Beating Heart Aortic Valve Replacement: The Future is Here

Ashok Babu, M.D.
Department of Surgery
University of Colorado
Aortic Stenosis

- Congenital, “degenerative”, and rheumatic
- 2-5% incidence in age >65
- 50,000 AVR’s performed annually in US

Otto et al. NEJM 1999
Indications for AVR in AS

- Critical valve area (<1.0 cm$^2$ or <0.6cm$^2$/m$^2$) AND symptoms
  or
- Progressive LV dysfunction
  or
- Hypotensive response to exercise
Standard AVR is a safe procedure

• STS database—33,000 isolated AVR in 2004
  – 4% mortality, 13% serious complication

• Germany
  – 2.4% mortality with mechanical valve
  – 3.8% mortality with tissue valve

Walther et. al. EJCTS 2006
Kalmar et. al. TCVS 2004
Why minimally invasive?

- Age—15% mortality in age 80-85
  - 18% mortality in age 85+
- LV dysfunction confers 10% plus mortality
- Euro Heart Survey—5100 pts with severe valvular disease
  - 31.8% did not undergo indicated intervention due to:
    - Cardiac—poor function
    - Non-cardiac—age, ESRD, COPD, short life exp.

Iung et. al. Eur Heart J 2003;24:1231-43
Balloon valvuloplasty

- Used in past to temporize non-surgical candidates with critical AS
- Functional improvement occurs but transient
- 80% restenosis rate at 15 months

Preliminary Communications

CATHETER-MOUNTED VALVE FOR TEMPORARY RELIEF OF AORTIC INSUFFICIENCY

The technique described here is aimed at saving those patients with gross aortic insufficiency who are dying in cardiac failure and are too ill for surgery. Such cases are by no means uncommon, especially following bacterial endocarditis. The clinical benefit which follows successful insertion of a Hufnagel valve in the descending aorta or the placement of a homograft aortic valve in the same site suggested that similar relief might be attained by simpler means.

A cone-shaped valve mounted on a cardiac catheter (gauge 5F) was designed, and construction of a prototype undertaken by the U.S. Catheter Co., Glens Falls, New York. This valve is in the form of a parachute (fig. 1) and

Fig. 1—The valve.
Animal Data

  - Porcine valve sewn into balloon-expandable stent
  - Retrograde delivery via femoral artery in pigs
  - 3/9 with coronary ischemia due to obstruction
Animal Data

  - Bovine jugular vein with valve sewn into balloon-expandable stent
  - Right carotid artery retrograde – 40kg lambs
  - When deployed in native location all had complications:
    - Mitral valve injury
    - Coronary occlusion
    - Distal migration
    - Paravalvular leak
Technical Considerations

• Site of new valve
  – Supracoronary—great vessel obstruction / migration / coronary diastolic pressure?
  – LVOT—paravalvular leak and proximity to mitral valve
  – Native—coronary ostia

• Migration/embolization

• Paravalvular leak

• Route of delivery—antegrade/ retrograde / transapical
1st Human Perc. Aortic Valve-2002

- Cribier et. al. (University of Rouen group)
  - 3 equine pericardial leaflets sewn into an expandable steel stent
  - 14mm length
  - 23 or 26mm valve diameter
  - Durability tested to 5 years

1st Human Perc. Aortic Valve-2002

- 57M with severe calcific AS
- Presented in cardiogenic shock
- Severe PAOD s/p aorto-bifem
- EF 14% with no contractility reserve by dobutamine stress test
- Transient improvement following balloon valvuloplasty
- Denied for surgical AVR by multiple consultants

1st Human Perc. Aortic Valve-2002

• “Antegrade” delivery via femoral vein
  – 24 French sheath
  – Puncture and balloon dilation of interatrial septum to 10mm
  – Balloon valvuloplasty to 23mm
  – Device deployed with annulus at its midpoint under V-pace at 220
1\textsuperscript{st} Human Perc. Aortic Valve-2002

- Post-op course
  - Immediate hemodynamic improvement
  - Valve Area 0.6\(\rightarrow\)1.9 cm\(^2\)
  - Transvalvular gradient 30mmHg\(\rightarrow\)6mmHg
  - q2 week echo demonstrated no migration or valve dysfunction
  - Died at 17 weeks due to sepsis following R AKA (occluded limb of ABF pre-op)

Rouen Group—Early results

- Technical Success Rate = 75%
- 36 patients—NYHA IV, ≤0.7 cm², and mult. comorbidities
- Predicted surgical mortality of 25% by EuroSCORE
- Success = accurate placement and hemodynamic improvement
- MAE = death, MI, emergent surgery, CVA
- Mean follow-up 12 months

Cribier et al. JACC 2006.
Rouen Group—Early results

- 30 day Major adverse events = 26%
  - Anoxic brain injury (1), CVA (1)
  - Death due to tamponade (2), urosepsis (1), unknown (1)
- 6 month MAE = 37% (unrelated to procedure)
- Device failure = 0%
- Paravalvular leak was common: Grade 0-1 (10), 2 (12), 3 (n=5)

Cribier et. al. JACC 2006.
Rouen Group—Early results

- Majority of survivors had improved NYHA classification IV→II
Femoral antegrade vs. retrograde

- **Retrograde arterial**
  - Arterial complications
  - Inability to accommodate 24F sheath
  - Greater risk of embolus

- **Antegrade venous**
  - Trans-septal guidewire interaction with anterior mitral valve leaflet
  - Creation of ASD
  - Technical difficulty
Vancouver Group—Retrograde approach

