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Angiogenesis Research At NewYork-Presbyterian Hospital

In both the laboratory and clinic, growth factors show promise in reducing the incidence of cardiovascular disease among aging and refractory patients.

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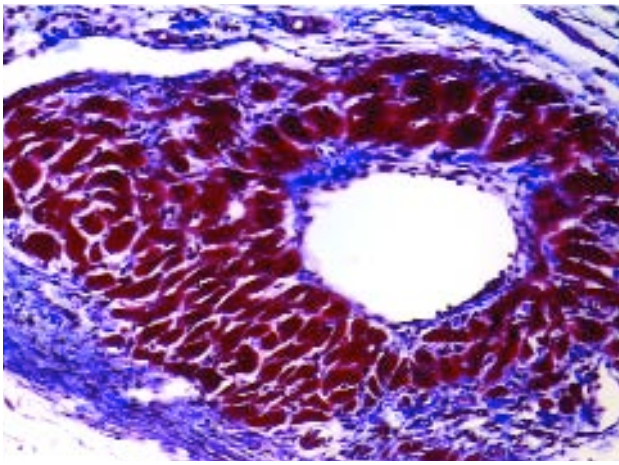
During the last decade, varied attempts have been made to induce growth of new cardiac blood vessels. Most have since fallen aside as viable prospects, due to safety concerns or from lack of efficacy. Yet for patients with severe or refractory cardiovascular disease, the hope of therapeutic angiogenesis remains a compelling goal, and perhaps their only hope. Having learned from the successes and failures of early trials, researchers at NewYork-Presbyterian Hospital are now investigating some of the most promising angiogenesis prospects today.

At NewYork-Presbyterian Hospital/Weill Cornell Medical Center, a team led by Jay M. Edelberg, MD, PhD has identified the mechanisms by which the aging heart is predisposed to more severe cardiovascular disease, and is currently studying each of the key components involved in angiogenesis. Dr. Edelberg's team has defined the role that platelet derived growth factor (PDGF), vascular endothelial growth factor (VEGF), and angiopoeitin-2 (Ang-2) play in the vascular impairment associated with aging. Now they are conducting further study on each of these mediators so that they may ultimately target therapies at restoring this endogenous pathway in the aging heart.

"We have found that PDGF stimulates the production of VEGF and Ang-2 in young hearts, but not older hearts," says Dr. Edelberg. "Now we are looking at the mechanisms by which these function, as well as ways we can exploit them for therapeutic use."

Dr. Edelberg's team also worked with others at NewYork-Presbyterian/Weill Cornell, including



Bone marrow-derived cardiac myocytes.

Shahin Rafii, MD and Takashi Mikawa, PhD, to show that PDGF is upstream of VEGF in the induction of new cardiac myocytes from bone marrow cells. Based on these findings this team hypothesized that it might be possible to increase the number of myocytes and, potentially, reduce the damage caused by acute myocardial infarction, by injecting PDGF. In a study published in 2004, Dr. Edelberg's team proved this hypothesis correct: by injecting combinations of the growth factors directly into the heart in an acute MI model, they promoted the generation of cardiac myocytes from adult bone marrow cells, reducing the damage caused by MI. Dr. Edelberg's team is continuing to investigate approaches to improve the methods for the generation of cardiac myocytes from bone marrow cells as a means of developing clinical strategies for the treatment of cardiovascular diseases.

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Jeffrey W. Moses, MD performs the majority of catheterization procedures in the VEGF-2 trial.

"We are in the beginning of a revolution in cardioprotective therapies," explains Dr. Edelberg. "It looks as though stem cells and new mechanisms of growth factors are going to play an important role in the treatment of heart disease. We look forward to the development of therapies to target the body's own stem cells to regenerate the heart muscle that is damaged by heart attacks and coronary artery disease."

