



THORACIC SURGERY NEWS

THE OFFICIAL NEWSPAPER OF THE AMERICAN ASSOCIATION FOR THORACIC SURGERY



Dr. Mark Iannettoni (R) guides residents Dr. Dawn Hui and Dr. Elan Burton through a simulated open lobectomy.

COURTESY THORACIC SURGERY DIRECTORS ASSOCIATION

Resident 'Boot Camp' Introduces Techniques

BY MARK S. LESNEY
Elsevier Global Medical News

Ensuring that cardiothoracic surgery residents receive appropriate training in core CT-surgical techniques is a critical issue in a world of rapidly changing technology and educational demands. Innovative training methods are required, and the Thoracic Surgery Directors Association has been at the forefront of efforts to improve the learning experience for today's residents.

A prime example of these efforts is the TSDA Cardiothoracic Surgery Resident Boot Camp. The annual Boot Camp was held on July 8-11, 2010 at the William and Idie Friday Center of the University of North Carolina, Chapel Hill, N.C. The program was developed and hosted by the Thoracic Surgery Directors Association and was funded in part through a grant from the Joint Council on Thoracic Surgical Education, Inc.

Now in its third year, the Boot Camp uses cardiothoracic simulator-based training to give res-

idents some of the basic skill sets necessary to enhance their residency educational experience, especially in the operating room.

More than 30 highly experienced cardiothoracic surgery educators and guests from around the country donated their time and expertise to lead the resident courses in thoracic endoscopy (Dr. Alberto de Hoyos, course director), cardiopulmonary bypass (Dr. James Gangemi, course director), open lobectomy (Dr. Daniel Miller, course director), and vascular anastomosis (Dr. James Fann, course director). Each course used recently-developed cardiothoracic-specific simulators, including the Ramphal Cardiac Surgery Simulator, the Carolina Lung Surgery Simulator, the Heart Case Platform, and Mediastinoscopy Man.

"Over the last three years, we have learned a tremendous amount about resident education and especially how effective simulator-based training can

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PCI vs. CABG: Which Is Best for Complex CAD?

Outcomes gap may be narrowing.

BY RICHARD M.
KIRKNER
Elsevier Global Medical News

NEW YORK — Coronary artery bypass grafting may remain the standard treatment for left main coronary artery and complex multivessel disease, but results achieved using percutaneous coronary intervention with drug-eluting stents have come close to those seen with coronary bypass.

Dr. Upendra Kaul of Fortis Escorts Heart Institute in New Delhi and Dr. Alfredo Rodriguez, head of the cardiac unit at Otamendi Hospital in Buenos Aires, debated the merits of the two interventional approaches at the Mt. Sinai Symposium of Complex Coronary and Vascular Cases.

"The difference between bypass surgery and angioplasty in complex and left main artery disease has always been one of

higher reintervention rates; and, as we know, restenosis is not a benign entity," Dr. Kaul said. He acknowledged that recent clinical trials have shown that drug-eluting stents (DES) have substantially lower rates of reintervention than do bare-metal stents, but he painted a different picture when comparing either stenting modality with coronary artery bypass grafting (CABG) in complex and left main artery stenosis.

"The rates of repeat vascularization very clearly favor bypass surgery," he said, citing a 2008 trial (*N. Engl. J. Med.* 2008;358:331-41). Among patients with two-vessel disease, CABG had slightly better outcomes than did DES: 96% vs. 94.6% for adjusted survival rate, and 94.5% vs. 92.5% for myocardial infarction-free survival.

Dr. Rodriguez countered

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TSN launches its new section for residents featuring info on education, training, and other issues of interest to residents and their educators. • 2

General Thoracic Living Longer

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Adult Cardiac Six of One ...

Little difference seen between transapical or transfemoral aortic valve implantation in high risk patients. • 11

Lung Transplant Survival Varies by Center

BY MARY ANN MOON
Elsevier Global Medical News

Survival after lung transplantation varies widely across the 61 U.S. medical centers where it is performed, according to a report in *JAMA*.

However, only 15% of that variation can be attributed to the volume of procedures done at each center, said Dr. Gabriel Thabut of the department of health sciences research at the Mayo Clinic in

Rochester, Minn., and his associates.

"We assessed the association of center volume and survival using different time frames, different definitions of volume, and different statistical methods. All analytic frames showed

a consistent and statistically significant positive association between center volume and survival." However, volume contributed only a small amount to mortality after lung transplant, and several low-

and medium-volume centers achieved good outcomes, showing that "volume alone does not determine performance," they noted.

The investigators undertook their study because research has suggested that outcomes vary greatly from one center to the next. "For example, studies from several large centers report 3-year survival rates greater than 70% and even

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THORACIC SURGERY NEWS ONLINE!

Visit our new interactive editions.
See our new 'Residents' Corner' section on pages 2-3 for details.

Welcome to Our Residents' Section

BY DR. YOLONDA COLSON
Medical Editor

Hard to believe we are already into fall. Hope all of you had time for some relaxation and reflection over the summer, mixed with a little fun and adventure with friends and family. It is times like these that make us truly appreciate what we do everyday—we strive to make such memories possible for our patients by restoring their health and giving them a new lease on life.

As we begin a new academic year, THORACIC SURGERY NEWS has many new initiatives to bring new life into our world as well. The mission of the AATS has always been focused on the promotion and fostering of education and research in the field of cardiothoracic surgery.

As academic cardiothoracic surgeons we are a small, close community with a strong commitment to the education and development of the next generation of surgeons. Although an overused cliche, we really do recognize that the next generation is our future and our legacy, building the future is our responsibility.

Our community is too small and our expertise too important to not cultivate the talent among us and make the next generation even greater than ourselves. This challenge and responsibility has always been accepted by CT surgeons with great pride and enthusiasm.

It is with this focus of welcoming our residents and fellows into the AATS, building bridges among the eager to learn and the eager to teach, and the desire to pass along our rich heritage to the next generation that we proudly introduce our two new resident associate editors and the launch



DR. YOLONDA COLSON

of a resident-centered section in the TSN newspaper and website. In order to get this initiative started with lots of face-to-face brainstorming time, we have been fortunate to recruit two talented cardiothoracic residents representing cardiac and thoracic educational interests.

In alphabetical order, Stephanie Mick is a cardiac surgery resident at Brigham and Women's Hospital, Boston, raised in Dayton, Ohio and moved to New York, New York for college at Columbia. She attended Cornell Medical School and completed her General Surgery Residency at New York Presbyterian Hospital, Cornell.

Christian Peyre was born and raised in Los Angeles and completed his under-

graduate degree at UC Berkeley before going to USC for both medical school and general surgery residency. He is now a thoracic track cardiothoracic surgery resident also at BWH.

Together, they have worked with TSN to establish a Residents' Corner, a "Training Table" if you will, where residents can come any time of day or night for a few minutes and drink in some sustenance in the field of cardiothoracic surgery.

In coming issues, we will start a "case of the month" column with images to learn from on bread and butter topics (no pun intended but it works), expert commentary, review of classic cardiothoracic papers, updates on Joint Council on Thoracic Surgery Education (JCTSE) initiatives and other educational news, articles about cardiothoracic pioneers and our history, and mentoring advice on how to start your career or at least things we wished we had known when we were in your shoes.

It will be a place to find information

about the events and deadlines that are important to cardiothoracic residents and fellows, here and abroad, and it will serve to highlight the commitment to education that AATS already exemplifies through the AATS Traveling Fellowship and Scholarship Programs, the Summer Internship Program, the C. Walton Lillehei Resident Forum, and our joint support of Thoracic Surgery Foundation for Research and Education (TSFRE) and JCTSE programs.

We will draw on great mentoring resources like the AATS Academy, Developing the Academic Surgeon Symposium, the Grantsmanship Course and the wisdom of experience that the AATS membership already possesses, but we will also draw on other resources including our recent collaboration with Thoracic Surgery Residents Association (TSRA). AATS has always been a strong supporter of resident education and research, with resident resources available on their web page (www.aats.org/TSR/index.html), but we have not had an ongoing forum to interact, teach, and learn from the residents.

Through resident editors, TSN will be able to provide a window for the TSRA to let us know how we can better help residents become the best partners and cardiothoracic surgeons possible and we will be able to get important AATS opportunities and TSRA information to the sometimes "missing-in-action" CT resident through an always available website.

I invite all of you, resident and attendings alike, to take a look at the new section, send new ideas, volunteer to add expert commentary and help us make TSN the best place for a "quick bite" of CT surgery news and education.

Feel free to contact us at aats.prri.com. And to see the latest edition of TSN on our redesigned website please visit www.aats.org/Association/Thoracic_Surgery_News.html.

Making the Match in 2010

BY MARK S. LESNEY
Senior Editor

This year's Thoracic Surgery Fellowship Match Day was held June 9 and the trend of comparatively few applicants per position continued. A total of 99 certified applicants applied for 113 positions in 80 certified thoracic surgery programs.

In part, because there were fewer applicants compared with the number of fellowships, only 88 of these positions were filled (78%). A total of 95% of 65 certified U.S. graduate applicants from U.S. programs were matched, compared with 72% of 18 certified foreign applicants. U.S. applicants trained at foreign institutions did not fare as well as their U.S.-trained peers, with only 75% of 8 certified candidates being matched (www.nrmp.org/fellow/match_name/thoracic/stats.html).

Registration for the 2010 Match began Jan. 6, 2010, for the appointment year 2011. The Thoracic Surgery Fellowship Match is conducted by the National Resident Matching Program. Low numbers of applicants are traditionally considered less than ideal for a profession for the obvious reasons that employers are best served by larger number of applicants, which ensures that there will be a larger pool of above-average individuals to choose from and that all positions will be fillable from the pool. Unmatched positions usually indicate a competition for candidates and lack of acceptable applicants from which to select. This year 25 (22%) positions went unfilled.

Conversely, having less competition is ideal for those who are actually applying for positions. In this case, overall 89% of the 99 applicants matched.

Further information on the match statistics and the National Resident Matching Program is available at www.nrmp.org.



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'Educating the Educator' Symposium Held

BY REBECCA J. MARK
JCTSE, Administration and Education Manager

The Joint Council on Thoracic Surgery Education, Inc. held its first *Educate the Educator* symposium on July 9, 10, and 11, 2010 in Chapel Hill, North Carolina. The course was developed based on the specific needs of cardiothoracic surgeons and ran in conjunction with the Thoracic Surgery Directors Association 2010 Boot Camp III, which was supported in part by JCTSE (see accompanying story).

