Current Strategies in Cardiac Surgery

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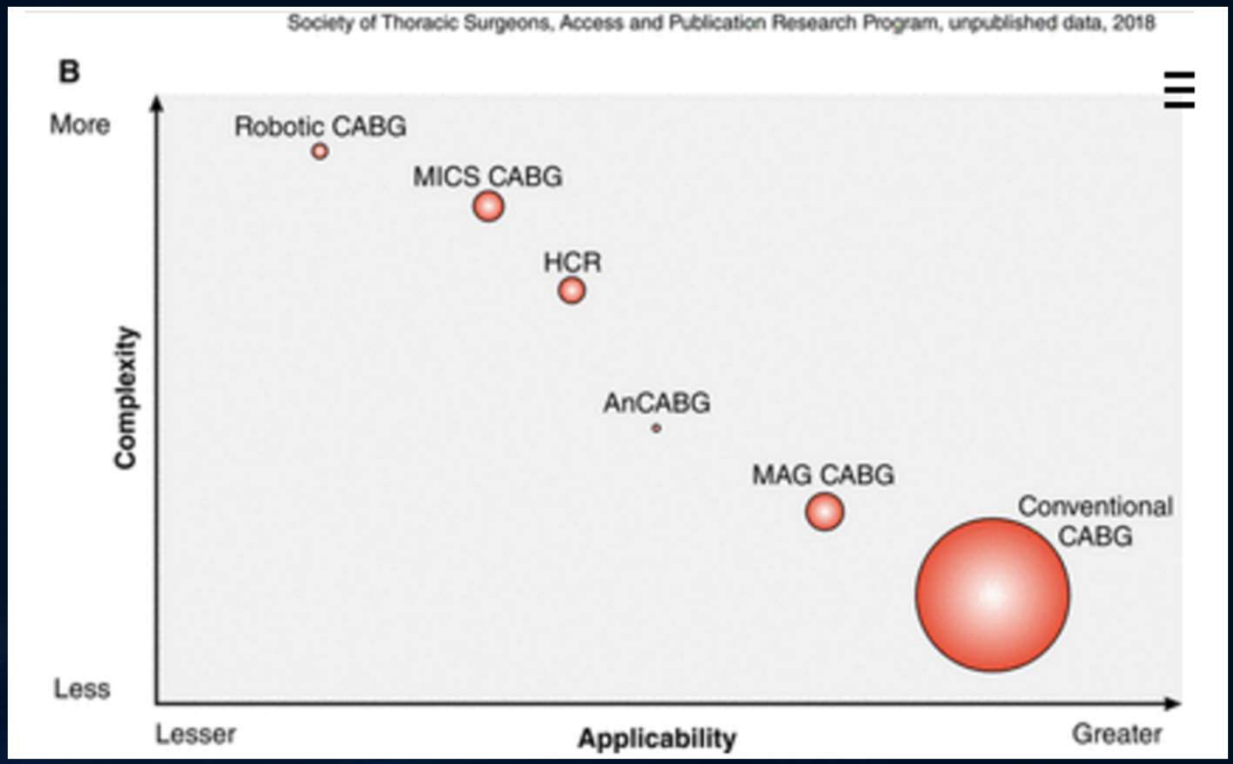
Surgical Revascularization

