“Rather than doing things retroactively after a catastrophic event has occurred, the surgeon can see the images in advance and know what they need to do – planning or altering their surgical methods to avoid a problem.”

Milind Y. Desai, MD
Dear Colleagues,

As chairman of the Department of Thoracic and Cardiovascular Surgery from 1989 to 2004, Delos M. Cosgrove, MD, was responsible for some major innovations. Among them was his decision to gather the department’s data on volumes, outcomes and procedures and publish them for the whole world to see. No one had ever done this at Cleveland Clinic, or at any other center, as far as we know. This annual outcomes report allowed referring physicians to see and assess the department’s capabilities, and facilitated quality improvement in the areas measured.

When Dr. Cosgrove was appointed CEO and president of Cleveland Clinic in 2004, among his first acts was to ask all clinical departments to gather and publish their own outcomes data. Ever since, Cleveland Clinic has published a full library of outcomes reports every year, in print and online (www.clevelandclinic.org/quality).

This year, for the first time, Cleveland Clinic Heart & Vascular Institute is combining outcomes from Thoracic and Cardiovascular Surgery, Vascular Surgery and Cardiovascular Medicine in a single report. This report includes data on volumes, outcomes, case mix, demographic mix, comparative procedures, publications, clinical trials and innovation for the full range of cardiovascular care at Cleveland Clinic. It is a must read for anyone in a cardiovascular specialty.

The 2007 Heart & Vascular Institute outcomes report is released as a service to colleagues, referring physicians, patients and the community. We believe that with comparative information, physicians can make the best recommendations for the patients, and patients can empower themselves to make the best decisions for their care.

Please go to www.clevelandclinic.org/heart to see the 2007 Heart & Vascular Institute outcomes report, and download the PDF. We believe that you will find much there that will interest you.

Sincerely,

Christopher Bajzer, MD  
Associate Director, Peripheral Intervention  
Interventional Cardiology

Sean Lyden, MD  
Staff Surgeon,  
Vascular Surgery

A. Marc Gillinov, MD  
The Judith Dion Pyle Chair in Heart Valve Research  
Thoracic and Cardiovascular Surgery

Cardiac Consult offers updates on state-of-the-art diagnostic and management techniques from Cleveland Clinic heart and vascular specialists. Please direct correspondence to:

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clevelandclinic.org/heart offers information on new procedures and services, clinical trials, and upcoming CME symposia, as well as recent issues of Cardiac Consult.

The Cleveland Clinic Heart and Vascular Institute, ranked No. 1 in the nation for cardiac care by U.S.News & World Report every year since 1995, accommodates more than 234,000 patient visits each year in world-class facilities. Staff are committed to researching and applying state-of-the-art diagnostic and management techniques. Cleveland Clinic is a not-for-profit, multispecialty academic medical center.

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Heart Surgery Patients Transfused With Older Blood Face Significantly Greater Risks, Study Finds

The risk of postoperative death increases when patients receive blood stored more than 14 days, according to a Cleveland Clinic study published recently in the New England Journal of Medicine.

The study reports that heart surgery patients who receive transfusions with blood that has been stored more than 14 days are more likely to suffer complications and may face reduced short- and long-term survival.

“As many as half of all heart surgery patients receive blood transfusions,” explains the study’s lead author Colleen Gorman Koch, MD, MS, Vice Chair of Research and Education in Cleveland Clinic’s Department of Cardiothoracic Anesthesiology.

“How frequently transfusions take place and at what point varies among physicians. This study reiterates the need for patients to understand their surgeon’s philosophy on giving blood transfusions,” she adds.

CURRENT BLOOD STORAGE STATISTICS
More than 14 million units of blood are transfused in the United States annually and the median duration of blood storage is 15 days. Regulations set forth by the U.S. Food and Drug Administration allow for blood to be stored up to 42 days before it must be discarded.

Prior research has shown that the risk of complications, even death, in heart surgery patients increases with blood transfusions.

In their work, Cleveland Clinic researchers examined the data on 6,002 patients who received blood transfusions while undergoing bypass grafting and/or heart-valve surgery between June 30, 1998 and January 30, 2006. Of the patients, 2,872 received 8,802 units of blood that had been stored 14 days or less, whereas 3,130 patients received 10,782 units of blood that had been stored for more than 14 days.

