CARDIAC SURGERY UPDATE: SMALLER INCISIONS AND LESS COUMADIN

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DEVELOPMENT OF THE CONTEMPORARY STERNOTOMY

Open Heart Surgery 2007

Open Heart Surgery 2017
DEVELOPMENTS LEADING TO A SMALLER STERNOTOMY

- Understanding Sternal Spreading vs Incision length
- Better Cardiac Positioning
- New Cardioplegia options
- Femoral canulation - reducing clutter
Most postoperative pain is related to rib cage distraction – not the sternal incision itself.

- Reduced narcotic use
- 2 inches of sternal spreading
- Ligaments, and joints are much less traumatized
CARDIAC POSITIONING IS IMPROVED

- Off Pump surgery required new techniques for Cardiac positioning
- Surgeons grew accustomed to working in narrower windows of exposure
- Entire team is more adept at assisting in a limited visibility environment
WHY CANNULAS MATTER
FEMORAL CANNULATION

- Limited dissection – Only single purse string
- 3 cm incision
- Cannulas are no longer in the chest incision
- Placement is performed under TEE guidance
- Very little post-operative impact – pain, mobility etc.
FEMORAL ARTERIAL AND VENOUS CANNULATION
Retrograde Catheters
CARDIOPLEGIA

- **Retrograde Cardioplegia**
  - Gold standard since 1990
  - Revolutionized safety of Cardiac surgery
  - Must be given every 15-20 minutes
  - An additional catheter in the operative field
  - Placement of the catheter requires the surgeon to place his hand in the chest

- **Custodial Cardioplegia**
  - Developed for Transplant preservation
  - Delivered through the aortic root “Antegraded”
  - Given every 90 minutes
  - One less cannula in the field
  - No need for the surgeon to place his hand in the chest
PARTIAL STERNOTOMY FOR AVR
PARTIAL STERNOTOMY FOR AVR
MVR/TVR AND MAZE - RHEUMATIC
MITRAL REPLACEMENT
TRADITIONAL VS CONTEMPORARY STERNOTOMY
Figure 1: Step Wise Reduction of Sternal Trauma

A: Full sternotomy incision; B: Hemi upper sternotomy with 'T' incision; C: Upper hemisternotomy with 'T' incision; D: Non-ster nal incision – right anterior mini-thoracotomy. 1,2,3 intercostal spaces.
WHY DOESN’T EVERYONE GET A SMALL INCISION?

- Cardiomegaly – Dilated and Hypertrophic
- Multiple left sided grafts
- Obesity – both inside chest and outside
- Multiple procedures
- Recent MI
- Surgeon comfort
Less Coumadin for Mechanical Aortic Valves

Improved Patient Experience
Implications for Valve Choice
2014 AHA/ACC Guidelines: Mechanical Aortic Valve Anticoagulation

Patients with bileaflet aortic valves:
INR of 2.5 (between 2.0 and 3.0)
“...Provides a reasonable balance [of risks]”

Patients with higher thromboembolic risk:
INR of 3.0 (between 2.5 and 3.5)
AF, previous thromboembolism, hypercoagulable state, severe LV dysfunction, etc...

All patients with mechanical valves:
75-100 mg Aspirin daily is recommended unless contraindicated
The Dilemma: Revisited

Mechanical Valves

Tissue Valves

What if there was a safer anticoagulation therapy for mechanical aortic valve patients?
MECHANICAL VALVE: HISTORICAL OVERVIEW

**1950’s**

- 1952
  - 1st clinical use of mechanical heart valve prosthesis

**1960’s**

- 1960
  - Starr-Edwards Ball and Cage Valve

**1970’s**

- 1969
  - Tilting-disc valve
- 1977
  - St. Jude Medical® bileaflet valve

**1980’s**

- 1969
  - Pyrolytic carbon, developed by Dr. Jack Bokros, was 1st used in a heart valve
- 1986
  - Carbomedics® Standard Aortic Valve

**1990’s**

- 1992
  - ATS Medtronic® Open Pivot™ Valve
- 1993
  - CarboMedics Top Hat Supra-annular Aortic Valve
- 1996
  - On-X Aortic Valve with Standard Sewing Ring

**2000’s**

- 2014 - 2015
  - On-X Aortic Valve INR 1.5-2.0*
  - CE7 & FDA8 Approvals

*After 3 months standard therapy.
ADDRESSING THE CAUSES OF VALVULAR TE: ON-X VALVE UNIQUE MATERIAL AND DESIGN

1. **90° leaflets**: Promotes Laminar Flow
2. **Pure Pyrolytic Carbon**: Reduces thrombogenicity
3. **Flared Inlet**: Organizes flow; prevents pannus

