

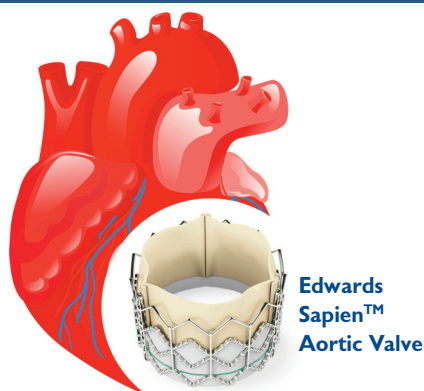
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*Craig R. Smith, MD,
Chairman, Department of
Surgery and Chief, Division
of Cardiothoracic Surgery*

Aortic Valve Surgery

Pivotal trial finds transcatheter aortic valve replacement as good as open surgery.

Approximately 300,000 patients in the United States have aortic stenosis (narrowing of the aortic heart valve), and about one third of these patients are too sick or too old to undergo surgical replacement. Under the leadership of NewYork-Presbyterian Hospital's Division of Interventional Cardiology and Cardiothoracic Surgery, a new, minimally invasive method of replacing the aortic valve is under study across the U.S. This approach, called transcatheter aortic valve implantation or transcatheter aortic valve replacement (TAVI or TAVR), has shown excit-

ing promise in the landmark PARTNER trial, which studied the safety and efficacy of the Edwards Sapien™ Aortic Valve. According to results released in the fall of 2010 and spring of 2011, transcatheter aortic valve replacement is as good as open surgery in terms of one year survival, and compared to medical management, it improves survival by 20% at one year.

During TAVR, the new aortic valve is implanted without open-heart surgery. In most patients, the new valve is inserted through the groin and advanced to the heart using a specially designed delivery catheter. The valve is positioned and implanted in the heart using x-ray for guidance. With this technique, the aortic valve can be replaced without incisions and without stopping the heart. In patients who can not have catheterization of the femoral artery due to disease in the vessels, the valve can be delivered instead through a small chest incision between the ribs. Because TAVR is done with a less invasive procedure, elderly or frail patients who could not tolerate open surgery may be able to have their aortic valves repaired this way instead.

The multicenter trial of the procedure, known as PARTNER, is one of the most important trials concerning valve disease to take place in decades. Led by Principal Investigators **Craig Smith, MD**, Chief, Division of Cardiothoracic Surgery and **Martin B. Leon, MD**, Division of Interventional Cardiology, the trial is largely conducted by faculty at the Heart Valve Center at Columbia University Medical Center, which treats patients with heart valve conditions. Investigators at NewYork-Presbyterian/Columbia include **Jeffrey Moses, MD**, **Susheel Kodali, MD**, and **Mathew Williams, MD**.

Dr. Smith presented the results of one segment of PARTNER (cohort A) to the American College of Cardiology 2011 Scientific Summit in New Orleans April 3, 2011.* This arm of the study found that when compared to open surgery, both TAVI and open surgery were equal in terms of one year survival. Patients who underwent transcatheter aortic valve replacement were at slightly higher risk of stroke and vascular complications, while those undergoing open surgery were at greater risk of major bleeding. "The study shows that the top 5% (high risk) patients with aortic stenosis should probably be treated with TAVI," says Dr. Smith.

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Advances in Breast Surgery: Preventing Lymphedema

NYP/Columbia implements novel initiative to prevent lymphedema after breast cancer surgery.

As if undergoing surgery for breast cancer were not enough to worry about, patients may also be concerned about what they may face after surgery. A common concern is the risk of developing lymphedema, or swelling of the arm and hand. Although most women do not experience this problem after breast surgery, approximately 19% of women who have lymph node dissection (as opposed to sentinel node biopsy) eventually develop some degree of lymphedema, according to **Sheldon M. Feldman, MD**, Chief, Breast Surgery Section.

If breast cancer cells are detected in the lymph nodes under the arm by sentinel node biopsy, a standard part of treatment has been to remove the majority of the lymph nodes in order to prevent recurrence of the cancer (called lymph node dissection). When that normal pathway of lymph drainage is removed, sometimes the lymph fluid is unable to find another adequate path, causing the fluid to back up in the arm.

Lymphedema can vary greatly in severity, and is classified as subclinical, mild, moderate, or severe. Most cases are subclinical, meaning that symptoms are so mild that patients are unaware it is occurring. Mild or moderate cases might involve minor swelling of the arm, hand, or even a single finger. The more severe it becomes, however, the more debilitating lymphedema can be. Swelling can become severe, patients may lose motion in the limb, and the pressure of the extra fluid can cause chronic skin damage, leading to serious infections such as lymphangitis and cellulitis.

