# NEWYORK-PRESBYTERIAN LECTRONIC CONTRACTOR OF THE SECTION OF THE S

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Fall 2007

## Percutaneous Valvular Repair And Replacement Cut Open Ops

ach year in the United States, approximately 100,000 open heart valve operations are performed, more than half of which involve the aortic valve, with the remainder involving the mitral valve.

More than 30 years of refinements have led to today's high success rate for surgical repair or replacement of the mitral valve, according to Richard Devereux, MD, Director of the Adult Echocardiography Laboratory, NewYork-Presbyterian/Weill Cornell Medical Center. As such, there is a high benchmark for any purported advancement in mitral valve restoration. Performance standards are also high following replacement (and sometimes repair) of the aortic valve.

Regardless of the valve involved, operative mortality risk is relatively low, at between 6.68% and 8.23% (1995-1997), according to the National Cardiac Surgery Database from the Society of Thoracic Surgeons (see Table, page 6). Nevertheless, significant numbers of patients are not eligible for corrective valve surgery, either because of advanced age or the presence of multiple comorbidities. For this group of patients—expected to expand significantly in the coming years because of the aging population—no treatment options exist and the prognosis is uniformly poor.

This unmet need has fueled a growing interest in the use of percutaneous

see Percutaneous, page 6

#### Minimally Invasive Techniques Emerge for the Heart Itself

inimally invasive surgical procedures have been evaluated in every corner of medicine because of the opportunity they provide for less trauma and faster recovery. The cardiovascular system has been no exception. Most notably, percutaneous transcatheter stent placements allow thousands of individuals each year to avoid the burdens of coronary artery bypass grafting. Now, minimally invasive techniques for the heart itself have begun to emerge.

#### Minimally Invasive Repair of Structural Defects

While exciting progress in stent development continues at NewYork-Presbyterian Hospital and elsewhere, a new frontier has been opened in valve repair, and results so far with a transcatheter approach have indeed been impressive. "The immediate application of the minimally invasive valve repair procedures is going to be in high-risk patients. This has the very real potential for being lifesaving in a group of individuals for whom open surgery would not be an option," said Jeffrey W. Moses, MD, Professor of Medicine at NewYork-Presbyterian Hospital/Columbia University Medical Center, and Director of the Center for Interventional Vascular Therapy, which is also located on the NewYork-Presbyterian/Columbia campus. "Encouraging pilot studies have already led to large randomized studies. I think the substantial activity in this area suggests



Sternotomies are avoided with new MIS procedures.

that this is going to evolve quickly, with perhaps several new devices and new approaches coming forward."

The work in minimally invasive repair of structural defects in the heart builds on the ongoing innovation in vascular stents. On the NewYork-Presbyterian/Weill Cornell Medical Center campus, Shing-Chiu Wong, MD, Director of the Cardiac Catheterization Laboratory, is now at work testing third-generation coronary stents as well as evaluating novel access closure devices, which enable early ambulation following those catheterization

see Minimally Invasive, page 2

#### Save These Dates

The 19th annual TCT is coming! See page 2 for full details.

The 5th annual "Advances in the Treatment of Coronary Artery Disease," a comprehensive review CME conference, is scheduled for May 2, 2008, at the Grand Hyatt Hotel, New York City.

## NEWYORK-PRESBYTERIAN

#### Minimally Invasive

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procedures, such as angioplasty, that involve access through the femoral artery.

Faculty at NewYork-Presbyterian/ Weill Cornell also have been active in exploring other types of minimally invasive procedures, including transcatheter mitral valve repair. Karl H. Krieger, MD, the Philip Geier Professor of Cardiothoracic Surgery and the Vice Chairman of the Department of Cardiothoracic Surgery at NewYork-Presbyterian/Weill Cornell, said these efforts are part of the focus on not just saving lives but on improving the patient's quality of life during the recovery period.

"When results of a minimally invasive surgery procedure are competitive with those that require greater trauma and longer recovery, this can be a big advantage for the patient. Minimally invasive procedures in some cases may provide an opportunity to improve outcomes. Some of these procedures are made possible by technological advances, and we have several members on the staff who have been involved in developing these strategies," Dr. Krieger said.