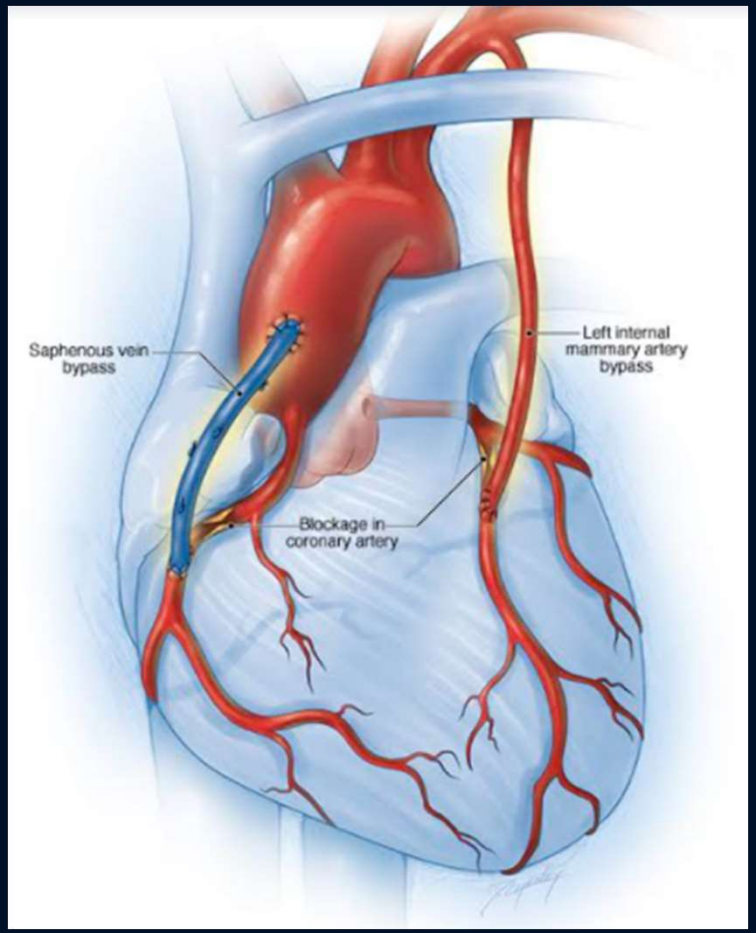
- Coronary Artery Bypass Grafting
  - 1968 Renee Favaloro published first series of coronary artery bypass grafting (CABG)
  - Modern technologies have improved outcomes but the improvement in percutaneous techniques have replaced CABG except for the most complex disease patterns.
  - Longer term graft patency in addition to “less” invasive procedures have kept CABG relevant in the modern era.