According to JCTSE Surgical Director of Education, Dr. Edward Verrier, "One of the advantages of running these programs side-by-side was to capitalize on the presence of

the cardiothoracic surgical trainees. This provided a unique opportunity for faculty to observe and improve teaching skills—an opportunity that is not currently available with other faculty development programs."

The goals and objectives of this course were derived from national surveys of US cardiothoracic surgery faculty and residents. The findings from these surveys guided Educate the Educator Course Co-Directors, Dr. Stephen C. Yang, and Dr. Ara Vaporiyan, in planning a program that focused on effective delivery of skills-based education (simulation and intra-operative teaching) and methods to convert educational efforts into career

advancement (grants and promotion). The 2½ day course was created in collaboration with nationally respected ex-

"The purpose of this program was to enhance the teaching skills of cardiothoracic surgical faculty, while promoting

the concept of career advancement through education. While other courses such as this exist (most notable being the week-long Surgeons as Educators program run by the American College of Surgeons), interest in these programs by cardiothoracic surgeons has been limited both because of the time commitment required and the broad focus of the curriculum," stated Dr. Yang.

"This endeavor was done with the hope of generating an 'army of educators' who will lead the new wave of education for the next generation of CT

surgeons, thereby, elevating thoracic surgery education in priority, quality, and reward," Dr. Vaporiyan added.

As a result of this program, attendees are now better prepared to enhance educational efforts at their home institution. This enhancement may come in the form of initiating a skills laboratory with a complete curriculum or developing a separate program to address a specific educational need. JCTSE intends to remain connected to those who attended this outstanding program to help guide attendees as they make inroads into improved cardiothoracic surgery education in the future. In addition, plans are already underway to offer this program again in 2011. ■

THIS ENDEAVOR WAS DONE IN HOPE OF GENERATING AN 'ARMY OF EDUCATORS' WHO WILL LEAD THE NEW WAVE OF CT EDUCATION.

perts in surgical education. Content areas for the program included adult learning theory, how to teach in the operating room, curriculum development and implementation, how to improve assessment skills, and how to use the science of education as a faculty advancement tool.

'Boot Camp'

Education • from page 1

be," said Dr. Richard Feins who, along with Dr. George Hicks and Dr. James Fann, served as a Boot Camp III Director.

"In addition, the residents get a very clear message that their education is of paramount importance to our specialty. We are hopeful that the 'boot camp' concept will be expanded in the years ahead and that simulator-based training will become a part of every cardiothoracic residency program," Dr. Feins added.

Feedback from the residents indicated that Boot Camp III was a resounding success. Evaluation comments

included, "The CPB emergency simulation was fantastic;" "Excellent course;" "Thank you for this amazing opportunity;" and "I loved every minute."

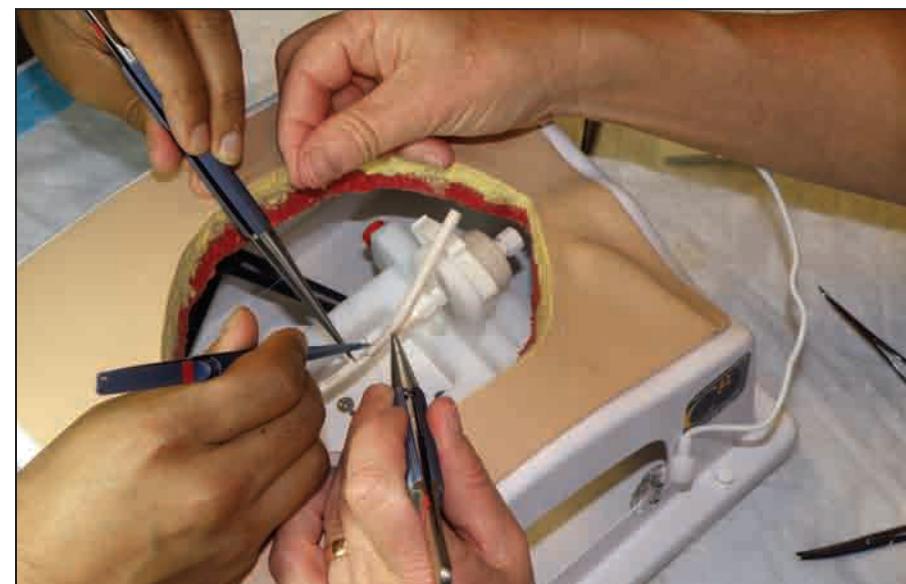
Residents also expressed gratitude to the "very helpful" faculty who volunteered their time for this "fantastic and very rewarding event." And, as one resident noted, "It would be wonderful if all residents could participate."

In addition to the 8 hours of training residents received each day, keynote addresses delivered during group meals provided additional didactic education on relevant topics. Ron Maness, former chief pilot for contract simulator training at USAirways, spoke on simulation-based training in aviation and its implications for cardiothoracic surgery training.

Dr. K. Anders Ericsson, noted author and researcher at Florida State University, discussed his work on achieving technical expertise through deliberate practice.

Dr. G. Alec Patterson, past president of the American Association for Thoracic Surgery, presented highlights from his recent AATS presidential address on how proper leadership translates into accomplishment.

Finally, Dr. Paul



The Boot Camp faculty used a simulator heart case to educate residents during the large/small vessel anastomosis session.

Sergeant, past president of the European Association of Cardio-Thoracic Surgery and currently the editor of CTSNet, presented his insights on leadership, hierarchy, and surgical education.

"I am very proud of the work the TSDA is doing to make cardiothoracic surgery resident training innovative, relevant, and effective," said Dr. Hicks, president of the TSDA. "The great success of Boot Camp is just the beginning, and we expect the years ahead to be very exciting for everyone involved in resident education," he added.

Information about future Boot Camp events will be posted on www.TSDA.org when available.

Powerpoints of these educational session presentations are available at the TSDA website as well (www.tsda.org/sections/meetings/2010%20Boot%20Camp/index.html).

Along with funding by the JCTSE, the residents' boot camp was supported by the University of North Carolina, Chapel Hill, division of cardiothoracic surgery, and in-kind support from a variety of health care and medical device companies. ■



L to R: Dr. Cameron Wright assists resident, Dr. Sagar Damle. Mannequins and scopes were utilized during the bronchoscopy/mediastinoscopy session.

Some Online Resources of Interest

AATS Resident Resources: www.aats.org/TSR/index.html

CTSNET Residents Section: www.ctsnet.org/sections/residents

Thoracic Surgery Directors Association: www.tsda.org

Thoracic Surgery News: www.aats.org/Association/Thoracic_Surgery_News.html

Thoracic Surgery Residents Association: www.tsranet.org

Thoracic Surgery Foundation for Research and Education: www.tsfre.org

ACGME: Reduce Resident Duty Hours in First Year

BY ALICIA AULT
Elsevier Global Medical News

The Accreditation Council for Graduate Medical Education revisited its standards for resident duty hours and determined that modifications should be made, mostly for first-year residents. All other residents should still be subject to an 80-hour work week and up to 24 hours of continuous duty, according to an online article in the New England Journal of Medicine.

The ACGME task force that wrote the standards will review public comments and make any modifications considered necessary before July 2011, when the new standards will go into effect.

The ACGME standards, established in 2003, have been controversial, with opinions differing over whether they have been too restrictive or too loose to properly protect patients and ensure a good quality of life for residents.

According to the latest report, written by Dr. Thomas J. Nasca and colleagues on behalf of the ACGME task force, the 2003 standards had the following three "problematic" elements, as identified by the educational community and the public:

- The limits on duty hours may have created a shift mentality among residents, which tends to conflict with the duty to serve patients.
- Many programs began focusing on meeting the duty hour restrictions, perhaps at the expense of education.
- The 80-hour work week, with up to 24 hours of continuous duty, was seen as compromising patient safety.

In 2008, the Institute of Medicine looked at the ACGME standards and recommended that no residents should exceed 16 hours of continuous duty. The ACGME convened the task force to consider the IOM recommendations. One of the biggest challenges was to

reconcile the IOM's suggestion for an across-the-board restriction with the plea from academic programs that duty hours needed to be tailored to each specialty (N. Engl. J. Med. 2010 [doi:10.1056/NEJMsb1005800]).

The ACGME panel also weighed whether there was sufficient evidence to show that working more than 16 hours or up to 30 hours continuously led to more medical errors, as suggested by many critics of the duty hour standards. According to the panel, the data thus far indicate only that first-year residents are more prone to mistakes as a result of sleep deprivation. Therefore, they urged a new paradigm for first year residents, whereby they can't be on duty longer than 16 hours continuously with 10 hours off and 8 hours free of duty between scheduled duty periods. They are also not allowed to moonlight, and must have direct, in-house, attending-level supervision. All residents are allowed to work up to 4 more hours to facilitate patient hand-offs—an area of concern for patient safety. The panel decided not to tailor hours to specialties.

The IOM also criticized the ACGME for not enforcing the duty hours. The task force said that enforcement is an "inherent" challenge, partly because there are some 9,000 accredited programs. However, the ACGME is now undertaking annual site visits and analyzing whether institutions can comply. Eventually, the ACGME will give each institution a report on its compliance status and recommendations for resolving problems.

Wake Up Doctor, a coalition of public interest and patient safety groups pushing the ACGME to further restrict resident hours, said that the new standards don't go far enough. The group gave the ACGME an "F" for failing to comply with the IOM recommendation that continuous duty be restricted to 16 hours for all residents. However, the recommendation for greater su-

pervision of first-year residents got higher marks.

On August 9, The Society of Thoracic Surgeons, the AATS, the American Board of Thoracic Surgery, the Thoracic Surgery Directors Association, and the Thoracic Surgery Foundation for Research and Education, and other representatives of the thoracic surgery community, sent a letter to the ACGME responding the proposed change. They identified difficulties with the proposed maximum duty length of 16 hours for first year residents.

"Of necessity, at least two shifts (a day and a night shift, and probably an overlapping third shift) of thoracic surgical residents will be required to cover any 24-hour period. The thoracic surgical resident workforce to provide such shift work simply does not exist," they warned. With the structure of thoracic surgery resident education changing from independent to integrated programs "the resident component for each of these six-year programs is typically only one resident per year." The proposed changes would "have a devastating effect" and "will lead to program closures."

The letter pointed out that "the proposed change in work hours will be detrimental to resident education," with night shifts having no access to didactic conferences or clinical teaching, and providing only minimal interaction with faculty and senior residents. This would "stunt the growth of professionalism and limit the acquisition of medical knowledge among first-year residents" and "preclude responsiveness to patient and family needs."

Since the implementation of the 2003 ACGME work hour regulations, the clinical and operative experience has significantly decreased for thoracic surgical residents, an outcome coinciding with a near doubling of the failure rate among thoracic surgery residency program graduates on the American Board of Thoracic Surgery certifying examination.

