



The Society of Thoracic Surgeons

48th Annual Meeting



Late-Breaking Clinical Trial Abstracts

Late-Breaking Clinical Trial Abstract Presentations

Monday, January 30, 2012

1:30 pm – 3:30 pm

The Society of Thoracic Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Society of Thoracic Surgeons designates this live activity for a maximum of 28.75 *AMA PRA Category 1 Credits*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity. The Late-Breaking Clinical Trial Abstract component of the STS 48th Annual Meeting has been designated for a maximum of 2.0 *AMA PRA Category 1 Credits*[™].

The American Board of Cardiovascular Perfusion designates this activity for 2.4 Category I CEUs.

Late-Breaking Clinical Trial Abstract Presentations:

Adult Cardiac, General Thoracic, and Congenital

Monday, January 30, 2012

4:15 pm – 5:15 pm

The Society of Thoracic Surgeons is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

The Society of Thoracic Surgeons designates this live activity for a maximum of 28.75 *AMA PRA Category 1 Credits*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity. The Late-Breaking Clinical Trial Abstract component of the STS 48th Annual Meeting has been designated for a maximum of 1.0 *AMA PRA Category 1 Credit*[™].

The American Board of Cardiovascular Perfusion designates this activity for 1.2 Category I CEUs.

Unless otherwise noted in this handout or by the speakers, speakers have no relevant financial relationships to disclose and will only be presenting information relevant on devices, products, or drugs that are FDA approved for the purposes they are discussing.

Unless noted with an asterisk (*), presenting authors are listed first on each abstract.

Late-Breaking Clinical Trial Abstract Presentations

Monday, January 30, 2012

1:30 pm – 3:30 pm

Moderators: D. Craig Miller, Stanford, CA and A. Pieter Kappetein, Rotterdam, The Netherlands

FINANCIAL DISCLOSURE D.C. Miller, Research Grant, Edwards Lifesciences LLC, Nonremunerative Position of Influence, Edwards Lifesciences LLC, Consultant/Advisory Board, Medtronic, Inc.

1:30 pm

Do Blood Transfusions Affect the Risk of Infections After Cardiac Surgery? Experience of the NIH/CIHR Cardiothoracic Surgical Trials Network

K. A. Horvath¹, M. A. Acker², H. Chang³, E. Bagiella³, P. K. Smith⁴, A. Iribarne³, I. L. Kron⁵, P. Lackner⁶, M. Argenziano⁷, D. D. Ascheim³, R. Michler⁸, D. Van Patten⁷, J. Puskas⁹, K. O'Sullivan³, D. Kliniewski², N. Jeffries¹, P. O'Gara¹⁰, A. J. Moskowitz³, E. Blackstone¹¹

¹National Heart, Lung, and Blood Institute, Bethesda, MD, ²University of Pennsylvania Medical Center, Philadelphia, PA, ³Mount Sinai School of Medicine, New York, NY, ⁴Duke University Medical Center, Durham, NC, ⁵University of Virginia Medical Center Health Sciences Center, Charlottesville, VA, ⁶Cleveland Clinic, Cleveland, OH, ⁷Columbia University Medical Center, New York, NY, ⁸Montefiore Medical Center, Albert-Einstein College of Medicine, New York City, NY, ⁹Emory University School of Medicine, Atlanta, GA, ¹⁰Brigham and Women's Hospital, Boston, MA, ¹¹Cleveland Clinic, Cleveland, OH

Purpose: The relationship between blood transfusions and adverse outcomes after cardiac surgery is controversial. The goal of this study was to characterize the relationship between blood transfusions and risk of major post-operative infection.

Methods: 5,184 adult cardiac surgery patients were prospectively enrolled in a 10 center cohort study to assess major/minor infections based on CDC/NHSN definitions. All infections were adjudicated by an independent committee of ID experts. Multivariable logistic regression and Cox modeling were used to assess the independent effect of blood and platelet transfusions on major infection (e.g. pneumonia, mediastinitis, blood stream infection) within 60±5 days of surgery, time to infection, LOS, and mortality.

Results: Packed red blood cells (PRBCs) and platelets were transfused in 48% (n=2,491; mean 4.1±5.0 units) and 31% (n=1,610; mean 5.9±13.8 units) of patients, respectively. The mean age was 64.4±13.2 and mean baseline hemoglobin was 13.2 mg/dL. The most common procedures were isolated CABG (31%; n=1,597) and isolated valve (30%; n=1,549) with a mean bypass time of 115.4 minutes; 1.4% were re-ops. PRBCs and platelets were independently associated with risk of major infection [Table 1]. There was a dose-dependent association between quantity of PRBC and risk of infection with the crude risk increasing by 31% with each PRBC unit (p<0.001) [Figure 1]. By contrast, platelet transfusion decreased the risk of infection. Among those receiving transfusions, the most common major infections were pneumonia (3.7%) and blood stream (2%); the risk of death was 3.2 times higher adjusting for overall risk for infection, and the risk of an additional day of stay was 1.32 times higher.

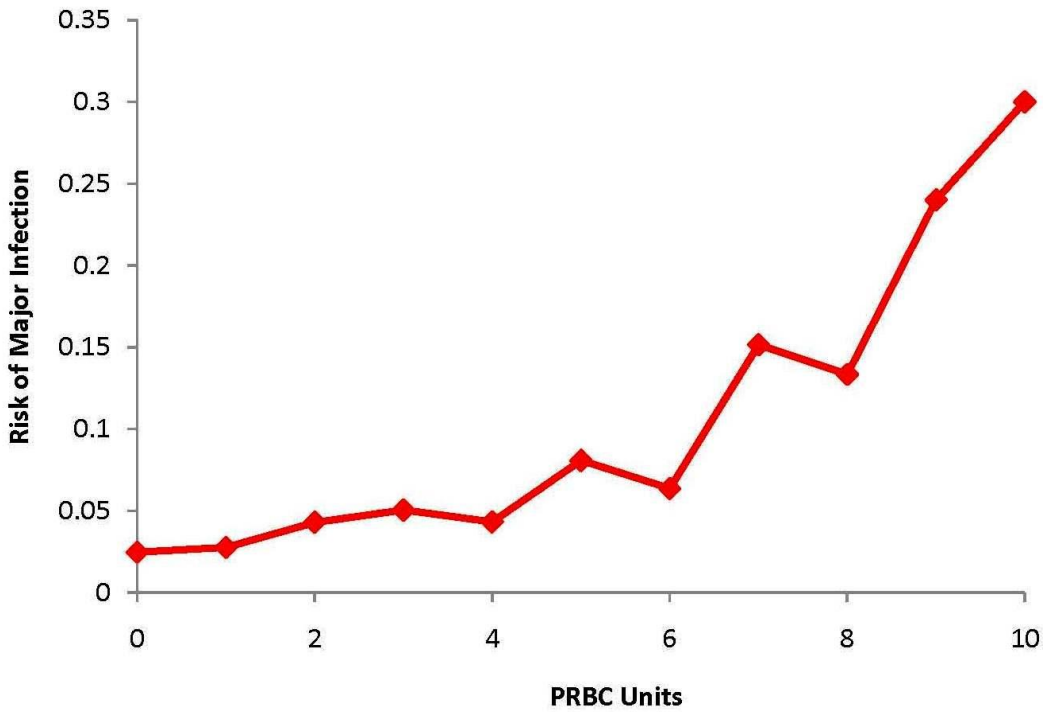
Conclusions: PRBCs are independently associated with increased risk of major infection after surgery. Efforts to reduce PRBC transfusions may significantly reduce the incidence of major post-operative infections.

Table 1 continued on next page

Table 1: Multivariable logistic regression of risk factors for post-operative infection

Risk factor	Odds Ratio	95% Confidence Interval
Packed red blood cells (per 1 unit)	1.27	1.20 – 1.33
Platelets	0.65 *	0.45 - 0.92
Bypass time (per 15 minutes)	1.06	1.03 – 1.10
CHF	1.50	1.13 – 2.00
COPD (severe)	2.10	1.07 – 4.12
Pre-op Creatinine ≥ 1.3 mg/dL	1.64	1.22 – 2.21
Pre-op WBC ($\geq 11 \times 10^3$ mL)	1.83	1.18 – 2.83
Pre-op Corticosteroids	1.85	1.08 – 3.17

* Decreased risk of infection



Pneumonia After Cardiac Surgery: Experience of the NIH/CIHR Cardiothoracic Surgical Trials Network

G. Ailawadi¹, J. Alexander², A. Iribarne³, M. Parides³, T. B. Ferguson⁴, H. Chang³, E. Moquete³, K. Gahring¹, V. Thourani⁵, Y. J. Woo⁶, S. Robichaud⁷, J. J. DeRose⁸, A. M. Gillinov⁹, A. O'Neal², W. C. Taddei-Peters¹⁰, M. Miller¹⁰, T. J. Gardner¹¹, A. Gelijns³, L. P. Perrault⁷

¹University of Virginia, Charlottesville, VA, ²Duke University Medical Center, Durham, NC, ³Mount Sinai School of Medicine, New York, NY, ⁴East Carolina Heart Institute at ECU, Greenville, NC, ⁵Emory University, Atlanta, GA, ⁶University of Pennsylvania Medical Center, Philadelphia, PA, ⁷Montreal Heart Institute, Montreal, Canada, ⁸Montefiore Medical Center, Albert-Einstein College of Medicine, New York, NY, ⁹The Cleveland Clinic Foundation, Cleveland, OH, ¹⁰National Heart, Lung, and Blood Institute, Bethesda, MD, ¹¹Christiana Care Health System, Wilmington, DE

Purpose: The causes and prevalence of pneumonia (PNA) after cardiac surgery remain poorly defined. The goal of this study was to prospectively examine the frequency and risk factors, including process of care (POC) measures, for post-operative PNA.

