INTERVENTIONS AT THE VA

Vasilios Papademetriou, MD
Professor of Medicine
Georgetown University
The Veterans Health Administration Today

- 8.8 million patients
- 168 Medical Centers
- 300 Vet Centers
- 827 Community-based Outpatient Clinics (CBOC)
- 135 Community Living Centers
- 6 Independent Outpatient Clinics
- 103 Residential Rehabilitation Centers
- $180 billion budget

The largest Health Care System in the US
1995: Creating VISN’s

Objective to transform from VA “Hospitals” to a “Health System”

From “Safety Net” to “Health Promotion & Disease Prevention”

Creating “System-ness”
- VISN Funding
- Performance Measures
- Electronic Health Records

In January 2002
VISNs 13 and 14 were integrated and renamed VISN 23
Main Objective 1995 -2005

- Improvement in Patient care
- Decrease in cost
- Improvement in outcomes

Safe, Effective, Efficient, Compassionate Health Care
Without the Need for an Advocates
Integrate Notes, imaging, Pharmacy, labs, orders etc
VistA Use

- **Documents** (Progress Notes, Discharge Summaries, Reports)
  - 796,000,000 ........ +586,000 each workday
- **Orders**
  - 1.55 Billion ........ ... +916,000 each workday
- **Images**
  - 454,000,000 ........ +633,000 each workday
- **Vital Sign Measurements**
  - 977,000,000 ........ +672,000 each workday
- **Medications Administered**
  - with the Bar Code Medication Administration (BCMA) system
  - 776,000,000 ........ +599,000 each workday
ELECTRONIC MEDICAL RECORDS
Good things are happening at the VA with all three pillars of Academic Medicine:
- Clinical Medicine
- Medical Education
- Medical Research
The VA is the largest provider of medical training in the United States

<table>
<thead>
<tr>
<th>Trainee Type</th>
<th>Description</th>
<th>VA</th>
<th>U.S. Total (including VA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Students</td>
<td>The VA serves as a site for clinical rotations during medical school; this is also called undergraduate medical education.(^a)</td>
<td>22,931</td>
<td>113,079</td>
</tr>
<tr>
<td>Medical Residents</td>
<td>Through affiliations with hospitals and academic medical centers, the VA serves as a training site for medical residents; this is also called graduate medical education (GME).</td>
<td>41,223</td>
<td>118,366</td>
</tr>
<tr>
<td>Fellows</td>
<td>Through affiliations with hospitals and academic medical centers, the VA serves as a training site for fellows (individuals who have completed residency training and are pursuing additional training in order to subspecialize.)</td>
<td>311</td>
<td>20,779</td>
</tr>
</tbody>
</table>
Animal Research

Biosafety and biosecurity research

Co-operative studies program: Mission statement
- To advance the health and care of Veterans through cooperative research studies that produce innovative and effective solutions to Veteran and national healthcare problems.
- CSP has a clinical research infrastructure that operates under the management of Central Office in Washington, D.C.

35 active co-op studies
- CSP #474 - Radial Artery vs. Saphenous Vein Grafts in Coronary Artery Bypass Surgery (Radial Artery)
- CSP #592 - Efficacy and Safety of ICD Implantation in the Elderly (PI: Steve Singh)
- CSP #517-FS - ROOBY Trial Extension (Randomized on pump and off pump bypass surgery: Long Term Follow-up)
- CSP #571—DES vs BMS in vein grafts

Million Veteran Program (MVP)
HYPERTENSION

Hypertension treatment and control saves lives

1967: Va co-op Severe HTN
1972: VA co-op study Moderate HTN
1980s: VA monotherapy
2000s: ALLHAT ACCORD
2015: SPRINT

ED D Freis
VA Co-op studies
The program is entering the next phase of making these data available, first to VA investigators with plans for expanding in the future to non-VA investigators, for genomic and epidemiological studies that will inform health care delivery.