"In summary, the ACGME proposed changes in work hours will compromise patient care and resident education....We strongly urge the ACGME to withdraw this proposal," their letter concluded. ■

AATS, STS, AND OTHERS WROTE TO THE ACGME IDENTIFYING DIFFICULTIES WITH A MAXIMUM DUTY LENGTH OF 16 HRS FOR FIRST-YEAR RESIDENTS.

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Featured in the JTCVS

The following articles are featured in the September 2010 issue of the *Journal of Thoracic and Cardiovascular Surgery*.

Presidential Address

Non Solus—A Leadership Challenge
G. Alexander Patterson

Expert Review

Epithelial to mesenchymal transition: The doorway to metastasis in human lung cancers

Chadwick E. Denlinger, John S. Ikonomidis, Carolyn E. Reed, and Francis G. Spinale
Lung cancers metastasize through a reversible process involving epithelial to mesenchymal transition in which malignant cells lose intracellular adhesions and become mobile. Subsequent reversion to an epithelial phenotype allows metastatic growth. Ongoing clinical and basic science studies will identify ways to exploit this process for clinical benefits.

Congenital Heart Disease

Atrioventricular valve repair in patients with functional single ventricle
Tomohiro Nakata, Yoshifumi Fujimoto, Keiichi Hirose, et al.

Our 10-year experience with 65 con-

secutive patients with functional single ventricle undergoing atrioventricular valve repair suggests the midterm results were favorable and cardiac function was maintained effectively. However, young and small patients, especially those with hypoplastic left heart syndrome, still had poor outcomes. Therefore, more efforts should be made.

General Thoracic

National Emphysema Treatment Trial redux: Accentuating the positive

Pablo Gerardo Sanchez, John Charles Kucharczuk, Stacey Su, Larry Robert Kaiser, and Joel David Cooper
For patients in the NETT trial with heterogeneously distributed, upper lobe predominant emphysema, LVRS provided significant long-term survival and functional benefit compared with similar patients randomized to medical therapy alone.

Acquired Cardiovascular Disease

Functional mitral stenosis after surgical annuloplasty for ischemic mitral regurgitation: Importance of subvalvular tethering in the mechanism and dynamic deterioration during exertion

Kayoko Kubota, Yutaka Otsuji, Tetsuya Ueno, et al.

In patients with annuloplasty for ischemic mitral regurgitation, diastolic mitral valve area was frequently less than 1.5 cm² (functional mitral stenosis) and significantly correlated with restricted leaflet opening, left ventricular dilatation, and New York Heart Association class. Leaflet tethering in the presence of surgical annuloplasty in ischemic mitral regurgitation frequently causes functional mitral stenosis.

Perioperative Management

Simulation-based training delivered directly to the pediatric cardiac intensive care unit engenders preparedness, comfort, and decreased anxiety among multidisciplinary resuscitation teams

Catherine K. Allan, Ravi R. Thiagarajan, Dorothy Beke, et al.

Successful resuscitation of pediatric cardiac patients requires advanced technical skills and multidisciplinary collaboration. A Crisis Resource Management Training Program was developed to address specific technical and teamwork training needs of teams caring for this unique patient population. Participants reported in-

creased comfort and confidence participating in code events after course participation.

Cardiothoracic Transplantation

Standard versus bicaval techniques for orthotopic heart transplantation: An analysis of the United Network for Organ Sharing database

Ryan R. Davies, Mark J. Russo, Jeffrey A. Morgan, Robert A. Sorabella, Yoshifumi Naka, and Jonathan M. Chen

A review of 20,999 heart transplants from 1997 to 2007 demonstrates that those performed with biatrial anastomoses require postoperative permanent pacemaker implantation at higher frequency (odds ratio, 2.6; 95% confidence intervals, 2.2–3.1) and have a small but significant disadvantage in survival (hazard ratio, 1.11; 95% confidence intervals, 1.04–1.19) compared with bicaval anastomoses.

Brief Technique Report

Bridge to lung transplantation using short-term ambulatory extracorporeal membrane oxygenation

Abeel A. Mangi, David P. Mason, James J. Yun, Sudish C. Murthy, and Gosta B. Pettersson

PCI vs. CABG

Debate • from page 1

that Debateer trials have shown more equivocal comparisons, particularly in non-diabetic populations, even with bare-metal stents (*Circulation* 2009;120: S967). "We got almost identical survival between bare-metal stents and CABG in multivessel coronary artery disease, and almost identical incidents of death, MI, and stroke at 5 years' follow-up," he said.

"The difference in event-free survival has been shrinking," Dr. Kaul said. He cited the Arterial Revascularization Therapies Study II (ARTS II, *J. Am. Coll. Cardiol.* 2010;55:1093-1101), which showed that patients with multivessel disease who had sirolimus-eluting stents had a rate of major adverse cardiac and

patients with left main artery disease, but this population was too small to stand alone in a published report, Dr. Rodriguez said. However, that cohort showed little variation in clinical events between CABG and either bare-metal or drug-eluting stents. "The only difference was in total vessel revascularization rates."

"Extension of coronary artery disease does not predict better survival with

CABG in any randomized study in the post-DES era," Dr. Rodriguez said. In fact, he argued, first-generation DES in complex coronary artery disease achieved better safety and efficacy at mid-term than did CABG, although long-term outcomes remain unknown.

"Left main stenting can be safely attempted and appears to be—for me at least—first choice in selective cases," Dr. Rodriguez said.

Dr. Kaul wasn't so sure, but he added that a way to improve outcomes is to use a multidisciplinary heart team and pre-operative planning. "It should not be de-

cided on the table by a doctor in the cath lab," he said. "Avoid ad hoc PCI in selective patients with multivessel disease."

For Dr. Kaul, the clinical trials still point to CABG in patients with complex CAD. "If you look at the results from the SYNTAX study, you can see the conclusion was that CABG remains the standard of care for patients with three-vessel disease or left main coronary artery disease, because it results in lower rates of the combined end point of major adverse cardiac and cerebrovascular events."

Neither Dr. Rodriguez nor Dr. Kaul had any relevant conflicts to disclose. ■



The predilection of poor [PCI] outcomes in diabetics has carried into the DES era.

DR. RODRIGUEZ

cerebrovascular events (MACCE) of 27.5% at 5 years compared with 21.1% in the earlier ARTS I CABG trial. But the SYNTAX trial (*N. Engl. J. Med.* 2009;360:961-72) still showed significantly higher rates for MI, repeat vascularization, and MACCE across the board for stenting compared with CABG, Dr. Kaul said. The variations among diabetic patients were even wider.

"Of course, the big difference is in the diabetic population," Dr. Rodriguez acknowledged, and the Bypass Angioplasty and Revascularization Investigation 2 Diabetes (BARI 2D) (*Circulation* 2009;120:2529-40) recognizes this, he said. However, the BARI trial itself showed almost identical survival outcomes in non-diabetics who had either PCI or CABG, he added.

Furthermore, much of the evidence against stenting in multivessel disease was gathered in "the pre-drug-eluting stent era" Dr. Rodriguez said. "These investigators found no significant interaction between the number of diseased vessels and treatment assignment. Thus, the conclusion is that only diabetics are predictable of poor outcomes in multivessel coronary artery disease with CABG." The predilection of poor outcomes in diabetics carried into the DES era, "The only advantage of CABG was in diabetic patients."

However, among study cohorts in the SYNTAX trial, the rates of MACCE among patients who had PCI continued to increase between 1 and 2 years post-procedure, Dr. Kaul said. "So at the limited duration follow-up of 2 years, there was a survival advantage with CABG for almost 80% of patients with three-vessel disease and a SYNTAX score greater than 32, and 65% of similar patients with left main coronary artery disease," he said.

The ERACI II trial (*Circulation* 2008;118:1146-54) included a cohort of

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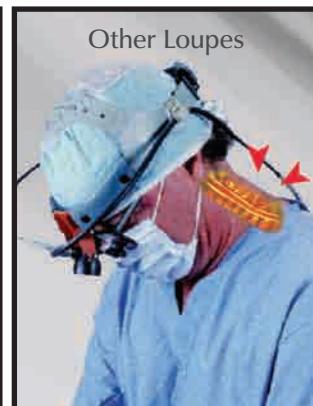


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Selenium Fails to Prevent Second Lung Cancers

BY JANE SALODOF MACNEIL
Elsevier Global Medical News

CHICAGO — Selenium supplementation does not prevent second cancers in survivors of early stage lung cancer—and may even make these patients more vulnerable to new tumors.

Indeed, although the differences did not reach statistical significance, patients who used supplements developed more second cancers, including lung tumors, than those who did not take selenium in a randomized controlled phase III chemoprevention trial that was stopped early for futility.

"We can say for sure that the selenium was not beneficial," Dr. Daniel Karp said at the annual meeting of the American Society of Clinical Oncology, where he presented data on 1,522 patients, who had been randomized from October 2000 to November 2009 and followed for a median of more than 4 years.

As of August 2009, the trial population had developed 216 second primary tumors, including 84 new lung cancers in 83 patients (one patient developed two new lung tumors). The incidence of second primary tumors was 1.91 per 100

person-years followed in the selenium group vs. 1.36 per 100 person-years in the placebo group. Overall, the incidence of second primary tumors of any type after 1 year was 4.11% in the selenium cohort and 3.66% among those who were not given supplementation.

The progression-free survival rate at 5 years was also slightly better in the placebo group (78% vs. 72%), as was overall survival at 3 years (90% vs. 85%) and 5 years (80% and 75%).

The Eastern Cooperative Oncology Group (ECOG) started the intergroup trial after a study failed to show selenium could prevent skin cancers suggested that it could reduce the incidence of lung, colorectal, and prostate cancers by as much as 30% (JAMA 1996;276:1957-63).

The ECOG trial enrolled patients 6-36 months after complete resection of stage 1 non-small cell lung cancer. All had no sign of disease as evidenced by a negative mediastinal node biopsy.

Randomization was 3:1 to 200 micrograms daily of selenium yeast for 4 years or placebo yeast. Dr. Karp, a professor of thoracic/head and neck medical oncology at the University of Texas M.D. An-

derson Cancer Center in Houston, said that most patients had normal selenium levels when they entered the trial.

Particularly concerning, he noted, was that the amount of selenium in the supplement used in the trial is comparable to the amount in most daily multivitamins. "We need to find people who are deficient and make sure they



'We need to find people who are [selenium] deficient and make sure they have a normal amount.'

DR. KARP

have a normal amount," he said, questioning the wisdom of a one-size-fits-all approach that gives supplements to everyone.

