveals the metabolic activity of that mass, as well as its precise location in the lung. The fused image can help physicians with diagnosing and staging the disease, as well as tailoring the treatment plan.

Courtesy of Siemens



"With respect to clinical cancer imaging research, PET/CT is the state of the art," says **Philip O. Alderson, MD**, *James Picker Professor of Radiology* and *Chairman* of the Department of Radiology. "It is the modality being used on virtually all the NIH/NCI (National Institutes of Health/National Cancer Institute) imaging protocols across the country to evaluate cancer staging and restaging."

PET/CT & Clinical Care

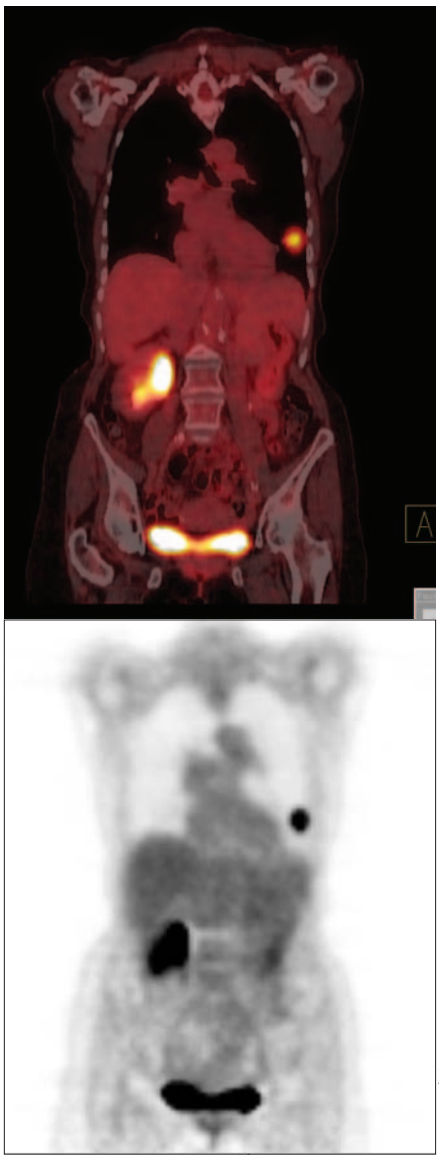
In addition to its research applications, PET/CT can improve clinical care. Taking the two scans virtually simultaneously ensures that the patient remains in place and, therefore, that the two images form a precise computer overlay—that the tumor "hot spot" on the PET scan corresponds directly to the physical mass on the CT scan. It also eliminates the common problem of a delay between the two studies, during which time the patient's condition may change. A study from Germany, presented at the 2003 meeting of the Radiological Society of North America (RSNA), reported that PET/CT fusion images made a critical diagnostic difference in approximately 20% of cases. In the study, radiologists reviewed the same cases—first using a traditional side-by-side visual comparison of PET and CT images, and then with the additional option of a fused, PET/CT image.

According to **Ronald L. Van Heertum, MD**, *Professor of Radiology* and *Director*, Columbia Kreitchman PET Center, "PET/CT should be the baseline of diagnostic care for many oncology patients since it has the potential to substantially impact treatment plans. PET/CT is estimated to change up to 45% of treatment plans for radiation oncology, by either increasing or decreasing the suggested radiation field. That has enormous significance because the better you can target the field, the better you can reach all the cancer cells while avoiding damage to the surrounding healthy tissue. It plays a similar role for surgeons by helping to pinpoint exactly where to perform a biopsy or surgical excision."

PET/CT fusion imaging is most valuable for cancers located in regions of the body that have a complicated anatomy, such as the neck and lower pelvis. These areas of the body contain organs, tissue, muscles, bones, lymph nodes, air, fluids, etc., all in close proximity—making the precise overlay of PET and CT particularly helpful. Similarly, PET/CT can aid in multifocal diseases, such as lymphoma, by providing more exact locations for biopsies and surgery.