- **Genetics of Cardio-Metabolic Diseases in the VA Population**
  - Dr. Philip Tsao at the VA Palo Alto Health Care System and Dr. Kyong-Mi Chang at the Philadelphia VA Medical Center will lead a study to explore the role of genetics in obesity, diabetes, and abnormal lipid levels (namely, cholesterol and triglycerides), as drivers of heart disease. This project will help more thoroughly understand underlying causes of cardiometabolic disease and develop new therapies that are safe, effective, and personalized.

- **Pharmacogenomics of Risk Factors and Therapies Outcomes of Kidney Disease**
  - Dr. Adriana Hung at the VA Tennessee Valley Healthcare System will lead a study focusing on how genes affect the risk and progression of kidney disease, one goal is to examine how patients with diabetes—who often develop kidney problems—respond differently to the drug metformin, the standard first-line treatment for diabetes, based on their genetic profile. The project will also look at the genetics of hypertension, a major risk factor for kidney disease.

- **Cardiovascular Disease Risk Factors, Prevalent Cardiovascular Disease and Genetics in the Million Veteran Program**
  - Dr. Peter Wilson at the Atlanta VA Medical Center and Dr. Kelly Cho at the Boston VA Healthcare System will lead an effort probing the genes that influence how obesity and lipid levels affect heart risk. Using MVP data, this study will also look at whether these genetic factors differ among African Americans and Hispanics.
VINCI is an initiative to improve researchers access to VA data and to facilitate the analysis of those data while ensuring Veterans' privacy and data security. VINCI welcomes all researchers in the VA community to explore the environment and tools available.

VINCI is a partner with the Corporate Data Warehouse (CDW) and hosts all data available through CDW as well as some unique data.

Extracts data from:
- CDW extractions from VistA
- MedSAS in SAS and SQL
- DSS in SAS and SQL
- TIU
- Radiology notes

For more information visit VINCI Central Intranet site at: http://vaww.vinci.med.va.gov/vincicentral/default.aspx

VINCI has a common access point using Remote Desktop Connection to connect from anywhere within the VA network.
Fiscal Year 2016 Update
(October 2015-September 2016)

Thomas M. Maddox MD MSc
Director, VA CART Program
December 20, 2016
The VA CART Program is a clinical quality program for all VA cath labs.
CART mission statement

The VA Clinical, Assessment, Reporting, and Tracking (CART) Program is a clinical program to improve cardiac outcomes. Its mission is to optimize Veterans' cardiac outcomes by supporting a learning healthcare system that integrates information technology into healthcare delivery to facilitate safe, effective, and high-value care; to implement quality initiatives; and to generate and disseminate knowledge.
DIGITAL CAPTURE OF CORONARY PROCEDURES

CART data digitally captures each coronary procedure.
CART collects data at the point of care, integrated into clinical workflow.
CART adverse event and device complications are rapidly reviewed by clinical experts.
Adverse event “lessons learned” are shared with all VA cath labs.

- In FY16, 41 (0.07%) major adverse events out of 49,083 coronary procedures were identified
- 23 deaths, 8 strokes, 9 emergent revascularization, 1 other
- 6 (14.6%) with possible quality issue
- Issues included better coordination of heart teams, need for anticoagulation protocols, hemodynamic support in high-risk PCI, better documentation
Device complications are shared with VA Patient Safety Office and FDA.

- In FY16, 231 (0.5%) coronary device issues out of 49,083 coronary procedures were identified
- 15 (6.5%) were reported to the FDA for monitoring
- Continual, bidirectional coordination with FDA and VA National Patient Safety Office
- In talks with the FDA National Evaluation System for Health Technology (NEST)

Contrast-Induced Nephropathy (CIN)

risk prediction program

- CART has developed a VA-specific CIN model (*Brown JR, et al, JAHA 2015*)
- Conducting a CIN prevention practice variation analysis
- Assessing if machine-learning techniques improve prediction
- Will build prediction model into CART workflows to allow for selective deployment of risk mitigation strategies
Vascular bleeding risk prediction program