While he stopped short of saying people should be dissuaded from taking supplements, Dr. Karp said he emphasizes to his patients that they should eat a healthy diet and stop smoking.

Also noteworthy was that active smok-

ers had a 30% chance of developing lung cancer at 5 years vs. 24% for former smokers and 20% for never smokers. A subgroup of 94 never smokers had a slight trend toward benefit from selenium, he said.

One possibility Dr. Karp suggested in a press briefing is that antioxidants might have a harmful effect in the presence of carcinogens such as tobacco. Another study found worse outcomes—higher incidence of lung cancer and risk of death from the disease—in people who took beta carotene (N. Engl. J. Med. 1996; 334:1150-5).

For Dr. Mark G. Kris, chief of the thoracic oncology service at Memorial Sloan-Kettering Cancer Center in New York City, an important message from the new trial was the high rate of survival in these early-stage patients. The primary focus of efforts to prevent second tumors, as well as lung cancer itself, should be getting people not to smoke, Dr. Kris said at the press briefing, which he moderated.

Dr. Karp disclosed research funding from Pfizer Inc., and Dr. Kris disclosed consulting or advisory roles with seven drug companies. ■

Early Palliative Care Boosts Lung Cancer Survival

BY JANE SALODOF MACNEIL
Elsevier Global Medical News

CHICAGO — Patients who began receiving palliative care when diagnosed with metastatic lung cancer lived longer, were less depressed, and had better quality of life than their counterparts who received only standard care in a randomized phase III clinical trial.

The survival improvement was unexpected, as survival was not an end point of the study, which challenged the traditional paradigm by which palliative care is offered only after treatment options are exhausted. Moreover, it occurred despite less-aggressive end-of-life

care and longer hospice stays in the intervention arm of the trial.

That left 151 patients who were randomized 77 to early palliative care and 74 to standard care. Both groups had a median age of 65 years and were similar with respect to sex, race, and marital status. In response to an audience question, Dr. Temel said the lines of chemotherapy were also identical.

The protocol called for patients in the intervention arm to meet with the palliative care team within 3 weeks of consenting to the trial and at least once a month thereafter; patients in the control arm also could receive palliative care, but by request of the patient, family members, or oncology clinician. While most standard care patients did not see the palliative care team within 12 weeks of entering the trial, 88% of the palliative arm had at least three visits by that time point.

Dr. Temel of Harvard Medical School and Massachusetts General Hospital in Boston emphasized that "the nature of palliative care visits were not scripted or pre-scribed." The team addressed education about lung cancer treatment, symptom management, stress, decision making, and coping, as needed.

By the 12-week benchmark when psychological distress was measured, 27 patients had died—10 in the standard care arm and 17 given palliative care. In addition 10 standard care and 7 palliative care patients did not complete the trial. All were followed until death. Dr. Temel said only 10 were still alive at the time of presentation.

She reported depression was significantly less at 12 weeks whether measured by Hospital Anxiety and Depression Scale (38% vs. 16%, $P = .01$) or the more rigorous Diagnostic and Statistical Manual of Mental Disorders criteria for major depressive disorder (17% vs. 3.5%, $P = .04$). Anxiety was not significantly different.

Quality of life also was better in the early palliative care cohort as measured by the FACT-Lung (91.5 vs. 98.0, $P = .03$) and FACT Trial Outcomes Index (59.0 vs. 53.0, $P = .01$) at 12 weeks. Indeed, both measures im-

proved from baseline in the intervention arm, while declining among patients who received standard care.

More than half (54%) of patients in the standard care arm but only a third of the early palliative care group received aggressive end-of-life care ($P = .05$). The standard care patients were more likely to be admitted to a hospital or emergency room within 14 days of death (55% vs. 39%), spent fewer days in hospice (a median of 4 vs. 11), and were less likely to have documentation of their resuscitation preferences (28% vs. 53%).

Dr. Temel suggested the better quality of life and reduced depression could be caused by better symptom management (along with illness acceptance further reducing depression). As for the gains in survival, she said the investigators hypothesized that it might be related to "earlier recognition and management of medical issues, improved quality of life and mood, less chemotherapy at the end of life, [and] longer hospice admissions."

Dr. Hassan noted and Dr. Temel acknowledged that the trial had a number of limitations, including the large proportion of patients who chose not to participate, a very small proportion with an ECOG performance status of 2, and lack of ethnic and racial diversity. "What component of palliative care intervention resulted in beneficial effect is unclear," Dr. Hassan said.

The investigators are planning another study to address many of the questions raised, such as which services were most used and contributed to the improved survival. "We didn't know what we were going to find, so did not collect all the information needed," Dr. Temel said in an interview.

The current trial was supported by an ASCO Young Investigator Award and the palliative care visits covered by the patients insurance, according to Dr. Temel. "We didn't have reimbursement issues; there may be state-to-state issues," she said.

Asked what prompted her interest in early palliative care, Dr. Temel explained, "The reason I chose to do lung cancer after my fellowship was I wanted to take care of ill patients and dying patients, and it didn't take doing it very long to realize we weren't doing a very good job of it." ■

'I WANTED TO TAKE CARE OF ILL PATIENTS AND DYING PATIENTS, AND IT DIDN'T TAKE DOING IT VERY LONG TO REALIZE WE WEREN'T DOING A VERY GOOD JOB OF IT.'

Patients randomized to early palliative care lived a median of 11.6 months vs. 8.9 months in the control group ($P = .02$), Dr. Jennifer Temel reported at the annual meeting of the American Society of Clinical Oncology. After controlling for age, sex, and ECOG performance status, the adjusted hazard ratio was .59 ($P = .01$).

"It clearly shows that palliative care and active cancer therapy can go hand in hand," said Dr. Raffit Hassan, a senior investigator at the National Cancer Institute, Bethesda, Md., in an invited discussion of the trial. He noted that it was the first randomized study of early palliative care in newly diagnosed lung cancer and called for more randomized studies with survival as a primary end point.

Patients were eligible for the trial within 8 weeks of diagnosis with metastatic lung cancer, if they had an ECOG performance status of 0-2, could read and answer questions in English, and planned to receive care at the tertiary care institution where the study was conducted. From June 2006 to July 2009, 283 patients were screened, but 59 declined to participate, 60 were not invited to participate, 9 were excluded, and the study closed while 4 others were eligible.

Blacks More Likely to Opt Out of Lung Resection

BY MARY ANN MOON
Elsevier Global Medical News

Too many” patients with early stage non-small cell lung cancer forgo potentially curative resection, and the leading risk factor for missing this life-saving opportunity is being black, according to a report in JAMA.

“Patients who do not undergo appropriate surgery face a median survival of less than 1 year and the sequelae of progressive cancer and then death, while those who undergo appropriate surgery have a median survival of more than 4 years” and good quality of life after the surgery, said Dr. Samuel Cykert of the University of North Carolina, Chapel Hill, and his associates.

They examined a cohort of 386 patients who had received a clinical diagnosis of probable stage I or II non-small cell lung cancer but had not yet decided on a treatment plan. The patients were members of five health care systems in North Carolina and South Carolina, which served urban and rural populations in both university and community settings.

More than 90% of the study subjects had health insurance, so access to care was not a major factor in their treatment decisions. Twenty-nine percent were black and the remainder were white.

These patients were being treated by primary care physicians (24%), pulmonologists (40%), thoracic surgeons (20%), or medical oncologists (16%).

The primary outcome of the prospective study was surgical resection within 4 months of diagnosis. Only 241 patients (62%) underwent such resection. The rate was 66% among white patients, compared with only 55% among black patients. However, black patients were significantly younger and therefore better surgical candidates than the whites were and thus likely to benefit more from treatment, wrote the investigators.

When the analysis was restricted to only the 257 patients whose cancers were confirmed by biopsy, the gap between whites and blacks again emerged: 75% of white patients underwent resection, compared with only 63% of black patients, Dr. Cykert and his colleagues said (JAMA 2010;303:2368-76).

Black race was the primary factor associated with the decision to forgo resection. However, a black patient was no more likely than a white patient to refuse resection if it were recommended by a physician. Therefore, it appears that “physicians’ surgical recommendations may have been framed in less favorable terms” when they were addressing black patients, the researchers said.

In particular, black patients who had two or more comorbidities “had a very low chance of surgery, while the same situation in white patients was not associated with a limited rate” of resection. Reports in the literature indicate that even for patients with severe comorbidities, average survival after resection is 3 years, the investigators noted.

Similarly, black patients who lacked a regular source of health care were more likely to forgo resection, whereas white patients in this category were not.

A patient’s perception of poor communication with physicians also lowered the chance that he or she would choose surgical resection, regardless of race. This problem probably was more prevalent among black than among white patients, since previous reports have documented that communication with black patients is characterized by “limited questioning, less dialogue, and fewer explanations,” Dr. Cykert and his associates said.

Other factors associated with the decision to forgo resection, among both groups, were patient age of 73 years or older, the belief that prayer or faith alone could cure cancer, the belief that the cancer diagnosis might be incorrect, and the feeling that overall quality of life would be worse after resection than

without resection.

These findings “suggest the need for preoperative discussions that pay close attention to the prognosis for functional and pulmonary recovery after surgery, compared with expected cancer progression without intervention,” the researchers said.

“Given the consequences of lung cancer surgery decision making and the limited time to reverse course, decisions against surgery should be subject to real-time tracking, be consistently flagged, and systematically readdressed,” they added.

Since physicians in practice are subject to time constraints and are unlikely to be able “to meet all communication needs,” the researchers suggested that a cancer educator who is trained in active listening, patient-centered communication, and teach-back methods might be helpful.

“This supernavigator could serve as a physician communication extender who addresses unmet needs beyond the limits of clinical visits [and who] could identify misperceptions of process, surgical risk, and long-term prognosis while providing a forum to vent concerns and resolve them,” they said.

The study was funded by the American Cancer Society. Dr. Cykert and his associates reported no financial conflicts. ■

AATS 91ST
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CALL FOR ABSTRACTS

Submission Deadline
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**2010 Heart Valve Summit:
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ventional Decision-Making
October 7 - 9, 2010
Chicago Marriott Downtown
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The American College of Cardiology Foundation (ACCF) and the American Association for Thoracic Surgery (AATS) have once again joined together to develop a unified program, the 2010 Heart Valve Summit, that will provide a stimulating and in-depth look at valvular heart disease from both a cardiology and surgical point-of-view.

Using an integrative approach to managing medical, surgical, and interventional

challenges in valvular heart disease, world renowned cardiologists and cardiac surgeons will provide clinically relevant data on the current and future directions in valvular heart disease. Geared towards practicing clinicians across multiple disciplines, this unique program will include real world interactive case-based patient management discussions, review of current practice guidelines and focused breakout sessions.