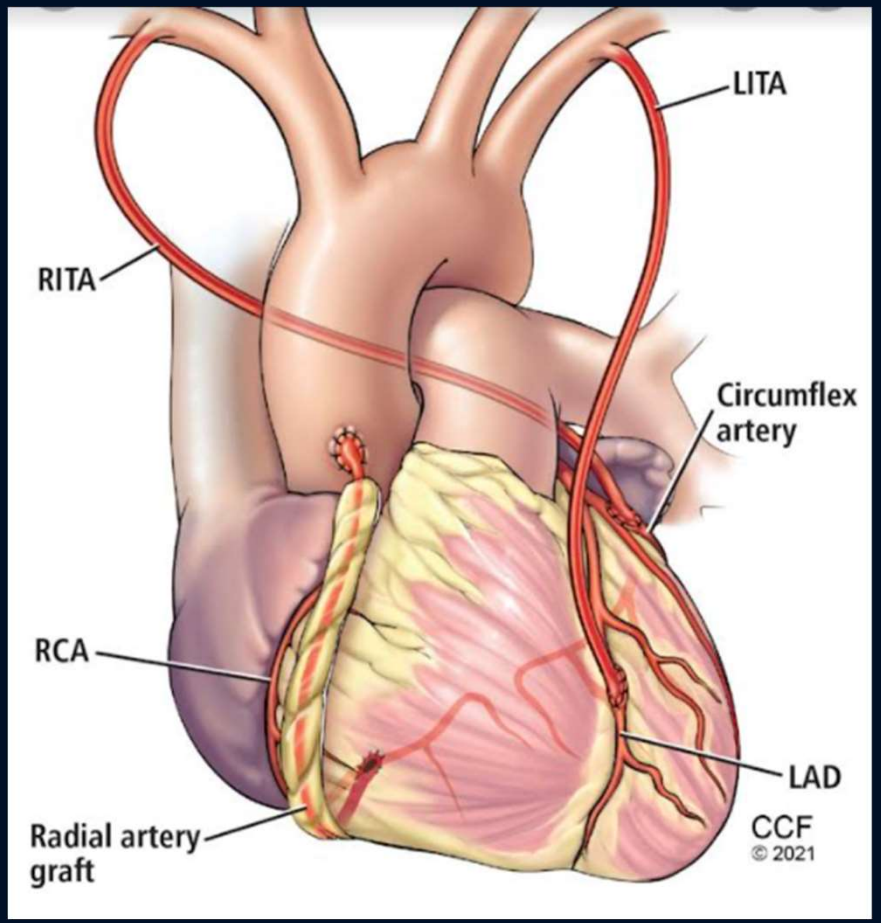
Progression of CABG Technique



Arterial Conduits in CABG

- Meta-analysis demonstrate significantly higher patency rates with arterial grafts than saphenous vein grafts
- Observational studies report longer survival with bilateral vs single internal thoracic arteries
- Low adoption rates of arterial conduits over the last 20 years reflect the increased technical and time demands of utilizing these grafts
- Less than 10% of cardiac surgery programs routinely use multiple arterial conduits.


Saphenous vein bypass
Left internal mammary artery bypass
Blockage in coronary artery


LITA
RITA
Circumflex artery
RCA
LAD
Radial artery graft
CCF
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Arterial Conduits in CABG

- ART Study
  - Randomized trial of bilateral vs single internal thoracic arteries (ART)
  - 3102 patients enrolled in 7 countries
  - No difference in primary end points in 5 years, but higher incidence of sternal complications with BIMA
  - At 10 years, no survival benefit, or difference in CVA, MI, and repeat revascularization noted
  - One thought is that 14% BIMA arm received only a single ITA and 22% of the SITA group received a radial artery conduit.

Arterial Conduit in CABG

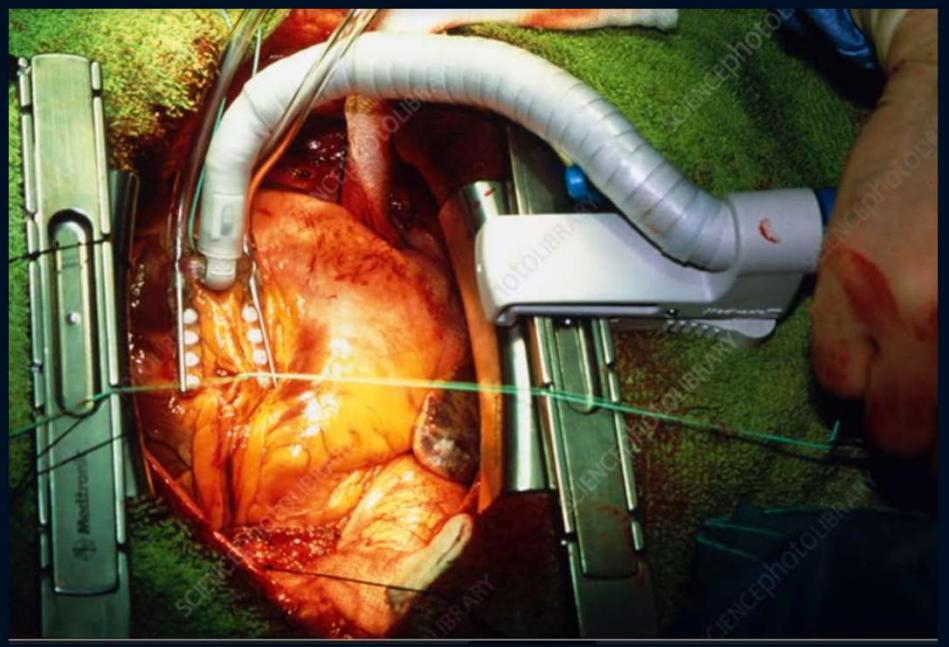
- The ROMA Trial
  - Randomized comparison of single vs multiple arterial grafts
  - Patients younger than 70 years randomized 1:1
  - Lateral wall grafted with radial artery conduit or second ITA
  - Plan to enroll 4500 subjects in over 25 international centers
  - Primary end point is to assess reduction in mortality, CVA, MI, repeat revascularization
  - Secondary end point will be MAG associated with improved survival