PET/CT may herald a new direction for diagnostic imaging. "Currently, the concept of PET/CT is unique because it's the first type of commercially available dual scanner," says Dr. Alderson. "In fact, I think that PET/CT is just the first of a number of dual image scanners to come. In the future, MRI probably will be combined with PET and also with new technologies such as optical imaging—enabling even greater advances in research and clinical care."

For more information about the PET/CT non-small cell lung cancer trial (IRB# AAAA1625), please contact Dr. Gewanter at 212-305-5841.



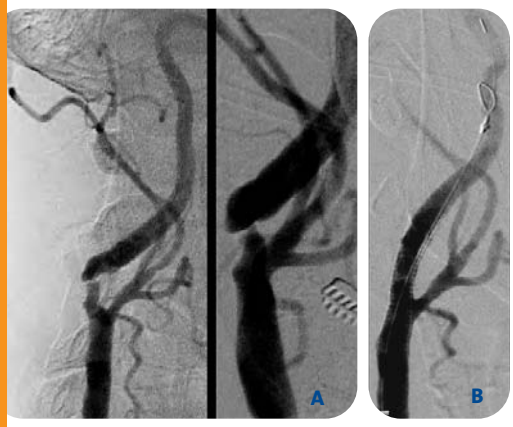
Courtesy of Siemens

The PET image *(above)* shows increased metabolic activity in the body through darkened "hot" spots. When PET is combined with CT, *(above top)*, that metabolic activity is placed in the context of the anatomy. The hot areas at the bottom of the image correspond with the natural physiologic activity of the bladder and the right kidney, while a suspicious mass is revealed in the patient's left lung.

A Minimally Invasive Alternative for Stroke Prevention:

Carotid Artery Angioplasty and Stenting

Stroke is the third leading cause of death in the United States. Strokes are commonly caused by narrowing and blockages in the carotid arteries, the blood vessels in the neck which supply blood to the brain. Fat and cholesterol build-up blocks the arteries as a result of atherosclerosis (hardening of the arteries). Individuals with severe blockages may experience symptoms, such as blurred vision, slurred speech, or weakness—all signs of stroke. Removing the fat and cholesterol build-up inside the arteries helps to restore adequate blood flow to the brain and prevent strokes. Until recently, a surgical procedure called carotid endarterectomy was the only form of care for patients. Today, physician-scientists in the Vascular Surgery Division at NewYork-Presbyterian Hospital are expanding the possibilities—by investigating a minimally invasive alternative.



A. Narrowing is present in the carotid artery as demonstrated by angiography. B. After successful angioplasty, the narrowing has been completely resolved and the potential for stroke has been reduced.

Peter L. Faries, MD, *Adjunct Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons, *Assistant Professor of Surgery* at Weill Cornell Medical College and *Chief of Endovascular Surgery* at NewYork-Presbyterian Hospital is the study's principal investigator. "We are participating in a multi-center clinical trial looking at carotid artery angioplasty and stenting, which is the newest form of treatment to prevent stroke. The treatment can essentially be done through a needle-stick, rather than an operation. Our goal is to compare the outcomes of the new procedure with the previously established surgical approach," says Dr. Faries.

"The first step is to open the blockage with the angioplasty. In an angioplasty, a thin, balloon-tipped tube is threaded through the blood vessels to the blockage, where the balloon is inflated, expanding the vessel. The second step is to place a

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For more information about the Carotid Artery Angioplasty and Stenting clinical trial (IRB # 0902-489) or the Thoracic Aortic Stent-graft clinical trial (IRB # 0104-088), please contact either Dr. Faries at 212-746-3492 or Dr. McKinsey at 212-342-3255. For more information on the Division of Vascular Surgery, please visit www.nypvascularcare.com

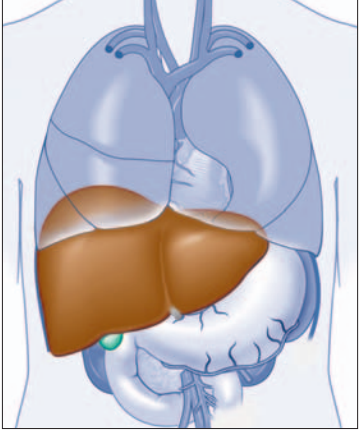
Thoracic Aortic Stent-graft Takes on a Silent Killer