One such staff member is Arash Salemi, MD, Assistant Professor of Cardiothoracic Surgery at NewYork-Presbyterian/Weill Cornell. Like Dr. Moses, Dr. Salemi foresees the rapid evolution of minimally invasive techniques, particularly for valve repair.

"This is a very exciting technology. There is a very substantial number of patients who could benefit from valve replacement who are turned away because of comorbidities that make them poor surgical candidates," Dr. Salemi noted. Like Dr. Moses, Dr. Salemi stressed that valve replacement for many of these patients has the potential to not only reduce symptoms, but also to extend survival.

#### **Transcatheter Aortic Valve** Replacement

At NewYork-Presbyterian/Columbia, where most of the transcatheter valve

replacement procedures have been performed and which has become an international training site for this technology, the preclinical and clinical development has been proceeding for more than 7 years. The major advantage of a catheter-based aortic valve replacement is that it not only avoids opening the chest cavity but it also avoids cardiopulmonary bypass, which is required in an open surgical approach. Although several techniques are being considered, the current multicenter trial involves threading a catheter through the femoral artery, an approach that also has the most clinical experience. The prosthetic valve, which is crimped into a valvuloplasty balloon, is passed over a wire within the catheter into the aortic annulus. Inflation of the balloon deploys the valve into the annulus.

"The placement of the valve is carefully guided by several types of imaging, and the deployment is very much like that of an intracoronary stent," explained Dr. Moses, who said that more than 35 such procedures have now been performed on the NewYork-Presbyterian/ Columbia campus.

"The immediate application of the minimally invasive valve repair procedures is going to be in high-risk patients. This has the very real potential for being lifesaving in a group of individuals for whom open surgery would not be an option."

- Jeffrey W. Moses, MD

In pilot studies, the blood flow with transcatheter placement of the aortic valve has been even better than it has been after an open procedure, an advantage credited by Dr. Moses from the absence of stitches. Although the valve, which is currently made out of bovine pericardium, is imbedded by the balloon inflation, tissue eventually proliferates to keep it appropriately situated. The old valve is simply moved

#### 19th Annual

Transcatheter Cardiovascular Therapeutics (TCT) Scientific Symposium

#### October 20 - 25, 2007 Washington Convention Center, Washington, DC

- Widely acknowledged as the signature event in interventional cardiology and endovascular medicine, TCT is a global gathering of more than 11,000 physician-scientists, clinicians, nurses, technologists, and biomedical industry colleagues and government regulators. TCT features late-breaking trials, lectures, workshops, medical simulation, and numerous symposia.
- The centerpiece of TCT is the video transmission of 100 or more live patient procedures from medical centers around the world, accompanied by commentary from world-renowned specialists. Scientific symposia feature hundreds of faculty from more than 80 countries.
- Participants can tailor their experience by choosing from three distinct clinical tracks: coronary, peripheral, and structural heart disease.

For more information, visit www.TCT2007.com

aside by the introduction of the new valve.

This approach is gaining a number of proponents, including Dr. Salemi at NewYork-Presbyterian/Weill Cornell, who emphasized, "There is no sternotomy, no cardiopulmonary bypass, and a relatively short procedure time."

This explains why an otherwise highly demanding procedure can be performed in patients at very high risk, such as those with impaired function of vital organs, including the heart, or the elderly. In the Phase III trial now under way, the patients being recruited are either very high risk for open surgery or are otherwise inoperable. Although Dr. Salemi believes that the transcatheter approach in healthier patients is some distance away, Dr. Moses sees this future as less distant.

"First we have to demonstrate that this is viable in a large study of high-risk patients," observed Dr. Moses, who noted that Martin Leon, MD, Professor of Medicine, and Craig Smith, MD, Professor of Surgery, both at NewYork-Presbyterian/Columbia, are the principal investigators of the multicenter Phase III trial of aortic valve replacement, called PARTNER (Placement of AoRTic TraNscathetER Valves). "But if the trial is positive, I think it will lead to a lot more interest in how we might perform other

#### NewYork-Presbyterian Heart

is comprised of physicians of the Columbia University College of Physicians and Surgeons and the Weill Cornell Medical College representing medical and surgical disciplines working together with other health professionals in a collaborative process.