Methods: 5,184 adult cardiac surgery patients were prospectively enrolled in a cohort study in 10 centers to assess major/minor infections based on CDC/NHSN definitions. All infections were adjudicated by an independent committee of ID experts. Multivariable logistic regression and Cox modeling were used to assess the independent association of baseline characteristics and management practices on the development of PNA within 60±5 days of surgery, time to infection, LOS, and mortality.

Results: Pneumonia was the most common major infection, occurring in 2.4% (n=123) of enrolled patients. The mean age of the study population was 64.4±13.2 and 33% were women. The two most common procedures were isolated CABG (31%; n=1,597) and isolated valve (30%; n=1,549), with a median bypass time of 105 minutes. The median time to extubation was 0.62 days. The mean and median time to development of PNA was 14.3 and 8 days, respectively, with 68% of events occurring during the index hospitalization. Significant baseline and POC predictors of PNA are summarized in Table 1. There was no variation among sites in use of head elevation, nasopharyngeal decontamination, and aspiration of secretions, which eliminated them from the model. Adjusting for risk of infection, the risk of death was 9.4 times higher, and the risk of an additional hospitalization day was 2.4 times higher for patients with PNA.

Conclusions: Pneumonia was the most prevalent infection following cardiac surgery, with a significant impact on mortality and LOS. Adjusting for baseline risk, various POC measures significantly affected PNA. The identification of these practices should guide national quality improvement initiatives.

Table 1: Multivariable logistic regression of risk factors for post-operative pneumonia

Risk factor	Odds Ratio	95% Confidence Interval
Baseline & operative characteristics		
Surgery time (hours)	1.35	1.22 – 1.49
Creatinine ≥1.3 mg/dL	1.69	1.13 – 2.52
Corticosteroids	2.06	1.02 – 4.13
COPD (mild – moderate)	1.67	1.05 – 2.66
COPD (severe)	4.34	2.12 – 8.89
WBC (≥11x10 ³ mL)	1.92	1.07 – 3.44
CHF	1.87	1.27 – 2.74
Process of care		
Post-op antibiotics < 24 hours	0.46*	0.23 – 0.93
Post-op antibiotics 24 – 48 hours	0.30*	0.14 – 0.65
Post-op antibiotics > 48 hours	1.19	0.57 – 2.48
Post-operative dialysis	2.17	1.03 – 4.58
Nasogastric tube	2.13	1.26 – 3.61
Packed red blood cells (per 1 unit)	1.12	1.05 – 1.20
Prolonged ventilation (> 72 hours)	3.57	2.18 – 5.85

*Decreased risk of infection

2:00 pm

Predictors of Long-Term Survival Following Coronary Artery Bypass Grafting: Results From the ASCERT Study

D.M. Shahian¹, S.M. O'Brien², S. Sheng², F.L. Grover³, J.E. Mayer⁴, J.P. Jacobs⁵, J.M. Weiss⁶, E.R. DeLong², E.D. Peterson², W.S. Weintraub⁷, M.V. Grau-Sepulveda², L.W. Klein⁸, R.E. Shaw⁹, K. Garratt¹⁰, I. Moussa¹¹, C.M. Shewan¹², G.D. Dangas¹³, F.H. Edwards¹⁴, Chuck McKay¹⁵, Laura Ritzenthaler⁶, John Messenger³, Paul Kolm¹⁶, Zugui Zhang¹⁶

¹Massachusetts General Hospital, Boston, MA, ²Duke Clinical Research Institute, Durham, NC, ³University of Colorado School of Medicine, Aurora, CO ⁴Children's Hospital, Boston, MA, ⁵The Congenital Heart Institute of Florida, St. Petersburg, FL, ⁶American College of Cardiology, Washington, DC, ⁷Christiana Care Center for Outcome Research, Newark, DE, ⁸Gottlieb Memorial Hospital, Melrose Park, IL, ⁹California Pacific Medical Center, San Francisco, CA, ¹⁰Lenox Hill Heart and Vascular Institute, New York, NY, ¹¹Mayo Clinic, Rochester, MN, ¹²The Society of Thoracic Surgeons, Chicago, IL, ¹³Columbia University Medical Center, New York, NY, ¹⁴University of Florida Shands Jacksonville, Jacksonville, FL, ¹⁵Los Angeles Biomedical Research Institute, ¹⁶Christiana Care Health System

FINANCIAL DISCLOSURE F.H. Edwards, PI of ASCERT Trial; Consultant/Advisory Board, Humana; E.D. Peterson, Research Grant, Johnson & Johnson Services, Inc., Eli Lilly and Company; D.M. Shahian, Investigator, ASCERT Grant; W.S. Weintraub, Speakers Bureau/Honoraria, Shionogi & Co., Ltd., CardioNet, AstraZeneca, Bayer AG, Pfizer Inc., Bristol-Myers Squibb, sanofi-aventis U.S. LLC., Eli Lilly and Company; Research Grant, AstraZeneca, Abbott Laboratories, Otsuka America, Inc., Bristol-Myers Squibb, sanofi-aventis U.S. LLC.; R.E. Shaw, Research Grant, National Heart, Lung, and Blood Institute, ASCERT Trial; K. Garratt, Research Grant, Boston Scientific Corporation, Abbott Laboratories, Medtronic, Inc., Speakers Bureau/Honoraria, Boston Scientific Corporation, Abbott Laboratories, Medtronic, Inc., Consultant/Advisory Board, Boston Scientific Corporation; John Messenger, Research Grant, Medtronic, Inc.

Purpose: As short-term mortality rates progressively decline, longer-term survival following coronary artery bypass grafting surgery (CABG) is an increasingly important consideration. We estimate a long-term CABG survival model using linked data from the Society of Thoracic Surgeons Adult Cardiac Surgery Database and Centers for Medicare and Medicaid Services (CMS) claims.

Methods: We linked CMS claims data and STS clinical data from 348,341 isolated CABG patients \geq 65 years of age, discharged between January 1, 2002 and December 31, 2007 from 917 STS-participating hospitals. Vital status was ascertained from date of surgery through December 31, 2008 (1 - 6 year follow-up). Because of non-proportional hazards, we fit four Cox regression models conditional on being alive at the beginning of the following intervals: 0 -30 days, 31 – 180 days, 181 days – 2 years, > 2 years.

Results: Kaplan-Meier estimated mortality was 3.2% at 30 days, 8.1% at one-year, and 23.3% at 3 years follow-up. Harrell's C statistic for overall survival time prediction = 0.732. Traditional short-term risk factors (e.g., emergency status, shock, reoperation) predicted early mortality, but for early survivors these often became non-significant within 2 years. Other adverse predictors (e.g., dialysis-dependent renal failure, insulin-dependent diabetes) increased in importance over time.

Conclusions: Using linked clinical registry and longitudinal claims data, we developed a long-term survival prediction model for isolated CABG. This information can be used to facilitate shared decision-making, comparative effectiveness research, quality improvement, and provider profiling.

ASCERT Trial continued on next page

ASCERT Trial continued from previous page

Survival Analysis of Clinical Subsets From the ASCERT Study (ACCF-STS Database Collaboration on the Comparative Effectiveness of Revascularization Strategies): CABG Compared to Percutaneous Stent Placement in 189,793 Patients With Multivessel Coronary Disease

F.H. Edwards¹, E.D. Peterson², W.S. Weintraub³, and the ASCERT Investigators

¹University of Florida Shands Jacksonville, Jacksonville, FL, ²Duke Clinical Research Institute, Durham, NC,

³Christiana Care Center for Outcome Research, Newark, DE

FINANCIAL DISCLOSURE F.H. Edwards, PI of ASCERT Trial; Consultant/Advisory Board, Humana; E.D. Peterson, Research Grant, Johnson & Johnson Services, Inc., Eli Lilly and Company; D.M. Shahian, Investigator, ASCERT Grant; W.S. Weintraub, Speakers Bureau/Honoraria, Shionogi & Co., Ltd., CardioNet, AstraZeneca, Bayer AG, Pfizer Inc., Bristol-Myers Squibb, sanofi-aventis U.S. LLC., Eli Lilly and Company; Research Grant, AstraZeneca, Abbott Laboratories, Otsuka America, Inc., Bristol-Myers Squibb, sanofi-aventis U.S. LLC.; R.E. Shaw, Research Grant, National Heart, Lung, and Blood Institute, ASCERT Trial; K. Garratt, Research Grant, Boston Scientific Corporation, Abbott Laboratories, Medtronic, Inc., Speakers Bureau/Honoraria, Boston Scientific Corporation, Abbott Laboratories, Medtronic, Inc., Consultant/Advisory Board, Boston Scientific Corporation; John Messenger, Research Grant, Medtronic, Inc.

Purpose: To compare survival after stented percutaneous coronary intervention (PCI) to survival after coronary artery bypass grafting (CABG).