Determining the best delivery method remains one of the primary challenges to the use of growth factors. Dr. Edelberg suggests that the development of smaller molecules might enable them to be targeted specifically at the heart, and delivered intravenously. After completing small animal studies this spring, the team will progress to larger animals and human trials.

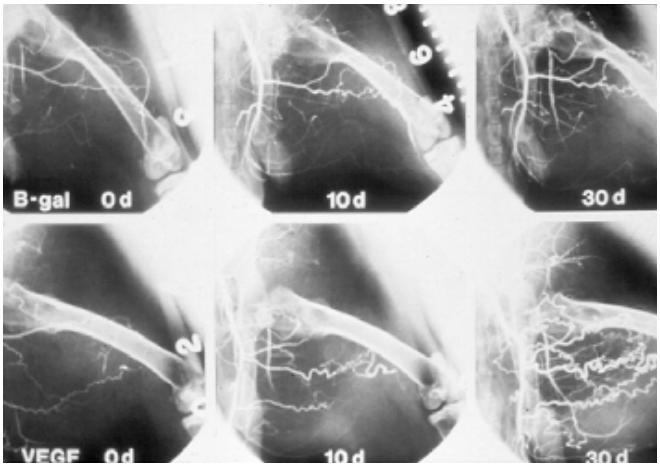
The Center for Interventional Vascular Therapy, in conjunction with the Cardiovascular Research Foundation (CRF) is conducting a clinical trial on VEGF-2 for refractory angina. In this multicenter, randomized, blinded study, Jeffrey W. Moses, MD, Giora Weisz, MD, and Martin B. Leon, MD are injecting "naked" DNA for VEGF-2 via catheter into the hearts of patients who have class III or IV exercise-induced angina, to try to stimulate growth of new blood vessels.

About 3-4% of patients entering the cardiac catheterization laboratory have refractory angina – blood vessels so diseased that they can not be helped by conventional medications, angioplasty or surgery. VEGF-2 could be the first therapy to help this "no-hope" population. "It is clear with our growing population of patients with coronary artery disease that there is a need for this type of therapy," Dr. Moses explains. The primary endpoint in this study is improved exercise ability at three months after treatment. Patients will be monitored for one year.

This will be the largest clinical trial using the catheter system to inject VEGF-2 directly into the heart. The team is using the Stiletto catheter, a small catheter that permits precise placement of the DNA and the use of standard angiography. Drs. Leon and Moses believe this approach is highly promising and very safe, based on pilot studies to date.

"This approach has survived because of efficacy demonstrated in earlier trials," says Dr. Moses. Past efforts have included other studies of drugs injected into a vein or coronary artery (instead of directly targeting the heart), delivery of growth factors with viral vectors, and injections of the protein itself rather than the DNA encoding it. Having learned from the problems associated with each of these approaches, Dr. Moses explains, "This is the second wave of research now that we understand some of the fundamentals."

"There are no approved gene therapies for cardiovascular disease," says Dr. Leon. "This could be the first." If results are positive, an FDA review of the therapy will likely follow. ■



At 30 days after treatment, the animals treated with VEGF DNA (bottom row) **show a dramatic increase in blood vessels compared to controls** (top row).

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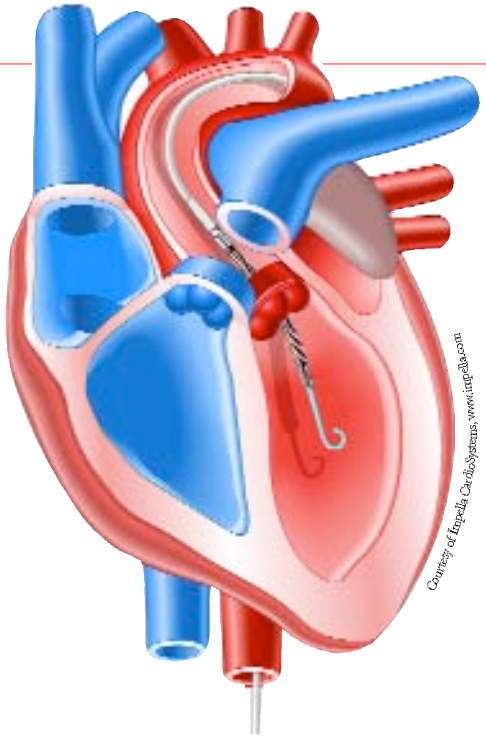
Evolving uses of ventricular assist devices

An explosion of development may reduce hospitalization among advanced heart failure patients, and achieve bridges to recovery.