STUDY RESULTS
The study’s results show that patients who received older blood experienced higher rates of the following:

- in-hospital death (2.8% vs. 1.7%, P=0.004)
- prolonged intubation (9.7% vs. 5.6%, P=0.001)
- kidney failure (2.7% vs. 1.6%, P=0.003)
- sepsis (4.0% vs. 2.8%, P=0.01)

Likewise, multiple complications were more common in patients transfused with older blood (25.9% vs. 22.4%, P=0.001). At one year, death was significantly less in patients given newer blood (7.4% vs. 11%, P<0.001), study results show.

“Our findings suggest a need for more studies to examine blood inventory management practices and the structural and functional changes that take place when blood is stored for increased duration periods,” Dr. Koch says.

The study appeared in the March 20 issue of the New England Journal of Medicine.

FURTHER RESEARCH LAUNCHED
Researchers at Cleveland Clinic have launched a randomized trial to further examine the relationship between blood storage duration and transfusion. Results should be available within the next two years.
A protein carried by high-density lipoprotein (HDL) plays a significant role in the prevention of heart disease, according to Cleveland Clinic Heart and Vascular Institute and Lerner Research Institute investigators.

A team led by Stanley Hazen, MD, PhD, Co-Section Head of Preventive Cardiology and Rehabilitation at Cleveland Clinic and Faculty in Lerner Research Institute’s Department of Cell Biology, recently published work in the *Journal of the American Medical Association* showing that the protein, PON1 (paraoxonase), promotes potent anti-oxidant activity in humans and is strongly linked to protection from heart attack, stroke and death in subjects. They also determined that measurement of PON1 activity serves as an important predictor of increased risk for major adverse cardiac events (MACE), even in subjects not otherwise identified as being at risk.

“The ability to predict risk for heart attacks, stroke and death over three years in individuals without a history of heart disease who have just undergone a cardiac catheterization that showed essentially normal results is astounding.” Dr. Hazen says. “It makes low serum PON1 activity levels an incredibly powerful risk predictor for identifying individuals at risk who are not currently deemed as such with current medical screening practices.”

HDL is known to transport cholesterol from artery walls to the liver (Reverse Cholesterol Transport) from where the cholesterol can enter the intestines and ultimately be eliminated from the body. HDL also exhibits alternative athero-protective properties, such as helping to prevent inflammation and the generation of harmful oxidants that contribute to artery wall injury and the development of heart disease. Researchers have previously hypothesized that some of the beneficial functions of HDL may be mediated entirely, or in part, by proteins that are carried on HDL-like cargo, including PON1.

Until now, researchers’ understanding of the cardio-protective properties linked to PON1 has been predominantly based on animal studies. Prior research has shown that animals in which PON1 has been genetically deleted have accelerated atherosclerosis or accumulation of plaque in the arteries, whereas animals with increased levels of PON1 are protected from developing atherosclerosis.

The findings appear in a special genetics in medicine issue published by the *Journal of the American Medical Association* on March 19. In addition to Dr. Hazen, the team of Cleveland Clinic investigators was comprised of Tamali Bhattacharyya, MD, MS; Danielle M. Brennan; Marie-Luise Brennan, PhD; Stephen G. Ellis, MD; Xiaoming Fu, MS; Stephen J. Nicholls, MBBS, PhD; Mingyuan Shao, MS, David Schmitt, BA; Eric J. Topol, MD (now at Scripps Clinic in La Jolla, Calif.), and Renliang Zhang, MD, PhD. Also participating on the project were researchers from the University of California (Aldons Lusis, PhD and Xia Yang, PhD) and the University of Southern California (Hooman Allayee, PhD).

In the study, the measurement of PON1 activity in serum in patients was shown to predict increased risk for adverse cardiac conditions over a three-year period in individuals with no known coronary artery disease and who had just undergone a cardiac catheterization that showed no significant heart disease.
In April 2008, an expert panel of the American College of Cardiology (ACC) recommended that the drugs simvastatin (Vytorin®) and ezetimibe (Zetia®) should only be used in patients as a “last resort,” after all other cholesterol-lowering drugs have failed. This advice followed the release of the result of the ENHANCE multi-center clinical trial, which reported that the two drugs did not slow progression of atherosclerosis among patients with heterozygous familial hypercholesterolemia. Some physicians and patients had questions about these findings. As an expert on cardiovascular disease and past-President of the ACC, Dr. Nissen was widely quoted in the national media regarding the ENHANCE results. Dr. Nissen’s most urgent recommendation has been that patients consult their physicians before taking any action on their medications. Below, he shares some further thoughts on the ENHANCE trial and its results.