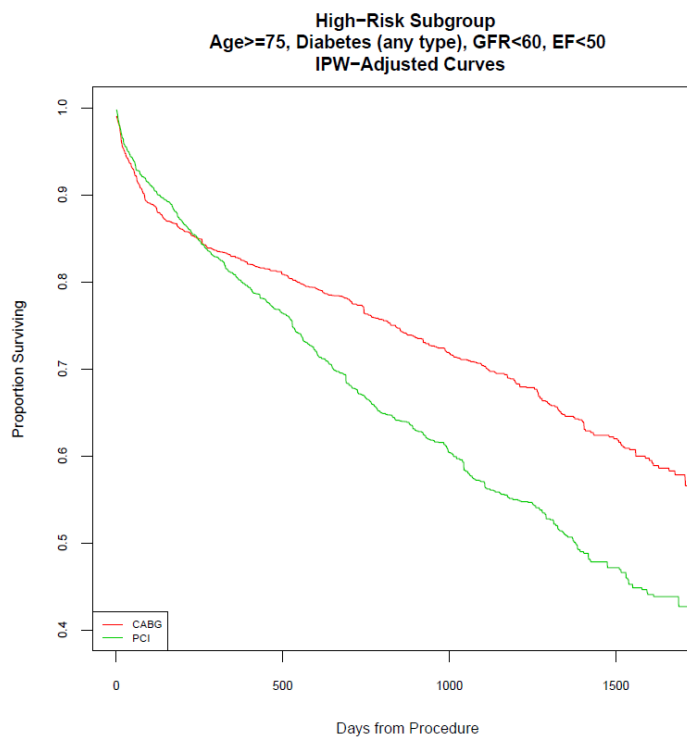
Methods: The study population consisted of patients with 2 and 3-vessel disease who underwent revascularization from 2004 through 2007. Patients having left main disease or emergency procedures were excluded. The CABG population was taken from the STS National Database and the PCI population from The American College of Cardiology National Cardiovascular Data Registry. To obtain long-term follow-up, patient records were linked to administrative data from Centers for Medicare and Medicaid Services. Propensity scores and inverse probability weighting (IPW) were used to create CABG and PCI groups having similar clinical characteristics. Before results were obtained, numerous clinically important subgroups were specified. In each subgroup, IPW-adjusted survival curves for CABG patients were compared to those for PCI patients. Mortality risk ratios (RR) were calculated.

Results: There were 86,244 CABG and 103,549 PCI patients. The mean age was 74 years with a median 2.67 years follow-up. In all subgroups, survival in the first year favored PCI. At 1 year and beyond, all subgroups showed a progressively increasing survival advantage for CABG. The spectrum of propensity scores was divided into quintiles of CABG and PCI patients having similar clinical characteristics. CABG survival advantage persisted across each quintile (RR for mortality at 4 years ranged from .75 to .82). A high risk group (age \geq 75, Diabetic, EF $<$ 50%, GFR $<$ 60) demonstrated a CABG survival advantage (RR at 4 years = 0.72; 95% CI 0.62-0.81) as did a low-risk group (RR at 4 years = 0.74; 95% CI 0.64-0.84). Similar RR were seen for all subgroups and similar results were noted using several different analytic methods.

Conclusions: In this large observational study of patients with multi-vessel disease, one to four years after the index revascularization all clinical subsets demonstrated progressively higher survival for CABG patients compared to PCI patients.

Figure 1 continued on next page

Figure 1



2:30 pm

Mid-Term Analysis of TEVAR in Acute Complicated Type B Aortic Dissection From the FDA IDE Valiant Dissection Trial

J.E. Bavaria¹, R. White², W.T. Brinkman³, W.Y. Szeto¹, G.C. Hughes⁴, F.P. Beavers⁵, W.A. Lee⁶

¹Hospital of the University of Pennsylvania, Philadelphia, PA, ²Harbor-UCLA Medical Center, Los Angeles, CA,

³The Heart Hospital, Plano, TX, ⁴Duke University Medical Center, Durham, NC, ⁵Washington Hospital Center, Washington, DC, ⁶Christine E. Lynn Heart Institute, Boca Raton Regional Hospital, Boca Raton, FL

FINANCIAL DISCLOSURE J.E. Bavaria, Research Grant, Medtronic, Inc.; G.C. Hughes, Speakers Bureau/Honoraria, Medtronic, Inc.; Consultant/Advisory Board, Medtronic, Inc.; W.Y. Szeto, Research Grant, Medtronic, Inc.; R. White, Research Grant, Medtronic, Inc., W. L. Gore & Associates, Inc., Volcano Corporation, Endologix, Inc., Consultant/Advisory Board, Medtronic, Inc., W. L. Gore & Associates, Inc., Volcano Corporation, Endologix, Inc.; W.A. Lee, Research Grant, Medtronic, Inc.

REGULATORY DISCLOSURE This presentation will address the off-label use of the Medtronic Valiant Thoracic Stent Graft for type B dissection. The Medtronic Valiant Thoracic Stent Graft is FDA approved.

Purpose: Conventional open repair of acute Stanford Type B aortic dissection complicated by malperfusion and rupture has been associated with significant morbidity and mortality. Thoracic Endovascular Aortic Repair (TEVAR) is being evaluated as a potential treatment for acute descending aortic dissection. This is a report of the first ever FDA IDE trial on TEVAR in the treatment of acute complicated Type B aortic dissection.

Methods: Fifty patients in the United States will be treated with the Valiant Thoracic Stent Graft with Captivia delivery system (Medtronic, Santa Rosa CA). For this study, acute Type B dissection is defined as within 14 days of onset of symptoms. "Complicated" is defined as clinical or radiologic evidence of malperfusion or rupture. Primary endpoint is all cause mortality at 30 days.

Results: To date, 25 patients have been treated with a mean age of 54.6±13 years. Patients were predominately Caucasian (56%) and male (72%). Patients presented with back or chest pain (84%), hypertension (48%), abdominal pain (44%), and paraparesis (16%). Rupture was the presenting scenario in 5 patients and malperfusion in 19 patients. Time from onset of symptoms to procedure was 4.3 days. The Valiant graft was successfully delivered in 100% of patients with proximal entry tear successfully covered in all patients. Overall median hospital stay was 10 days. 30-day mortality was 8% (2/25). There was 1 proximal type I endoleak. One patient (4%) experienced a retrograde Type A dissection on postop day 6, which was operated upon with no complications. Postoperatively, stroke occurred in two patients with no incidence of spinal cord ischemia. On CT scan followup, 66.7% (12/18) patients demonstrated either complete or partially thrombosed false lumen in the stented segment of the thoracic aorta. In the non-stented segment of thoracic aorta, the majority of patients (66.7%, 12/18) had patent false lumen. At 6 months, maximum total aortic lumen diameter decreased by 3.1±7.1 mm.

Conclusions: Initial results of the Valiant Thoracic Stent Graft in the treatment of acute complicated type B aortic dissection are encouraging with high technical success rates and good clinical outcomes. Longer term outcomes including false lumen thrombosis and aortic remodeling are needed to assess the long term benefit of TEVAR.

2:45 pm

Off-Pump, Transapical Placement of Artificial Chordae Tendinae to Correct Mitral Insufficiency: Update From the European TACT Trial

R.C. Daly¹, J. Seeburger², J. Seaberg³, J. Zentgraf³, G. Speziali⁴

¹Mayo Clinic, Rochester, MN, ²Heart Center Leipzig, Germany, ³NeoChord, Inc., Minnetonka, MN, ⁴University of Pittsburgh Medical Center, Pittsburgh, PA

FINANCIAL DISCLOSURE R. Daly, Ownership Interest, NeoChord, Inc.; Consultant/Advisory Board, NeoChord, Inc.; J. Seeburger, Consultant/Advisory Board, NeoChord, Inc.; J. Seaberg, Employment, NeoChord, Inc.; J. Zentgraf, Employment, NeoChord, Inc.; G. Speziali, Ownership Interest, NeoChord, Inc.; Consultant/Advisory Board, NeoChord, Inc.

Purpose: The TACT Trial [Trans-apical Placement of Artificial Chordae Tendinae (ACT)] is a multi-center, prospective, single-arm evaluation of the correction mitral regurgitation (MR) with the NeoChord instrument.

Methods: The instrument is introduced through the left ventricular (LV) apex. Echocardiography is used to guide the instrument to the mitral valve (MV) and to place the ACT, as well as providing real-time feedback on establishing the length of the ACT which is anchored at the LV apex.

Results: Fourteen patients in 6 centers have been enrolled in the TACT Trial to date. ACT were not placed in 3 patients for technical or patient-specific reasons. ACT were deployed in 11 patients with acute procedural success in all 11 (defined as: placement of at least one ACT and reduction of MR to < 2+). Single ACT were placed in the prolapsed MV leaflet in the first 2 patients in the trial and both developed recurrent MR within 30 days; both had successful standard open mitral valve repair. Multiple ACT were deployed in each of the next 9 patients; all had acute procedural success. Five of these 9 patients had durable repair (MR <2+) at follow-up: 1 at 30 days and 4 at 1 year. Four of the 9 patients had recurrent MR at follow-up; 2 of these 4 patients had open surgery with successful MV repair, one is being followed, and one was entered in the trial in cardiogenic shock and died when support was withdrawn after 4 days.

Conclusions: We report early results of the ongoing TACT trial. The trial evaluates off-pump, trans-apical placement of ACT with the NeoChord instrument. Acute procedural success was noted in all 11 patients in whom ACT were deployed. Both patients with a single ACT had chordal dehiscence and recurrent MR. Of 9 patients with multiple ACT, 5 had durable results at follow-up (1 at 30 days, 4 at 1 yr), and 4 patients had recurrent MR with dehiscence of at least one ACT. Patient selection has evolved. Technical modifications are in progress.

3:00 pm

Initial Safety Trial of a Synchronous, Partial Circulatory Support Device

R. Cecere¹, N. Giannetti¹, R. Dowling², D. Raess³, E. Gratz³, A. Cheung⁴

¹McGill University Health Centre, Montreal, Canada, ²DCI, Inc., Louisville, KY, ³Abiomed, Inc., Danvers, MA,

⁴University of British Columbia, Vancouver, Canada

FINANCIAL DISCLOSURE R. Cecere, Consultant/ Advisory Board, Abiomed, Inc.; N. Giannetti, Consultant/ Advisory Board, Abiomed, Inc.; R. Dowling, Employment, Abiomed, Inc.; D. Raess, Employment, Abiomed, Inc.; E. Gratz, Employment, Abiomed, Inc.; A. Cheung, Consultant/ Advisory Board, Abiomed, Inc.