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#### NewYork-Presbyterian Heart

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the center of the valve to limit movement of the valve's leaflets, thereby reducing leakage. Again, a favorable pilot study has led to a multicenter trial called EVEREST (Endovascular Valve Edge-to-Edge REpair

"Minimally invasive procedures in some cases may provide an opportunity to improve outcomes."

- Karl H. Krieger, MD

repairs of the heart without opening the chest wall. If we can achieve the same results with a minimally invasive procedure, then obviously this approach will be more attractive." The PARTNER trial will include an evaluation of hard end points, including cardiovascular events and survival.

#### Transcatheter Mitral Valve Repair

At the same time, investigators at both Columbia and Weill Cornell are pursuing mitral valve repairs by the transcatheter route. In this case, the technique involves delivering a small clip that is deployed in

STudy) in which investigators on both campuses are participating.

The transcatheter procedure to place the clip in the mitral valve is performed under general anesthesia. "Many patients return home the day after the procedure," Dr. Salemi said. Again, this means no sternotomy, no cardiopulmonary bypass, and a procedure time that is a fraction of that required when mitral valve repair is performed with an open approach.

"In the high-risk patients who are being considered for these repairs, the transcatheter approach is the only viable option for controlling leaks. This can

mean an important improvement in quality of life for these individuals, who often suffer from significant symptoms," Dr. Moses observed. He said that in the controlled study, the mitral valve repair is being compared to conventional surgery in patients of average risk. If the efficacy is comparable to that observed in the pilot studies and the complication rates are low, results of the Phase III trial will mean a major step forward for a large patient population. The attendant registry of highrisk patients may open the door to a sicker population that now is limited solely to a medical alternative.

"There are thousands of patients in the United States with mitral valve prolapse who are not undergoing surgery because they are considered to be too high risk," Dr. Moses said. "This will be a very important advance if the Phase III studies confirm the preliminary experience."

Success here is likely to breed more success. According to Dr. Salemi, "the door is wide open for new techniques and different approaches for structural valve repairs in the heart." The same point was made by Dr. Moses. He counted a half dozen

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#### Minimally Invasive

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other approaches to minimally invasive mitral valve repair, most of which employ the transcatheter route, that have reached at least experimental testing. Some use mini-thoracotomies that may permit video-assisted or robotic techniques, whereas new suturing techniques through laparoscopic portals may yield another

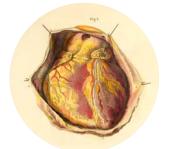
promises to make it far easier to customize the length of the stent to more precisely match the lesion of the patient. In 1 design, stents are being deployed in segments of 6-mm increments, allowing lengths of 6 mm, 12 mm, and 18 mm to be placed as needed.

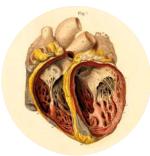
There is great interest on both the Weill Cornell and Columbia campuses in determining what causes late thrombosis. Although there has been concern that

stents, we will see even greater long-term safety than is already being achieved."

Rates of late thrombosis will be followed closely in the third-generation devices now being tested by Dr. Wong and his colleagues, and this question is also being addressed at NewYork-Presbyterian/Columbia. A recent landmark paper led by Columbia investigators, which was based on data from 9 double-blind trials, compared the 2 major types of approved drug-eluting stents to a bare metal stent for long-term efficacy and safety (N Engl J Med 2007;356:998-1008). Although it had been previously contended that drug-eluting stents









alternative. There are also conceptual approaches awaiting the instrumentation that will make them possible.

"There is a lot being achieved in terms of the technology. Developing the tools to coordinate with small incisions and better imaging will continue to advance this field," Dr. Salemi predicted.

