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Variety of exhibits, presentations within tight surgical target
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SAN DIEGO - Health conferences usually come with a clear target focus - that is, after all, what they are all about - but of all such meetings the annual meeting of the Society of Thoracic Surgeons held at the end of January probably has one of the tightest centers of that target, attendees almost exclusively cardiovascular surgeons. At the same time, however, the 43rd annual event at the end of January showcased a broad variety of topics within that focus - ranging from the hands-on, interactive strategies to demonstrate technique to a broader, thought-provoking discussion of the ethical issues facing these practitioners.

The "hands-on" portion of the conference this year was facilitated in the conference's "simulator village," one area of the village offering the experience of doing aortic valve replacement, but in a risk-free way.

El Shafei Hussein, MD, a general thoracic surgeon with Aberdeen Royal Infirmary (Aberdeen, UK) - with considerable curiosity showing on his face - was one of those who stepped up to a SimSuite operating table to test out his endovascular skills using guidewires, catheters, sheaths, and imaging technology supplied by Edwards Lifesciences (Irvine, California). "For someone like me," Hussein said, "having never done it before and wanting all the time to do it, and being scared to do it in a patient, [the simulation] shows you that it is do-able and it takes off the anxiety of trying it on a human being," said Hussein, whose specialties include adult cardiac surgery, general thoracic surgery, and peripheral vascular surgery.

As Hussein operated on "Simantha," a simulated patient on the operating table wearing a surgical cap and covered by a blue paper sheet, Chris Weeze, a radiology technologist with Medical Simulation (Denver), stood beside him in royal blue scrubs, talking him through each step and directing him on how to use the foot pedal. "Now we're going to put a guided catheter in," Weeze instructed. And a few minutes later he told him, "right about there, this is where you pull the wire out."

And on Hussein's left side, as keenly interested in observing the simulated operation as the doctor was about performing it, a curious Cardiovascular Device Update reporter watched as two dots on a monitor

above the operating table indicated exactly where the guided catheter was positioned in the patient. The 15-minute session was a way to give Hussein and other physicians at the conference a taste of what the company's individual hands-on training course would be like. "Brilliant, brilliant, brilliant," Hussein said of the experience, afterwards.

Samuel Peppers, director of clinical education for Medical Simulation, told CDU that his company has partnered with Edwards to develop "intense, simulation classes for a day-and-a-half." At Edwards' headquarters in Irvine, those classes including training on a range of simulated procedures for coronary, renal and iliac interventions.

Simulating surgical ablation

At another exhibit in the simulator village area, Boston Scientific (Natick, Massachusetts), offered physicians the chance to test out its Flex 10 XE microwave surgical ablation probe using its FlexTech simulator.

Angela Breaux, a marketing specialist for Boston Scientific, told CDU that the FlexTech simulator is designed to help physicians meet the challenges of thoracoscopic ablation through five hands-on procedure modules, including right-sided pericardiometry. The simulation booth was a hit, she said, with physicians stopping by during breaks in the STS meeting schedule to try out this approach. Beaux said, "It's been pretty exciting - there's a lot of buzz down here."

Other simulated procedures physicians could try with the FlexTech included: dissection into the transverse and oblique sinuses, and placement of FlexGuide routing tools, left-sided pericardiotomy and retrieval of FlexGuide routing tools, positioning of the Flex 10 XE microwave surgical ablation probe, and creation of microwave lesions. Similar to the SimSuite operating room, the FlexTech is designed to simulate the look and feel of live surgery. It also includes on-screen demonstrations and case studies to provide context for trainees as they work, and an automatic, objective assessment allows physicians to track their progress.

It also was difficult for STS attendees walking into the simulator village room to miss the large semi-truck parked there, a mobile therapy procedure training center developed by Medtronic (Minneapolis, Minnesota), with physicians taking turns practicing simulated hands-on endosurgical techniques.

"We're giving cardiac surgeons a comfortable environment to learn these skills because it's like learning a foreign language," Christina Lin, a provider relations specialist for Medtronic, told CDU.

Concentration on the AF opportunity

A prominent focus of the STS meeting was the treatment of atrial fibrillation (AF), an increasingly important territory for the cardiac surgeon, one under increasing investigation but still relatively uncharted in terms of truly effective treatment and so offering large opportunity for innovation - and

speculation.