Purpose: We have developed a simple circulatory support device that is placed with a minor operation, provides synchronous, partial support and is designed for use in ambulatory heart failure (HF) patients. This approach was chosen to promote native heart recovery. In contrast, current LVADs require a major operation, are indicated for advanced HF and have low rates of recovery. The goal of this device is to provide an efficacious therapy that improves hemodynamics and quality of life, facilitates native heart remodeling and recovery, is a potential adjunct to current and future HF therapies (pharma, stem cell), and is cost effective.

Methods: The device is a 30 ml pumping chamber that is sewn via a short graft to the subclavian artery. Placement is above the pectoralis muscle similar to a pacemaker. The device is timed to the ECG to remove blood from systemic circulation during systole (reducing LV work) and return blood during diastole to augment systemic and coronary perfusion. Pre-clinical studies showed significant improvements in LV function and coronary and systemic flow. A clinical safety trial has been initiated.

Results: Approval for the study has been received by Health Canada and enrolling centers. Key inclusion criteria are: 1) ambulatory HF, NYHA class IIIB or IV, 2) 6 min walk >200 M and 3) LVEF <40%. Exclusion criteria include: 1) >1+ AI, 2) advanced RV failure and 3) inotrope dependency. The primary endpoint is a composite of major adverse events. Secondary endpoints include assessment of functional class, LV function and 6 min walk test. Patient screening has been initiated at approved centers.

Conclusions: We have developed the first implantable circulatory support device that can be placed without the need for a major operation, provides synchronized partial circulatory support and has the goal of native heart recovery. An initial safety trial outside the US is underway. We will report on the initial clinical data with this device.

3:15 pm

A Novel Blood-Sparing Drug in Cardiac Surgery? First-in-Patient Experience With The Synthetic Serine Protease Inhibitor MDCO-2010

L. Englberger¹, W. Dietrich², B. Eberle¹, A. van de Locht³, T. P. Carrel⁴

¹University Hospital Berne, Switzerland, ²University Munich, Germany, ³The Medicines Company, Munich, Germany, ⁴Clinic for Thoracic and Cardiovascular Surgery, Bern, Switzerland

FINANCIAL DISCLOSURE L. Englberger, Research Grant, The Medicines Company; Consultant/Advisory Board, The Medicines Company; W. Dietrich, Consultant/Advisory Board, The Medicines Company; B. Eberle, Research Grant, The Medicines Company; A. van de Locht, Employment, The Medicines Company; T. Carrel, Research Grant, The Medicines Company

Purpose: Effective and safe pharmacological interventions to reduce bleeding after cardiac surgery are limited. MDCO-2010 is a novel, synthetic, serine protease inhibitor. This first-in-patient trial investigates pharmacokinetics, pharmacodynamics, and safety of MDCO-2010.

Methods: Phase IIa, single-center, double-blind, placebo-controlled, dose-escalation study with 32 patients undergoing primary on-pump CABG. After heparinization, one of five MDCO-2010 doses or placebo was given as loading and continuous infusion until sternal closure.

Results: Study groups showed comparable characteristics. Pharmacokinetic analysis showed linear dose-proportional correlation between MDCO-2010 infusion rate and plasma concentrations. MDCO-2010 had dose-dependent antifibrinolytic effects by suppression of D-dimer generation and inhibition of tPA-induced lysis in ROTEM® analysis. MDCO-2010 showed dose-related prolongation of ACT, aPTT and thrombelastometry coagulation times, indicating anticoagulant activity (Figure). Bleeding, incidence and volume of RBC transfusions (according to institutional transfusion guideline) were significantly lower with higher dosed MDCO-2010 (Table). No differences in cardiac enzymes, ALAT, ASAT, creatinine, IL-6, and IL-10 were observed between MDCO-2010 groups vs. placebo. No systematic differences in overall AEs were observed between MDCO-2010 and placebo. Three patients in MDCO groups experienced SAEs: one classified as possibly related to study drug. No re-exploration for mediastinal bleeding was required, and there was no 30-day mortality.

Conclusions: This first-in-patient study demonstrated predictable pharmacokinetics and acceptable safety of escalating MDCO-2010 doses in primary CABG. MDCO-2010 shows intended antifibrinolytic effects and has moderate anticoagulant properties. Observed clinical effects make this compound a promising antifibrinolytic to reduce blood loss and transfusion requirements in cardiac surgery.

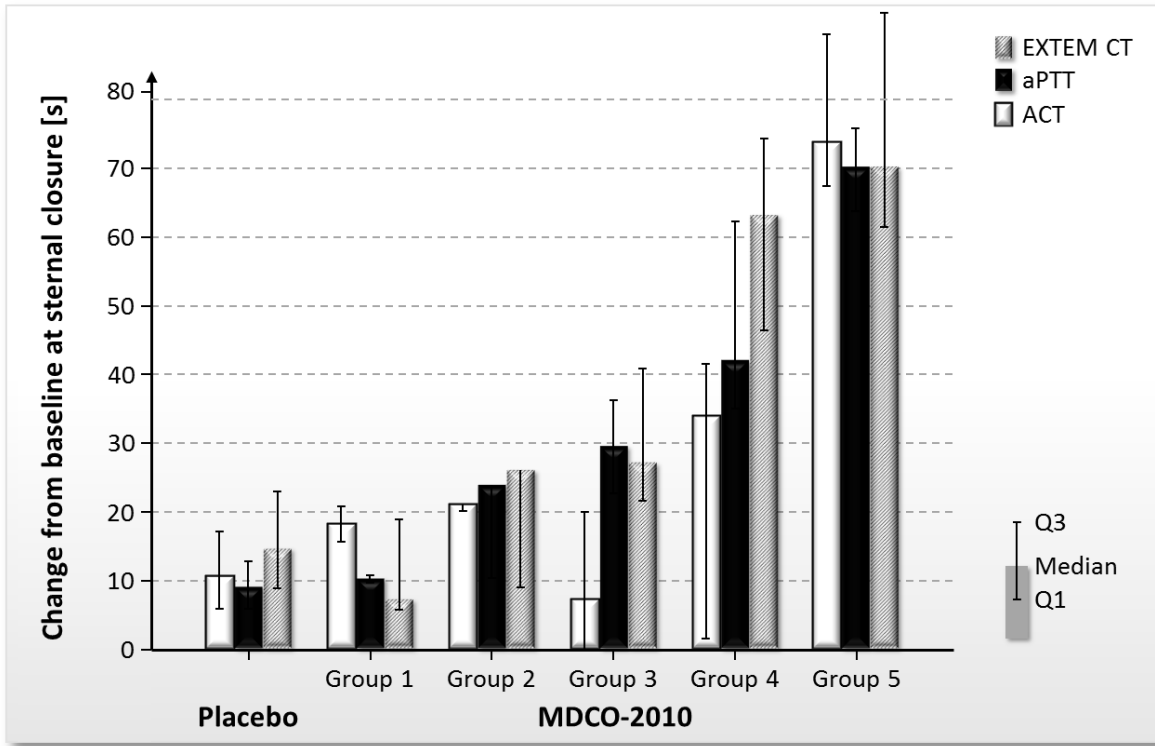
Table: Blood loss and transfusions

	Placebo	MDCO-2010 group 3	MDCO-2010 group 4	MDCO-2010 group 5
12 hour postoperative chest tube drainage [mL; median (Q1, Q3)]	900 (815, 950)	350 (300, 370)*	350 (300, 450)*	360 (350, 400)*
Patients receiving transfusions	4/8	1/6	1/6	2/6
Average number of RBC transfusions per patient	2.0	0.33	0.17	0.67
Total number of blood products	RBC: 16 Platelets: 5 FFP: 10	RBC: 2	RBC: 1	RBC: 4

* $p < 0.05$ MDCO-2010 group vs. placebo

Figure 1 continued on next page

Figure 1



**Late-Breaking Clinical Trial
Abstracts: Adult Cardiac Surgery**

**Monday, January 30, 2012
4:15 pm – 5:15 pm**

Moderators: Joseph F. Sabik, III, Cleveland, OH and Joseph E. Bavaria, Philadelphia, PA

FINANCIAL DISCLOSURE J.F. Sabik, Speakers Bureau/Honoraria, Edwards Lifesciences LLC, Medtronic, Inc., Consultant/Advisory Board, ValveXchange; J.E. Bavaria, Research Grant, Edwards Lifesciences LLC, Consultant/Advisory Board, St. Jude Medical, Inc.