1. On-X Prosthetic Heart Valve Instructions for Use.
MATERIALS AND SURFACE COMPARISON$^{1,2}$

On-X Aortic Valve

- Smooth Pivot
- Pure Pyrolytic Carbon

All Other Bileaflet Aortic Heart Valves

- Rough Machined Pivot
- Silicon Alloyed Pyrolytic Carbon
PROACT
PROSPECTIVE RANDOMIZED ON-X VALVE REDUCED ANTICOAGULATION CLINICAL TRIAL

- Prospective, Randomized, Multicenter FDA IDE Trial
- Isolated AVR with On-X Aortic Valve

Test Group: INR 1.5–2.0  n=185  766.2 pt-yrs
Control Group: INR 2.0–3.0  n=190  878.6 pt-yrs

- Randomized after 3 months standard therapy
- 81 mg aspirin daily for all patients
- Home INR monitoring provided for both groups

1. On-X Prosthetic Heart Valve Instructions for Use
PROACT
AVR HIGH RISK GROUP

**Inclusion Criteria:**
- Chronic atrial fibrillation
- LVEF < 30%
- Enlarged left atrium >50mm diameter
- Spontaneous echo contrasts in the left atrium
- Vascular pathology
- Neurological events
- Hypercoagulability
- Left or right ventricular aneurysm
- Lack of platelet response to aspirin or clopidogrel
- Women receiving estrogen replacement therapy

**Exclusion Criteria:**
- Right sided valve replacement
- Double valve replacement (MV Repair is okay)
- Active endocarditis at implant
- Previous confirmed or suspected thromboembolic event or thrombophlebitis occurring or resolving within the last year prior to enrollment
- Terminal Illness
- Emergency Cases
- Inability to return for follow-up
- Unable to give adequate consent
On-X Aortic Heart Valve
New FDA Approval for less anticoagulation

On-X Aortic Heart Valve
Unique materials and hemodynamic design

New Recommended Patient Management
(applies only to On-X aortic valves)

INR 1.5-2.0 (following 3 months standard therapy)

FDA Approval of Lower INR April 2015
Test group had >60% reduction in bleeding events

No difference in TE rates between groups
PROACT Results
INR Distributions

INR Readings within Range

<table>
<thead>
<tr>
<th>Test (1.5–2.0)</th>
<th>Control (2.0–3.0)</th>
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<tr>
<td>64.1%</td>
<td>70.4%</td>
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- Similar percent in INR range, despite narrower test group target range
- Most out of range readings in test group in 2.0–3.0 range
INR 1.5-2.0
Benefits for Patients

- Fewer very high INR readings.

- Lower INR range simplifies bridging when necessary.

- Reduced bleeding risk is more similar to general population than it is to typical mechanical valve patients.

- Reduced reoperation rates compared with tissue valves.

- No structural valve deterioration which causes restenosis, poor hemodynamics, and calcification.
The Dilemma Revisited
The On-X Aortic Valve: A Unique Option
New Generation Mechanical Valve

On-X Mechanical Valve

On-X Advantages Over Mechanical Aortic Valves
- Reduced Anticoagulation
- Fewer bleeds
- Easier to manage

On-X Advantages Over Tissue Valves
- Lifetime Durability
- Reduced Risk of Reoperation compared to tissue valves

Tissue Valves
QUESTIONS?
Fig 2. Age-stratified freedom from structural valve deterioration necessitating reoperation using the Carpentier-Edwards pericardial aortic bioprosthesis. (Blue line = age less than 65 years; red line = age 65 to 75 years; green line = age 75 years or more.)
Longevity of Tissue Valves in Patients 50-65 yrs

Perception:
“[...] expected valve durability is 19 years”

Reality:
• Explants for SVD begin before 5 yrs and the rate increases
• “[...] Reoperation for SVD was common but associated with a low risk of mortality.”

Figure 4: Kaplan–Meier estimates of freedom from reoperation due to structural valve deterioration (SVD) by age group. Age was not a significant risk factor among this age subgroup. SVD: structural valve deterioration.
Reoperation Risk: Tissue vs. Mechanical Aortic Valves

For 55 year old patients, tissue valve risk of reoperation is ~10x higher than mechanical valves.
**Perception:** VIV hemodynamics are as good as surgical valves.

**Reality:** VIV hemodynamics are poor.

**VIV Registry Data:**

- 62% PPM*
- 31.8% Severe PPM
- Gradients in many patients: ≥20 mmHg to >40 mmHg

VIV: each one is smaller than the last

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*Tallahassee Memorial Healthcare*

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**Mean age:** 77.6
Valve In Valve

- An excellent salvage option
- A poor elective strategy when a safe alternative exists