Off pump vs On pump CABG

- Initial coronary revascularization was performed "beating heart"
- Conventional bypass grafting surgery relies on a nonmoving decompressed heart in a relatively bloodless field.
- This relies on the use of a heart/lung machine to perform the gas exchange and develop a pressure head for organ perfusion. It also relies on a cardioplegia solution to arrest the heart and protect the myocardium during a period of suspended coronary perfusion.

Off pump vs On pump CABG

- The deleterious effects of such a departure from normal physiology could be mitigated by simply stabilizing the area intended for coronary anastomosis.
- Development of the devices in the late 90s led to rapid expansion of "off pump" CABG 2000-2005
- Meta-analysis of 35 propensity matched studies found off pump CABG to be superior to on pump CABG for all short-term outcomes including mortality
- Despite initial enthusiasm, off pump CABG is performed in less than 15% of patients.

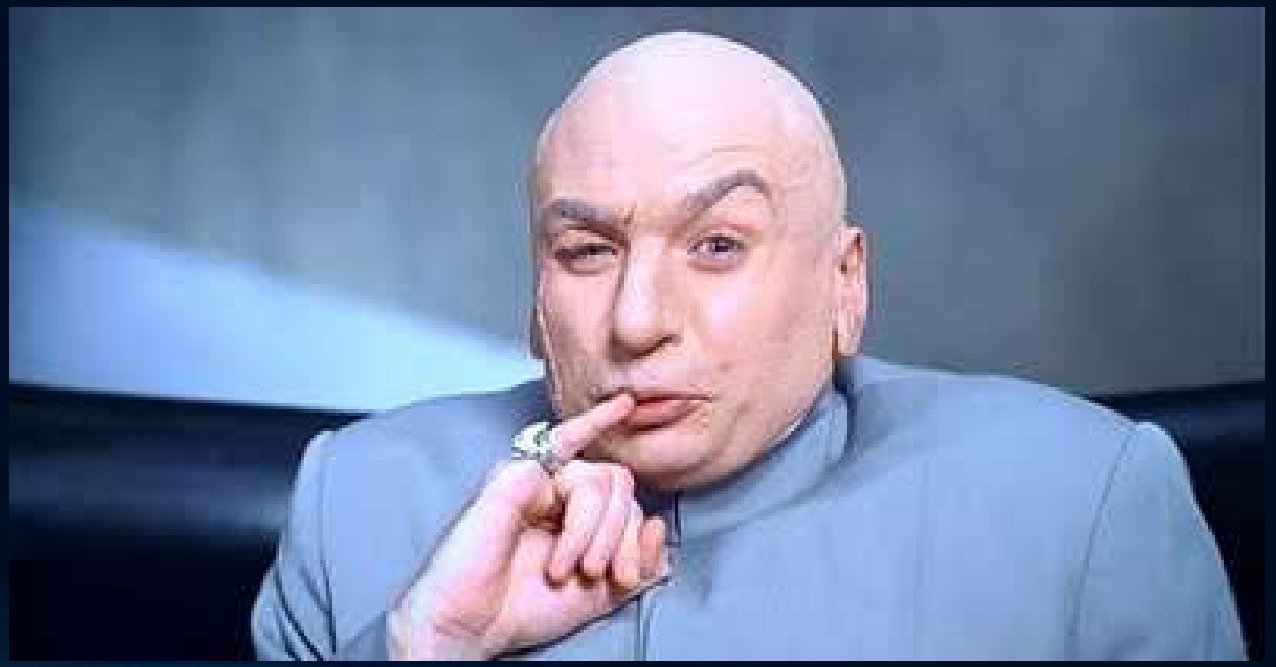


Off pump vs On pump CABG – ROOBY Trial

- 18 center VA cooperative prospective randomized single blinded trial Feb 2002-May 2008
  - On pump -1099 patients
  - Off pump – 1104 patients
- Primary composite outcome at 30 days, similar for both groups
- At 12 months, primary outcome favored on pump (9.9% vs 7.4% for composite outcomes)
- At 5 years, trial demonstrated worst survival in off pump patients (84.8% vs 88.1%) as well as increased need for revascularization
- In contrast, the 10 data (released Feb 2022) show comparable rates of all-cause death between off pump and on pump groups and no difference in secondary outcomes of repeat revascularization. Off pump resulted in an earlier need for revascularization.

Off pump vs On pump CABG

- Early survival benefit in this trial appears to be tied to completeness of revascularization and graft patency.
- What went wrong?



Off pump vs On pump CABG – ROOBY Trial

- Role of surgeon experience
  - 53 participating surgeons enrolled 8 patients per year on average
  - 60% of cases, the resident was the primary surgeon
  - Criteria for surgeon experience was defined as having performed 20 off pump CABG procedures
- Initial data shows less grafts were performed than initially intended in the off pump CABG arm
- The CORONARY trial and the GOPABE trial had stricter criteria for surgeon experience and results in no outcome differences at 5 years.

Off pump vs On pump CABG