"If treated promptly, lymphedema can be reversed and controlled," explains Dr. Feldman. "But the longer fluid stands in the arm, the more it builds up in the soft tissue within the fat, making it more impossible to remove."

Until now, monitoring and treatment of lymphedema has been done as an ancillary part of care after breast surgery. Testing usually has been performed only after visible observation of swelling — a stage too late in the process to optimally treat. Treatment, which includes compression bandaging and avoidance of any trauma or injury to the arm, is limited in effectiveness, especially in more advanced cases.

The Breast Surgery Section at NewYork-Presbyterian/Columbia has now instituted a brand-new program to prevent the development of lymphedema using a testing method called bioimpedance spectroscopy, which measures extracellular fluid in the limbs by passing low-dose electric current through the limb, to detect the way the body responds to fluid changes. The test is painless, fast (five minutes), noninvasive, and portable.

"Our model is based on preempting lymphedema from the very beginning, particularly among patients at high risk," says

Lymphedema and Lymph Node Dissection

Lymph nodes are small, round organs located throughout the body, with clusters in the armpit, groin, neck, abdomen, and chest. Lymph nodes are connected by lymphatic vessels that drain milky lymph fluid from all parts of the body.

A sentinel lymph node is the lymph node located closest to a tumor, and the first to receive drainage from it. By examining the fluid in the sentinel lymph nodes, physicians can determine whether cancer cells have spread beyond the tumor and might potentially travel to other parts of the body. If cancer cells are found in the sentinel lymph node, traditional treatment has called for removal of the surrounding lymph nodes, or dissection, in order to prevent the spread or recurrence of breast cancer. The more nodes that are removed during surgery, the greater the risk that the patient may develop lymphedema.



Lymphedema in the left arm of patients at stage 0 (figure 1), stage 1 (figure 2), stage 2 (figure 3) and stage 3 (figure 4).

Images courtesy of Dr. Charles McGarvey of CLM Consulting, and Guenter Klose of Klose Training and Consulting, LLC.

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Healers in the Operating Room

Breast program welcomes alternative practitioners before and during breast surgery.



Sheldon Feldman, MD,
Chief, Breast Surgery
Division

Physicians, surgeons, and nursing staff at NewYork-Presbyterian/Columbia understand that emotional well-being plays an important role in healing, and they do as much as possible to address the full scope of patients' needs before, during, and after surgery. **Sheldon Feldman, MD**, Chief of the Breast Surgery Section, believes so strongly in the importance of patients' overall well-being that he is spearheading a program to welcome healers into the operating room during breast surgery.

In this program, healers such as energy workers or reiki masters may be present while a patient undergoes mastectomy or other surgical procedures. According to Dr. Feldman, "Patients may be going through very difficult problems, such as accepting the loss of a breast or the ability to breastfeed. Healers can help patients on the emotional level, which helps on the physical level. The positive impact on healing after surgery can be potentially huge."

Patient Carolyn Dwyer could not agree more. Diagnosed with stage IV breast cancer in the summer of 2009, Carol enlisted the help of Reverend Diane Epstein, a longtime friend and transformational healer. Carol had previously received occasional massages from Diane, but was not aware of the full extent of Diane's healing work. Upon her diagnosis, they set to work with great focus. First, Diane helped Carol use imagery to welcome into her body the chemotherapy medications she was receiving to shrink her tumors. "I chose for these medications to save my life," Carol explains. "This was very empowering to me. All along, I wasn't nearly as wiped out by chemotherapy as other people who undergo the same treatment." She reached a point in her work with Diane that she felt the doctors were not doing things *to* her, but *for* her. The chemotherapy effectively shrunk her tumors in both breasts and her spine, where it had spread. With the tumors at their smallest, she was ready for surgery.

During Carol's double mastectomy in January 2010, Diane was present in the operating room, along with Dr. Feldman and the surgical team, doing energy work. "Dr. Feldman was focused on my body, and Diane was focused on my energy, my spirit. I felt like I was in such good hands from top to bottom," says Carol. Had she not worked with Diane, Carol believes that the entire process would have been frightening and overwhelming, and that she would not have been able

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Dr. Feldman. "If we can detect lymphedema very early on, before the patient notices any swelling, it is possible to treat it and avoid long-lasting effects."

How the Lymphedema Screening Program Works

Before surgery for breast cancer at NYP/Columbia, women will undergo a baseline measurement to determine their normal fluid levels. After surgery, patients will be assessed again at frequent intervals (usually during regular office visits). Through continuous monitoring, any arm swelling will be detected in its earliest stages. Patients are not charged any fees for this screening.