Each year, more than 20,000 Americans are diagnosed with thoracic aortic aneurysms. These aneurysms occur when a section of the aorta running through the chest weakens and bulges outward like a balloon. The aorta is the body's main circulatory vessel. If an aortic aneurysm expands to the point where it ruptures, the resulting internal bleeding is life threatening. Thoracic aortic aneurysms are known as a silent killer since patients typically have no symptoms until the aneurysm begins to leak or expand. Most commonly caused by atherosclerosis (hardening of the arteries), these aneurysms can be detected through a chest X-ray or a chest CT scan.

James F. McKinsey, MD, *Interim Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Site Chief* of the Division of Vascular Surgery at NewYork-Presbyterian Hospital/Columbia University Medical Center is the principal investigator of a clinical trial focused on a less invasive treatment for patients with thoracic aortic aneurysms. "In the Thoracic Aortic Stent-graft trial we are testing a new, minimally invasive way of repairing these aneurysms without the need for major surgery," says Dr. McKinsey. "In this new endovascular approach, we make small incisions in the groin while the patient is under a local anesthetic. Using those incisions, we guide a catheter through the patient's arteries into position at the aneurysm site. We then secure a two-piece, self-expanding stent-graft inside the weakened section of the thoracic aorta. The stent-graft relieves the pressure on the aneurysm, reducing the risk of rupture," adds **Peter L. Faries, MD,** *Adjunct Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons, *Assistant Professor of Surgery* at Weill Cornell Medical College and *Chief of Endovascular Surgery* at NewYork-Presbyterian Hospital.

Eligibility criteria for the trial include:

- A history of other medical problems, such as heart disease or lung disease
- Adequate fixation sites above and below the aneurysm in the aorta
- Aneurysms greater than 5 cm, penetrating ulcers, or aortic dissections



Nancy Heim

Viramidine for Hepatitis C

A New Therapy Enters the Mix

An estimated four million Americans are currently infected with Hepatitis C, a viral disease that forces the liver to swell and prevents it from functioning properly. Hepatitis C-related liver disease is the most common reason for liver transplantation in adults. A multifunctional organ, the liver fights infections and stops bleeding, it removes drugs and other poisons from the bloodstream, and it stores energy for when you need it. Hepatitis C is caused by the Hepatitis C virus (HCV) and is spread by contact with infected blood—typically through sexual transmission or unsafe injection practices.

The Hepatitis C virus mutates frequently, hindering the search for a vaccine to combat the disease. However, Hepatitis C's slowly progressive infection means that infected patients can experience long life expectancies and, with proper treatment, many of them can recover completely. **Robert S. Brown Jr., MD, MPH,** *Associate Professor of Clinical Medicine and Pediatrics* at Columbia University College of Physicians & Surgeons and *Medical Director* of the Center for Liver Disease and Transplantation at NewYork-Presbyterian Hospital, is fighting to give more Hepatitis C patients a complete recovery through a new clinical trial called Viser 1.

The Viser 1 trial is a phase III randomized, double-blind, multi-center study comparing the standard treatment for chronic Hepatitis C to a new therapy. Currently, chronic Hepatitis C is treated with a drug called Peginterferon, usually in combination with the drug Ribavirin. Ribavirin is an oral antiviral agent that has activity against a broad range of viruses. By itself, Ribavirin has little effect on HCV, but adding it to interferon increases the sustained response rate.