- Experienced centers continue to provide evidence for improved outcomes in patients undergoing off pump CABG
- Off pump CABG provides the opportunity to perform revascularization on high-risk patients with ascending aortic calcification that would prevent traditional on pump CABG.
- Off pump CABG can be used in select scenarios such as concomitant lung transplantation or minimally invasive procedures.
- In particular, women show improved survival outcomes with off pump CABG.

Ter Woorst JF, Hoff AHT, Haanschoten MC, Houterman S, van Straten AHM, Soliman-Hamad MA. Do women benefit more than men from off-pump coronary artery bypass grafting? Neth Heart J. 2019 Dec;27(12):629-635. doi: 10.1007/s12471-019-01333-9. PMID: 31541397; PMCID: PMC6890870.

Valvular Heart Disease in the Modern Era

- Transcatheter Aortic Valve Replacement (TAVR)
  - First balloon aortic valvuloplasty performed by Alain Cribier in 1985.
  - First in man implant of a transcatheter aortic valve by Alain Cribier in 2002 in a 57-year-old male who survived for 4 months.
  - First retrograde TAVR performed in 2006 John Webb
  - PARTNER Trial, first RCT that proved efficacy.
  - FDA approval for Edwards TAVR in 2011.
  - Initial issues with vascular complications, CVA, permanent pacemaker implantation, and peri-valvular leak have been addressed progressive design improvements.

TAVR

- Initially used in high-risk patients, devices received approval for intermediate risk, and subsequently low risk (FDA approval 2019).
- No formal age limit for device availability
- Evidence for low-risk patients based on 3 RCTs – NOTION, PARTNER 3, and EVOLUT low risk. Mean age of patients 68-79.
- No RCT trials in young (<65-year-old) patients.

TAVR vs SAVR – PARTNER 3 Trial

- TAVR superior to surgical AVR at 1 year for death, stroke, rehospitalization (8.5% vs 15.1%) and non-inferior at 2 years (11.5% vs 17.4%)
- Exclusionary criteria:
  - Bicuspid Aortic Valve
  - Aortopathy
  - Complex CAD (SYNTAX > 22)
  - Moderate or Severe MR
  - Tricuspid Regurgitation
  - Heavy LVOT calcium

TAVR – Point of Concern in Younger Patients

- Future coronary access
- Coronary obstruction with TAVR – in- TAVR
- Surgical TAVR explantation
- Bicuspid aortic valves
  - PVL
  - CVA
- Durability of TAVRs
- Long term impact of PVL
- Long term impact of PPM

TAVR – Concomitant Conditions

- Aortopathy – progression of ascending aortic aneurysms
- Coronary artery disease
- Mitral valvular disorders
- Endocarditis