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REGISTRATION

Space is limited, register today at www.acc.org/HVS2010.

Please note that if you are a member of AATS, ASE, SCAI or STS, you must submit your

registration form through fax or mail to receive the member rate.

ACCREDITATION

Physicians:

The American College of Cardiology is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The ACCF designates this educational activity for a maximum of 18.25 AMA PRA Category 1 Credits™. Physicians should only claim credits commensurate with the extent of their participation in the activity.

Nurses:

The American College of Car-

diology Foundation is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

The ACCF designates this educational activity for a maximum of 18.25 continuing education hours. Requirements for successful completion are attendance in a session in its entirety and completing the evaluation tool.

Each attendee should only claim credits commensurate with the extent of their participation in the activity.

While offering credits noted above, the program is not intended to provide extensive training or certification in the field. ■

Cardiothoracic Surgery Funding and Grants

NCI: Clinical Proteomic Technologies for Cancer Initiative (CPTC): Proteome Characterization Centers (U24)

In an effort to build upon the proteomic standards, technologies, standard operating procedures, workflows, and reproducibility of protein identification and quantification developed through the Clinical Proteomic Technologies for Cancer initiative (CPTC); the NIH is soliciting grant applications to build a multidisciplinary collaborative team of Proteome Characterization Centers (PCCs). These PCCs are expected to advance multi-institutional and trans-disciplinary interactions using data and selected biospecimens from cancer genomics programs to systematically define the functional cancer proteome that derives from alterations in cancer genomes, discover and verify protein (and peptide) biomarkers, and in doing so, drive the development of proteomic technologies. Application Receipt Date: September 29, 2010

For more information or to apply: <http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-10-016.html>

NHLBI: New Strategies for Growing 3D Tissues (R01 and R21)

Two Funding Opportunity Announcements have been issued that seek to improve the understanding of how cells respond to their environment and to develop accurate assays and methods to understand how organogenesis may instruct the creation of functional 3D engineered cellular aggregates. This program will require collaborations of scientists from two or more disciplines such as developmental biology, computational science and systems biology, cell biology, tissue engineering, chemistry, physics, or organ physiology. Use of the multiple PI mechanism is strongly encouraged.

For more information on R01: [http://grants.nih.gov/grants/guide/rfa-](http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-10-016.html)

files/RFA-HL-11-025.html

For more information on R21: <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-11-026.html>

NHLBI Request for Information: Ideas for improvements in a research network to advance the treatment science of critically ill patients with Acute Lung Injury

This Notice is a Request for Information (RFI) for ideas to update and improve the structure of NHLBI-supported clinical research network of pulmonary and critical care investigators and to seek research ideas that have the most promise to improve outcomes in the intensive care unit.

NHLBI requests input on new approaches to clinical trials that might be incorporated into a network, opinions on whether the scope of research questions previously addressed by ARDSnet should change, how input from the community and basic science might be fed into a network, and identification of the most important research questions that can improve patient outcomes in the intensive care unit.

To respond by September 10, 2010, please complete and submit the form on line at: www.surveymonkey.com/s/TRF6CRN

NHLBI announces Pediatric Heart Network Clinical Centers & Data Coordinating Center Funding Opportunities

The NHLBI has issued two Funding Opportunity Announcements to support the Clinical Center and Data Coordinating Center for the Pediatric Heart Network. The mission of the Network is to improve the health and quality of life for children, adolescents, and young adults with congenital and acquired heart disease through multicenter collaborative clinical research. The Network provides an infrastruc-

ture to permit multicenter evaluation of medical, interventional, and surgical therapies; to serve as a training platform for fellows, junior faculty, and nurses; and to disseminate results of studies to improve the scientific basis for the care of affected individuals

NHLBI requests applications to participate as a Clinical Center or Data Coordinating Center in the Network, a cooperative network of pediatric cardiovascular clinical research centers. The goal of the Network is to evaluate therapeutic and management strategies for children and adults with congenital heart defects and for children with inflammatory heart disease, heart muscle disease, and arrhythmias through multicenter clinical research.

Letters of Intent Receipt Date: September 29, 2010

Application Receipt Date(s): October 29, 2010

For more information, please visit: <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-11-010.html> for Clinical Center or <http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-11-027.html> for Data Coordinating Center.

NIH R01 Award Announcement to Support Bioengineering Research Partnerships

The NHLBI and NCI invite applications for R01 awards to support Bioengineering Research Partnerships for basic, applied, and translational multidisciplinary research that addresses important biological, clinical, or biomedical research problems. In the context of this program, a partnership is a multi-disciplinary research team, that applies an integrative, systems approach to develop knowledge and/or methods to prevent, detect, diagnose, or treat disease or to understand health and behavior. The Partnership must operate according to a clear leadership plan and include appropriate bioengi-

neering or allied quantitative sciences in combination with biomedical and/or clinical components. Partnerships may propose, within a 12-page research strategy section, design-directed, developmental, discovery-driven, or hypothesis-driven research at universities, national laboratories, medical schools, large or small businesses, or other public and private entities or combinations of these entities, and will be evaluated against expanded review criteria. It is expected that a Partnership will have a well-defined goal or deliverable that will be achieved in a 5-10 year time frame based on objective milestones specified in the initial application. For more information, please visit: <http://grants.nih.gov/grants/guide/pa-files/PAR-10-234.html>. ■

Online AATS Membership Applications

Applications for membership in the Association are now available online at www.aats.org. Interested applicants are encouraged to review the membership requirements and guidelines on the AATS Website.

To apply for membership a current member of the Association must act as the primary sponsor by initiating the application process in the Members Only area of the AATS Website. Applications must be received by November 30, 2010 for consideration. All applications received after that deadline will be automatically deferred until November 2011. ■

New – 2011 Mitral Conclave, Call for Abstracts & Videos



The Abstract and Video Submission Deadline for the 2011 Mitral Conclave is **January 7, 2011**. Visit www.aats.org/mitral to submit.

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The 2011 MITRAL CONCLAVE will bring the world's leading figures in mitral valve disease together for two days of incisive discussion. Faculty presentations of the latest available data, techniques, and state of the art reviews will be supplemented by abstract and video presentations selected by the program committee from submitted original work. Selected manuscripts from accepted presentations will be considered for publication in a supplement to *The Journal of Thoracic and Cardiovascular Surgery*.

Authors submitting abstracts and videos for 2011 MITRAL CONCLAVE must use electronic submission ONLY. Abstracts are limited to 400 words. You may use ONE image OR ONE table within your abstract which will NOT deduct from the word count.

Accepting Abstracts and Videos in the following categories:

- Degenerative Valve Disease
- Mitral Regurgitation in Heart Failure
- Novel Repair Techniques
- Other Mitral Valve Disease
- Outcomes Following Mitral Valve Surgery
- Tricuspid Valve Disease

Video Submissions:

All video submissions must be accompanied by an abstract with a maximum of 400 words submitted via the abstract submission site. Two copies of the video must be mailed to the Association offices by the January 7 deadline and may not exceed 5 minutes in length. Complete submission guidelines can be found online at www.aats.org/mitral.

Log on to the 2011 MITRAL CONCLAVE Website at www.aats.org/mitral and select the Abstract and Video Submission Link. Specific instructions for abstract and video submissions are located on the website, including how to submit images or tables.

Abstracts and videos must be received by **Friday, January 7, 2011** by 11:59 p.m. Eastern Standard Time.

Accreditation:

The American Association for Thoracic Surgery is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

This activity has been approved for AMA PRA Category 1 Credits™.

Save the Date for the 91st AATS Annual Meeting

May 7 – 11, 2011

Pennsylvania Convention Center Philadelphia, PA

Join us in Philadelphia from May 7–11, 2011 for the American Association for Thoracic Surgery's 91st Annual Meeting. This robust, high-quality five-day program, chaired by Irving L. Kron, M.D., of the University of Virginia, is designed with a primary focus on delivering cutting-edge education to improve cardiothoracic surgical practice. Gather with the world's leading scientists and medical professionals in the specialty at this premier continuing medical education event.

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The AATS Annual Meeting is specifically designed to meet the educational needs of:

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- Fellows and Residents in Cardiothoracic and General Surgical training programs
- Allied Health Professionals involved in the care of cardiothoracic surgical patients including Nurses, Physician Assistants, Perfusionists, and Allied Health Professionals involved in the care of cardiothoracic surgical patients
- Medical students with an interest in cardiothoracic surgery

AATS Annual Meeting Accreditation

The American Association for Thoracic Surgery is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

This activity has been approved for AMA PRA Category 1 Credit(s)™.

CALL FOR ABSTRACTS:

Authors submitting abstracts must use electronic submission ONLY. Please visit <http://aats2011.abstractcentral.com> to submit an abstract. Specific instructions for abstract submission are located on the website, including how to submit graphics and charts. Manuscripts are due in advance of the meeting for all accepted abstracts. Please note: Videos and PowerPoints are not accepted as part of abstract submissions for the 2011 AATS Annual Meeting. **For the first time in 2011, the AAATS encourages submissions in Endovascular/Transcatheter Valve.**

Presentation Types include:

- Regular Session
- Laboratory Research Forum
- Emerging Technologies Forum
- C. Walton Lillehei Resident Forum

Abstracts may be submitted for the following categories:

- Adult Cardiac
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- Endovascular Transcatheter Valve—**NEW IN 2011!**
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Lillehei Resident Forum

Residents are encouraged to submit abstracts, based on basic science, for the 14th Annual C. Walton Lillehei Resident Forum which will consist of presentations of original work by North American thoracic surgical residents and/or residents in general surgical training programs who are working in a cardiothoracic surgical laboratory or clinical rotation. The presentations are selected by the AATS Cardiothoracic Residents' Committee.

For further info on submitting abstracts please visit www.aats.org.

2010/2011 AATS Meetings & Sponsored Events

September 21- 25, 2010

TCT for Surgeons*
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September 30 - October 2, 2010

Cardiovascular - Thoracic (CVT)
Critical Care 2010**
Omni Shoreham Hotel
Washington, DC

October 7 - 9, 2010

Heart Valve Summit 2010
Chicago Marriott
Downtown Magnificent Mile
Chicago, Illinois

October 21 - 22, 2010

21st Century Treatment of Heart Failure 2010*
The InterContinental Hotel and Bank of

America Conference Center
Cleveland, Ohio

December 9 - 11, 2010

Dallas Leipzig International Valve*
Westin Galleria Hotel
Dallas, Texas

December 9 - 11, 2010

Multidisciplinary Symposium in Thoracic Oncology**
Hilton Chicago
Chicago, Illinois

February 10 - 13, 2011

11th Annual International Symposium on Congenital Heart Disease*
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March 5, 2011

Grant Writing Workshop

Bethesda Marriott
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May 7 - 11, 2011

AATS 91st Annual Meeting
Pennsylvania Convention Center
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Percutaneous or Surgical AVR for High-Risk Patients?