Vytorin and Zetia in the Spotlight
An interview with Steven Nissen, MD, Chairman of Cardiovascular Medicine

Dating back to its FDA approval in 2004, you have adopted a conservative stance regarding the use of Vytorin and Zetia. Why?

I was always a bit skeptical. I have not written prescriptions for Vytorin, even though the drug became a very big seller. I have prescribed Zetia in addition to a statin. My perspective is that we just didn’t have clear evidence that lowering cholesterol with products containing ezetimibe would produce comparable benefits to statins. On the other hand, clinical trials involving statin drugs have studied more than 100,000 patients. Every statin on the market has shown a reduction in the outcomes we are most concerned about: heart attack, stroke and death. The bottom line is that we don’t have any of that evidence for either Zetia or Vytorin.

Why do you think that lack of data was overlooked or disregarded?

What I think happened is that the drug was very aggressively marketed, through lots of direct-to-consumer ads. I, frankly, was not happy about it, because I thought it was driving patients toward a therapy that we didn’t have enough information about.

How did the landscape change with the results of the ENHANCE study, which was released in January 2008?

The ENHANCE study results didn’t show any evidence for a benefit from adding ezetimibe to a statin. There are several alternative explanations for that result. Regardless of the explanation of the results of ENHANCE, in my view, when you have one class of drugs for which you have proof of benefit and another class of drugs which might benefit patients, you go with the evidence. What I think we’re seeing is a torrential return to using statins.

How do you personally choose one cholesterol drug over another for your patients?

If a patient won’t tolerate one of the statin drugs, I try another. I literally try every statin drug before abandoning this approach. Some of the statins have a very low incidence of adverse effects. I have a handful of patients who just don’t tolerate high doses of statins and a few of whom don’t tolerate statins at all. If I’ve tried three, four or five statins and patients develop the same problem with all of them, even in the lowest doses, then I will use ezetimibe. Occasionally, we’ll see patients who will tolerate an entry dose of a statin, but will get muscle pains if you escalate to a higher dose. When I see that, I stay at the low dose, and then I may add ezetimibe. I’m even less likely to do that now, because we have some other add-ons, like niacin, which has the benefit of producing additional LDL reduction, but also raises HDL. I think that we are going to see increasing use of niacin.

How do you think the ENHANCE study and ACC panel recommendation should affect the way these two drugs are prescribed for patients with high cholesterol?

I continue to stand behind the same message I’ve been delivering all along, which is that we should use ezetimibe as a second-line drug. We should use it only when we’ve tried statin therapy and patients either can’t get to goal, or won’t tolerate the statins, but still have high cholesterol levels. Ultimately, these drugs (Zetia and Vytorin) may prove beneficial, but we’re not going to get an answer until 2012 at the earliest. And so if you’re a patient with heart disease or at high risk for heart disease, going with something that is evidence-based makes the most sense.

Contact Dr. Steven Nissen at nissens@ccf.org.
PERISCOPE Study Shows Pioglitazone Prevents Progression of Coronary Heart Disease

For the first time, a drug that is used to lower blood sugar in diabetes has been found to halt the progression of plaque buildup in coronary arteries, a Cleveland Clinic-led study reports.

Steven E. Nissen, MD, Chairman of Cleveland Clinic’s Department of Cardiovascular Medicine and the study’s Primary Author, shared the findings at the American College of Cardiology’s (ACC) 57th Annual Scientific Session. His research, “Pioglitazone Effect on Regression in Sonographic Coronary Obstruction Evaluation (PERISCOPE),” was simultaneously released online in the Journal of the American Medical Association.

Conducted at 97 centers in North and South America, the 18-month PERISCOPE study compared use of pioglitazone (Actos®) and glimepiride (Amaryl™) in 543 patients with Type 2 diabetes. While both drugs lowered blood sugar levels to a similar extent, patients treated with glimepiride showed progression of coronary plaques, p<0.001, whereas pioglitazone-treated patients actually showed a slight decrease in plaque.

The differences between the two approaches to diabetes management were highly significant, p =0.002. The plaque buildup was measured using intravascular ultrasound (IVUS).