TAVR

- Valve Durability and Age
  - Surgical data shows higher rate of structural deterioration (SVD) in surgical valves performed in patients < 65 years old.
  - Average life expectancy of a 65-year-old is 18-21 years
  - Valve-in-valve data is weak for durability information. Other concerns are patient prosthetic mismatch, endocarditis, anatomic limitations.
  - TAVR explantation is associated with a high mortality rate

TAVR – Conduction Disturbances and Perivalvular Aortic Insufficiency

- TAVR associated with 3-fold incidence of LBBB as well as increased need for PPM
- Both new LBBB and RV pacing associated with lower EF, increase hospitalization, and higher mortality
- Moderate or Several PVL: PARTNER 3 0.8% vs 0% - EVOLUT low risk 3.5% vs 0.5%
- Long term impact unknown

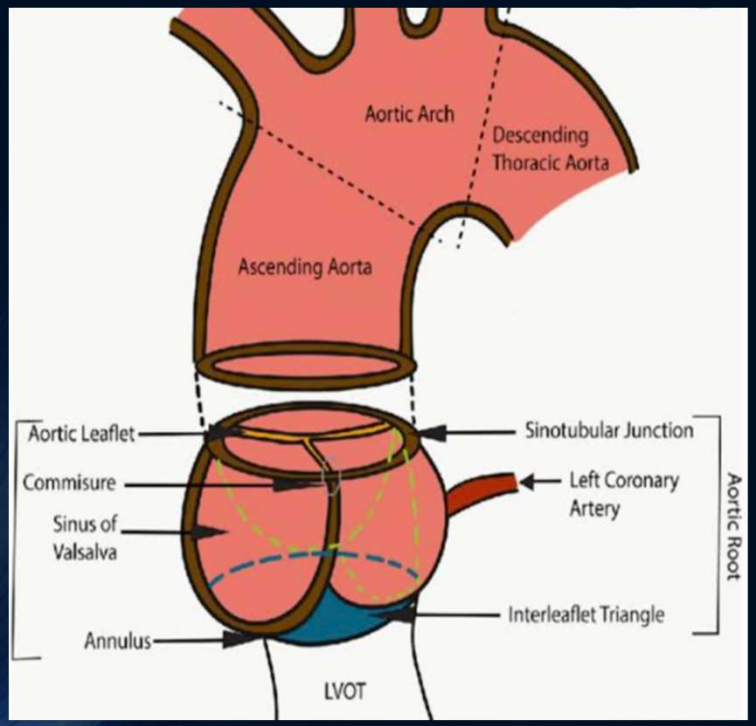
Guidelines for Surgical Aortic Valve Replacement

- Patient younger than 50 years old, best served with mechanical valve
- Patients less than 65 years old, in good health, should undergo surgical AVR
- Mechanical vs Bioprosthetic SAVR in 50–65-year-old requires significant decision making

Future PARTNER 3 Trial Results

- Differentiation of all-comers vs trial exclusion criteria (BAV, Cardiomyopathy, complex CAD, anemia, lung disease)
- 2-year outcomes – relevance of gradients and PVL
- Parallel curves or divergence?
- A new era for mechanical valves?

Surgical Approach in the Modern Era- Aortic Pathology – The Aortic Root



- The aortic valve leaflets
- The AV leaflet attachments
- Sinuses of Valsalva
- Interleaflet trigones
- Sinotubular junction
- Annulus

Pathology Involving the Proximal Aorta

- Genetic:
  - Marfan Syndrome
  - Ehlers-Danlos
  - Loeys-Dietz
  - Turner Syndrome
- Atherosclerosis
- Inflammatory
  - Giant cell arteritis
  - Takayasu arteritis
- Valvular
  - Bicuspid aortic valve
- Infection
- Trauma

Aortic Pathology

- Symptoms:
  - Chest or back pain
  - Hoarseness
- Complications:
  - Aortic dissection
  - Aortic valve insufficiency