BY RICHARD M. KIRKNER
Elsevier Global Medical News

NEW YORK — Percutaneous aortic valve repair may be the preferred procedure in high-risk patients with aortic stenosis, according to Dr. Jeffrey Popma of Beth Israel Deaconess Medical Center, Boston. He and Dr. Satyavan Sharma debated the merits of surgical aortic valve repair (AVR) vs. percutaneous repair in high-risk patients at the Mt. Sinai Symposium of Complex Coronary and Vascular Cases. Dr. Sharma is professor of cardiology at Bombay Hospital and Medical Research Center in Mumbai.

The high-risk patient profile was composed of people aged 80 years and older, and those with a host of comorbidities such as chronic occlusive pulmonary disease, renal failure, peripheral vascular disease, coronary artery disease, history of stroke, or previous cardiac surgery. Dr. Sharma noted the “impressive results” of one trial involving octogenarians who had surgical AVR: a 30-day mortality of 9% and 5-year survival of 56%.

Dr. Sharma pointed to the limitations of Euroscore, a widely used scoring system to predict the mortality of surgical AVR and select patients for percutaneous AVR. Several publications have emphasized that Euroscore overestimates the surgical mor-

tality and is not an ideal scoring system for selecting patients for percutaneous AVR. It is likely that some patients eligible for surgical AVR are denied the procedure because of assumptions of high mortality by Euroscore, he said.

Dr. Popma noted that an 80-year-old patient has a mortality risk of 2.9% in the Society for Thoracic Surgery database “with no other comorbidity risk factors.” These patients are often otherwise “healthy” when going into surgery, he noted. “But the question is, are all symptomatic patients with aortic valve stenosis now being treated with surgical AVR? The answer is no,” Dr. Popma said. “As a matter of fact, about 50% of patients with aortic stenosis are deemed not suitable operative candidates by cardiologists or primary care providers.”

A recent abstract from the EuroPCR meeting reported on patients with aortic valve disease who had either surgery, percutaneous AVR, or no intervention. The latter group “did awfully,” Dr. Popma said, with significant mortality rates at 2 years. “There is clearly an unmet need, and these are the patients who are not necessarily nonoperable but are simply high risk,” he added.

Percutaneous AVR carries with it a number of challenges, Dr. Sharma said. No calcified valves, particularly bicuspid

valves, are suitable for percutaneous AVR, he said. Noncircular stent deployment is common in bicuspid valves and can lead to premature failure of the valve.

“The procedure looked very simple to us when there was a demonstration from



About 50% of patients with aortic stenosis are deemed not suitable operative candidates.

DR. POPMA

a highly technically efficient center, but there are all sorts of complications that can occur from transcatheter AVR—access and delivery site complications, complications in positioning and deployment, and a very high incidence of complete heart block,” Dr. Sharma said. Further, he called the need for permanent pacing in the core valve “disturbingly high”—in the range of 10%-25%.

Patients with peripheral vascular disease and access site tortuosity are not suitable for percutaneous AVR, he said. The transapical approach requires surgical assistance and left ventricular puncture. Still, the overall success rate of

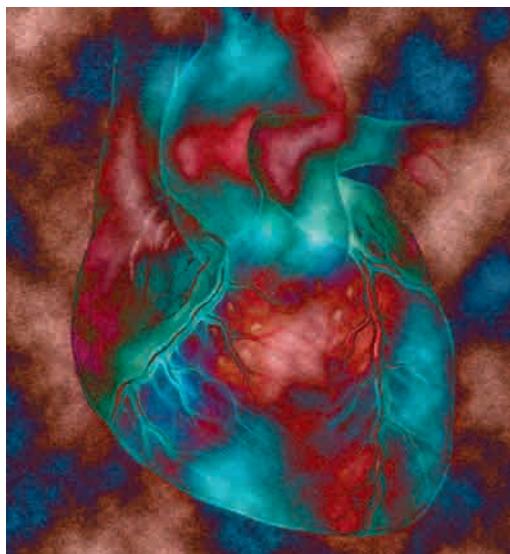
percutaneous valve implants is 85%-90% in most experienced centers, although failure rates can be high early in a surgeon’s experience, he added.

Dr. Popma acknowledged the Italian TAVI (transcatheter aortic valve implantation) registry showed that 50% of treated patients died of noncardiac causes 30 days after the procedure out to 2 years with conservatively defined stroke rates of 9.6% in the initial series. However, results are improving with better case selection. “Fortunately and more to the question of embolic protection, the stroke rate is much lower in those now treated in recent concurrent registries,” he said.

“Surgical AVR is a time-honored technique and remains supreme,” Dr. Sharma concluded. “We do need to define certain issues better: an accurate definition of the patient ineligible for surgical AVR, a better definition for successful treatment and clinical follow-up, and durability of the prosthetic valve.”

He anticipates that trials in the United States and Europe, including the PARTNER (Placement of Aortic Transcatheter Valve) now underway, should yield some answers.

Dr. Popma disclosed relationships with Abbott Pharmaceuticals, Boston Scientific, Cordis, and Medtronic. Dr. Sharma has no relevant disclosures. ■



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Hyperoxia After Resuscitation Raised Mortality

BY MARY ANN MOON
Elsevier Global Medical News

Highly concentrated supplemental oxygen given after cardiac arrest often led to arterial hyperoxia, which in turn raised the risk of in-hospital mortality, according to an observational study.

Ironically, mortality rates after exposure to too much oxygen were greater than mortality rates after oxygen deprivation—the very indication for which supplemental oxygen is given, said Dr. J. Hope Kilgannon of the department of emergency medicine at Cooper University Hospital, Camden, N.J., and her associates (*JAMA* 2010;303:2165-71).

"This is the first large multicenter study documenting the association between [post-resuscitation] hyperoxia and poor clinical outcome," the researchers noted. "These data support the hypothesis that high oxygen delivery in the post-cardiac arrest setting may have adverse effects."

Current American Heart Association guidelines for cardiopulmonary resuscitation advocate the use of 100% oxygen to maximize the chance of restoring spontaneous circulation. "However, after circulation is successfully restored, clinicians frequently maintain [supplemental oxygen] for variable periods," the investigators said.

Controversy has arisen recently regarding that routine practice, because it is feared that too much oxygen may trigger neuronal injury and apoptosis. However, there has been a lack of clinical data on the issue, they added.

Dr. Kilgannon and her colleagues used data from a network of adult intensive-care units across the United States to study the question. The database included medical, surgical, and multidisciplinary ICUs from a variety of community, academic, private, public, urban, suburban, and rural hospitals.

They assessed 6,326 adults who received CPR after nontraumatic cardiac arrest and were admitted to a participating ICU in 2001-2005. Hyperoxia was defined as an arterial partial pressure of oxygen (PaO_2) of 300 mm Hg or greater on the first arterial blood gas obtained on admission.

Hyperoxia was common, affecting 18% of patients. Approximately half of those patients had a PaO_2 of 400 mm Hg or greater. Most patients (63%) developed hypoxia, defined as a PaO_2 of less than 60 mm Hg, and the remaining 19% maintained normal blood oxygen levels.

In-hospital mortality was greatest in the group with hyperoxia, at 63%, compared with 57% in the hypoxia group and 45% in the normoxia group, Dr. Kilgannon and her associates said. A further analysis of the data revealed that hyperoxia was an independent and strong predictor of in-hospital death (732 of 1,156 patients).

Moreover, patients with hyperoxia who survived to hospital discharge were significantly more likely to have poor functional outcomes (38%) than those with normoxia (29%).

Analogous to the concept that hyperoxia exposure may be associated with harm in the resuscitation of neonates, the ongoing oxidant stress with hyperoxic reperfusion may be capable of worsening anoxic brain

injury in adult patients with post-cardiac arrest syndrome," the researchers said.

The observational study could not determine causality, but its findings "provide scientific rationale for clinical trials of controlled reoxygenation during the postresuscitation period," they added.

The true incidence of hyperoxia is probably much higher than 18%, given that the investigators used "a rather conservative definition" of the disorder, noted Dr. Patrick M. Kochanek and Dr. Hülya Bayir of the University of Pittsburgh in an editorial comment accompanying the report.

They concurred that a large clinical trial of the issue is warranted to resolve whether clinicians should be more meticulous about titrating oxygenation after cardiac arrest, "and whether an alarm threshold should be set for arterial saturation ... after return of spontaneous circulation" (*JAMA* 2010;303:2190-1).

In addition, "unconventional resuscitation strategies that [have been] considered but heretofore unproven (such as intermittent, controlled, or even delayed reperfusion)" are now being investigated, they said.

The study was supported by the Emergency Medicine Foundation, the National Institutes of Health, the National Institute of General Medical Sciences, and the National Heart, Lung, and Blood Institute.

Dr. Kilgannon had no financial disclosures. One of Dr. Kilgannon's associates reported receiving support from Ikaria Inc. and Spectral Diagnostics Inc. Dr. Kochanek reported being a co-patent holder on Emergency Preservation, and Resuscitation. ■

Transapical Implants Match Transfemoral Outcomes

BY MITCHEL L. ZOLER
Elsevier Global Medical News

TORONTO — Using a transapical approach for aortic valve implantation produced safety and efficacy outcomes as good as those from transfemoral aortic valve replacement in a series of 299 patients treated at the University of Leipzig, Germany, the largest series of transapical aortic valve replacements collected to date.

"There is no evidence for a 'transfemoral first' approach. I would go 50:50," Dr. Thomas Walther said at the meeting.

"There are some clear indications" for each approach. Transapical works better for patients with poor peripheral vessels, while transfemoral hold the edge for patients with poor lung function because it doesn't require intubation. "But otherwise you can do either, and you should do a 50:50 split," said Dr. Walther, formerly with the Leipzig group and now medical director of thoracic and cardiovascular surgery at the Kerckhoff Clinic in Bad Nauheim, Germany.

"Transapical is slightly better [than transfemoral] because it uses an antegrade approach so you can better direct and more precisely implant the valve," he said in an interview. The antegrade approach also makes wire adjustments easier, and the stepwise inflation that transapical makes possible is another advantage.

But transcatheter valve replacement currently sits on procedural turf that's

split between cardiologists and cardiothoracic surgeons. Cardiologists generally favor the transfemoral approach, and it's diplomatic to let them do roughly half the cases, while surgeons handle the rest, usually with the transapical approach, Dr. Walther said.