4:15 pm

Transapical Aortic Valve Replacement For Critical Aortic Stenosis: Results From the Non-Randomized Continued Access Cohort of the PARTNER Trial

T.M. Dewey¹, V. Thourani², J.E. Bavaria³, V. Babaliaros⁴, J. Tyner⁵, D. Brown⁶, C. Smith⁷, D.C. Miller⁸, L.G. Svensson⁹, G.P. Fontana¹⁰, M. Leon¹¹, P. Tierstein¹², M.J. Mack¹³

¹Medical City Dallas Hospital, Dallas, TX, ²Emory University, Atlanta, GA, ³Hospital of the University of Pennsylvania, Philadelphia, PA, ⁴Emory University Hospital, Atlanta, GA, ⁵Scripps Clinic & Foundation, La Jolla, CA, ⁶The Heart Hospital Baylor Plano, Dallas, TX, ⁷Columbia Presbyterian Medical Center, New York, NY, ⁸Stanford University Medical School, Stanford, CA, ⁹Cleveland Clinic, Cleveland, OH, ¹¹New York Presbyterian/Columbia, New York, NY, ¹³Heart Hospital Baylor Plano, Plano, TX

FINANCIAL DISCLOSURE M. Leon, Research Grant, Edwards Lifesciences LLC; T.M. Dewey, Speakers Bureau/Honoraria, Edwards Lifesciences LLC, Ownership Interest, CARDIAPEX Ltd.; V.H. Thourani, Research Grant, Edwards Lifesciences LLC; Ownership Interest, Apica Cardiovascular, Inc., Consultant/Advisory Board, St. Jude Medical, Inc., Sorin Group USA, Inc.; J. Bavaria, Principal Investigator of PARTNER Trial, Edwards Lifesciences LLC; C.R. Smith, Principal Investigator of PARTNER Trial, Edwards Lifesciences LLC; Paul Tierstein, Research Grant, Edwards Lifesciences LLC, Medtronic, Inc., Speakers Bureau/Honoraria, Edwards Lifesciences LLC, Medtronic, Inc., Consultant/Advisory Board, Edwards Lifesciences LLC, Medtronic, Inc.; M.J. Mack, Nonremunerative Position of Interest, Executive Committee of the Partner Trial, Edwards Lifesciences LLC; D.C. Miller, Research Grant, National Heart, Lung, and Blood Institute, National Institutes of Health, The PARTNER Trial, Edwards Lifesciences LLC, Executive Committee, PARTNER U.S. Pivotal Trial, Edwards Lifesciences LLC, Consultant/Advisory Board, Abbott Vascular, St. Jude Medical, Inc., Medtronic, Inc.; G.P. Fontana, Research Grant, Edwards Lifesciences LLC, St. Jude Medical, Inc., Medtronic, Inc., Speakers Bureau/Honoraria, Edwards Lifesciences LLC, St. Jude Medical, Inc., Medtronic, Inc., Sorin Group USA, Inc., Ownership Interest, Entourage Medical Technologies, Consultant/Advisory Board, Edwards Lifesciences LLC, St. Jude Medical, Inc., Medtronic, Inc., Sorin Group USA, Inc.; D. Brown, Research Grant, Medtronic, Inc.; V. Babaliaros, Consultant/Advisory Board, Direct Flow Medical, Inc., Symetis, Research Grant, Edwards Lifesciences LLC

REGULATORY DISCLOSURE This presentation will address the off-label use of the Edwards SAPIEN transcatheter heart valve in transapical approaches. The Edwards SAPIEN transcatheter heart valve is FDA approved.

Purpose: Transapical aortic valve implantation (TA-AVR) was an integral part of the recently reported Partner trial. However, only 104 procedures were performed as part of the Partner trial TA cohort (PT-TA), thus reflecting the preliminary experience of many of the participating centers. Upon completion of the Partner trial, participating centers were able to continue to enroll patients into a Non-Randomized Continued Access (NRCA) program. We compared the outcomes of the TA-AVR procedures performed as part of the NRCA program to those seen in the PT-TA cohort.

Methods: 823 patients had a TA-TAVR as part of the post-Partner trial NRCA program. The average STS PROM was 12.4 ± 4.8 , and the average Logistic EuroSCORE was 29.1 ± 16.8 . 83.2% of patients (548/659) had a history of coronary artery disease, 50.6% (334/660) previous coronary artery bypass grafting, and significant peripheral vascular disease noted in 61.6% (402/653). Inclusion and exclusion criteria were unchanged in comparison to the Partner trial.

Results: Results will be provided at the time of presentation.

Conclusion: Improvement was seen in the major outcome variables death, stroke and bleeding in the NRCA TA patients compared to the Partner trial. These improvements can be attributed to a number of factors including: improved patient selection, individual centers surmounting the procedural learning curve, and refinements in surgical technique. These results mirror those seen in the Partner trial transfemoral cohort.

4:30 pm

Transcatheter Aortic Valve Replacement With Edwards SAPIEN Valve via Transaortic Route: European Multi-Center Experience

V. Bapat¹, M. Romano², P. Etienne³, O. Wendler⁴, M. Thielmann⁵, E. Raanani⁶, S. Doshi⁷, D. Muir⁸, S. Kennen⁹, S. Tsui¹⁰, H. Amrane¹¹, L. Ihlberg¹², L. Van Gaarsse¹³, T. Lefevre², M. Thomas¹

¹St. Thomas Hospital, London, United Kingdom, ²Institute Cardiovascular Paris, Massy, France, ³St. Luc Hospital, Bouge, Belgium, ⁴Kings College Hospital, London, United Kingdom, ⁵West German Heart Center, Essen, Germany, ⁶Sheba Medical Centre, Tel Hashomer, Israel, ⁷University of Birmingham, United Kingdom, ⁸James Cook Hospital, Middlesbrough, United Kingdom, ⁹Barts and London Chest Hospital, London, United Kingdom, ¹⁰Papaworth Hospital, Cambridge, United Kingdom, ¹¹Medical Centre of Leeuwarden, Netherlands, ¹²Helsinki University Hospital, Finland, ¹³Maastricht University Medical Center, Netherlands

FINANCIAL DISCLOSURE V. Bapat, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; Consultant/Advisory Board, Medtronic, Inc.; M. Romano, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; O. Wendler, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; Consultant/Advisory Board, Edwards Lifesciences LLC; M. Thielmann, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; S. Doshi, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; D. Muir, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; L. Ihlberg, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; L. Van Gaarsse; Speakers Bureau/Honoraria, Edwards Lifesciences LLC; T. Lefevre, Speakers Bureau/Honoraria, Edwards Lifesciences LLC; M. Thomas; Speakers Bureau/Honoraria, Edwards Lifesciences LLC; Consultant/Advisory Board, Edwards Lifesciences LLC

Background: The Edwards SAPIEN valve is usually implanted through either transfemoral (TF) or transapical (TA) route. We evaluate feasibility and results of implantation of Edwards SAPIEN valve through Transaortic (TAo) route in patients with aortic stenosis.

Methods: Between January 2008 and May 2011 a total of 1236 patients underwent TAVI using the Edwards Lifesciences SAPIEN valve in our institutions, of which 158 patients (12.8%) underwent a TAo procedure using Ascendra delivery system. All patients were discussed in a multidisciplinary meeting and the decision for TAVI was based on high predictive risk for AVR. Patients with poor vascular access who were considered unsuitable for TF approach were considered for TAo approach. We evaluated the clinical outcomes according to the VARC definitions. The access was through upper mini-sternotomy in majority of cases (152/158) or through right anterior mini-thoracotomy (6/158). Ascendra delivery system was used in all patients. Eleven of these patients had also undergone at least one previous heart operation (6.9%).

Results: Mean age was 80 ±6.6y and 61% were female (n=96). Mean logistic Euroscore was 32 ±16 and STS score 8.09 ±3. The mean ejection fraction was 45 ±16 %, valve area 0.6 ±0.2cm² and peak gradient 67 ±19mmHg. All procedures were performed under general anaesthesia. Valve sizes used were 23mm (n=74), 26mm (n=76) and 29mm (n=8). In 6 patients, complete off-pump revascularisation was performed in the same session. Procedural success was achieved in all patients (100%). Post procedural mean and peak gradients were 6.2 and 11mmHg respectively. Transfusion ≥4 units was required in 1 patient. There were no incidences of valve migration or conversion to open surgery. There were no access site complications. None of the patients had more than Grade 2 AR at discharge. None of the patients suffered postoperative stroke or persistent AV block. Incidence of renal failure requiring dialysis was 5.2% and major vascular complication was observed in 1.2%. The overall 30-day mortality was 7%.

Conclusion: Trans-aortic TAVI is a feasible and safe approach in the treatment of aortic stenosis using Edwards SAPIEN valve and Ascendra delivery system with low in-hospital complication rates. This approach may become a promising alternative to the conventional Transapical approach.

4:45 pm

European Experience of Direct Aortic TAVI With a Self-Expanding Prosthesis

N. Moat, J.C. Laborde and G. Bruschi (On behalf of the EU CoreValve collaborative group)

FINANCIAL DISCLOSURE N. Moat, Speakers Bureau/Honoraria, Medtronic, Inc.; Consultant/Advisory Board, Medtronic, Inc.; Giuseppe Bruschi, Research Grant, Medtronic, Inc.; J.C. Laborde, Consultant/Advisory Board, Medtronic, Inc.

REGULATORY DISCLOSURE This presentation will address the off-label use of the Medtronic CoreValve for direct aortic access. The Medtronic CoreValve has an FDA status of investigational.

Purpose: The safety and effectiveness of transcatheter aortic valve implantation (TAVI) for the treatment of severe symptomatic aortic stenosis have been demonstrated in numerous studies. The self-expanding CoreValve prosthesis is implanted retro-gradely with vascular access usually via the femoral or subclavian arteries. However, in certain patients these access routes are either not possible or are deemed to carry a high risk of vascular injury. The aim of this report is to describe the use of a direct aortic (DA) approach for TAVI in this patient cohort.

Methods: All European centres with experience of CoreValve implantation were surveyed re their use of the DA approach. Those centres with 3 or more implants were invited to contribute procedural data and outcomes onto a dedicated database.

Results: This multi-center experience comprises 115 patients implanted at 19 centers in 8 countries in Europe. To date detailed data are available on 52 patients from 5 centers. The mean age was 79.8 ± 5.6 years. 41% were male. The mean logistic EuroSCORE was 22 ± 16 . Peripheral vascular disease was present in 74% of the patients and 34% had undergone previous coronary artery bypass surgery. 14 of the procedures were performed via a mini-sternotomy and 38 through a mini-thoracotomy (2nd right intercostal space). Procedural success was achieved in 51 (98%) of cases. There were no procedural deaths and 30-day mortality was 4/52 (7.7%). The incidence of CVA was 3/52 (5.7%) and 7/52 required a new permanent pacemaker (13.4%).

Conclusion: Direct aortic access is a feasible approach for TAVI with the self-expanding CoreValve prosthesis. These initial and provisional results with this technique are encouraging given the high-risk patient cohort (with a particularly high incidence of concomitant vascular disease) and the fact that this series includes each unit's initial experience and early learning curve with this approach.