#### Advances in Intracoronary Stenting

Although percutaneous valve replacement has attracted a lot of recent attention, there also continues to be incremental but important progress being made in intracoronary stenting. Again, significant activity is ongoing at both NewYork-Presbyterian/Columbia and Weill Cornell. Percutaneous transluminal angioplasty and stent placement are arguably the most important innovations in cardiovascular medicine over the last 50 years, but there is still room to reduce both the early and late thrombosis rates.

"We are involved in several trials evaluating new stents that contain new polymers, new drug coatings to inhibit foreign body reactions, as well as new designs," said Dr. Wong, who has published widely on this subject. One of the new designs

drug-eluting stents produce greater late thrombosis than bare metal stents, the relative increase is small, generally ranging from 0.2% to 0.5% per year. Nonetheless, substantial research is being devoted to reducing rates of late thrombosis regardless of type of stent. Investigators are looking at both stent design and better regimens of anticoagulation.

"We really do not yet understand the mechanism of very late thrombosis. This could represent a patient-specific phenomenon, such as an allergic reaction to 1 of the materials in the stent, a procedural issue in which stents have not been optimally placed, or a device issue, in which some change in the design of materials will reduce the risk," Dr. Wong said. "The hope is that as we move into newer-generation

substantially increase the risk of late thrombosis by preventing tissue regrowth, the authors found only a slight advantage for bare metal stents. Perhaps more importantly, they found no difference in myocardial infarction (MI) or death, and drug-eluting stents led to marked reductions in recurrent angina and ischemia necessitating subsequent percutaneous coronary intervention and bypass surgery procedures. Dr. Moses, who was second author on that paper, indicated that it is important to follow the objective data.

"There has been a lot of recent miscommunication about stents, particularly in the national press. We have enormous data that demonstrate unquestionable benefits for stents when used appropriately," said Dr. Moses, who has led some pivotal trials

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not only of stents but of anticoagulation regimens that have been instrumental in reducing the risk of rethrombosis.

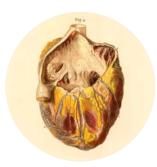
Particular controversy was generated by results of the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) study, which evaluated stents in patients with stable coronary artery disease. The authors' conclusions from COURAGE were that stents are no better than medical therapy because of a similar rate of death and MI among those who did and did not receive a stent. However, these conclusions were highly controversial because it is not clear that events should have been the basis of

faster recovery and discharge. In addition, the device permits almost pain-free recovery," said Dr. Wong, who said that the clinical study involves a comparison with manual compression.

Perhaps the most minimally invasive of all procedures now being pursued at NewYork-Presbyterian/Weill Cornell is the delivery of stem cells to the myocardium of patients with advanced angina. This approach is being tested in patients who are not candidates for bypass grafting or other types of revascularization. The experimental and early clinical data suggesting that regeneration of myocardium through stem cell

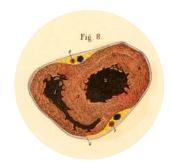
Although event-free survival remains the ultimate test of an effective procedure, these new approaches are also offering the potential for faster recovery and a better quality of life during recovery.

"The work here at Columbia is focused on better patient care as well as better outcomes. I think the work we are doing now in percutaneous valve replacement is very meaningful from that perspective, and I think it is leading us down the path toward more innovations of the same kind," Dr. Moses said.









comparison in a relatively low-risk population. Meanwhile, many reports further confused the issue by failing to specify the population was low risk. In fact, the results have no bearing on the overwhelming evidence that stents save lives in patients with a recent MI or unstable cardiovascular disease. Some of the major studies proving the value of stents involved investigators at NewYork-Presbyterian/Columbia, including Drs. Moses and Leon, and NewYork-Presbyterian/Weill Cornell.

#### More Innovation

Recently, 1 important initiative at Weill Cornell to improve the experience of percutaneous procedures has been the development of femoral artery closure devices. Dr. Wong is the national principal investigator for a study testing a new device that is placed at the femoral artery puncture site, which accelerates the time to ambulation. Made of biodegradable materials, the device stops bleeding and then remains in situ through the healing period, eventually being reabsorbed. Preliminary clinical studies have been very encouraging.