AF is a disease with a huge prevalence. Until several months ago, the domestic pool was generally agreed to be about 2.2 million persons. However, an article in the July 11, 2006 issue of Circulation, titled "Secular Trends in Incidence of Atrial Fibrillation in Olmsted County, Minnesota, 1980 to 2000, and Implications on the Projections for Future Prevalence," revealed that AF has been dramatically underestimated and that the prevalence exceeds 5.1 million. Moreover, by 2050, it is expected to balloon to nearly 16 million.

But the current "gold standards" for AF treatment are not working well. Anti-arrhythmic drugs are generally regarded as ineffective in 40% to 50% of AF patients, and the blood thinner Coumadin, given to prevent ischemic stroke, has dismal compliance. Hence, many patients suffer an ischemic stroke because of their AF.

The percutaneous, catheter-based approach also shows poor results. According to an article in the April 2006 issue of the Journal of Interventional Cardiac Electrophysiology, the long-term, single-procedure efficacy of catheter ablation of AF is 28%. Moreover, a major complication occurred in 8% of the patients. In spite of this, it was estimated at the Boston Atrial Fibrillation Symposium last month that 30,000 to 35,000 "off-label" AF catheter ablations were performed in the U.S. in 2006.

These procedures, which increased significantly during 2005, are being performed by electrophysiologists with catheters that are not FDA-approved for AF treatment, while surgical ablation has grown significantly in the past few years, reaching about 22,000 procedures in the U.S. in 2006. The goal of surgical ablation is to destroy the atrial tissue that is causing the chaotic electrical activity in the atrium. After an ablation, these aberrant electrical impulses cannot cross the burn scars that separate the areas of the atria, thereby halting the atrial fibrillation.

'Cruising' for AF attention

During an evening boat cruise and program titled "Late Breaking AFib Clinical Data Symposium, Atricure (West Chester, Ohio) sponsored three prominent physician experts in the AF arena, presenting information concerning this emerging field.

Patrick McCarthy, MD, chief of the division of cardiothoracic surgery at Northwestern Memorial Hospital (Chicago), strongly advocated that all AF patients undergoing either a CABG or valve procedure should receive a concomitant AF ablation. He said that in his institution, the percentage of patients in this category has risen in the past couple of years from 38% to 86% and would be 100%, except for those few patients contraindicated for an ablation procedure. "I believe that AFib ablation is a safe and successful procedure and that the vast majority of these patients should be treated," McCarthy stated.

Ralph Damiano, MD, chief of cardiac surgery at Barnes-Jewish Hospital (St. Louis), echoed McCarthy,

saying that his group's results of a concomitant surgical ablation in treating paroxysmal (intermittent) AF were excellent, with more than 92% AF-free at 12 months.

And James Edgerton, MD, from the Texas Hospital of the Southwest (Plano, Texas), was ebullient about AF ablation, backed by perhaps the most impressive clinical data. Based upon a rigorous definition of success - freedom from any episode of AF lasting three seconds or longer - Edgerton reported an 89% success rate with his cohort of patients who received a concomitant AF ablation. He also reported impressive results with his Minimally Invasive Surgical Ablation (MISA) trial, in 111 patients treated thus far. This approach is different than the concomitant one, in that it is performed through two small non-rib-spreading mini-incisions, one on each side of the chest. It is far less invasive for the patient than a concomitant one, where the chest is already for open for a CABG or valve surgery.

This approach is called minimally-invasive although technically it is not, since it does not utilize endoscopic port access. There are other energy sources either FDA-approved (e.g., microwave and high intensity focused ultrasound) or nearing FDA approval (YAG laser) that can be delivered endoscopically. The physicians all employed the Atricure bi-polar radio frequency (RF) devices in their work. And analysts following the company estimate that Atricure has captured 45% to 50% of the concomitant ablation market and about two-thirds of the far smaller but rapidly growing minimally-invasive standalone market.

AtriCure was showcasing its new Synergy RF system at the STS. Whereas its first-generation device employs one parallel electrode, the Synergy uses two parallel electrodes embedded in the jaws of the clamp that pulse on-off alternately to create a cumulative heat base in the middle of the tissue. The company believes this new design enables increased depth of penetration, for wider, more consistent lesions.

Based upon numerous talks at STS, it is clear that the most important feature of any ablation device is the ability to produce full thickness, transmural lesions that are reproducible.