5:00 pm

Short- and Mid-Term Outcomes in Patients Undergoing Transcatheter Versus Minimally-Invasive or Full Sternotomy Aortic Valve Replacement: Results From a U.S. Multi-Institutional Trial

V.H. Thourani¹, V. Babaliaros¹, T.M. Dewey², R.A. Guyton¹, P. Block¹, M.B. Leon³, C.R. Smith³, D.C. Miller⁴, E.M. Tuzcu⁵, M. Williams³, J.E. Bavaria⁶, G.P. Fontana⁷, W.Y. Szeto⁶, W.N. Anderson⁸, J.J. Akin⁸, M.J. Mack⁹

¹Emory University, Atlanta, GA; ²Medical City Dallas Hospital, Dallas; ³Columbia University, New York, NY;

⁴Stanford University, Palo Alto, CA; ⁵Cleveland Clinic, Cleveland, OH; ⁶University of Pennsylvania, Philadelphia, PA; ⁷Cedars-Sinai, Los Angeles, CA; ⁸Edwards Lifesciences Consultant, Irvine, CA; ⁹Baylor Health Care System, Plano, TX

FINANCIAL DISCLOSURE V.H. Thourani, Speakers Bureau/Honoraria, Edwards Lifesciences LLC, Sorin Medical, Consultant/Advisory Board, St. Jude Medical; M. Leon, Research Grant, Edwards Lifesciences LLC; T.M. Dewey, Research Grant, Edwards Lifesciences LLC; C.R. Smith, Research Grant, Edwards Lifesciences LLC; J.E. Bavaria, Research Grant, Edwards Lifesciences LLC, Medtronic Inc., Consultant/Advisory Board, St. Jude Medical; G.P. Fontana, Research Grant, Edwards Lifesciences LLC, St. Jude Medical, Inc., Medtronic, Inc., Speakers Bureau/Honoraria, Edwards Lifesciences LLC, St. Jude Medical, Inc., Medtronic, Inc., Sorin Group USA, Inc., Ownership Interest, Entourage Medical Technologies, Consultant/Advisory Board, Edwards Lifesciences LLC, St. Jude Medical, Inc., Medtronic, Inc., Sorin Group USA, Inc.; W.Y. Szeto, Research Grant, Medtronic, Inc.; M.J. Mack, Nonremunerative Position of Interest, Executive Committee of the Partner Trial, Edwards Lifesciences LLC; M. Williams, Research Grant, Edwards Lifesciences LLC; W.N. Anderson, Consultant/Advisory Board, Edwards Lifesciences; J.J. Akin, Employment, Edwards Lifesciences LLC

Purpose: Transcatheter aortic valve replacement (TAVR) has been reported as an alternative for high-risk patients with severe aortic stenosis (AS). However, there remains a paucity of data comparing TAVR with minimally invasive AVR (MI-AVR). The objective of this study was to compare short- and mid-term outcomes of TAVR, MI-AVR, and full-sternotomy (FS) AVR.

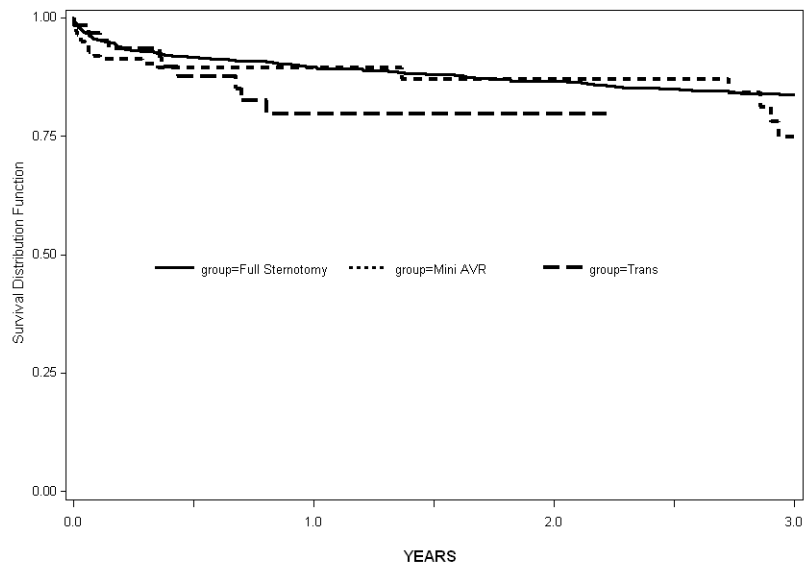
Methods: Patients randomized in the high-risk surgical arm of the PARTNER IA trial (Edwards LifeSciences) from May 2007 – Sept. 2009 were evaluated. The as-treated patients were divided into three groups: TAVR [n= 344: transfemoral (n= 240) and transapical (n= 104)], MI-AVR (n= 49), and FS-AVR (n=264). An additional 42 randomized patients did not receive either TAVR or AVR, and are not reported in this study. Multivariable logistic regression analysis with odds ratios (AOR) and 95% confidence intervals (CI) was performed to evaluate the association between surgery group and mortality, adjusted for the STS Predicted Risk of Mortality (PROM).

Results: The mean age was similar among groups: (TAVR: 83.6±6.8, MI-AVR: 84.7±6.7, FS-AVR: 84.4±6.3, p=NS). The mean STS-PROM was similar among groups: TAVR (11.8±3.3%), MI-AVR (11.2±3.6%), and FS-AVR (11.8±3.3%) (p=NS). Prior CABG was significantly more common in the TAVR group compared to MI-AVR (42.4% vs 8.2%, p<0.0001), but less than the FS-AVR group (42.4% vs 51.1%, p=0.04). The ejection fraction was similar among groups: (TAVR: 52.6±13.3%, MI-AVR: 57.3±11.5%, FS-AVR: 52.6±12.6%, p=NS). Thirty day mortality rates were: TAVR (5.2%), MI-AVR (14.3%) and FS-AVR (6.8%). Patients receiving FS-AVR had odds of death 1.33 times higher than TAVR patients (p=0.41); while patients receiving MI-AVR had odds of death 3.02 times higher than TAVR (p= 0.02). Major vascular complications were significantly higher in TAVR patients: [TAVR: 11.1%, MI-AVR: 2.0% (p=0.0006), FS-AVR: 4.2% (p=0.001)]. Kaplan-Meier stroke rates (unadjusted) were similar among the groups: FS-AVR (2.3%), MI-AVR (4.1%), TAVR (4.4%) (FS-AVR vs TAVR, p=0.15; MI-AVR vs TAVR p=0.91). One-year unadjusted Kaplan-Meier survival estimates were similar among groups FS-AVR vs. TAVR (AOR= 1.06, p=0.76) and MI-AVR vs. TAVR (AOR= 1.17, p= 0.65). After adjustment for PROM, the groups remain similar at one year follow-up: FS-AVR vs. TAVR (AOR= 1.14, p= 0.50) and MI-AVR vs. TAVR (AOR= 1.35, p= 0.40).

Conclusions: When compared to TAVR, early mortality was significantly higher in MI-AVR patients, but not in FS-AVR patients. TAVR had similar mid-term outcomes when compared to MI-AVR and FS-AVR. Careful preoperative planning is required to optimize patient outcome in this high-risk patient population.

Figure 1 continued on next page

Figure 1



Late-Breaking Clinical Trial Abstracts: General Thoracic Surgery

**Monday, January 30, 2012
4:15 pm – 5:15 pm**

Moderators: David R. Jones, Charlottesville, VA and John D. Mitchell, Aurora, CO

4:15 pm

Clinical Trial of Video-Assisted Thoracoscopic Segmentectomy Using Infrared Thoracoscopy With Indocyanine Green

*Y. Kasai, N. Misaki, S. Tarumi, S. Chang, T. Go, H. Yokomise
Kagawa University, Kagawa, Japan*

Purpose: Maintaining a good surgical view is the surgeon's gold standard, and this is particularly important for video-assisted thoracoscopic surgery (VATS). For routine segmentectomy, it is necessary to re-inflate the lung in order to identify the intersegmental line. However, such re-inflation can occasionally obstruct the surgical view. Infrared thoracoscopy (IRT) with indocyanine green (ICG) can reveal the intersegmental line on the basis of blood flow, without the need for inflation. The purpose of this study was to confirm the usefulness of IRT with ICG for VATS.

Methods: Between October 2008 and February 2011, 32 consecutive patients underwent segmentectomy at our institution. In 9 of these patients, VATS segmentectomy using IRT with ICG was employed. Informed consent was obtained from all patients. Computed tomography was performed to clarify the dominant pulmonary artery supplying the target segment. The operations were performed using two ports and one mini-thoracotomy (3-6 cm). The dominant arteries were interrupted, and the intersegmental line was identified using IRT with ICG.

Results: Identification of the intersegmental line was possible in 7 of the 9 patients (77.8%). The patients had an average age of 72 years, and five were males. The mean operation time was 172 min, and the mean bleeding volume was 70 ml. These surgery-related factors were comparable to those of the 23 patients who underwent thoracotomy (162 min / 115 ml, $p=0.56/0.433$, respectively). No complications attributable to IRT with ICG were observed.

Conclusions: VATS segmentectomy using IRT with ICG allows a clear surgical view to be maintained, and identification of the intersegmental line in a high proportion of cases. Therefore we consider it to be useful for minimally invasive thoracic surgery.

4:30 pm

Atorvastatin for Prevention of Postoperative Atrial Fibrillation (POAF)

D. Amar¹, B. J. Park², H. Zhang¹, M. Fleisher¹, W. Shi¹, H. Thaler¹, V. W. Rusch¹

¹Memorial Sloan-Kettering Cancer Center, New York, NY, ²Hackensack University Medical Center, Hackensack, NJ

REGULATORY DISCLOSURE This presentation will address the off-label use of atorvastatin to prevent postoperative atrial fibrillation. Atorvastatin is FDA approved.