- CART is building a VA-specific bleeding model
- Conducting a bleeding prevention practice variation analysis
- Assessing if machine-learning techniques improve prediction
- Will build prediction model into CART workflows to allow for selective deployment of risk mitigation strategies
Internal CART research projects

• 14 peer-reviewed publications in FY16
• 38 since program inception
• Examples:
  — Risk for CIN
  — Pulmonary HTN outcomes
  — Peri-operative risks in PCI patients
INTEGRATION WITH GENETICS

Partnership with Million Veterans Project

“The Genetics of Cardiometabolic Disease in the Veteran Population”
CARDIOLOGY PROCEDURES IN 2016

- 78 cath labs
  - 39,735 coronary angiographies
  - 12,305 PCIs
  - 6,902 CABGs
  - 1,783 peripheral angiographies
  - 8,452 right heart caths

- Electrophysiology:
  - 554 permanent pacemakers,
  - 501 temporary wires
  - 297 ICDs
  - 217 ablation procedures
  - 193 Bive+ICDs

- Structural:
  - 280 TAVR procedures
  - 71 valvuloplasties
  - 17 pfo closures

GOOD THINGS ARE HAPPENING AT THE VA
GOOD THINGS ARE HAPPENING IN CARDIOLOGY
CORONARY ANGIOGRAPHY
N=39,375
<table>
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<tr>
<th>REASONS FOR PCI</th>
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<tr>
<td>Stable angina</td>
<td>3117</td>
<td>34.6%</td>
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<tr>
<td>Unstable angina</td>
<td>2,292</td>
<td>25.4%</td>
<td>ACS</td>
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<tr>
<td>NSTE MI</td>
<td>2,053</td>
<td>22.8%</td>
<td>ACS</td>
</tr>
<tr>
<td>STE MI</td>
<td>576</td>
<td>6.4%</td>
<td>ACS</td>
</tr>
<tr>
<td>Other</td>
<td>990</td>
<td>11%</td>
<td></td>
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<tr>
<td>Restenos is etc</td>
<td>507</td>
<td>6.5%</td>
<td></td>
</tr>
</tbody>
</table>
PRESENTATION OF STEMI

Median contrast for PCI 200 cc, fluoro time 20.4 min
NUMBER OF LESIONS TREATED

#lesions

1
2
2
2
0
unprotected LM

#lesions
Interesting-Didactic Cases

Vasilios Papademetriou, MD
VA Medical Center
Washington DC
68 YO M with DM, HTN, HLD, CKD-3
- Drove to the ER at 9 am, feeling dizzy, c/o nausea/vomiting.
- Got out of the car and passed out in the parking lot
- ER personnel to the rescue
- ER, c/o N/V, lightheadedness, but no C/P. Thought had food poisoning
- BP 80/54 mmHg, P=110
- ECG ??
- Troponin in ER 2.3
- Bedside echo shows inferolateral hypokinesis’
  - Overall LV function preserved.
  - Patient denies h/o c/p, CAD
  - Labs: Glucose 110 mg/dl, BUN/CR= 34/2.4, K=4.1, Na=141
AJ-ER ECG

5 JUN 1948 (68 yr)
Sex: Male
Race: Black

Ventricular rate: 115 BPM
PR interval: * ms
QRS duration: 108 ms
QT/QTc: 378/522 ms
P-R-T axes: * 83 145

Technician: [Signature]
Test ind: [Signature]

Motion: Slight

Referral by: [Signature]
Confirmed by: MICHAEL R. FRANZ MD

Arrhythmia: Atrial fibrillation with rapid ventricular response
ST elevation: Consider inferior or injury or acute infarct
Consider right ventricular involvement in acute inferior infarct
Abnormal ECG

When compared with ECG of 13-FEB-2017 11:06, no significant change was found.
Confirmed by FRANZ MD, MICHAEL R (173) on 2/14/2017 11:49:59 AM

Date: 02/13/2017 11:06:41
VAS: [Signature]
5-JUN-1948 (63 yr)