"Patients are able to walk in 1 or 2 hours instead of 4 hours, and this means

transplant is a viable strategy has led to a clinical trial. Dr. Wong has been involved in this work as well as in a study of systemic delivery of erythropoietin. This strategy, which is also being tested in a multicenter clinical study, is based on preclinical evidence that erythropoietin is effective in reducing infarct size. Both approaches are emblematic of new strategies to repair tissue by means that require minimal or no incisions.

"This is a very exciting time in cardiovascular medicine, particularly in the cath lab where we see promise for a number of new approaches," Dr. Wong said. "If we can treat disease with minimally invasive techniques, it means faster recovery, a better experience for the patient, and probably lower costs."

At NewYork-Presbyterian/Columbia, Dr. Moses agreed. His recent work in minimally invasive valve replacement has been built on his long experience in the development of percutaneous placement of stents. As a result of the potential for transcatheter and endovascular techniques that reduce the trauma associated with surgery, the goals have become richer and more complex.

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#### **Percutaneous**

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techniques to not only repair leaky mitral valves but to replace diseased or stenotic aortic valves, especially in highrisk patients. In this effort, researchers at both NewYork-Presbyterian Hospital/Columbia University Medical Center and Weill Cornell are leading the way.

#### Percutaneous Valve Repair

"My interest in developing our program in valvular heart disease here was to make us a leader in what I thought would be an important emerging therapeutic area, and it turns out that this is true, and we are now a national leader in it," said Allan Schwartz, MD, the Seymour Milstein and Harold Ames Hatch Professor of Medicine and Chief of Cardiology, NewYork-Presbyterian/ Columbia.

The most mature experience using the interventionalist approach is in the repair of mitral valve regurgitation. Dr. Devereux explained that this procedure—an adaptation of the Alfieri

mitral valve repair—"has been emulated by the development of a clip that can be passed into the heart in the catheterization lab and the mid-portion of the 2 mitral leaflets clasped so they are drawn together, thereby reducing a leak across the central portion of the mitral valve." Dr. Devereux himself provides precision

Indeed, Columbia cardiologists were among the first group to show that percutaneous placement of the Evalve® device could be done successfully with a very low complication rate. The procedure also significantly improved mitral regurgitation in the majority of registry patients in the EVEREST (Endovascular Valve Edge-to-Edge REpair STudy) clinical trial. At 3 years, treatment effects appear to be durable, with some patients requiring elective mitral valve repair later on, Dr. Schwartz said.

"My interest in developing our program in valvular heart disease here was to make us a leader in what I thought would be an important emerging therapeutic area, and it turns out that this is true, and we are now a national leader in it."

— Allan Schwartz, MD

online imaging that is required to visualize the valve during the procedure and to guide passage of the device into the optimal position.

Faculty from NewYork-Presbyterian/ Columbia invented and patented key concepts that led to the development of the technology.

Findings from the EVEREST I trial prompted initiation of EVEREST II, in which the percutaneous approach using the Evalve clip will be compared with mitral valve repair or replacement surgery in patients who meet standard echocardiographic criteria for mitral

> Dr. Shing-Chiu Wong, Director of the Cardiac Catheterization Laboratory at NewYork-Presbyterian/Weill Cornell, is the lead investigator of the Hospital's EVEREST II trial, which includes team members from both Weill Cornell as well as NewYork-Presbyterian/ Columbia.

valve repair or replacement.

"Until this technique came along, mitral valve repair required open-heart surgery," Dr. Schwartz said.