Left ventricular assist devices (LVADs) have revolutionized the care of patients with end-stage heart failure who are listed for transplantation but too ill to sustain the wait for a donor organ. They have allowed patients not only to survive to transplantation, but also to recover during the waiting period so that they may undergo transplantation in better condition. In efforts to improve the prospects for patients with end-stage disease, the Heart Failure programs at NewYork-Presbyterian Hospital are now participating in a number of clinical trials evaluating new cardiac assist devices. Such efforts are leading to devices that are smaller, more durable, and less prone to complications than currently available models, and that will broaden the applications to a wider spectrum of patients.

As the largest heart transplant and mechanical assist device center in the U.S., NewYork-Presbyterian/Columbia is in the forefront of assist device research. One exciting area of activity is in the development of strategies to use LVADs as a bridge to recovery of the patient's heart and so avoid the need for transplantation.

One device under clinical investigation in the U.S. for this purpose is the Impella Recover® LP 5.0, a "mini-LVAD" or ventricular unloading catheter that can support patients temporarily during an episode of severe cardiac compromise, such as after a large acute myocardial infarction (MI). As a triage device, it rests the heart for up to five days, during which time it becomes clear whether patients may regain their natural heart function or will require a longer term, implantable device as bridge-to-transplantation.



"The Impella device is a unique temporary LVAD that does not require a major surgical operation and can support the patient until the initial insult is resolved," says Simon Maybaum, MD. "Some patients present with severe decompensation after a large MI, but their heart function may improve over the subsequent 48-72 hours. The Impella device provides a minimally invasive way to support these patients until they recover or go on to a longer term LVAD. " So far, two NewYork-Presbyterian/Columbia patients have received the Impella device. Of these, one patient was successfully bridged to an implantable LVAD and transplanted in February 2005. A second patient died. According to Dr. Maybaum, "This technology will provide treatment options for patients who are too sick for conventional LVADs."

According to Yoshifumi Naka, MD, PhD, "The Impella device will merge surgical and medical teams more tightly together, as the pump requires intense coordination between the teams for its implantation." The minimally invasive Impella device is inserted in a retrograde fashion through the femoral artery or axillary artery. Because of its relatively large width, the presence of a surgeon is required during insertion. Once placed, Impella sits across the aortic valve, where it delivers blood from the left ventricle into the ascending aorta. With the continuous-flow axial pump, the Impella device can move up to five liters of blood per minute. Open surgery is not required for placement or removal, although it may also be placed via a small chest incision if necessary. The main risks associated with the device include infection, injury to the blood vessel, and vascular complications