- Black

- Male

- 82 BPM

- PR interval: 182 ms

- QRS duration: 90 ms

- QT/Qc: 346/404 ms

- P-R-T axes: 6 51 53

Normal sinus rhythm
Normal ECG

When compared with ECG of 03-OCT-2005 11:19,
No significant change was found

Confirmed by FRANZ MD, MICHAEL (173) on 8/17/2011 2:33:37 PM

Technician form: Test re FL elevated potassium

Referred by:

Confirmed By: MICHAEL FRANZ MD
Patient transferred to the Cath lab
CASE-1 JA
MR-JA
Moral: N/V can be lethal

Q: Large thrombus: Aspirate or just STENT

Q: Just the Culprit or complete revascularization

Good things are happening in Cardiology at the VA
Patient is 78 YO oriental male

Admitted with chest pain and positive cardiac enzymes
  - Serum troponin I, 1.2

Initial cardiac cath showed:
  - Occluded LCx, Collaterals from the left
  - Occluded RCA, Collaterals from the left
  - 90% proximal LAD
  - EF 45%
ECG AT PRESENTATION

78 yr Male Asian
Vent. rate 69 BPM
Normal sinus rhythm
PR interval 186 ms
Possible Left atrial enlargement
QRS duration 132 ms
Right bundle branch block
QT/QTc 442/473 ms
Inferior infarct (cited on or before 16-JUN-2008)
P-R-T axes 57 51 -58
Abnormal ECG
When compared with ECG of 16-JUN-2008 09:14,
No significant change was found

Technician: MCCOY

Referred by: PETER CARSON, MD
Confirmed by: HANS MOORE MD
MR W
Patient schedule for bypass surgery the next day
At 1 AM patient walked to the shower, coded!!!

Code blue called, CPR performed for 20 min,
  - Patient intubated, pulse stabilized

ECG significant for marked ST elevation/depression

Acute MI team called for emergency PCI
Acute inferior infarct (cited on or before 16-JUN-2008) with anterior ischemia
Abnormal ECG
When compared with ECG of 17-JUN-2008 00:56,
Vent. rate has increased by 59 BPM
Questionable change in QRS duration
Questionable change in initial forces of inferior leads

Referred by:

Confirmed by: HANS MOORE MD
- Patient taken to the cath lab
- RCA and Lcx re-vascularized
- Patient stabilized with an IABP
- Taken to CCU
Patient did well, stabilized. Transferred to CCU, low dose dopamine, planning staged PCI next day
Taken to CCU in stable condition
POST 3 VESSEL PCI. 2 DAYS LATER PATIENT DOING WELL

Technician: MCCOY

Referred by: PETER CARSON, MD
Confirmed by: HANS MOORE MD
Unfortunately the next day patient developed bleeding PUD and perforation! underwent surgical repair!!
Troponine-I

[Graph showing troponine-I levels over time]
Serum Creatinine
Blood Pressure
Patient did well, Discharged to home
  Pre-discharge echo, EF = 45%
Attends clinics regularly
Very compliant to Meds
Enjoys life

Good things are happening at the VA
Animal Research
Biosafety and biosecurity research
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- CSP #571—DES vs BMS in vein grafts
Million Veteran Program (MVP)
Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merrill Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

COURAGE 2007
STABLE CORONARY DISEASE
MEDICAL THERAPY VS PCI

All Cause Mortality + MI

Overall Survival

Survival free of ACS

Survival free of MI
Effect of PCI on Long-Term Survival in Patients with Stable Ischemic Heart Disease

Steven P. Seldin, M.D., Pamela M. Hartigan, Ph.D., Koon K. Tsoo, M.B., B.Ch., Ph.D., David J. Maron, M.D., John A. Spertus, M.D., M.P.H., G. B. John Mancini, M.D., William Kostuk, M.D., Iberard R. Chaitman, M.D., Daniel Berman, M.D., Jeffrey D. Lorin, M.D., Marcia Dada, M.D., William S. Weintraub, M.D., and William E. Boden, M.D., for the COURAGE Trial Investigators