Aortic Pathology – Management

- Intervention is based on size, location, rate of growth, associated risk factors
- Recommendation for ascending aorta: >5.5 cm or expansion of >3mm in a year
- Type A Aortic Dissection
  - In hospital mortality 57% without surgery and 17-25% with emergent surgery
  - Lower threshold in associated conditions:
    - BAV – 5cm
    - Marfans 4.5 – 5 cm

Aortic Pathology – Repair

Aneurysm of root, ascending aorta, aortic arch

- Sternotomy and cardiopulmonary bypass
- Considerations: aortic valve, addressing the root, partial or complete arch

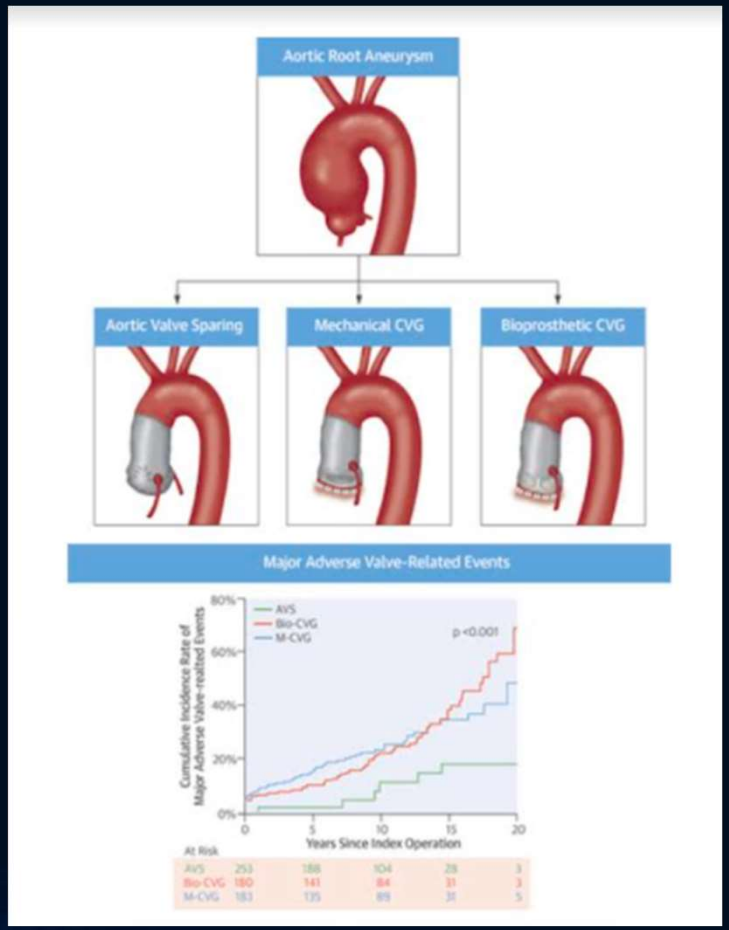
Aneurysm of the descending aorta

- Primarily treated with endovascular percutaneous technique although distal arch vessel management can be addressed.
- Open surgical repair for unfavorable anatomy or genetic syndromes