Deciding whether to perform aortic valve replacement by a transcatheter approach or by open surgery raises another issue that requires careful judgment. Dr. Walther and his former colleagues in Leipzig adhere to the 2008 recommendations of the European Society of Cardiology and the European Association of Cardio-Thoracic Surgery, which favored transcatheter valve replacement over open surgery only for elderly, high-risk patients or those with contraindications for open surgery (*Eur. Heart J.* 2008;29:1463-70). The recommendations said that clinical judgement should be the main determinant of which patients had high risk, along with quantitative scoring methods such as the logistic EuroScore and the Society of Thoracic Surgeons (STS) predicted risk of mortality score.

These limitations for transcatheter valve replacement continue to make sense because open surgical repair has a very low mortality rate of 1%. "What could do better than that?" he said. Open replacement "gives good hemodynamic function and has proven long-term durability. With the transcatheter approach you always have the risk of a paravalvular leak, which may pose problems especially in younger patients who

exercise. Plus, new procedures [such as transcatheter valve replacement] have some inherent risks. To match a mortality rate of 1% is very difficult."

Transcatheter valve implantation has not yet received U.S. marketing approval from the Food and Drug Administration.

The Leipzig group performed 299 transapical aortic valve implantations since it started in 2006 through the beginning of 2010, as well as a roughly equal number of transfemoral implantations. The average age of the transapical patients was 82, and 70% were women. Their average logistic EuroScore was 31%, and their average STS score was 12%. Ninety percent of the procedures occurred off pump. Thirty-day mortality in the patients was 8.7%. A total of 28% died during an average follow-up of about 16 months (the longest follow-up was 4 years). Cardiac mortality predominated, followed by respiratory causes of death.

Thirty-two patients had a periprocedural complication, such as need for a second valve, conversion to open surgery, or need for cardiopulmonary bypass. Thirty-day mortality in this subgroup was 31%. In the remaining 267 patients, 30-day mortality was 6%.

The logistic EuroScore provided a good indication of how likely patients were to die following valve implantation. The series included 80 patients with a EuroScore of less than 20%; their average EuroScore was 15%, and their average STS score was 9%. Their 30-day mortality was 5%, and total mortality during complete follow-up was 22%.

A second subgroup of 142 patients

had a EuroScore of 20%-40%, with an average score of 29% and an average STS score of 12%. Their 30-day mortality was 10%, with 25% overall mortality during complete follow-up. The remaining 77 patients had a EuroScore of more than 40%, with an average EuroScore of 53% and an average STS score of 17%. In this sickest group, 30-day mortality was also 10%, but a total of 39% died during complete follow-up.

Two patients had a stroke within the first 30 days following their procedure, with one additional stroke occurring during full follow-up. One patient developed endocarditis. Two patients required reoperation for aortic insufficiency within the first 6 weeks, and 15% of patients needed temporary renal replacement therapy.

Using echocardiography, the surgeons found mild aortic insufficiency in 37% of patients immediately after surgery, and in 54% after 1 year. During longer follow-up the prevalence remained at about this same level. Moderate aortic insufficiency appeared in 4% right after surgery, and held at a level of 4%-5% during up to 3 years of follow-up.

Follow-up telephone interview of 80 patients an average of 1.7 years after their procedure showed that on average these long-term survivors had a quality of life that closely matched historical octogenarian controls who had not undergone aortic valve implantation.

Overall, the findings show that transapical aortic valve implantation is a reasonable, minimally invasive option for high-risk patients, he concluded.

Dr. Walther said that he has received honoraria from Edwards Lifesciences. ■



FROM THE ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR THORACIC SURGERY

Changes to Senning and Mustard Lowered Morbidity

BY MARK S. LESNEY
Elsevier Global Medical News

TORONTO — The double-switch operation for congenitally corrected transposition of the great arteries prevents long-term systolic dysfunction of the systemic ventricle. The Senning and Mustard procedures for simple transposition have demonstrated significant long-term morbidity, specifically related to sinus node dysfunction and superior vena cava baffle obstruction, according to Dr. Sunil P. Malhotra of the University of Florida and his colleagues.

At the meeting, they discussed the use of a modified atrial switch, consisting of a Hemi-Mustard to baffle inferior vena cava return to the tricuspid valve in conjunction with a bidirectional Glenn (BDG), to avoid such complications. They postulated that right ventricle (RV) unloading may lessen the impact of RV dysfunction, prolong the life of the RV-pulmonary artery (PA) conduit, and decrease tricuspid regurgitation.

In addition, simplifying atrial baffle may reduce sinus node dysfunction and atrial dysrhythmias as well as systemic and pulmonary venous pathway obstruction, and it might be helpful with positional anomalies such as situs solitus with dextrocardia, mesocardia, and situs inversus.

Their study involved 56 patients with congenitally corrected transposition of the great arteries (cc-TGA) who were managed surgically between January 1993 and September 2009. Prereconstruction pulmonary banding was performed using a strict protocol whereby all patients except for the younger patients are banded for at least a year. "We then restudy them looking at ECHO, CATH, and MRI characteristics, looking at appropriate LV function and increase of LV mass," said Dr. Malhotra.

The subsequent anatomic repair was achieved in 48 of the 56 patients (86%). The other eight patients also received pulmonary banding in preparation for eventual reconstruction; of those, five appeared to be progressing but had not yet



FROM THE ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR THORACIC SURGERY

reached appropriate LV mass and function at the time of the study, and three appeared unlikely to achieve appropriate function, according to Dr. Malhotra. For those three, medical management would be the choice since they do not meet the requirements for transplantation, he added.

There were positional anomalies in 17 of the 48 reconstruction patients (35%). The median age of these patients was 3.0 years (range 3.9 months to 24 years).

The Rastelli and atrial switch (RAS) was performed in 25 patients, 22 with pulmonary atresia and 3 with severe subpulmonary stenosis. An arterial/atrial switch (AAS) was performed in 23 patients, 17 of whom required a pulmonary artery bypass (PAB). A Hemi-Mustard was the atrial switch for 33 of 48 anatomic repairs (69%). The Hemi-Mustard patch used was always a simple circle that bent appropriately around the tricuspid valve annulus and inferior vena cava orifice. The conventional atrial baffle procedure was performed in the other 15 patients when BDG was contraindicated.

There was one in-hospital death (2.1%) following anatomic repair, and there have been no late deaths to date. None of the patients have required cardiac transplantation. Postoperative extracorporeal membrane oxygenation support was required in 2 patients, and postoperative heart block occurred in 10 of 48 patients (21%).

At a median follow-up of 59.3 months (range 3 months to 14.2 years), 43 of 47 survivors were in New York Heart Association class I status. Normal left ventricular systolic function was demonstrated by follow-up echocardiography in 41 of 47 patients (87%). All patients were acyanotic. There have been no baffle-related reoperations. Tricuspid regurgitation decreased significantly from a mean grade 2.3 to 1.2 after repair.

The Hemi-Mustard results compared favorably with those reported for the standard Senning-Mustard procedure, according to Dr. Malhotra. Among the

33 patients with the Hemi-Mustard procedure, there was no baffle obstruction or sinus node dysfunction. According to the literature, 5%-15% of Senning-Mustard patients had baffle obstruction, and 35%-46% had sinus node dysfunction. Similarly, there was just one atrial tachyarrhythmia requiring ablation with the Hemi-Mustard procedure vs. a rate of 8%-15% in Senning-Mustard patients.

monary vascular resistance.

Dr. David Barron, the designated discussant, asked about the necessity of epicardial pacing and repeat surgery resulting from heart block in patients with a BDG. "It is one of the drawbacks of this approach that it limits the access for pacing procedures. But we think the benefits certainly outweigh the downsides of that," Dr. Malhotra stated.

In answer to Dr. Barron's question regarding the functional difference between this type of procedure and a full biventricular repair, Dr. Malhotra said that, based on follow-up, he felt there was no evidence that functional results were unacceptable.

"A 15-year experience with anatomic repair for cc-TGA using a modified atrial switch has shown favorable midterm results. Cardiac transplantation was avoided in all cases, and excellent functional status was observed at follow-up," Dr. Malhotra concluded.

Dr. Malhotra reported that he had no conflicts of interest in this study. ■

WITH THE HEMI-MUSTARD PROCEDURE, NO BAFFLE OBSTRUCTION OR SINUS NODE DYSFUNCTION WAS SEEN.

The two BDG complications that occurred in infants under 4 months of age led Dr. Malhotra to conclude that the Hemi-Mustard procedure should be avoided in the youngest patients who are at highest risk of elevated pul-

Don't Dismiss Senning?

COMMENTARY This study showed a 20% incidence of heart block across the series. This is not unusual; it is part of the underlying condition and is also a recognized high incidence after this sort of surgery. But what concerns me is that if you have a bidirectional Glenn, that really limits your options for pacing now and pacing in the future. And this is committing those patients to epicardial systems and repeated surgeries. It thus seems to me that the heart block is more of a concern than sinus node dysfunction. In addition, in defense of the Senning, it appears that the problems occur from the Mustard, rather than from the Senning. The arrhythmia complications are much more likely from the full Mustard than the full Senning. There is also quite good

evidence, I think, that the functional capacity of the physiology of this type of 1 and 1/2 repair compared to a true biventricular repair is significantly different. And even though this is shown to be a very safe operation, with outstanding results, my feeling is that we should not dismiss the Senning. This study showed they actually got excellent results with the Senning, and certainly I believe you get a better functional result with the full Senning.

DR. DAVID J. BARRON, F.R.C.S., is a consultant cardiac surgeon at Birmingham (England) Children's Hospital. He was the designated discussant at the meeting, and reported that he had nothing to disclose with regard to his remarks.

Observation May Suffice After Ascending Aorta Procedure

BY RICHARD M. KIRKNER
Elsevier Global Medical News

NEW YORK — Observation is an acceptable alternative to surgical management of ascending aortic dilatation in adult patients with congenital heart disease, judging by a series of 81 patients with long-term follow-up.

Thoracic surgeons have long disagreed over the need for repairing a dilated ascending aorta during aortic valve repair in such patients. The controversy surrounding the need for per-

forming prophylactic surgery of the moderately dilated ascending aorta during aortic valve repair centers on how large the dilatation should be before starting a repair, and what types of patients should have the preventative operation, Dr. John M. Stulak said at the American Association for Thoracic Surgeons Aortic Symposium 2010.

To assess the risk of progressive ascending aortic dilatation or dissection in patients with congenital heart failure, Dr. Stulak and his colleagues at the Mayo Clinic in Rochester, Minn., ana-

lyzed data on 81 patients with congenital heart failure who were followed over 35 years; 53 had isolated aortic valve repair and 9 had combined valve and ascending root repair (7 had aortic root replacement, and 2 had aneurysm repair). Patients ranged in age from 18 to 59 years. Four patients in the entire series required reoperation during a median follow-up of 3.8 years.