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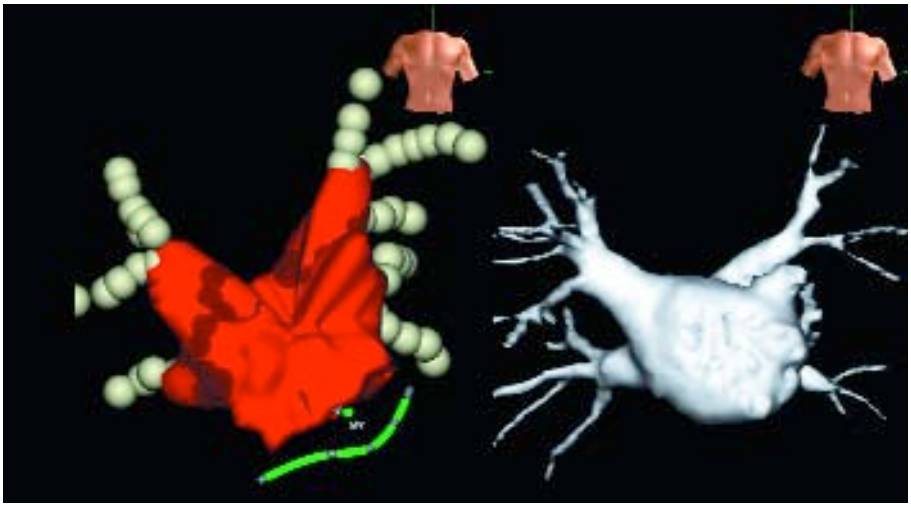
Ablation of Arrhythmias

Recent advances are broadening the application of ablation procedures to a wider spectrum of arrhythmias.

Two million people in the U.S. have arrhythmias today, most commonly atrial fibrillation (AF). Paroxysmal and persistent AF have been successfully treated through open-heart ablation procedures for the past decade. Today, due to recent advances in technique, technology and safety, the indications for catheter-based endocardial AF ablation are rapidly expanding to broader patient populations.

"Electrophysiologists at the Cardiac Electrophysiology Laboratory at NewYork-Presbyterian/Weill Cornell routinely treat patients with persistent AF through catheter ablation," according to Steven Markowitz, MD. They are able to successfully eliminate AF in 70-80% of symptomatic, drug-refractory patients without structural heart disease.

"Modifications to catheter ablation have made it a safer and more effective alternative to drug therapy," Dr. Markowitz explains. He points to knowledge gained from MAZE surgery, which was then translated into the development of the catheter-based ablation procedure. He also cites lessons learned from experience with pulmonary vein isolation in improving ablation of the pulmonary veins: they have learned that by performing wide encircling lesions around the pulmonary veins (moving from the pulmonary veins into the surrounding atrium), pulmonary vein narrowing is reduced. Also, the placement of additional linear lesions in the left atrium has improved success rates in patients with persistent AF. "By minimizing the risks associated with pulmonary vein ablation and increasing the efficacy for patients with persistent AF, we can offer this procedure to larger numbers of patients who qualify," says Dr. Markowitz.



Computerized reconstruction of the left atrium acquired at the time of ablation defines the anatomy and aids navigation within the left atrium in order to guide ablation around the pulmonary veins. This computerized image is compared to an MRI image of the left atrium in the same patient.

Cryoablation

Almost one-third of ablation procedures involve ablation near the atrioventricular (AV) node. The potential risk of causing inadvertent heart block makes safety a paramount issue when ablating in this area. During the past year, electrophysiologists at NewYork-Presbyterian/Weill Cornell have adopted the use of cryoablation as an alternative method for these ablations because it provides an inherent safety net — reversibility.

During cryoablation, the targeted area is first chilled temporarily. Only after confirming that the site is safe and accurate through EP testing is it then permanently ablated. If the temporary treatment proves problematic, the site is allowed to recover, with no harmful consequences, and the process is repeated until the correct cells are precisely identified.

Explains Kenneth Stein, MD, "Compared to radiofrequency (RF) ablation, cryoablation has a significantly lower risk of AV block." The risk of heart block is 2-5% with RF ablation near the AV node, compared to less than 1% with cryoablation (there have been no reports of inadvertent heart block with cryoablation to date). When the AV node is damaged during RF ablation, however, implantation of a pacemaker may be required. This unattractive prospect has proved a sufficient deterrent for some young, healthy patients, until recently leading some to choose medical therapy over ablation. Now, many are choosing cryoablation over lifelong drug therapy.

In addition to the benefit of reversibility, cryoablation offers improved stability over some other forms of

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ablation. "It can sometimes be difficult to keep RF catheters stable in the heart," says Dr. Stein. "When the cryoablation catheter gets cold, it freezes to the wall of the heart, affording better stability."