ABSTRACT

Percutaneous coronary intervention (PCI) relieves angina in patients with stable ischemic heart disease, but clinical trials have not shown that it improves survival. Between June 1999 and January 2004, we randomly assigned 2287 patients with stable ischemic heart disease to an initial management strategy of optimal medical therapy alone (medical-therapy group) or optimal medical therapy plus PCI (PCI group) and did not find a significant difference in the rate of survival during a median follow-up of 4.6 years. We now report the rate of survival among the patients who were followed up for 15 years.

METHODS

We obtained permission from the patients at the Department of Veterans Affairs (VA) sites and some non-VA sites in the United States to use their Social Security numbers to track their survival after the initial trial period ended. We searched the VA National Corporate Data Warehouse and the National Death Index for survival information and the dates of death from any cause. We calculated survival according to the Kaplan-Meier method and used a Cox proportional-hazards model to adjust for significant between-group differences in baseline characteristics.

RESULTS

Extended survival information was available for 1211 patients (53% of the original population). The median duration of follow-up for all patients was 6.2 years (range, 0 to 15); the median duration of follow-up for patients at the sites that permitted survival tracking was 11.9 years (range, 0 to 15). A total of 561 deaths (15.6% during the follow-up period in the original trial and 25.8% during the extended follow-up period) occurred: 284 deaths (29%) in the PCI group and 277 (28%) in the medical-therapy group (adjusted hazard ratio, 1.03; 95% confidence interval, 0.83 to 1.21; P = 0.7).

CONCLUSIONS

During an extended follow-up of up to 15 years, we did not find a difference in survival between an initial strategy of PCI plus medical therapy and medical therapy alone in patients with stable ischemic heart disease. (Funded by the VA Cooperative Studies Program and others; COURAGE ClinicalTrials.gov number, NCT00007657.)
KAPLAN–MEIER ESTIMATES OF SURVIVAL IN THE TWO TREATMENT GROUPS

A Whole Study Cohort

- PCI plus optimal medical therapy
- Matched U.S. population
- Optimal medical therapy alone

Unadjusted hazard ratio for death, PCI plus medical therapy vs. medical therapy alone, 0.98 (95% CI, 0.83–1.15)
P=0.79 by log-rank test

No. at Risk
Optimal medical therapy 1138 1072 869 590 455 403 280
PCI plus optimal medical therapy 1149 1088 894 620 486 416 302

Years in Study

B Extended Follow-up Study Cohort

- PCI plus optimal medical therapy
- Optimal medical therapy alone

Unadjusted hazard ratio for death, PCI plus medical therapy vs. medical therapy alone, 0.95 (95% CI, 0.79–1.13)
P=0.53 by log-rank test

No. at Risk
Optimal medical therapy 598 569 533 500 455 403 280
PCI plus optimal medical therapy 613 589 561 529 486 416 302

Years in Study

F/U courage NEJM 2015
Drug-Eluting Stents vs. Bare Metal Stents In Saphenous Vein Graft Angioplasty (DIVA)

Emmanouil S. Brilakis, MD, PhD
on behalf of the DIVA Trial Investigators and the Veterans Affairs Cooperative Studies Program #571 Study Team, USA
Natural history of SVGs

0 CABG

1 Early remodeling
Early occlusion

2 Intermediate lesions

3 Severe lesions

4 Occlusion

Ticagrelor (Target, POPular CABG)
Prasugrel SVG
eMESH-1
Statin – START CABG
Polyarginine, Duragraft
No touch