Atricure expects an FDA 510(k) approval imminently and says that it will make full commercial launch for the concomitant version of Synergy before the end of 1Q07. The company hopes to launch Synergy for minimally-invasive procedures in 3Q07.

AF treatment: works in progress

Though there are many advances being made in the treatment of AF, this field is still in a state of flux. For example, Damiano acknowledged that despite all the progress that has been made, "I am not sure that we know which lesion sets or energy source will deliver the best results for our atrial fibrillations patients." And he said that the cardiothoracic community needs better clinical trial results to convince its key referral sources (i.e., electrophysiologists and cardiologists) that "we know what we are doing."

The need for an effective, endoscopic, minimally-invasive procedure was emphasized by Edgerton, who

noted that "in our patients, we always opt for a less invasive procedure."

Thus far, there is no FDA-approved device that fills that bill.

Indeed, the results from a rigorous trial of microwave energy delivered endoscopically showed a disappointing efficacy rate of only 42%. The presenter of that data - from a study using a device marketed by Boston Scientific - J. Crayton Pruitt, MD, from Cardiac Surgical Associates (Clearwater, Florida), concluded that improvements to the technology are needed.

Another AF luminary, Marc Gillinov, MD, surgical director of the Center for Atrial Fibrillation-Cleveland Clinic Heart Center (Cleveland, Ohio), discussed the merits of removing the left atrial appendage, a thumb-like structure in the heart that some physicians believe can host clot formation that can precipitate an ischemic stroke.

His comments on how well this procedure works: "we think so, we hope so, but we just don't know for sure."

So, promising but needing better information - such is the state of AF ablation today.

Exhibit variety

Like the variety of the STS conference itself, the 120 booths in the exhibit area featured a varied range of companies, products and product targets, from very "niche" to broadly applicable to the field.

While a booth operated by a plastic surgeon is unexpected at a cardiothoracic conference, Tadeusz Wellisz, MD, from the University of Southern California (Los Angeles), told CDU how Ostene, made by his company ceremed (also Los Angeles), can be used by cardiac surgeons. A water-soluble, odorless, opaque wax-like material consisting of a sterile mixture of alkylene oxide copolymers, Ostene was designed as an alternative to using beeswax, or bone wax, to control bleeding during surgery.

At the start of heart surgery for coronary artery bypass grafts (CABG) or heart valve replacement, cardiac surgeons have to cut the patient's sternal bone, Wellisz said, and the bone morrow can pour out and bleed. For the past 100 years, he said, surgeons have been using beeswax to stop the bleeding, but that wax never goes away in the body, thus increasing the risk of infection and preventing the bone from healing. Ostene, on the other hand, is an "effective bone hemostasis agent that does not inhibit osteogenesis and bone healing," Wellisz said.

There have not been any clinical studies done using Ostene in humans, Wellisz acknowledged, but the company has received FDA 510(k) clearance.

Kimberly-Clark (Dallas) was showcasing its InteguSeal Microbial Sealant, a film-forming liquid designed to reduce surgical site infections. "It's new to the world," Ajay Houde, PhD, an engineer in the

company's product and technology development department, told CDU. "As you prep the skin you apply a thin layer [of the sealant] and it seals and immobilizes bacteria."

Because many of the clinical studies that have been done with the product have involved pigs, the company even had two pig's feet on display at its booth for demonstrations. But Houde said InteguSeal has also been used on 9,000 patients in the U.S. and has been available in Europe for about 10 months. "It works with all different preps, it does not wash off during the procedure, and it stays on for three to seven days and then comes off on its own," Houde said.

Alsius (Irvine, California) was featuring its Thermogard which attendees could feel for themselves was warm to the touch. Thermoguard is designed to keep patients warm during surgery, and attendees were offered that experience interactively. Traditional ways of warming up a patient during a procedure include turning up the heat in the operating room or putting a special type of blanket over them, Wes Long, a sales manager for Alsius, told CDU.

With the Thermogard, doctors insert the catheter directly into the patient's vein to warm their blood as it passes by, he said. Or, if the surgeon needs to induce hypothermia, the device can be used to cool the patient. It also acts as a central line. "You don't want people having to generate heat while they're going in for a cardiac procedure," Long said.

The Thermogard also can be used to comply with guidelines from the American Heart Association (Dallas) that require patients to be cooled at 33-degrees for 24-hours following a heart attack, Long said. "The company has been working with hypothermia for about five years, but this [device] is designed to maximize the warming capabilities," Long said.