Although cryoablation is most useful near the AV node, according to Dr. Stein it is also proving useful in the OR for ablation of atrial fibrillation.

The only disadvantage associated with cryoablation, says Dr. Stein, is a slightly higher rate of arrhythmia recurrence after the procedure. He believes this minor risk is worth the trade-off in safety, however: "Better to do no harm," he states. Many patients agree, and are seeking treatment at NewYork-Presbyterian/Weill Cornell for that reason.

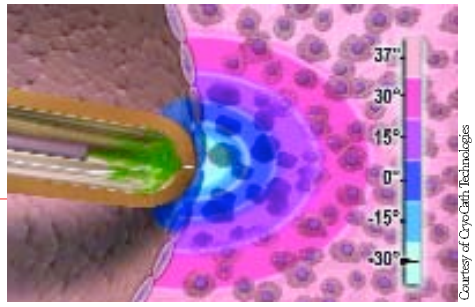
Ablation of Ventricular Tachycardia

Although most patients with ventricular arrhythmias can be effectively treated with an implantable cardioverter defibrillator (ICD), radiofrequency catheter ablation has a prominent role in treating some of these patients.

According to Suneet Mittal, MD, catheter ablation is the preferred therapy among patients with idiopathic ventricular tachycardia who do not have structural heart disease. In patients with structural heart disease, who usually undergo ICD implantation, catheter ablation may be required as adjunct therapy to prevent frequent ICD shocks.

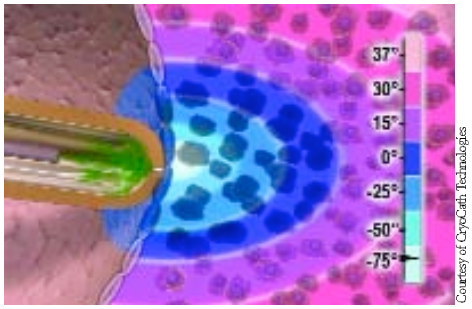
"The two most common forms of idiopathic ventricular tachycardias are both readily amenable to catheter ablation," says Dr. Mittal. "These include the adenosine sensitive form (originating from the right ventricular outflow tract) and the verapamil sensitive form (typically originating in the vicinity of the posterior fascicle within the left ventricle)."

NewYork-Presbyterian/Weill Cornell laboratories facilitate successful ablation by the use of several mapping systems that provide three-dimensional reconstruction of patients' hearts and clear identification of the tachycardia circuit. These include the



Courtesy of CryoCath Technologies

Cryomapping: temporary freezing, no permanent damage



Courtesy of CryoCath Technologies

Cryoablation: Permanent ablation of abnormal tissue

Biosense CARTO electroanatomic system and the Endocardial Solutions non-contact mapping system. "Concomitant acquisition of the electrophysiologic and anatomical data enhances identification of the most effective target for ablation," says Dr. Mittal. "Accurate navigation of the catheter also reduces injury to the structures behind the heart, particularly the esophagus," adds Dr. Markowitz.

Epicardial ablation

Although ablation has historically been performed through the endocardial aspect of the heart, electrophysiologists have recently recognized that some circuits may be located in epicardial aspects. "If the patient has atheromatous disease in the aorta (making it risky to enter the left ventricle), or has a thrombus in the left ventricle which precludes mapping in the left chamber, an endocardial approach is impossible," explains Dr. Mittal. To aid such patients, a group at NewYork-Presbyterian has begun a program for epicardial ablation.

"This involves a subxiphoid percutaneous entry into the epicardial space, which allows for mapping and ablation on the epicardial surface," says Dr. Mittal. Only recently have researchers developed this non-surgical method of accessing the epicardium. Dr. Mittal and colleagues were the first physicians in New York to perform this procedure. ■

Evolving uses of ventricular assist devices

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associated with lying flat for several days. "The potential benefit of minimally invasive implantation of assist devices is tremendous," says Dr. Naka.