"In the Viser 1 trial, we will be comparing the standard combination therapy (Peginterferon and Ribavirin) to a new combination therapy: Peginterferon and Viramidine. Viramidine is a new Ribavirin compound. Peginterferon and Ribavirin can offer the chance of a cure in about 50-70% of patients based on the patient's HCV genotype, or specific variation of HCV. But one of the major side effects of the current treatment with Ribavirin is anemia (a deficiency of red blood cells that can cause fatigue). Severe anemia may lead to either dose reduction of the Ribavirin, decreasing its efficacy, or early termination of therapy," explains Dr. Brown. "Viramidine differs from the old Ribavirin in that it requires an enzyme in the liver to become active. Hopefully, limiting Viramidine's exposure to the rest of the body will result in a lower occurrence of anemia."

To qualify for the Viser 1 trial, individuals must meet the following inclusion criteria:

- Chronic Hepatitis C
- No prior treatment for Hepatitis C
- Good liver function

Trial participants will receive a year of treatment and six months of follow-up care.

"Our goal with Viramidine is to provide higher cure rates and to make the treatment safer and more effective. The purpose of this phase of the trial is to test the effectiveness of the drug. Preliminary data from the preceding phase II trial indicated that Viramidine had statistically less anemia associated with it, so we feel we're moving in the right direction here—and that we may indeed have a new treatment on our hands that is better tolerated by patients," says Dr. Brown.

For more information on the Viser 1 trial (IRB # AAAA2565), please contact Dr. Brown at 212-305-0914.

Additional Clinical Trials in the Department of Surgery:

Mark A. Hardy, MD, *Auchincloss Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Director of Renal & Islet Transplantation* at NewYork-Presbyterian Hospital/Columbia University Medical Center, is the co-principal investigator of **a clinical trial testing a combination of two immunosuppressant drugs to prevent kidney transplant rejection.** For more information about the **Immunosuppression for High-Risk Patients** clinical trial (IRB# 20021200), please contact Dr. Hardy at 212-305-5502.

Kevan C. Herold, MD, *Associate Professor of Clinical Medicine* at Columbia University College of Physicians & Surgeons and *Associate Attending* at NewYork-Presbyterian Hospital/Columbia University Medical Center, is the co-principal investigator of **two clinical trials testing cellular and immune therapies against type 1 diabetes.** One of these trials—testing the experimental procedure of islet cell transplantation—is being conducted with Mark A. Hardy, MD. In January 2004, Dr. Herold and Dr. Hardy conducted the first islet cell transplant in New York State. For more information regarding either of the clinical trials dealing with type 1 diabetes (IRB#8773; IRB#9903), please contact Dr. Herold at 212-305-5836.

To read the full overviews of the above clinical trials, go to www.columbiasurgery.org and click on 'News'.

Clinical Trials

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with ensuring that all clinical trials within a given medical institution are ethical and that the rights of the participants in those trials are protected.

Clinical trials retain very specific participation guidelines. Establishing and maintaining these guidelines is a critical part of producing meaningful and reliable results. The factors that allow someone to participate in a clinical trial are called "inclusion criteria," while those that disallow someone are called "exclusion criteria." Typical criteria include age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.

The Challenges and Rewards

The importance of clinical trials to the advancement of modern medicine cannot be overstated. Clinical trials partner scientists and patients in a journey that may improve medical treatments and, in some cases, lead to spectacular medical breakthroughs. Dr. Spotnitz emphasizes that the journey is long, costly, and sophisticated, but also represents the core mission of dedicated physician-scientists.

"Clinical research differentiates us from routine practice. It allows us to offer the best-known therapies and diagnostic tests to patients and to achieve superior clinical results," says Dr. Spotnitz. "Today, our potential to help patients is limited primarily by our ability to assimilate a flood of information and imagine innovative ways to apply it. Also, research is heavily dependent on financial support from the government, industry, and philanthropy. Raising money for research is highly competitive and is one of the challenges all scientists face."

As to the rewards of medical research in general, Dr. Spotnitz is quick to answer. "There is nothing more exciting to a dedicated scientist than making a new discovery. To imagine a solution to an important problem, to actually solve the problem, and to use that solution to help patients is an almost unimaginable thrill. The best thing about research is the sense that you are doing something that is important to other human beings, and that makes the journey—and struggles along the way—certainly worth the effort.