- Cribier-Edwards Device in 23 and 26mm
- Utilized a flexible deflection catheter to improve retrograde arterial success rate

Vancouver Group—Retrograde approach

- 18 patients denied surgery for symptomatic critical AS mean age 82 years
- First 6 under MAC anesthetic
- Last 12 general to facilitate arteriotomy closure / TEE
- 78% technical success rate
- 11% (2) access complications:
  - Iliac dissection requiring repair
  - Iliac hemorrhage req repair → MOF → death
- 5% (1) with visual field defect resolved at 30 days
- 89% (16/18) survival at Mean F/U 73 days
  - 2nd mortality due to left main occlusion from native cusp

Vancouver Group—Retrograde approach

• Technical Failures
  – Valve migration—2 immediate events only with 23mm graft
    • Both were moved to a safe location in the arch
    • No delayed migration
  – Inability to negotiate calcified aortic valve (1)
  – Inability to negotiate iliac artery (1)

• 0% embolization rate with 26mm graft

• Median paravalvular leak grade I for 26mm vs. grade II for 23mm

CoreValve Device—Siegburg, Germany group

- Retrograde approach
- Bioprosthetic valve
- Self-expanding nitinol stent
- 21mm valve in 21F sheath
- Utilized femoro-femoral bypass during deployment

CoreValve Device—Siegburg, Germany group

- 25 patients mean age 80 years
- Inclusion:
  - Valve area < 1cm$^2$ and/or >3+ regurgitation
  - Annulus diameter 20-23mm
  - Ascending aorta diameter < 3cm
  - Contraindication to surgery due to comorbidities
- Mean valvular gradient 69 mmHg, area 0.7
- 96% NYHA Class III/IV

CoreValve Device—Siegburg, Germany group

- 84% acute technical success rate
  - 2 patients device deployed too high → large paravalvular leak and urgent open AVR
  - 1 patient—unable to cross valve after successful valvuloplasty—died suddenly 12 hrs later
  - 1 patient—wire perforation of LV → tamponade → death

CoreValve Device—$2^{nd} / 3^{rd}$ gen

- $3^{rd}$ gen device decreased sheath diameter to 18F
- 86 patients—first 50 received $2^{nd}$ gen device
- Mean EuroSCORE mortality prediction 22%
- 88% Acute technical success
  - 6 patients—distal placement led to urgent operative AVR
  - 2 patients—unable to negotiate across valve
  - 2 patients—placement of $2^{nd}$ device due to regurg
- MAE (Death, stroke, MI) = 18%
  - death after open AVR (1), valvuloplasty only (1), tamponade (3)
  - CVA (9), nonlethal tamponade (3)
- Overall Success excluding patients with MAE = 74%
- Overall 30 day mortality = 12%

Grube et. al. JACC 2007.
CoreValve Device—$2^{nd}$ / $3^{rd}$ gen

- NYHA class 2.8→1.8
- Most patients had reduced AR though 20% had increased AR post-procedure due to paravalvular leak
- No AR worse than 2+
- Only 30% of patients treated with 18F device required extracorporeal circulation (operator-determined)

Grube et. al. JACC 2007.
CoreValve Device

• Pros
  – May minimize paravalvular leak with self-expanding design
  – Secure fixation in ascending aorta
  – Can be used to treat lone AR
  – Avoids balloon trauma to new valve leaflets
  – 21F or 18F delivery catheter

• Cons
  – Need for extracorporeal circulation during deployment
  – Problems with thrombocytopenia
  – Only valve size is 21mm

Grube et. al. JACC 2007.
Transapical Delivery

- 5-8cm anterolateral thoracotomy over LV apex (6th ICS)
- Epicardial V-wires placed
- 2 pledgeted U-stitches in apex → Ramel tourniquet
- Needle → wire → sheath into LV apex

Vancouver group

- Transapical

• 7 patients with critical symptomatic AS
• 26mm Cribier-Edwards Device
• EuroSCORE predicted surgical mortality 35%
• Unsuitable for femoral retrograde valve due to aortoiliac disease or tortuosity
• 100% technical success rate
• 2/7 with excessive paravalvular leak had immediate repeat expansion of valve with good result
• Mean paravalvular leak Grade 1.0

Vancouver group—Transapical

- Acute mortality=0%
- CVA rate=0%
- 30 day mortality=14% (one patient died of PNA)
- 180 day mortality=42% (2 deaths from malignancy and lung disease)
- Median hospital stay 8 days
- All patients had improvement or resolution of symptoms related to AS
- At 180 days, mean gradient 10 mmHg, valve area 1.6, moderate paravalvular leak in 1, mild in 2, none in 1

Liepzig group—Transapical

- Same device (Cribier-Edwards AKA SAPIEN)—4 centers
- Only difference in implantation was the occasional use of femoro-femoral bypass
- EuroSCORE predicted surgical mortality 27%
- 59 patients—93% technical success (55/59)
  - 2 placed high, 2 placed low—all 4 with open AVR—50% mortality
- 48% patients underwent bypass (early in series)—Last 18 patients did not have bypass
- Average OR time 148 min→80 minutes in straightforward case
- CVA=3.4%
- 30 day mortality = 13.6%—none valve related
- At Mean F/U 110 days—22% mortality—none valve related

Technical obstacles

- Paravalvular Leak
- Size of valve orifice
- Size of delivery system
- Accuracy of placement
- Long-term durability
Top 5 reasons Transapical is Better

1. I can’t remember the last time I saw a cardiologist place a pursestring in the LV apex
2. Reduced rate of CVA
3. Increased applicability in patients with vascular disease
4. Improved technical success rate
5. No limitation in sheath diameter