Pioglitazone and glimepiride work by diametrically opposite mechanisms. Glimepiride lowers blood sugar by stimulating the body to make more insulin, whereas pioglitazone is an “insulin sensitizer” that works by increasing the body’s response to the insulin already present.

“While all diabetes drugs lower blood sugar, it has been extremely challenging to demonstrate that any specific approach to diabetes management can favorably affect heart-related outcomes,” Dr. Nissen says. “Now that we know the precise approach to lowering blood sugar does matter, we should reconsider our treatment goals for diabetes, perhaps focusing less attention on how much we lower blood sugar, and more attention on how we get there.”

The two drugs also showed major differences in effects on several biochemical measures. Pioglitazone increased HDL-C 16 percent vs. 4.1 percent, reduced triglycerides by 15.3 percent vs. an increase of 6 percent and reduced C-Reactive Protein by 44.9 percent vs. a reduction of 18 percent.

In the PERISCOPE study, both drugs were well tolerated, but exhibited a different pattern of adverse effects. Glimepiride-treated patients were more likely to experience episodes of low blood sugar or have angina, whereas, pioglitazone-treated patients were more likely to experience fractures or have edema.

“Given the recent controversy about the effects of diabetes treatments on cardiovascular disease, we urgently must close this knowledge gap,” says Dr. Nissen. “We hope the PERISCOPE trial will encourage further comparative studies examining alternative diabetes management strategies, particularly clinical outcomes trials.”
Drug Used to Reduce Abdominal Fat May Slow Heart Disease

An experimental drug used to reduce abdominal fat may also slow the accumulation of plaque in coronary arteries, according to a Cleveland Clinic-led study.

The research, “Strategy to Reduce Atherosclerosis Development Involving Administration of Rimonabant – The Intravascular Ultrasound Study (STRADIVARIUS),” was presented by lead author Steven E. Nissen, MD, Chairman of the Department of Cardiovascular Medicine at Cleveland Clinic, at the American College of Cardiology’s (ACC) 57th Annual Scientific Session and simultaneously published in the Journal of the American Medical Association.

The study comprised 839 patients with coronary blockages and severe abdominal obesity in North America, Europe and Australia. The patients weighed an average of 228 pounds and had a waist circumference exceeding 46 inches. During the study half of the patients received rimonabant, an investigational weight-loss drug approved in some European countries, but not the United States. The other half received a placebo for 18 months. At the end of the 18 months, the rimonabant-treated patients had lost approximately 9.5 pounds and reduced their waistlines by about 1.8 inches.

The STRADIVARIUS study measured the accumulation of plaque in the arteries or atherosclerosis over time using intravascular ultrasound (IVUS). For the primary measure of success, the rimonabant-treated patients showed a reduction in plaques that did not reach statistical significance, p = 0.22. However, the secondary IVUS endpoint did show a significant benefit, p = 0.03.

“Although the study did not achieve success for the primary endpoint, the reduction in plaque volume for the secondary endpoint suggests that this treatment strategy may work to limit progression of coronary disease,” Dr. Nissen says. “This should not be considered final proof of effectiveness, but these findings warrant additional studies to gather further evidence to assess whether reducing abdominal fat can slow progression of heart disease.”

In STRADIVARIUS, patients treated with rimonabant increased their levels of HDL-C by 22.4 percent, reduced triglycerides by 20.5 percent, and reduced C-Reactive Protein by 50.3 percent.

Rimonabant is the first of a new generation of weight-loss drugs that block the cannabinoid receptors in the brain. Research has previously shown that blocking the cannabinoid receptor results in reduced hunger, weight loss and favorable metabolic effects.

Rimonabant is not currently approved by the U.S. Food and Drug Administration, but has been available in Europe for more than a year. In the STRADIVARIUS study, a higher rate of psychiatric side effects was documented, occurring in 43.4 percent of rimonabant-treated patients and 28.4 percent of placebo-treated patients.

Staff News

A. Michael Lincoff, MD, an interventional cardiologist at Cleveland Clinic, has been appointed Vice Chairman for Clinical Research of the Cleveland Clinic Lerner Research Institute.

Dr. Lincoff will direct the newly-created Center for Clinical Research and be responsible for developing and coordinating administrative resources for clinical researchers throughout Cleveland Clinic. He will continue to serve as Director of the Cleveland Clinic Coordinating Center for Clinical Research (C5 Research), an academic research organization, and as Vice Chairman of Cleveland Clinic’s Department of Cardiovascular Medicine.

