Integrating Innovative Technologies into the Care of Cardiac Patients

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Presenter Disclosure Information

FINANCIAL DISCLOSURES:
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Epidemiology of Heart Failure in the United States

- 5.7 million symptomatic patients; estimated 10 million in 2037
- Incidence: About 550,000 new cases/year
- Prevalence is 1% between the ages of 50 and 59, progressively increasing to >10% over age 80

American Heart Association. 2013 Heart and Stroke Statistical Update.

Forbes

Cheney's Million Dollar Heart Stirs Health Care Debate: Who Lives and Who Dies?

- Age 37: AMI (1978)
- Age 47: AMI - CABG (1988)
- 1988 – 2000 Ischemic Cardiomyopathy
- Age 60 ICD (2001)
  - AF
  - VT
- CRT
- Age 69 LVAD (2010)
- Age 71 Cardiac Transplant (2012)
Overview

- Innovative technologies that are available now for:
  - Aortic valvular heart disease
  - Monitoring cardiovascular physiology in heart failure
  - Mechanical circulatory support

The Changing Face of Valve Disease

- Shift from rheumatic to “degenerative” etiologies
- Moderate to severe valve disease occurs in*:
  - 1.9% people 55 to 64 years-old
  - 8.5% people 65 to 74 years-old
  - 13.2% people 75 years and older
- Prevalence of valve disease increase as the elderly population continues to grow
- Elderly have an inherent increase in risks associated with surgery and complexity of medical management

Prevalence of Valve Disease by Age


Natural History of Aortic Stenosis

Calcific Aortic Stenosis: Mechanisms

- Calcific aortic stenosis is a biologically active process
- Lipid accumulation
  - LDL accumulation and oxidation
- Inflammation
  - T-cells, monocytes, inflammatory mediators, cytokines
- Calcification
  - Osteoblast expression, bone formation

Medical Therapy

- Medically therapy for aortic stenosis is limited
- Treat symptoms
- Slow progression of disease
- Improve survival
Statin Therapy to Slow AS Progression: SEAS (Simvastatin and Ezetimibe in Aortic Stenosis)

Aortic Valve Replacement Surgery
High Risk Surgical Patients

- Advanced age (>80)
- Redo cardiac surgery
  - especially prior CABG
- LV dysfunction (EF < 30%)
- Atherosclerotic aorta
- Cerebrovascular disease
- Peripheral artery disease
- Chronic kidney disease
- Chronic lung disease
- Diabetes

Transcatheter Aortic Valve Replacement

- Transfemoral
- Transapical
Sapien and CoreValve

Transcatheter Aortic Valve Implantation
Transcatheter Aortic Valve Implantation

PARTNER: Placement of AoRTic TranScatheterER Valves Trial

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

High Risk

Total = 1,057 patients
2 Parallel Trials: Individually Powered

Inoperable

ASSESSMENT: Inoperable

Primary Endpoint: All-Cause Mortality at 1 yr (Non-inferiority)

Primary Endpoint: All-Cause Mortality Over Length of Trial (Superiority)
Co-Primary Endpoint: Composite of All-Cause Mortality and Repeat Hospitalization (Superiority)

TF TAVR

VS

AVR

Primary Endpoint: All-Cause Mortality at 1 yr (Non-inferiority)

TF TAVR

VS

Standard Therapy

vs

AVR
**Inoperable AS Patients - All Cause Mortality**

HR [95% CI] = 0.57 [0.44, 0.75]  
\( p \) (log rank) < 0.0001

Δ at 1 yr = 20.0%  
NNT = 5.0 pts

Δ at 2 yr = 24.7%  
NNT = 4.0 pts

**High Risk AS Patients - All-Cause Mortality**

Conclusions

- TAVR significant benefits patients with severe symptomatic aortic stenosis who are inoperable for conventional aortic valve replacement
- TAVR is an acceptable alternative to AVR in selective high-risk operable patients
  - We are learning how peri-procedural risk factors such as age and comorbidities (renal dysfunction, LV dysfunction, etc.) should influence the clinical decision making in these patients
  - Advances in device technology and operator experience are likely to improve TAVR outcomes over time
- A multidisciplinary valve team approach benefits patient care, procedural outcomes, and clinical decision making

Hospitalization for Heart Failure in the US 1979-2006

- 1.1 million hospitalizations/yr
- Continues to rise!

30 day Rehospitalization rates for HF:
  - 1993: 17.3%
  - 2006: 20.1%

Source: NHLBI, NHDS/NCHS and NHLBI
Cost of Heart Failure to Society

$37.2 billion

*Direct and indirect costs in billions of $; estimated for year 2009

AHA. 2009 Heart and Stroke Statistical Update
Page RL et al. AHA Scientific Sessions 2008

The Marginal Benefit of Additional Treatments of Heart Failure with LVSD are Decreasing

*statistically significant treatment effect
The MGH Approach to Heart Failure

- Guiding principles
  - All patients and family/caregivers are capable of performing some level of self-management in their day-to-day living with heart failure
  - All patients should be enrolled in a standardized educational program tailored to their level of disease, family support, and health literacy

- Goals
  - Coordinate inpatient care consistent with best evidence medical practice
  - Standardize education program designed to promote disease self-awareness and self-management skills for patients and family members consistent with level of disease and health literacy
  - Collaborate with ambulatory care to align inpatient and outpatient management of HF to improve transitions
  - Connect HF patients with a specific management program tailored to the patient needs

- Metrics
  - Readmission Rates: 30 and 90 day
  - Benchmark against nationally recognized HF programs
  - VBP: education material
  - Patient satisfaction: HCAHPS reports

Can Technology Help?