During the past few years, experience with implantable LVADs has shown that although they may allow the heart muscle to heal, adequate heart function is not usually restored. To address this lapse, researchers at Columbia University are pursuing a number of innovative approaches to improve heart function during LVAD support. They will soon begin a novel study to evaluate the use of autologous stem cell transplantation to promote cardiac recovery in LVAD patients. Dr. Maybaum is Principal Investigator of a study using clenbuterol, a drug that is known to improve muscle strength and which has been shown in preliminary studies to boost cardiac function in LVAD patients.

The Heart Failure program at NewYork-Presbyterian/Weill Cornell, under the directorship of Maryjane A. Farr, MD, is also testing novel devices for advanced heart failure. At the forefront of cardiac resynchronization therapy, NewYork-Presbyterian/Weill Cornell is evaluating the reliability and value of the InSync Sentry™ system in caring for large numbers of patients with heart failure. This biventricular pacemaker/ defibrillator continuously measures intrathoracic impedance through its OptiVol™ component, triggering an alert to reassess the patient if increased fluid collects in the lungs. "Effective, early identification of patients with increasing volume status could potentially enable patients to begin treatment at home and avoid hospitalization," explains Dr. Farr.

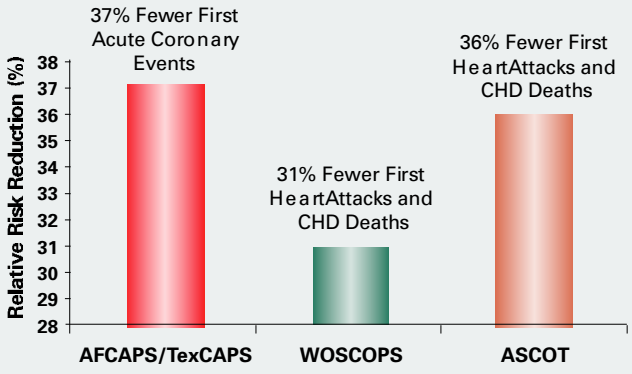
According to Dr. Farr, "We hope that the device will identify patients who are at the threshold of decompensation. The question is whether the device will duplicate what careful follow-up and physical exams do, or if it will actually identify earlier signs of decompensation." ■

Expanding the Use of Low-Dose Statins

Evidence calls for aggressive management of cholesterol to reduce coronary artery disease.

Coronary Heart Disease (CHD) remains the leading killer of both men and women in the U.S., and a high level of low-density lipoprotein cholesterol is a major modifiable risk factor for the disease. While the first line of prevention includes lifestyle changes such as diet, weight management and exercise, limitations on their effectiveness in reducing LDL may make additional therapies necessary. Statins are the most effective drugs for treating LDL, having clearly been proved to prevent atherosclerotic events in both high and intermediate risk patients.

Benefits of Statins in Patients without Heart Disease



Among patients at high risk for CHD (those with LDL above 190 mg/dl, or those with previous heart attack, other cardiovascular disease, diabetes, smoking, or multiple, poorly controlled risk factors), aggressive modification of risk factors under physician supervision is the clear standard of care. Whereas reducing LDL levels to less than 100 mg/dl had until recently been considered an optimal goal among high-risk patients, revisions to the Adult Treatment Panel (ATP) III guidelines in 2004 now allow for optional treatment to levels below 70 mg/dl in the highest-risk members of this population.

In intermediate and lower-risk patients (that is, those with no history of cardiovascular disease or fewer risk factors), treatment is less stringent. Guidelines defined intermediate risk as LDL levels between 130 and 160 mg/dl, with no history of heart attack or diabetes, but with two or more other risk factors for CHD. The goal is to treat these patients to an LDL less than 130 mg/dl. Based on compelling trial data, however, the 2004 modifications have suggested for some patients on the borderline between intermediate and high risk an optional target LDL level of less than 100 mg/dl — a level held by only about a quarter of U.S. adults today.