DIVA - DES
## RCTs: DES vs. BMS in SVGs

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>N</th>
<th>Primary endpoint</th>
<th>DES event rate (%)</th>
<th>BMS event rate (%)</th>
<th>P</th>
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<tbody>
<tr>
<td>RRISC</td>
<td>2006</td>
<td>75</td>
<td>6-month angiographic restenosis</td>
<td>13.6</td>
<td>32.6</td>
<td>0.031</td>
</tr>
<tr>
<td></td>
<td>2007</td>
<td></td>
<td>MACE at 32 months</td>
<td>58</td>
<td>41</td>
<td>0.13</td>
</tr>
<tr>
<td>SOS</td>
<td>2009</td>
<td>80</td>
<td>12-month angiographic restenosis</td>
<td>9</td>
<td>51</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>2010</td>
<td></td>
<td>Target vessel failure at 35 months</td>
<td>34</td>
<td>72</td>
<td>0.001</td>
</tr>
<tr>
<td>ISAR-CABG</td>
<td>2011</td>
<td>610</td>
<td>12-month composite of death, MI and TLR</td>
<td>15</td>
<td>22</td>
<td>0.02</td>
</tr>
<tr>
<td>BASKET-SAVAGE</td>
<td>2016</td>
<td>173</td>
<td>12-month composite of cardiac death, MI and TVR</td>
<td>2.3</td>
<td>17.9</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Study Design

• Prospective, double-blind, multicenter, randomized trial

• **Primary endpoint:** 12-month incidence of target vessel failure

  (TVF: composite of cardiac death, target vessel myocardial infarction, or target vessel revascularization)
Study Design

Baseline

12 m

12-60 m

SVG with 50-99% stenosis

R

DES

12-months P2Y12 inhibitor

BMS

1-month P2Y12 inhibitor (for non-ACS pts)

Clinical FU

blinded

Clinical FU

Design paper: Brilakis et al. Clinical Cardiology 2017; DOI: 10.1002/clc.22763
Initial sample size: 519 pts to achieve 90% power for the primary endpoint at 12 months FU assuming 12-month TVF rate 30% in BMS and 18% in DES

Interim analysis: sample size increased to 762 due to lower than anticipated TVF rate

Enrollment stopped 12/31/2015: 599 pts enrolled – 597 included in analysis due to improper consent in 2 pts
### Total SCREENED = 3482

<table>
<thead>
<tr>
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<th>Count</th>
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<tr>
<td>K. Mavromatis (Atlanta, GA)</td>
<td>218</td>
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<tr>
<td>S. Banerjee (Dallas, TX)</td>
<td>214</td>
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<tr>
<td>K. Shunk (San Francisco, CA)</td>
<td>91</td>
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<td>K. Ramanathan (Memphis, TN)</td>
<td>206</td>
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<tr>
<td>A. Bavry (Gainesville, FL)</td>
<td>249</td>
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<tr>
<td>E. McFalls (Minneapolis, MN)</td>
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<td>F. Latif (Oklahoma City, OK)</td>
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<td>H. Truong (Tucson, AZ)</td>
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<td>B. Uretsky (Little Rock, AR)</td>
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<td>E. Armstrong (Denver, CO)</td>
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<td>J. Ortiz (Cleveland, OH)</td>
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<td>H. Jneid (Houston, TX)</td>
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<td>J. Liu (Hines, IL)</td>
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<td>K. Aggarwal (Columbia, MO)</td>
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<td>S. Rao (Durham, NC)</td>
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<td>I. Bolad (Indianapolis, IN)</td>
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<td>A. Klein (St. Louis, MO)</td>
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<td>S. Kinlay (West Roxbury, MA)</td>
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<tr>
<td>K. Owen (Asheville, NC)</td>
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<td>K. Ziada (Lexington, KY)</td>
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<td>V. Papademetriou (Washington)</td>
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<td>S. Seldis (New York Harbor, NY)</td>
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<td>C. Duvernoy (Ann Arbor, MI)</td>
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<td>K. Lehmann (Seattle, WA)</td>
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<tr>
<td>D. M. Ratliff (Albuquerque, NM)</td>
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### Total RANDOMIZED = 597