Purpose: POAF has been linked to inflammatory mechanisms and is associated with significant morbidity. Atorvastatin has been shown to reduce POAF after cardiac surgery. We hypothesized that preoperative atorvastatin may lower the incidence of POAF via anti-inflammatory actions. Extracellular matrix degradation as predisposing to POAF risk was also examined.

Methods: In a randomized, double-blind study 87 patients without previous statin treatment undergoing major anatomic lung resection received atorvastatin 40 mg/d (n=43) or placebo (n=44) starting 7 days before and continued for 7 days after surgery. Inflammatory markers CRP, TNF α & myeloperoxidase (MPO) were sampled before treatment, on arrival to PACU & morning of postoperative day 3. Metalloproteinase-1 (MMP) and its inhibitor (TIMP-1), indices of extracellular matrix degradation, were sampled before treatment. All marker data were log transformed prior to this interim analysis.

Results: POAF occurred in 6/43 (14%) patients with atorvastatin vs. 11/44 (25%) without, p=0.19, respectively. The 2 arms did not differ in any patient characteristic or inflammatory marker (Data not shown). Regardless of treatment arm, POAF patients were older and had a lower preoperative diffusion capacity (Table, data are mean \pm SD or n (%)). Similarly, POAF patients had a higher CRP on postoperative day 3 than those without POAF but did not differ in MMP, TIMP or their ratio (Figure).

Conclusions: These preliminary data show that preoperative atorvastatin reduced POAF by 44% but this trend did not achieve significance with a small sample size. One week of intermediate dose atorvastatin pretreatment did not significantly lower inflammatory markers. However, independent of atorvastatin treatment patients who developed POAF had a greater postoperative inflammatory response. Extracellular matrix degradation does not appear to play a role in POAF. The mechanism by which atorvastatin may prevent POAF requires further study.

Patient Characteristics			
	POAF (n=17)	No POAF (n=70)	P Value
Age, yr	69 \pm 10	64 \pm 9	0.04
Male	43 (60)	36 (51)	0.06
CAD	1 (5.9)	2 (3)	0.54
HTN	3 (18)	27 (39)	0.10
Smoking	16 (94)	62 (89)	0.68
DM	1 (6)	5 (7)	1.00
Preop Chemo	6 (35)	27 (39)	0.80
β -blocker	3 (18)	11 (16)	1.00
FEV1 % pred.	88 \pm 21	86 \pm 19	0.73
DLCO % pred.	70 \pm 22	81 \pm 20	0.04

Table 2 continued on next page

Table 2

Plasma marker levels					
	POAF (n=17)		No POAF (n=70)		
	Mean	SD	Mean	SD	P-Value
CRP (mg/dL)					
Preoperative	0.4	0.5	0.5	0.9	0.97
PACU	0.5	0.4	1.8	5.0	0.98
Postoperative day 3	15.0	5.0	12.4	7.0	0.01
MPO (ng/mL)					
Preoperative	449.2	320.3	385.0	296.3	0.38
PACU	589.4	424.5	591.3	529.1	0.68
Postoperative day 3	1126.1	943.4	710.3	496.2	0.13
TNF-α (pg/mL)					
Preoperative	22.6	43.5	12.5	23.6	0.20
PACU	2.2	2.1	3.8	7.5	0.37
Postoperative day 3	13.9	26.9	7.1	9.6	0.35
Preop TIMP(ng/mL)	183.0	42	194.0	69.1	0.67
Preop MMP(ng/mL)	8.6	10.5	7.5	7.0	0.54
TIMP/MMPratio	198	554	67	155	0.61

4:45 pm

Prognostic Impact of Visceral Pleural Invasion in Early Non-Small Cell Lung Cancer: Is it Adequate That T1ab Tumors With Visceral Pleural Invasion are Upstaged as T2a?

U. Kazuya¹, M. Yoshimura², K. Suzuki³, T. Koike⁴, T. Shibata⁵, H. Asamura⁶, J. Yoshida⁷, H. Tada⁸, N. Yamashita⁹, T. Mitsudomi¹⁰, N. Ikeda¹¹, T. Nagayasu¹², H. Saji¹¹, M. Tsuboi¹³

¹Hyogo Cancer Center, Akashi City, Japan, ²Hyogo Cancer Center, Hyogo, Japan, ³Juntendo University, Tokyo, Japan, ⁴Niigata Cancer Center, Niigata, Japan, ⁵JCOG Data Center, Tokyo, Japan, ⁶Tokyo National Cancer Center, Tokyo, Japan, ⁷National Cancer Center Hospital East, Kashiwa, Japan, ⁸Osaka City General Hospital, Osaka, Japan, ⁹National Hospital Organization Shikoku Cancer Center, Matsuyama, Japan, ¹⁰Aichi Cancer Center, Aichi, Nagoya, Japan, ¹¹Tokyo Medical University, Tokyo, Japan, ¹²Nagasaki University, Nagasaki, Japan, ¹³Kanagawa Cancer Center, Yokohama, Japan

Purpose: Visceral pleural invasion (VPI) by non-small cell lung cancer (NSCLC) is known as a poor prognostic factor. In the 7th edition of the TNM Classification, using the VPI definition, tumors \leq 3 cm (T1ab) with VPI are upstaged as T2a. We evaluated whether this revision is appropriate and analyzed the prognostic impact of VPI in patients with early NSCLC enrolled in JCOG0201, prospective cohort study for stage IA NSCLC.

Methods: Patients with a tumor suspected or diagnosed as clinical T1N0M0 peripheral lung cancer were prospectively recruited by JCOG0201 between December 2002 and May 2004. Among a total of 811 patients enrolled from 31 institutions, 551 patients who had histologically proven NSCLC (pT1-2) and underwent lobectomy and systematic lymph node dissection were included in this study. OS and RFS were calculated by the Kaplan-Meier method. Multivariate analysis was performed using the Cox proportional hazards model.

Results: Patients' characteristics are as follows: sex: 237 men and 314 women; median age (range): 62 years (35-75); histological diagnosis: 545 adenocarcinomas and 17 others; pT: 510 pT1 and 40 pT2; VPI: 91 positives and 459 negatives; median follow-up time: 6.1 years. OS and RFS were significantly decreased in patients who were VPI positive ($p < 0.001$, HR=4.995, 95%CI=3.056-8.165 and $p < 0.001$, HR=4.038, 95%CI=2.664-6.120, respectively). HR (95%CI) of OS between pT1+VPI negative and pT1+VPI positive or pT2 was 4.977 (3.048-8.129), which was higher than that of pT1 and pT2 (HR=4.608, 95%CI=2.583-8.219). On the multivariate analyses, VPI proved to be an independently statistically significant risk factor for OS ($p < 0.0001$, HR=2.972, 95%CI=1.744-5.065) and RFS ($p = 0.013$, HR=1.823, 95%CI=1.137-2.922).

Conclusions: In the patients with early NSCLC, VPI was an independently significant risk factor for RFS and OS. Our results suggest that it is appropriate that tumors \leq 3 cm (T1ab) with VPI are upstaged as T2a using JCOG0201 cohort data base.

5:00 pm

Early Detection of Lung Cancer With Low Dose CT and Molecular Markers

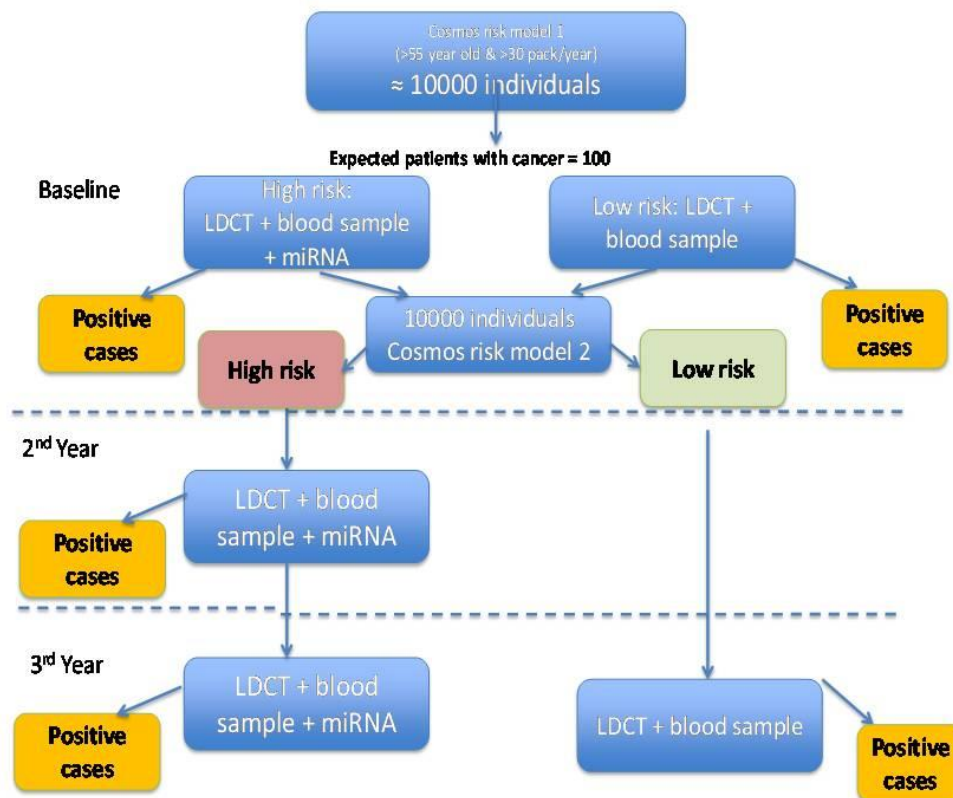
G. Veronesi, M. Bellomi, F. Bianchi, F. Nicassio, L. Spaggiari, P. Maisonneuve, A. Pardolesi, P. Di Fiori
European Institute of Oncology, Milan, Italy

Purpose: To improve large scale diffusion of lung cancer screening a risk model has been developed to optimize the interval between scans and select best target population. In addition a case control study has discovered a microRNA signature able to accurately predict the presence of lung cancer in asymptomatic high risk individuals. Objectives of this study are: 1) to validate the microRNA signature as a tool for early detection of NSCLC in a high risk population; 2) to validate the personalised risk model developed in the Cosmos population; 3) to integrate the molecular and radiological component in a sequential protocol for clinical application of lung cancer screening programs on large scale.