What are the Phases of **CLINICAL TRIALS?**

Clinical trials are conducted in phases. Each phase of a trial has a different purpose and helps scientists to answer specific questions:

PHASE I TRIALS—Researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a dosage range, and identify side effects.

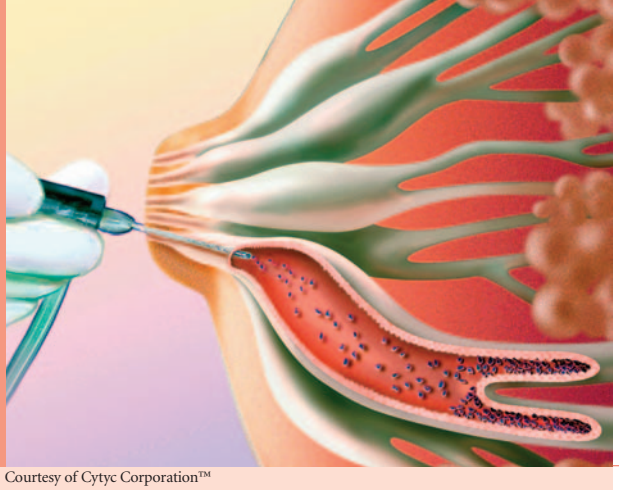
PHASE II TRIALS—The study drug or treatment is given to a larger group of people (100-300) to test its effectiveness and to further evaluate its safety.

PHASE III TRIALS—The study drug or treatment is given to large groups of people (1000-3000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

PHASE IV TRIALS—Post-marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

DUCTAL LAVAGE

Identifying a Woman at Risk



Courtesy of Cytyc Corporation™

The Ductal System of the Breast: Ductal Lavage with the FirstCyte® Breast Test is performed. A flexible microcatheter is inserted about 1 cm into the milk duct through the duct's natural opening on the nipple surface. A small amount of lidocaine is infused through the catheter to anesthetize the duct. Fluid is then slowly introduced into the milk duct to rinse the duct and collect epithelial cells.

As part of the effort to provide an accurate real-time assessment of a patient's risk of breast cancer, the Breast Surgery Section of NewYork-Presbyterian Hospital/Columbia University Medical Center is utilizing a new technique called ductal lavage. This technique is being integrated into breast centers around the country in an effort to help clinicians use new technology to help stratify a woman's breast cancer risk. Through the use of on-going clinical studies, the goal is to follow women over the course of years to identify changes in the cells lining the ducts of the breast that indicate a high risk of cancer development.

Breast cancer begins in the milk ducts of the breast. In ductal lavage, a physician flushes out the breast nipple ducts with a sterile solution in order to obtain sample cells from the milk duct lining. These cells are then examined to determine the presence or absence of abnormal cells, which are associated with an increased risk of breast cancer.

A tool to stratify a women's risk of breast cancer, ductal lavage does not detect breast cancer. "Its purpose is quantitative—to determine what is a women's risk of breast cancer. The test is almost like a pap smear of the breast in that it tells us what is the background of the breast tissue. It reveals if a patient's breast cells indicate abnormal changes," says **Beth Ann Ditkoff, MD,** *Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Director* of the Breast Clinic at Columbia University Medical Center.

There are multiple clinical studies being conducted at present, both at NewYork-Presbyterian Hospital/Columbia University Medical Center and across the country, that are directed at clarifying the ability of ductal lavage to accurately predict a woman's risk of breast cancer.

Risk-analysis for breast cancer is fluid. For example, a woman's risk of breast cancer increases as she ages, or with the new diagnosis of a family member with breast cancer. The more aware patients become of their changing risk factors, the better equipped they are to fight breast cancer.

"An abnormal finding through ductal lavage provides very useful information because it allows patients to choose among various risk-reduction strategies," says Dr. Ditkoff. "Until 1998, when the FDA approved Tamoxifen, we didn't really have anything to offer patients who were at increased risk for breast cancer. Today, we have a wide range of risk-reduction strategies to offer patients, as well as significantly improved surveillance techniques, such as mammograms, breast ultrasounds, and breast MRIs."