Datascope Cardiac Assist (Montvale, New Jersey) was showcasing its CS300 balloon pump, the second in a line of automatic pumps, bannering it as combining fiber-optic speed with automatic in vivo calibration. The result is faster time-to-therapy, faster signal acquisition, and faster adaptation to rate and rhythm changes, Datascope said.

SPY system data positive

Novadaq (Toronto) used the conference to report the results of an independent study that it said confirmed that the use of the SPY System during Coronary Artery Bypass Surgery (CABG) can lead to significantly improved outcomes. The SPY Intra-operative Imaging System, available worldwide, enables cardiac surgeons to visually assess coronary vasculature and bypass graft functionality during the course of open-heart surgery.

Dr. Arun Menawat, president/CEO of Novadaq, said that the results "confirm that the use of SPY can improve the outcome of heart bypass surgery and that identifying problems in the operating room with the SPY System can lead to significantly improved clinical results. These results are very important and the STS scientific meeting is the leading forum for presentation and discussion of important

advancements in care among cardiac surgeons."

The primary objective of this comparative study - including 2,738 patients, of which 384 (192 matched pairs) CABG patients were evaluated - was to determine if perioperative patency assessment with SPY fluorescence angiography decreased the amount of myocardial injury during or after CABG surgery.

"Up to half of all significant perioperative myocardial infarctions are related to graft failure. The immediate and long-term success of coronary surgery is dependent on the construction of a technically perfect anastomosis with a high quality conduit to an appropriate target coronary vessel, yet despite systematic improvements in the outcomes of coronary surgery, modern coronary bypass series continue to report perioperative graft occlusions rates as high as 3%-10%," said Nimesh Desai, MD, PhD, lead author and cardiac surgeon at Sunnybrook Health Sciences Centre (Toronto).

"The results of the study demonstrate that intra-operative angiography with graft revision led to significantly fewer perioperative myocardial injuries by enzymatic criteria. This data supports the increasing use of the intra-operative graft assessment to verify graft patency. These very early graft failures are usually related to technical problems at graft anastomosis sites and may be correctable if recognized intra-operatively."

Novadaq says its imaging platform can be used to visualize blood vessels, nerves and the lymphatic system during surgical procedures.

A challenge - to give more

Among the broader issues addressed at the STS conference was a challenge delivered by former U.S. Senate majority leader (R-Tennessee) and CT surgeon Bill Frist. Frist, in his Thomas B. Ferguson lecture, asserted: "There's something in all of us that wants to give just a little bit more than we give today . . . it's probably why many of you went into thoracic surgery."

Frist was the first to give this lecture, established in 2000 to honor Dr. Ferguson's contributions to thoracic surgery. In the '07 chapter of that lecture, "An Oath to Heal and an Oath to Govern: A Biased View of the Paradox No One is Addressing," Frist compared his 20 years in medicine with his 12 years in Congress. Unlike many GOP colleagues, Frist said his good-byes to Washington voluntarily. He said that he ran for the Senate in 1994 because he felt the country was moving in the wrong direction and he wanted to make a difference.

Frist said that he committed in advance to limiting his term because he believes in the citizen legislator - someone who goes to Washington for a period of time with a mission to accomplish, rather than a career to protect, and then goes back home to live under the laws that he helped pass. He likened that approach in politics to the trust between surgeons and patients.

Frist pushed his colleagues to put more effort into advocating for healthcare reforms in areas such as

liability insurance, Medicare reimbursement, and electronic health records. "STS does better than most specialty organizations, but your voice is not loud enough," Frist said. "Doctors are not at the table in sufficient numbers yet. Advocacy requires visibility and visibility requires money."

Frist - who has in each of the past 12 years participated in overseas medical missions through World Medical Mission (Boone, North Carolina) - besides urging time and money given to legislative advocacy also encouraged his colleagues to follow suit and "use medicine as the currency for peace."

To underline his message, Frist showed a video, "A Heart for Africa," of himself on a mission trip in Africa where he and other volunteer surgeons operated a hospital out of an abandoned school house in Sudan and on their first night there had to operate by flashlight. Frist's experiences in Africa changed his life, he said, and he urged attendees to volunteer their skills either locally or overseas.

"It expands you, you grow, it affects you as a person, you appreciate the blessing of being a surgeon . . . you feel a sense of patriotism."

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