“Michael’s experience and insight in supervising clinical research is a perfect complement to his new role,” says Paul E. DiCorleto, PhD, Chairman of the Lerner Research Institute. “Under his direction, the Center will build on Lerner Research Institute’s success of translating the discoveries made in laboratories into new diagnostic tests and new treatments and therapies for patients.”

The Center for Clinical Research will establish a central organizational infrastructure for services required by clinical research programs. The resources to be provided will include investigator and coordinator education in research methodology, supervision of regulatory compliance, financial budgeting and tracking, assistance with grant and proposal writing, and computational and analytical services.

Carmel Celestin, MD, has joined the Section of Vascular Medicine. Dr. Celestin’s specialty interests include lower extremity edema, peripheral arterial disease and upper extremity disorders, and minority and women’s health initiatives. She received her medical degree from Howard University College of Medicine in Washington, D.C., followed by an internal medicine residency at Baystate Medical Center in Springfield, Mass., and a vascular medicine fellowship at Cleveland Clinic. Dr. Celestin is fluent in Spanish.

Marcelo Gomes, MD, has joined the Section of Vascular Medicine. His specialty interests include deep venous thrombosis, pulmonary embolism, hypercoagulable states, thrombophilia, peripheral arterial disease and anticoagulant therapy. Dr. Gomes received his medical degree from the Universidade de Estado do Rio de Janeiro, Brazil. He completed his internal medicine residency at University Hospital of the Universidade do Estado do Rio de Janeiro and Cleveland Clinic, where he then completed a fellowship in vascular medicine and was a research associate in hematology and oncology with specialized training in clinical thrombosis. Dr. Gomes is fluent in Portuguese.
One reason for these improved outcomes is likely the use of multidetector computed tomographic angiography (MDCTA), according to a Cleveland Clinic study by Apur R. Kamdar, MD, et al. published in the April 2008 issue of The Annals of Thoracic Surgery. The study, which is the first large-scale study of its kind, examined the routine use of cardiothoracic MDCTA on patients undergoing RCS.

“What we are showing essentially is that routinely doing MDCTA helps surgeons plan and visualize preemptively,” explains lead author Milind Y. Desai, MD, Cardiovascular Medicine and Diagnostic Radiology. “Rather than doing things retroactively after a catastrophic event has occurred, they can see the images and know what they need to do – planning or altering their surgical methods to avoid a problem.”

“In the past there was no documented proof on the role of CT. Now, this study demonstrates that it is very beneficial.”

Agrees co-author Joseph Sabik, MD, Chairman of Cardiovascular and Thoracic Surgery, “When we do a first time operation the heart is sitting inside the pericardium and there are no bypass grafts, so opening the breastbone is a very safe procedure. When you do a reoperation, the pericardium is open and so you don’t exactly know where the heart structures are or the bypass grafts are in relation to the sternum.

So every once in a while when we would be doing a reoperation, we would have a catastrophe on opening because we might hit a bypass graft accidentally or hit the aorta. Having this preoperative imaging with the CT that tells us exactly what the relationships are of the heart structures to the sternum as well as the location of the bypass grafts allows us to prepare better and enables us to come up with a better strategy on opening.”

**STUDY DESIGN**

The observational, retrospective, single-center study examined 167 patients with a history of prior coronary bypass graft surgery (CABG) who underwent cardiothoracic MDCTA for preoperative planning, before contemplated RCS between 2003 and 2006.

Cleveland Clinic has been using MDCTA for RCS planning since 2002. In 2007, 27 percent of all open heart surgeries at Cleveland Clinic were redo operations. In the study population, as expected, there was a high prevalence of comorbidities and the preoperative risk score (Higgins score) was high. The vast majority of patients were undergoing their second cardiac operation (first RCS, 78 percent). Three quarters of the patients were referred to Cleveland Clinic from outside a 50-mile radius referral area.

The study found a significant association between a high-risk MDCTA finding and adoption of preventative surgical strategies, including cancelling the surgery (4 percent), nonmidline incision (8 percent), deep hypothermic circulatory arrest (5 percent), initiation of peripheral cardiopulmonary bypass (11 percent), and extrathoracic vascular exposure before incision (53 percent). These strategies were used at a higher frequency in patients with the high-risk MDCTA findings vs. those without (88 percent vs. 28 percent, p < 0.0001).