Pressure Sensors

Mechanical Circulatory Support
Pulmonary Artery Pressure Monitoring

Pressure sensor

Champion Study, Lancet 2010

Champion - Cumulative HF Hospitalizations

Target range (mmHg):
- PA systolic: 15-35
- PA diastolic: 8-20
- PA mean: 10-25

- 30%↓ in HF hospitalizations at 6 months
- 35%↓ in annualized HFH rates for the entire randomized follow-up
- ↑QoL score with treatment group
Why was the Cardiomems Device Not Approved by the FDA?

- The patient could take action to monitor themselves.
- The patient did not have the information to intervene on their disease process!

Direct Left Atrial Pressure Measurement - LAPTOP
Laptop includes a Patient Advisory Monitor that “Closes the Loop”

Left Atrial Pressure 2 Weeks and 12 Months after Device Implantation
HOMEOSTASIS II: Feasibility of Patients Using Data from a LA Pressure Monitor

After initiation of LAP-guided therapy
- The frequency of elevated readings (>25 mmHg) was reduced by 67%
- Mean daily LAP fell from 17.6 mmHg in the first 3 months to 14.8 mmHg
- Doses of ACE/ARB and beta-blockers were up-titrated by 37% and 40%, respectively, whereas doses of loop diuretics fell by 27%
- Reduced compliance and LAP> 25 were found to be associated with HF admissions

Summary

- Implantable devices are safe and effective in monitoring hemodynamic parameters in chronic heart failure patients.
- Where should they be deployed?
  - Right ventricle
  - Pulmonary artery
  - Left atrium
- Are implantable monitors better than a scale and a telephone call?
  - Laptop should give us the answer.

Circulation, Feb 2010; 121: 1086-1095
Why Mechanical Circulatory Support?

A plan to treat heart failure by transplantation is like a plan to treat poverty by the lottery!

Heart Failure Patients in US (Millions)
0 2 4 6 8 10 12
1991 2005 2037*

Development of LVADs – An example of Government Doing the Right Thing

1/77 NHLBI RFP HV-77-8 Left Heart Assist Blood Pumps
NHLBI RFP HV-77-9 Development of Electrical Energy Converters to Power and Control Left Heart Assist Devices

1/80 NHLBI RFP 80-3 Development of an Implantable Integrated Electrically Powered Left Heart Assist Device
The Evolution of MCS Devices

Made in Massachusetts

- PVAD
- Paracorporeal
- Pneumatic
- Pulsatile
- Uni-or Biventricular

- Heartmate XVE
- Implantable
- Pneumatic/Electric
- Pulsatile
- Large
- LVAD

- Heartmate II
- Implantable
- Electric
- Continuous flow
- Smaller
- Single moving part

- Heartware
- Implantable
- Electric
- Continuous flow
- Smaller
- Uni-or Biventricular

The REMATCH Trial of the Heartmate I Initiates Widespread Deployment of MCS

The New England Journal of Medicine

Long-term Use of a Left Ventricular Assist Device for End-stage Heart Failure

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Volume 345 November 15, 2001 Number 20

Survival: LVAD vs Medical Therapy

Continuous Flow Permits the Device to be Smaller and More Durable
Comparison of pulsatile to continuous flow LVADs

The New England Journal of Medicine

Original Article

Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device

Mark S. Slaughter, M.D., Joseph G. Rogers, M.D., Carmelo A. Milano, M.D., Stuart D. Berdan, M.D., John V. Conte, M.D., Daniel Feldman, M.D., Ph.D., Benjamin Sun, M.D., Antoine J. Tatooles, M.D., Reynolds M. Delgado, III, M.D., James W. Long, M.D., Ph.D., Thomas C. Wornak, M.D., Waqas Ghumman, M.D., David J. Farrar, Ph.D., and O. Howard Frazier, M.D., for the HeartMate II Investigators

NEJM (2009) 361:2241

Comparison of Survival with Pulsatile and Continuous Flow LVAD in Different Eras
HVAD: Heartware

Bridge to Transplant Results with Heartware Support
Bridge to Transplant Results with Heartware Support

The Total Artificial Heart

[Diagram showing bridge to transplant results with Heartware support]

[Diagram showing the total artificial heart]

[Text and images related to bridge to transplant results and the total artificial heart]
Summary

- Technology can improve and extend HF patients’ lives now!
  - Transcutaneous aortic valve replacement is an option for high-risk surgical patients. We will be learning more about expanding its use to patients with fewer surgical risks.
  - Implantable hemodynamic monitoring is safe and effective in providing physiologic data in ambulatory HF patients. Will it allow patients to become the master of their disease.
  - Mechanical Circulatory Support (MCS) will be the next big Advanced HF therapeutic. Transplantation will be reserved for patients unable to have MCS.