According to Dr. Feldman, who began the lymphedema screening program in 2010, this protocol has already succeeded in identifying patients who had subclinical levels of lymphedema. "Our screening program enables us to detect and treat lymphedema at far earlier stages than ever before, and will significantly improve the quality of life for many patients. I am very pleased to offer this service as a routine part of breast care for every surgical patient at our center," says Dr. Feldman. ■

NewYork-Presbyterian/Columbia is the only academic medical center in New York that offers a lymphedema prevention program. For more information, see www.breastmd.org or call 212.305.9676.

Breast Cancer Study Could Lead to Fewer Axillary Node Dissections

A pivotal study published in the Journal of the American Medical Association (JAMA) in February, 2011 found that removing the axillary lymph nodes did not lead to improved survival rates among women with breast cancer. For decades, it was commonly held that if breast cancer cells had spread to the lymph nodes under the armpits, it was important to remove these nodes. To the surprise of the researchers who conducted the study, results showed that removal of the lymph nodes did not improve survival or prevent recurrence of breast cancer. These findings, along with the risk of lymphedema, are leading breast surgeons to revise their recommendations concerning lymph node dissection in many patients.

The results of cohort A underscore the positive findings of the first phase of the PARTNER trial, cohort B, which were published in late 2010. This phase found that compared with medical therapy (including balloon valvuloplasty), transcatheter aortic valve replacement led to a 20% improvement in survival after one year among patients who were too sick or too old for surgery. "In addition to living longer, patients also felt much better and experienced fewer hospitalizations," says **Dr. Kodali, Co-Director, Transcatheter Aortic Valve Program, NewYork-Presbyterian/Columbia Center for Interventional Vascular Therapy.**

The highly positive results from both cohorts of the PARTNER trial mean that patients with aortic disease will have a new therapeutic option that works exceedingly well. Dr. Smith said in a statement that transcatheter aortic valve replacement is the most exciting new treatment for aortic stenosis in the past two to three decades.

"We already learned from the previous cohort that TAVR is the standard of care for patients who can't tolerate surgery...this [finding] opens up a new set of patients who may very well benefit as much with TAVR as with the gold standard surgery," said Dr. Smith during his presentation at the ACC.

At this time, transcatheter aortic valves are investigational devices in the US. Future studies will investigate the use of TAVI in lower risk patients. Already approved and on the market in other countries, it is expected that TAVI may gain FDA approval as early as late 2011, at least for patients ineligible for surgery. Because this procedure requires teamwork among cardiologists, surgeons, and imaging experts, it will likely become available initially at high-volume centers of excellence such as NewYork-Presbyterian/Columbia. ■

***Results of PARTNER cohort A will be published later in 2011.**

Healers in the Operating Room ~ continued from page 3

to proactively direct her healing process. "I wouldn't have understood that I needed to visualize the story of my healing." Today, Carol exudes confidence, happiness, and peace. "I am fine. I honestly am fine." To hear Carol's voice leaves no doubt in one's mind that she truly is doing well and living a life of vitality.

The NYP/Columbia program carries the torch from its Integrative Medicine Program, which included healers in the operating room during heart surgery. Led by **Mehmet Oz, MD** for 15 years, this program in complementary medicine continues to provide massage therapy, music therapy, and other healing techniques to patients undergoing heart surgery.

"Before surgery, patients always ask what they can do to get ready, to be prepared. Working with a healer can be very helpful," says Dr. Feldman. "We instituted this program so that this option can be available to everyone who wants it, not just the exceptional patient." The program is accessible to patients of all backgrounds: like yoga, healers may assist with relaxation and energy, regardless of one's religious beliefs or affiliation.

As another patient explains it, the presence of Reiki master Raven Keyes felt like having a 'surgical doula' – it made complicated procedures "not only tolerable, but a healing experience." Before her lumpectomy, this patient also read affirmations and prayers with everyone in the operating room. According to Dr. Feldman, "The team loved it. It made the whole environment more healing. It engaged the staff on a very personal level and elevated their awareness."

Both patients worked with their healers before and after surgery, but patients may choose to enlist a healer as many or as few times as they wish. They may enlist the help of Diane or Raven, who already work with Dr. Feldman's surgical team, or they may request that a new person be present, if they already have a relationship with someone.

Dr. Feldman's initiative strives not only to make healers in the OR accessible to patients, but also to study the effect of healers in the OR in order to objectively measure their effect. ■

For information about the Breast Surgery Program at NewYork-Presbyterian/Columbia, visit www.breastmd.org

SAVE THE DATES

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Information and reservations: Christine Rein
Telephone: 201.346.7014 Fax: 201.346.7011
E-mail: cmr2146@columbia.edu
Register online: www.columbiasurgery.org

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**Sunday, May 22, 2011, 10:00am
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**All proceeds benefit the
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