Thirteen million adult Americans take statins today. Yet according to Antonio M. Gotto, MD, DPhil, "The ATP III guidelines indicate that another twenty million may benefit from treatment – up to thirty-six million people in total. So far, optimal treatment is lagging far behind these new guidelines."

The evidence for primary prevention with a statin includes three large-scale, randomized, placebo-controlled clinical studies:

➤ **AFCAPS/ TEXCAPS (Air Force/Texas Coronary Atherosclerosis Prevention Study)** In this study, over 6000 healthy men and women (with average LDL, below average HDL, and no evidence of coronary heart disease) received lovastatin for five years. Lovastatin therapy reduced subjects' LDL levels from an average of 150 to 115 mg/dl. Although only 17% of this population would have been eligible for therapy according to the guidelines in place at the time, the use of the statin decreased the group's risk for a first atherosclerotic event by 37%.

➤ **WOSCOPS (West of Scotland Coronary Prevention Study)** This study evaluated treatment with 40 mg/day pravastatin among men whose total cholesterol was ≥252 mg/dl. On average, LDL levels dropped from 192 to 159 mg/dl over five years. Compared with placebo, pravastatin therapy reduced the incidence of nonfatal heart attack and death due to CHD by 31%.

➤ **ASCOT (Anglo-Scandinavian Cardiac Outcomes Trial)** Over 10,000 high-risk patients (individuals with hypertension, total cholesterol ≤250 mg/dl, and no prior MI, angina or cerebrovascular disease) received 10 mg/day of atorvastatin or placebo. The statin-treated group saw their LDL drop from an average of 133 to 90 mg/dl, and they experienced a 36% decrease in risk for heart attack and death, 27% decrease in risk for stroke, and 21% decrease in risk for total cardiovascular events. These compelling results prompted termination of the study two years earlier than planned.

In these studies, the rate of adverse events did not significantly differ among treatment groups. According to Dr. Gotto, currently approved statins have an excellent safety profile, with a risk for myopathy between one and five per 1000. Although the benefits of statins outweigh the risks for myopathy and hepatoxicity in most patients, those with liver disease, renal failure due to diabetes, frail elderly patients, and others

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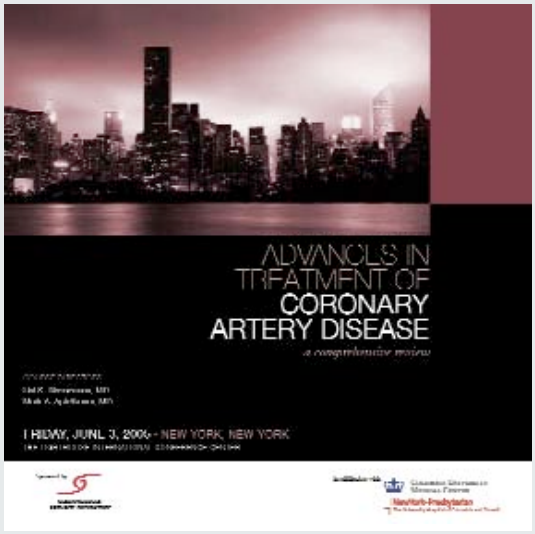
at high risk for these adverse effects must be carefully monitored or may be ineligible for statin therapy.

Based on the available research, the case for using low-dose statins in patients was strong enough that the first over-the-counter (OTC) statin, 10 mg simvastatin, was approved in Great Britain in 2004. A recent panel of the Food and Drug Administration considered the issue for the U.S. while asking the following questions: Who would benefit most, and who should be eligible for OTC statins? How effectively will the benefits outweigh the risks, especially in light of self-management? Although early data from the Consumer Use Study of OTC Mevacor (CUSTOM) suggest that patient self-management would be successful, the panel was not convinced and voted against approving OTC statins at the present time.