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<td>B. Uretsky (Little Rock, AR)</td>
<td>28</td>
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<tr>
<td>E. Armstrong (Denver, CO)</td>
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<tr>
<td>J. Ortiz (Cleveland, OH)</td>
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<tr>
<td>H. Jneid (Houston, TX)</td>
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<tr>
<td>J. Liu (Hines, IL)</td>
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<td>K. Aggarwal (Columbia, MO)</td>
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<tr>
<td>S. Rao (Durham, NC)</td>
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<tr>
<td>I. Bolad (Indianapolis, IN)</td>
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<td>A. Irmen (New Orleans, LA)</td>
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<td>A. Klein (St. Louis, MO)</td>
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<td>S. Kinlay (West Roxbury, MA)</td>
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<td>K. Owen (Asheville, NC)</td>
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<td>K. Ziada (Lexington, KY)</td>
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<tr>
<td>V. Papademetriou (Washington)</td>
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<tr>
<td>S. Seldis (New York Harbor, NY)</td>
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<tr>
<td>C. Duvernoy (Ann Arbor, MI)</td>
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<tr>
<td>K. Lehmann (Seattle, WA)</td>
<td>6</td>
</tr>
<tr>
<td>D. M. Ratliff (Albuquerque, NM)</td>
<td>0</td>
</tr>
</tbody>
</table>
Primary endpoint: 12-month TVF

Log-Rank = 0.43
p-value = 0.67
Total Events = 109
Hazard Ratio of DES Relative to BMS = 0.92

composite of cardiac death, target vessel myocardial infarction, or target vessel revascularization
12-month Outcomes I

Log rank p values

- TVF: P = 0.67
- Death: P = 0.64
- Cardiac death: P = 0.36
- MI: P = 0.63
- Target vessel MI: P = 0.71
12-month Outcomes II

Log rank p values

Revascularization: P = 0.57
PCI: P = 0.65
CABG: P = 0.82
TVR: P = 0.74
TLR:
12-month outcomes III

Definite stent thrombosis

- DES: 2
- BMS: 2

- Log rank p values: P = 0.84

Definite/probable stent thrombosis

- DES: 5
- BMS: 6

- Log rank p values: P = 0.68
Antiplatelet medications during FU

- Aspirin
- P2Y12 Inhibitor

12 Months: DES 97%, BMS 93%
P2Y12 Inhibitor 89%
Aspirin 93%

24 Months: DES 93%, BMS 93%
P2Y12 Inhibitor 64%
Aspirin 58%

36 Months: DES 86%, BMS 84%
P2Y12 Inhibitor 48%
Aspirin 44%
TVF during long-term FU
median FU: 2.7 years

Log-Rank = 0.73
p-value = 0.46
Total Events = 213
Hazard Ratio of DES Relative to BMS = 1.11

No. at Risk
DES  BMS
292  305
277  292
263  274
245  260
229  241
213  225
194  206
175  187
158  168
131  149
114  134
97   109
78   91
58   74
52   61
43   46
33   38
24   22
Long-term Outcomes I
median FU: 2.7 years

Log rank p values

TVF: P = 0.46
Death: P = 0.54
Cardiac death: P = 0.45
MI: P = 0.51
Target vessel MI: P = 0.76
Long-term Outcomes II
median FU: 2.7 years

Log rank p values

P = 0.15
P = 0.26
P = 0.18
P = 0.29
Long-term Outcomes III
median FU: 2.7 years

Definite stent thrombosis
- DES: 3
- BMS: 3
P = 0.89

Definite/probable stent thrombosis
- DES: 9
- BMS: 10
P = 0.69

Log rank p values
Limitations

• Nearly all patients were men
• Study completed before reaching revised enrollment target, but still more patients than initially planned
Conclusions

When stenting de novo SVG lesions:
• No difference in short- and long-term outcomes between DES and BMS
• Novel strategies needed for treatment of severe SVG lesions
OVERALL CONCLUSIONS

• The VA developed a successful interventional program that
  – Provides optimal treatment to patients with heart disease
  – Contributes to Medical education
  – Pursues innovative medical research