Methods: This is a multicentre prospective study in which high-risk subjects will undergo LDCT and blood sample for microRNA analysis. The study will involve 10.000 individuals and last 5 years. The miRNA test will be performed in a selected population with a predicted annual lung cancer risk of 2%. After baseline CT the high risk population will undergo annual LDCT while the low risk one, LDCT every 2 years. Accuracy, sensitivity and specificity of miRNA signature and LDCT will be evaluated, alone or combined.

Results: Preliminary results showed that the test based on 34 microRNAs could identify patients with early stage NSCLCs with 80% accuracy. We expect that the risk model could accurately predict lung cancers detected during the first year of screening and subsequent screening rounds.

Conclusions: The miRNA signature, if validated in a prospective independent cohort, may represent a non invasive test for a "first line screening" easily available for the population. Our risk model, if validated, can represent an useful tool for identifying lower risk persons in whom the time of the next screening CT can be safely increased, reducing radiation exposure, and lowering the risk of intervention for false positive findings.



Late-Breaking Clinical Trial Abstracts: Congenital Heart Surgery

**Monday, January 30, 2012
4:15 pm – 5:15 pm**

Moderators: David P. Bichell, Nashville, TN and James Jagers, Aurora, CO

4:15 pm

A Novel Near Infrared Cerebral Oximeter for Congenital Heart Disease

R. Kreeger¹, W. Ames², A. Glatz³, K. Hill², J. Hoffman⁴, A. Lobbestael⁵, C. Kurth¹, C. Ramamoorthy⁶, S. C. Nicolson³, L. Peng⁷, F. Ulrich⁵

¹Cincinnati Children's Hospital Medical Center, Cincinnati, OH, ²Duke University Medical Center, Durham, NC, ³The Children's Hospital of Philadelphia, Philadelphia, PA, ⁴Rush University Medical Center, Chicago, IL, ⁵Nonin Medical, Inc., Plymouth, MN, ⁶Lucile Packard Children's Hospital/Stanford University Medical Center, Palo Alto, CA, ⁷Stanford University School of Medicine, Palo Alto, CA

FINANCIAL DISCLOSURE R. Kreeger, Research Grant, Nonin Medical Inc.; W. Ames, Research Grant, Nonin Medical Inc.; A. Glatz, Research Grant, Nonin Medical Inc.; K. Hill, Research Grant, Nonin Medical Inc.; J. Hoffman, Research Grant, Nonin Medical Inc.; A. Lobbestael, Employment, Nonin Medical Inc.; C. Kurth, Research Grant, Nonin Medical Inc.; C. Ramamoorthy, Research Grant, Nonin Medical Inc.; S. Nicolson, Research Grant, Nonin Medical Inc.; L. Peng, Research Grant, Nonin Medical Inc.; F. Ulrich, Employment, Nonin Medical Inc.

Purpose: Cerebral hypoxia-ischemia remains a not infrequent complication in children with congenital heart disease (CHD) before, during and after cardiothoracic interventions. Near-infrared spectroscopy (NIRS), a non-invasive optical technology, can be utilized at the bedside to monitor brain oxygenation and detect hypoxia-ischemia. The purpose of this study was to calibrate and validate a novel NIRS device for CHD.

Methods: After parental consent and IRB approval, 100 children aged <12 years and <40 kg with CHD undergoing cardiac catheterization were enrolled into a two phase study. In Phase I (calibration phase), arterial and jugular bulb venous blood were obtained for co-oximetry simultaneously with NIRS signals to calibrate an algorithm for NIRS regional cerebral saturation (rScO₂) to a weighted average cerebral saturation (SavO₂= 0.7 S_jO₂ + 0.3 SaO₂). In Phase II, (validation phase), arterial and jugular bulb venous samples to calculate SavO₂ were compared with NIRS rScO₂ from the device algorithm. Correlation, bias, precision, and Arms between SavO₂ and rScO₂ were determined by linear regression and Bland-Altman analysis.

Results: Of 100 subjects, 86 met criteria for inclusion in the analysis. There were 7 neonates, 44 infants, and 35 children; of these, 54.7 % were female, 79.1% Caucasian, and 40.7% with cyanotic disease. SaO₂ and rScO₂ ranged from 34.4 to 100% and 34 to 92%, respectively. There were no differences in these data between calibration and validation phases. The Arms, bias, precision, and correlation coefficient were 5.4%, 0.5±5.38%, 5.39%, and 0.88 respectively. Age, skin color, and hematocrit did not affect these values.

Conclusions: This NIRS regional cerebral oximeter accurately measures the absolute value of cerebral saturation in children over a wide range of oxygenation and offers advantages in the detection of tissue hypoxia-ischemia in CHD over other devices.

4:35 pm

Cerebral and Somatic Oxygen Saturations Following Repair of Tetralogy of Fallot: The Effects of Converting From Positive Pressure Ventilation to Spontaneous Breathing on Regional Blood Flow

R. Bronicki¹, N. Anas², M. Bleiweis³, P. Checchia⁴, D. Penny⁴, L. Shekerdeman⁴

¹Texas Children's Hospital/Baylor College of Medicine, Houston, Texas, ²Children's Hospital of Orange County, Orange, CA, ³Shands Children's Hospital, Gainesville, FL, ⁴Texas Children's Hospital, Houston, TX

Purpose: Approximately 25% of infants following repair of tetralogy of Fallot (TOF) develop a low CO state resulting from RV diastolic heart failure. While negative pressure ventilation (cuirass) has been shown to improve stroke volume and CO, the effects that loading the respiratory pump has on the distribution of CO has not been studied. Increases in CO resulting from spontaneous respiration may be offset by an obligatory increase in respiratory muscle oxygen consumption and perfusion, compromising organ perfusion, including the brain, if CO were to remain limited. Hemodynamics and regional tissue oxygenation were measured prior to and following extubation in order to assess the effects of spontaneous respiration on the distribution of CO following repair of TOF.

Methods: We prospectively monitored arterial blood pressure (ABP), heart rate (HR) and central venous oximetry (SvO₂), and cerebral, renal and mesenteric tissue oxygenation using near infrared spectroscopy (NIRS) for 30 minutes prior to and following extubation. Hemodynamic measurements were recorded every 30 seconds and NIRS data every 6 seconds.

Results: Twenty-three consecutive infants were studied. Upon extubation, the ABP and SvO₂ increased significantly (96.1 to 103.8 mmHg, $p < 0.002$ and 65.1 to 70.7%, $p < 0.003$, respectively) while the change in HR was insignificant (143.8 to 145.7, $p = \text{NS}$); cerebral oxygenation increased significantly from 67.3 to 72.3 ($p < 0.0001$); mesenteric oxygenation decreased by $>5\%$ in 8 patients (35%) and for the entire group it decreased significantly from 74.7 to 72.7 ($p < 0.04$). There was no significant change in renal oxygenation (75.7 to 75.4, $p = \text{NS}$).

Conclusions: We found that despite an obligatory increase in respiratory pump perfusion upon extubation, cerebral oxygenation improved significantly albeit at the expense of mesenteric oxygenation.

4:55 pm

Technical Evolution of Preparative Bidirectional Glenn Procedure Aimed at "Off-Pump" Fontan Completion

Y. Atsuta, K. Kagisaki, T. Hoashi, T. Yagihara, H. Ichikawa
National Cerebral and Cardiovascular Center, Suita, Japan

Purpose: A Fontan operation without a cardiopulmonary bypass (CPB), so-called "off-pump Fontan," allows for a smooth initiation of Fontan circulation. We have been performing off-pump Fontan operations for selected patients since 1996 and are gradually expanding the indications. From 2008, we have used a short ePTFE graft that is simply sutured onto the inferior aspect of the branch pulmonary artery as a "pouch" (Figure A) during a 2nd stage bidirectional Glenn (BDG) procedure as preparation for off-pump Fontan. Coumadin is administered during the waiting period. We report early outcomes of this ongoing trial.

Methods: From November 2008, 46 patients underwent a BDG procedure at our institution, 35 of whom (20 males; median age 8.6 months) had an ePTFE pouch attached. In the next stage, off-pump Fontan with an extra-cardiac conduit (ECC) was accomplished by proximal conduit anastomosis following a simple clamp of the pouch (Figure B) and distal conduit anastomosis using a temporary IVC to atrium bypass (Figure C).

Results: Presently, 20 of the 35 patients have completed the Fontan operation at a median age of 1.7 years old, while the remaining 15 are waiting. None of the patients experienced thrombotic or hemorrhagic events during the study period. Eleven of the 20 patients (55%) underwent Fontan completion without a CPB, while the others required that due to placement of fenestration (n=4), integration of a separately draining hepatic vein and IVC (n=3), and intervention for an atrioventricular valve (n=2). Small amounts of thrombus were found in 2 patients in the pouch stump, which was easily removed after simple clamping. Postoperative catheter examinations showed no pressure gradient across the ECC in all patients.

Conclusions: An off-pump Fontan operation following a BDG procedure with placement of an ePTFE pouch was safely and simply done. Further follow-up examinations are mandated to reveal any long-term hemodynamic advantages.