#### **Aortic Valve Procedures**

Similarly, open-heart surgery has been the only effective long-term option for the treatment of aortic valve stenosis, yet it, too, is being subjected to intense exploration by interventionalists and supporting team members. "We were the lead center in the initial Phase I trial using the percutaneous tissue valve," noted Dr. Schwartz. The Phase I PARTNER (Placement of AoRTic

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Year	Percent	N*
1990	6.08	148
1991	8.18	269
1992	9.82	397
1993	7.47	509
1994	9.88	729
1995	6.68	868
1996	8.23	996
1997	7.71	1063

<sup>\*</sup> Includes primary and reoperation

Source: www.sts.org/graphics/sts/db/us98/gchart57.gif

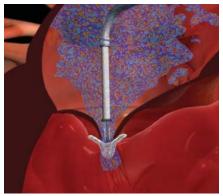


Fig. A illustrates severe mitral regurgitation in blue and the Evalve<sup>®</sup> clip (the MitraClip)<sup>®</sup> grasping the mitral valve leaflets

TraNscathetER Valves) trial, led by Jeffrey W. Moses, MD, Professor of Medicine and Director of the Center for Interventional Vascular Therapy,



Fig. B illustrates the PMR System prior to MitraClip<sup>®</sup> device deployment. Normal blood flows on both sides of the Clip.

percutaneous replacement of the aortic valve.

Results from this exploratory study were so encouraging—more than 80%

"Until this technique came along, mitral valve repair required open-heart surgery."

— Dr. Schwartz

at NewYork-Presbyterian/Columbia, was a safety and feasibility study of 55 patients who were too ill to undergo valvular replacement surgically and who were therefore selected to undergo of the valves were successfully implanted—that the Phase II PARTNER trial has now been launched to determine the safety and efficacy of using the transcatheter approach versus the surgical



Fig. D illustrates the MitraClip $^{\circledR}$  device used to treat mitral regurgitation.



Fig. C illustrates the reduction in mitral regurgitation and the MitraClip® device securely attached to both leaflets of the mitral valve.

aortic valve replacement in high-risk patients. PARTNER will also enroll patients who are too high-risk to undergo surgical aortic valve replacement and who will be assigned either to the interventionalist strategy or to receive the best medical therapy. The heart valve being delivered by catheter in PARTNER consists of a balloon-expanded stent and a bioprosthetic valve made of bovine pericardium.

"There's no cardiopulmonary bypass, no cutting of the chest," said Dr. Schwartz, although repair or replacement of either the mitral or aortic valve is still undertaken under general anesthesia to allow the use of transesophageal echocardiography, he added.

#### **Pulmonary Valve Replacement**

Another example where pioneers are pushing back the frontiers of interventional catheterization is in the use of percutaneous pulmonary valve replacement. As first explored by Dr. Philipp Bonhoeffer, of Great Ormond Street Hospital for Children NHS Trust, London, and Dr. Younes Boudjemlin, Hôpital Necker Enfants Malades, Paris, nonsurgical pulmonary valve replacement now appears feasible and may represent a new strategy for the management of pulmonary regurgitation and conduit obstructions.

Currently, William Hellenbrand, MD, Chief of Pediatric Cardiology, New York-Presbyterian/Columbia, is 1 of 3 investigators in the United States who have received FDA approval to explore the use of the Medtronic®

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#### Percutaneous

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percutaneous pulmonary valve in a feasibility study entitled "Implantation of the Medtronic Transcatheter Pulmonary have also received a previous artificial valve that has not performed well after surgery. Thus, the only option for these patients—many of whom have had multiple prior open-heart surgeries—is another open-heart procedure.

so far have been "quite good," he said. If results continue to be promising, "we can expand the trial to many more patients in the United States," Dr. Hellenbrand added.

"We can place a functioning pulmonary valve inside a previously damaged valve and push the damaged valve out of the way. It takes only 1 to 1.5 hours to do this [percutaneously], and there is no recovery period—patients are right back to normal activities."

— William Hellenbrand, MD

Valve in Patients with Dysfunctional RVOT Conduits." The study involves 3 children's hospitals in the United States, 1 of which is the Morgan Stanley Children's Hospital of NewYork-Presbyterian/Columbia.

"These are patients born with congenital heart disease in whom the pulmonary valve is dysfunctional," said Dr. Hellenbrand. Many of the same patients Using the percutaneous approach, however, "we can place a functioning pulmonary valve inside a previously damaged valve and push the damaged valve out of the way. It takes only 1 to 1.5 hours to do this, and there is no recovery period—patients are right back to normal activities," Dr. Hellenbrand said. The team has performed 10 such percutaneous replacements and results

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