"Rather than doing things retroactively after a catastrophic event has occurred, they can see the images and know what they need to do – planning or altering their surgical methods to avoid a problem."

For most patients, he says, it shows us that the surgeon can open safely. But in instances that the MDCTA shows the patient is at risk of injury – particularly in cases when there are bypass grafts, ascending aneurysms or the heart is very close to the sternum – the surgeon can adjust the surgical plan to prevent catastrophe and have a better outcome.
EVOLUTION OF A FIELD

This study, says co-author Paul Schoenhagen, MD, Diagnostic Radiology and Cardiovascular Medicine, demonstrates really how far the field of imaging has advanced in recent years. No longer are discussions focused on solely the clarity of imaging technology or comparing modalities, he says.

“Now, we’re focused on the more important aspect of imaging, which is how to use the imaging to change outcomes,” he says. Today, much more attention is paid to issues such as radiation burden and the potential for nephrotoxicity.

Another benefit of MDCTA, Dr. Desai adds, is that it has further strengthened cooperation between subspecialties including radiology, cardiology and cardiovascular surgery.

“It’s not just about the images anymore. It’s about cooperation,” he says. “So when I’m seeing something of concern, I pick up the phone and call the surgeon right then. He has the capability to pull up the images on his end. We look at them simultaneously and discuss the best possible strategy.”

Dr. Milind Desai can be reached at desaim2@ccf.org, Dr. Paul Schoenhagen at schoenp@ccf.org and Dr. Joseph Sabik at sabikj@ccf.org.

Venous thromboembolism (VTE) is a disease that is high on many organizations’ agendas for quality improvement with new Joint Commission guidelines to be implemented in 2009 to improve risk assessment, prophylaxis, diagnosis and treatment.

One important change will be the recommended use of thrombolytics to treat iliofemoral deep venous thrombosis. In prior versions, the American College of Chest Physicians guidelines recommended against the use of thrombolytics for treatment of VTE, citing the lack of data supporting its efficacy and usefulness.

The most recent review of the current literature for iliofemoral DVT showed that thrombolyis greatly helps reduce the swelling and discomfort of the affected leg and may preserve venous valve function, explains Cleveland Clinic vascular surgeon Sean Lyden, MD. More importantly, the use of thrombolytics reduces risk of developing the late complications of DVT, namely post thrombotic syndrome and venous ulceration.

VTE, which includes deep vein thrombosis and pulmonary embolism, is a common complication for inpatient populations. Hospital-acquired DVT is reported to be 10 to 20 percent among medical patients and 15 to 40 percent among surgical patients not receiving appropriate prophylaxis.

VTE Risk Assessment is Critical

“Proactive VTE risk assessment is especially important because patients with hospital-acquired DVT and pulmonary embolism often show no symptoms,” says Cleveland Clinic Section Head of Vascular Medicine John Bartholomew, MD. Because of this, Cleveland Clinic has launched a new initiative to assess all inpatients for their risk of developing DVT/PE. All hospital patients will now routinely undergo an individual thrombosis risk factor assessment, examining known risk factors such as age, type of surgery or injury, family history of thrombosis, inherited conditions that increase risk of blood clotting, obesity, pregnancy or postpartum (up to 6 weeks postpartum) or use of oral contraceptives or hormone replacement therapy.

“While the assessment is a critical tool, it is important to note that many patients with DVT have no identifiable risk factors,” Dr. Bartholomew says.

Clinical Trials Examine New Technologies

In addition to proper use of prophylaxis in all patients at risk, Cleveland Clinic continues to use new treatment options for patients who have been diagnosed with VTE. We currently use combination mechanical thrombectomy devices with pharmacological thrombolysis to speed the resolution of clot in the deep venous system. We are also investigating new mechanical devices to assist with the clearance of acute deep venous thrombosis. Studies currently underway include:

Study of the OmniWave™ Endovascular System in Subjects with Lower and Upper Extremity Deep Vein Thrombosis (SONIC I Study) – This study, led by Primary Investigator Daniel Clair, MD, is examining a percutaneous mechanical thrombectomy device developed by OmniSonics Medical Technologies, Inc. that uses transverse ultrasonic energy to treat thrombus.