"On an individual level, ductal lavage already provides us with useful information with which to stratify a woman's risk of breast cancer," says **Freya R. Schnabel, MD,** *Associate Professor of Clinical Surgery* at Columbia University College of Physicians & Surgeons and *Chief* of the Breast Surgery Section at NewYork-Presbyterian Hospital/Columbia University Medical Center. "Going forward, the longitudinal studies of women undergoing this procedure will be critical to our understanding of how best to monitor high-risk women, and what effect our treatment methods have on reducing the risk of breast cancer for these women."

For more information on the ductal lavage study, please contact Dr. Schnabel at 212-305-1534.

Carotid Artery Angioplasty and Stenting

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stent to keep the ballooned area open. A stent is similar to a wired-tube that holds out the edges of the artery to prevent future blockage," explains **James F. McKinsey, MD,** *Interim Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Site Chief* of the Division of Vascular Surgery at NewYork-Presbyterian Hospital/Columbia University Medical Center. "With the angioplasty and stent procedure, patients have a quick recovery, do not undergo general anesthesia, and experience less stress to the heart. In certain patients, like those who have additional medical problems such as heart or lung disease, preliminary studies have shown that the stent procedure offers a reduced rate of stroke, heart attack, and death than the surgical procedure."

Patients with one or more of the following characteristics may qualify for the trial:

- A history of previous carotid endarterectomy on the same area
- 80 years of age or older
- A history of other medical problems, such as heart disease or lung disease

LAP BAND®

continued from page 3

controls the passage of food between the two sections of the stomach and helps patients feel full after eating.

"Our clinical trial is looking at patients who aren't heavy enough for weight loss surgery based on standard criteria, but they are suffering from medical problems and quality-of-life issues," says **Marc Bessler, MD,** *Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Surgical Director* of the Center for Obesity Surgery at Columbia University Medical Center. "Their BMI is 30-35 (60-80 lbs. overweight) with additional health problems, or their BMI is 35-40 (80-100 1bs. overweight) without health problems. Those patients would not qualify for surgical treatment of obesity, but they are defined as obese. Since LAP BAND® is fairly safe and seems to work well for the lighter end of the morbidly obese patients, I think the surgical procedure will be effective and safe enough for these individuals ."

Dr. Bessler is the principal investigator of the trial, along with **Daniel G. Davis, DO,** *Assistant Professor of Surgery* at Columbia University College of Physicians & Surgeons and *Surgical Director* of the Center for Obesity Surgery at Lawrence Hospital.

Eligibility criteria for the trial include:

- Males and females 18-65 years of age
- BMI of 30-35 (60-80 lbs. overweight) with a medical condition caused by weight
- BMI of 35-40 (80-100 1bs. overweight) without health problems
- A reported history of at least three years of obesity (BMI>30) with unsuccessful efforts at more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification

In order to participate in the clinical trial, patients will have to pay roughly $12-15,000 to cover the discounted costs of surgery, hospital fees, etc. The procedure is not covered by insurance. Patients will be monitored for a two-year period after surgery to evaluate the procedure's long-term effectiveness.

"The end goal is to expand this beyond a trial, and to get insurance companies to recognize that LAP BAND® is a safe and effective therapy for this lighter group of patients," Dr. Bessler says. "There are about 25 million people in the United States who are not heavy enough for obesity surgery, but are heavy enough to be suffering from obesity—not just cosmetically, but with real medical risks. I'm optimistic that this approach will become the standard of care one day for these patients."

For more information about the LAP BAND® clinical trial (IRB# 20030549), please contact Dr. Bessler at 212-342-0085.

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Evalve for Non-Invasive Mitral Valve Repair

continued from page 4

Currently, the Evalve CVRS is the only device for valve repair in clinical trials in the United States. Columbia is proud to be one of only seven premier centers in the world—and the only center in the tri-state area—participating in clinical trials for Evalve.

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