After the initial operation, 96% of the patients in the study remained free from reoperation on the ascending aorta or aortic valve at 5 years and 90% at 8 years. Indications for subse-

quent operations were leakage of the prosthetic valve, severe aortic regurgitation after intensive aortic valve repair, and aortic root replacement caused by aneurysm.

"Moderate aortic enlargement is common in patients with conotruncal abnormalities," said Dr. Stulak, noting that these patients often require multiple procedures and the pathologies of their ascending aortas are frequently abnormal. "However, late aortic events—that is, dissection or aortic reoperation—are rare," he added. "The moder-

ately dilated aorta in the setting of a conotruncal abnormality, especially in patients undergoing isolated aortic valve replacement, may be observed.

"Importantly, there have been no late reoperations on the ascending aorta either after reduction ascending aortoplasty or supracoronary replacement of the ascending aorta," Dr. Stulak said. "In addition, to date there are no known late ascending aortic dissections in these patients."

Dr. Stulak had no disclosures relevant to his presentation. ■

Lung Transplant Survival

Center • from page 1

75%—rates that far exceed the average 3-year survival of 64%" reported nationally, they noted.

Data from the United Network for Organ Sharing was used. UNOS is a registry that includes all lung transplant cases since the first procedure was performed in 1987. They examined outcomes for 15,642 procedures. Approximately 13% were done in centers that performed fewer than 10 lung transplants annually, 39% in centers that performed 10-25 annually, 41% in centers that performed 25-50 annually, and 7% in centers that performed more than 50 annually.

Thus, transplant centers varied by as much as tenfold in the number of procedures they performed each year, the researchers noted.

Overall, median 1-month survival was 93%, 1-year survival was 80%, 3-year survival was 63%, and 5-year survival was 50%. Survival varied markedly among the different centers: In all, 1-month survival was 89%-95%, 1-year survival was 68%-85%, 3-year survival was 45%-72%, and 5-year survival was 30%-61%.

This variation in survival persisted after the data were adjusted to control for differences among transplant centers in donor selection, recipient selection, and surgical approaches. This finding "sug-

gests that centers may exhibit true differences in the quality of care provided during or following transplantation," Dr. Thabut and his associates said (JAMA 2010;304:53-60).

"That our central results remained unchanged through a series of sensitivity analyses testing these and other potential influences therefore strengthens considerably the conclusions that can be drawn. Specifically, our results suggest that the influence of center on survival after transplantation is large and... may be of comparable magnitude to the influence of recipient age," they noted.

In general, survival correlated with the volume of procedures performed, with high-volume centers showing better patient survival than did medium- or low-volume centers. However, volume accounted for only 15% of the variability among centers, and that variability remained strongly significant after the volume of procedures was controlled for.

Survival rates were most varied during the first year after transplant, then tended to become similar across transplant centers. This suggests that "there may be undue variability in centers' perioperative and early postoperative practices." It also indicates that "differences in surgical expertise might contribute to center

variability," the researchers said.

Unfortunately, the UNOS data were not sufficient to distinguish between a "center effect" and a "surgeon effect" on survival, because the registry does not include surgeon identities or practice characteristics that would indicate the surgeon's level of expertise.

The study findings suggest that it might be possible to identify specific practices that favor survival at high-performing centers, so that low-performing centers can adopt those practices and improve their outcomes. "The fact that some low-volume centers achieve good outcomes... suggests that excellence in lung transplantation is not merely a 'practice makes perfect' phenomenon," Dr. Thabut and his colleagues said.

In the meantime, clinicians may want to provide patients with center-specific outcome data so they can make more informed decisions as to which transplant center to attend. This information could be particularly important to patients who have conditions that benefit only modestly from lung transplantation, such as chronic obstructive pulmonary disease. "For such patients, the choice to be listed for transplantation or not could be sensitive to even moderate differences in the expected outcomes among local centers," they noted.

Dr. Thabut was supported by AstraZeneca and the Public Assistance Hospital of Paris, and an associate was

supported by the U.S. Agency for Healthcare Research and Quality. In an accompanying editorial (JAMA 2010;304:95-7) Dr. Edward H. Livingston, of the University of Texas Southwestern Medical Center, Dallas, and contributing editor to JAMA and Jing Cao, Ph.D., at Southern Methodist University, Dallas stated: The volume of lung transplant procedures was found to be significantly related to survival, such that centers that performed more transplants had better survival outcomes. Yet only 15% of the variance in survival among lung transplant centers could be attributed to annual procedural volume. How could such a small effect be statistically significant?

"The overall significance of center volume in the model was mainly influenced by the 15 very-high-volume centers. This demonstrates how the results of a few hospitals can disproportionately influence a statistical analysis and result in significant findings when the actual effect of volume on outcomes is small."

"Most published studies that have found an association between a higher volume of procedures and better survival outcomes have been methodologically flawed and have not accounted for this effect. This study demonstrates how researchers should quantify the degree to which volume contributes to outcomes."

Dr. Livingston and Dr. Cao reported no disclosures. ■



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Program Director: Yoshiya Toyoda, MD; Director, Cardiopulmonary Transplantation; Surgical Director, Pediatric Lung and Heart-Lung Transplantation

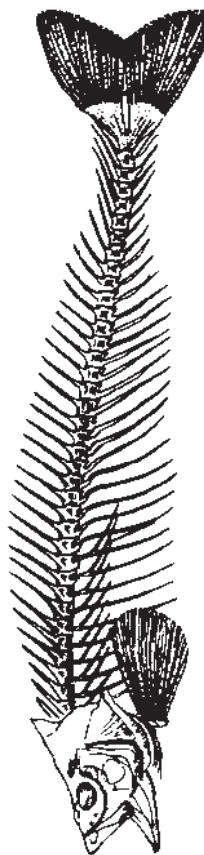
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ACC/AHA Stress Judgment on Clopidogrel's 'Boxed Warning'

BY MARY ANN MOON
Elsevier Global Medical News

The clinician's judgment is the key to interpreting the Food and Drug Administration's March announcement of a "boxed warning" concerning clopidogrel's reduced effectiveness in certain patients, according to a Clinical Alert issued June 28 by the American College of Cardiology and the American Heart Association.

"Adhering to existing ACC/AHA guidelines for the use of antiplatelet therapy should remain the foundation" of treatment. However, careful clinical judgment also is essential in light of the FDA's warning that clopidogrel (Plavix) is ineffective in an estimated 2%-14% of the population who are poor metabolizers of the drug, because they carry variations in the gene coding for CYP liver enzymes.

The role of genetic testing in everyday practice is not yet clear, and the FDA only informs physicians and patients that genetic testing is available to determine whether patients carry the variants.

"It neither mandates, requires, nor recommends genetic testing, thereby allowing for flexibility in clinical decisions," according to the Alert, which also was endorsed by the Society of Thoracic Surgeons and the Society for Cardiovascular Angiography and Interventions.

The American College of Physicians also participated in reviewing the FDA announcement to formulate this Clinical Alert.

The Alert notes that the CYP2C19 polymorphism accounts for only 12% of the variability in platelet response to clopidogrel, and that the positive predictive value of genetic testing is estimated to be only 12%-20% among patients with acute coronary syndromes undergoing percutaneous coronary intervention (PCI). And it remains unknown whether other genetic polymorphisms contribute to drug response, or whether the risk from a given genetic profile changes depending on the clinical scenario—for example, whether the patient has acute coronary syndrome vs. stable angina, is undergoing PCI vs. medical therapy,

has small-vessel vs. large-vessel disease, or is undergoing carotid stenting vs. medical therapy.

In short, "the evidence base is insufficient to recommend either routine genetic or platelet function testing at the present time." Similarly, the data are not available regarding different dosing regimens for clopidogrel, the substitution of newer antiplatelet drugs such as prasugrel or ticagrelor (which have not yet been FDA approved), or the addition of agents such as cilostazol to standard clopidogrel regimens, the statement said (*J. Am. Coll. Cardiol.* 2010 [doi:10.1016/j.jacc.2010.05.013]).

The 15-page Clinical Alert also includes a review of the available evidence on clopidogrel response, the current status of CYP genotyping assays, the data on alternative dosing regimens and alternative treatments, and ongoing clinical trials related to this issue. The Alert will be published in the July 20 issue of *Circulation* and is now available online at the ACC Web site (cardiosource.com) and also at the AHA Web site (my.americanheart.org). ■

Progress in the CT Surgery Network

The CT Surgery Network reached an important benchmark on June 30th. The 100th patient was randomized in a trial to evaluate the effectiveness and safety of mitral valve repair vs. replacement in patients with severe ischemic mitral regurgitation. Enrollment is expected to complete in spring 2011. CTSN investigators are also studying the preferred approach to moderate, ischemic MR (MMR) and have randomized nearly 90 patients in the MMR trial to evaluate the effectiveness and safety of mitral valve repair with CABG compared with CABG alone. Another area of focus for the Network has been atrial fibrillation (AF), one of the top priorities according to the IOM for comparative effectiveness research. The Network recently initiated a trial of surgical ablation with left atrial appendage (LAA) closure versus LAA closure alone in patients with persistent AF undergoing mitral valve surgery. Nested within this trial, is a further randomized comparison of 2 different lesions sets (pulmonary vein isolation and full Maze lesion set). Currently, 28 patients have been randomized. Finally, the Network is completing a prospective cohort study to better understand management practices (e.g., line and ventilator management) that put patients at risk for infections post-surgery, the main non-cardiac complication after heart surgery. More than 3,800 patients have been enrolled to date. For more information, visit www.ctsurgerynet.org.

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Wenzel, *The New England Journal of Medicine*, 2010

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References: 1. Wenzel RP. Minimizing surgical-site infections. *N Engl J Med.* 2010;362(1):75-7. 2. Darouiche R, Wall M Jr, Itani M, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. *N Engl J Med.* 2010;362:18-26. 3. Saltzman MD, Nuber GW, Gryzlo SM, Marecek GS, Koh JL. Efficacy of surgical preparation solutions in shoulder surgery. *J Bone Joint Surg Am.* 2009;91(8):1949-1953. 4. Ostrander RV, Botte MJ, Brage ME. Efficacy of surgical preparation solutions in foot and ankle surgery. *J Bone Joint Surg Am.* 2005;87:980-985. 5. Chaiyakunapruk N, Veenstra DL, Lipsky BA, Saint S. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site care: a meta-analysis. *Ann Intern Med.* 2002;136(11):792-801.

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