Ultrasound energy may offer certain advantages, such as faster treatment times, microfragmentation of thrombus, and the ability to treat a large thrombus volume with a small wire-based device. Ultrasonic energy is bioselective for elastic fibers: following ultrasonic energy delivery, healthy tissue rich in elastin and collagen (such as vessel walls) remains intact, whereas thrombus with minimal elastin support is readily ablated. This registry study will provide information on the newly U.S. Food and Drug Administration (FDA) cleared and available percutaneous mechanical thrombectomy device, the OmniWave™ Endovascular System.

Inclusion criteria includes subjects with peripheral veins large enough to accept a 7 French catheter with lower or upper extremity acute DVT, confirmed by venographic and Duplex ultrasound imaging modalities, which has been symptomatic for a maximum of 14 days or diagnosed within the past 14 days.

Ekos Ultrasound Accelerated Thrombolysis with lytic Bolus for Resolution of Arterial and Venous Occlusions (BRAVO Study) – This study, led by Primary Investigator Vikram Kashyap, MD, will evaluate the efficacy of ultrasound accelerated thrombolysis with a thrombolytic bolus plus standard infusion of thrombolytic drug in patients with arterial and venous occlusions. This study will document time to lysis and patient outcomes. The EKOS Echolocate System employs ultrasound energy to facilitate the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. The system generates ultrasound waves in the treatment zone of the catheter through the piezoelectric conversion of radiofrequency energy. The ultrasound emanates radially from the treatment zone to improve the dispersion of infused physician-specified fluids. Patients with acute iliofemoral or femoropopliteal occlusions are eligible for this trial.

Peripheral Use of AngioJet Rheolytic Thrombectomy with Mid-Length Catheters (PEARL Registry) – Led by Primary Investigator Sean Lyden, MD, the PEARL Registry will build upon the extensive published medical literature on various peripheral applications for the AngioJet® Rheolytic™ Thrombectomy System, manufactured by Possis Medical. The registry will collect observational data about how mid-length AngioJet catheters (i.e. XPEEDIOR® and DVX® models) are used in routine clinical practice.

The PEARL Registry is not a clinical study with a pre-defined treatment protocol directing how the AngioJet System will be used and how patients will be treated. Instead each participating physician determines and implements the best treatment strategy for his/her patient based on the clinical situation and local practices.

The ATTRACT (Acute Venous Thrombosis: Thrombosis Removal with Adjunctive Catheter-Directed Thrombolysis) Trial is a National Institutes of Health (NIH)-sponsored trial led by Primary Investigator Heather Gornik, MD. The primary objective is to determine whether the initial use of adjunctive catheter-directed thrombolysis will result in a lower incidence and severity of post-thrombotic syndrome and improved health-related quality of life in patients with femoral and/or iliac DVT.

For more information about these trials, please call 216.444.4508. Contact Dr. Bartholomew at barthoj@ccf.org or Dr. Lyden at lydens@ccf.org.
The Changing Face of Thoracic & Cardiovascular Surgery

New Chairman Joseph Sabik, MD, to lead the next generation of innovations at Cleveland Clinic

Cardiac surgery has changed dramatically in the four decades since Rene Favaloro, MD, performed the first coronary artery bypass at Cleveland Clinic. In this Q&A column, our new Chairman of Thoracic and Cardiovascular Surgery discusses his vision for the department and what he thinks lies ahead in a rapidly evolving field.

Q: How have new technologies revolutionized the types of procedures being performed today and how is your department positioned to continue leadership in this field?

A: Heart surgery is clearly changing. It’s not what it used to be two decades ago when the vast majority of our cases were isolated coronary operations, with a small number of isolated valves and a few hundred “complicated procedures.” Today, that’s all changed.

Although we still do a good number of coronary operations and isolated valve operations, the greater part of what we do is care for patients who need multiple procedures: multiple valves or coronary revascularization, along with valve surgery, aortic surgery, heart transplant or lung transplant.

I see that trend continuing. We’ll be seeing more complex pathology. Our future goals address the challenge of how to continue making these procedures safer for the aging baby boomer generation.

Another opportunity for us is to make sure innovation continues to flourish. While our current interventions are a vast improvement over those available 40 years ago, they are insufficient to meet the coming need. We continue pioneering work in areas such as robotically assisted minimally invasive cardiac surgery, aortic endografting and ventricular assist devices as destination therapy for patients with end-stage heart failure. We will continue making both complicated and routine cases safer and better. In thoracic surgery, we’re pursuing less invasive ways to treat lung and esophageal cancers.