Overall, however, Dr. Gotto believes that increasing the use of statins among both intermediate and high-risk patients would significantly reduce CHD in the U.S., and would likely impact the morbidity, mortality, and economic burden associated with the disease. "Low-dose OTC statins may be most useful for middle-aged individuals with two or more risk factors for CHD and an intermediate risk for developing the disease during the next ten years," explains Dr. Gotto. "OTC statins would provide an important therapeutic alternative for these patients." He notes that even among high-risk patients under physicians' care, however, statin therapy is often underused and inconsistent with guidelines. "CHD is such a pervasive and deadly problem for the entire world that a vigorous exploration of all the possibilities for preventing its spread is not only timely, but also crucial." ■

ADVANCES IN THE TREATMENT OF CORONARY ARTERY DISEASE:

A Comprehensive Review



Approximately 14 million Americans have coronary artery disease (CAD). Because cardiovascular disease remains one of the leading causes of death in the United States, physicians must remain current in the optimal diagnosis and treatment of CAD and its varied natural history. This program will provide:

1. a review of state-of-the-art interventional and surgical therapeutic options
2. the latest information about imaging modalities for CAD
3. an update on heart disease in women
4. advances in the therapy for acute coronary syndromes and myocardial infarction
5. advances in pharmaco-therapeutics and lipid management
6. treatment options for patients with CAD and diabetes

Date: Friday, June 3, 2005, 7:00 am – 5:30 pm
Location: The Lighthouse, 111 East 59th Street, New York, New York
Course Directors: Mark A. Apfelbaum, MD and Hal S. Wasserman, MD

This course is designed for clinical cardiologists, interventional cardiologists, internists and emergency medicine physicians with a special interest in diagnosing and treating patients with cardiovascular disease. Nurses, physician assistants, technologists and fellows who specialize in cardiovascular care are welcome to attend.

This CME course is sponsored by the Cardiovascular Research Foundation (CRF), in affiliation with NewYork-Presbyterian Hospital/Columbia University Medical Center and Columbia University College of Physicians and Surgeons.

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Faculty Highlights

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In less than a decade, the innovative work of Dr. Edelberg has already contributed greatly to our understanding of angiogenesis in the aging heart. Among his most important achievements are the identification of changes in growth factor pathways in aging cardiac vasculature, and the discovery of ways in which bone marrow gives rise to myocytes.

Dr. Edelberg received his medical and doctorate degrees from Duke University. In recognition of the profound implications his work has for prevention and treatment of cardiovascular disease, he was awarded the prestigious Paul Beeson Faculty Scholarship in Aging in 2001.

Recent publications include: "Platelet-Derived Growth Factor-AB Promotes the Generation of Adult Bone Marrow-Derived Cardiac Myocytes." *Circulation Research* March 2004;94e39-e45 and "Senescent Impairment in Synergistic Cytokine pathways That Provide Rapid Cardioprotection in the Rat Heart." *Journal of Experimental Medicine* March 2004; 199: 797– 804.

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Martin B. Leon, MD completed his internal medicine and cardiology training at Yale Medical School and spent nine years at the NIH, culminating as Director of the Catheterization Laboratories. When he founded the Cardiovascular Research Foundation in 1990, interventional cardiology was a burgeoning specialty. Since then, Dr. Leon has dedicated his career to non-profit excellence in cardiovascular research and education. In his work as a clinical interventionalist and as chairman of CRF, Dr. Leon has performed over 7000 interventional procedures and has authored over 1100 publications. His work has impacted all forms of experimental angioplasty including stents, lasers, atherectomy devices, intravascular ultrasound imaging, and he continues to pioneer the development of transcatheter valve therapies, angiogenesis therapies, and strategies for the prevention and treatment of acute MI. In collaboration with Gregg Stone, MD, Dr. Leon is coauthor of *Textbook of Coronary Stenting,* to be published in the fall of 2005.

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