This is a wonderful team. It has a new chairman, but this is a team that has been very successful. I’m very proud to lead them. Without the people, all of this is just ideas. My colleagues are the ones who are going to bring it to life, adding to a rich history of providing the highest level of quality care, research and innovation.

Q: Is residency long enough to learn this new technology?

A: I think cardiothoracic education has to change. Typically, cardiothoracic surgeons do five to seven years of general surgery, including research time, followed by two to three years of cardiac surgery. As cardiac surgery has changed, I think that we need a different type of training. Perhaps residents should begin training in cardiothoracic surgery after only two to three years after general surgery training. Then we have them for longer periods of time, without increasing the overall length of training. Using simulation to teach more complicated techniques will help make this possible.

Q: How will Cleveland Clinic’s new institute model, which replaces traditional divisions with an organizational model based upon disease- or organ-based institutes, affect patient care?

A: Although we have functioned collaboratively with our colleagues for years, the establishment of the Heart & Vascular Institute has really enabled us to strengthen the way cardiology, thoracic and cardiovascular surgery and vascular medicine and surgery work together. This is important because as treatments become more advanced, they cross over these traditional lines.

For instance, take a patient needing revascularization. We tend to put patients into one of two categories: coronary intervention with a stent or surgery. But in the future, we may be treating more patients with both therapies at the same time in combined or “hybrid” procedures. This type of collaboration is likely to extend across the board – whether it’s with aortic surgery and endografting or valve procedures using percutaneous valves. A huge part of our future is going to be increasing the collaboration among subspecialists to provide more individualized care.

Q: How will the new Sydell and Arnold Miller Family Pavilion, which opens this fall, change the way we provide care?

A: I think it’s going to be an incredible building. I sense that people are going to walk in there and be amazed by its beauty. Everything is first rate: operating rooms with high-tech visualization, robotic rooms, endovascular rooms, cath labs, ICUs, patient floors.

Having one building dedicated to heart, vascular and thoracic services will enable us to continue to innovate, discover and most importantly, put patients first in all we do. Making the patient experience and care better – that’s our ultimate goal.

Dr. Sabik, a 12-year-veteran of Thoracic and Cardiovascular Surgery, took over his new post earlier this year when former Chairman Bruce W. Lytle, MD, was named Chairman of Cleveland Clinic’s Heart and Vascular Institute. Dr. Sabik previously served as director of the department’s residency training program. He specializes in adult cardiac surgery, valvular heart disease, coronary artery disease, diseases of the thoracic aorta, minimally invasive cardiac surgery and off-pump coronary artery bypass surgery. Contact Dr. Sabik at sabikj@ccf.org.
DrConnect

Make Your Next Report Electronic

DrConnect is an Internet-based service developed to provide our community physician colleagues real-time electronic medical record information about the treatment their patients receive at Cleveland Clinic.

After establishing a DrConnect account with a secure log-in name and password, referring physicians may identify office personnel to receive security rights, allowing DrConnect patient updates to be immediately integrated into a busy medical practice’s daily activities and workflow.

A single daily email notification containing the DrConnect Web address (URL) gives you one-click access to all newly released patient-related information, which is presented in easy-to-navigate “What’s New” screens for quick access and effective case and time management.

Establishing your own DrConnect account is as easy as 1, 2, 3.

1) Log onto drconnect.clevelandclinic.org
2) Click on the OnLine Signup button
3) Simply fill out your physician participant information, including choosing a secure password, and submit.

If you have any difficulty, contact us at drconnect@ccf.org or by calling the DrConnect Customer Support line at 216.738.5073 or 877.224.7367 (877.CCHS.EMR) Monday – Friday 8 am to 6 pm.

Referrals

To refer cardiology patients, please call 216.444.6697 or 800.553.5056.

To refer surgical patients, call 877.843.2781.

New patients, in most cases, can be seen by a cardiologist within one week of calling for an appointment. Most patients requiring surgery also can be accommodated within one week.

Special Assistance for Out-of-State Patients

The Cleveland Clinic’s Medical Concierge program is a complimentary service for patients who travel to Cleveland Clinic from outside Ohio. Our patient care representatives facilitate and coordinate the scheduling of multiple medical appointments; provide access to discounts on airline tickets and hotels, when available; make reservations for hotel or housing accommodations; and arrange leisure activities. For more information: call 800.223.2273, ext. 55580, visit clevelandclinic.org/services, or email medicalconcierge@ccf.org.