Hybrid approach employed for extensive TAA

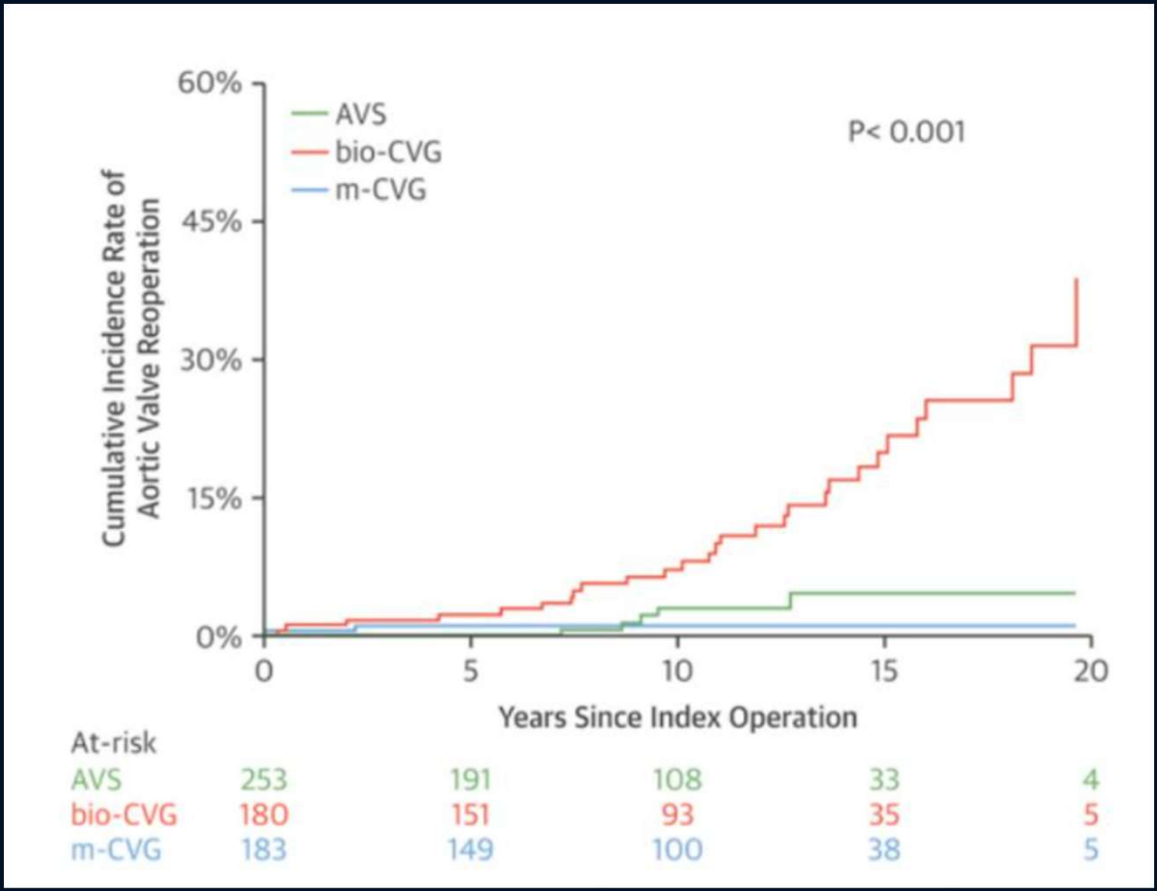
Aortic Pathology – Aortic Root Procedures

- Valve Replacement
  - Bentall procedure (Hugh Bentall 1968) – utilizing a bioprosthetic valve or mechanical valve
  - Valve-Sparing Root Replacement (VSRR)



Aortic Pathology – Aortic Root Procedure Considerations

- Mechanical Bentall = long-term durability but at the price of long-term anticoagulation
- Bioprosthetic Bentall = reduces need for chronic anticoagulation at the expense of long-term durability
- VSRR = in theory offers advantages of both durability and freedom from anticoagulation


60%
45%
30%
15%
0%
AVS
bio-CVG
m-CVG
P< 0.001
Cumulative Incidence Rate of Aortic Valve Reoperation
0
5
10
15
20
Years Since Index Operation
At-risk
AVS 253 191 108 33 4
bio-CVG 180 151 93 35 5
m-CVG 183 149 100 38 5

Aortic Pathology – Aortic Root Procedure Considerations

- VSRR is more technically challenging, carries a higher risk of AI, and requires longer CPB times.
- VSRR – Younger patients with normal aortic leaflets. Preop AI, not a contributing factor.
  - Less likely to be emergent cases
  - Higher prevalence of Marfan
  - Significantly longer cardiopulmonary bypass and cross clamp times

Aortic Pathology – Comparison of Techniques

- Multiple retrospective studies show excellent short and mid-term results with various techniques
- Baylor, large surgical center study:
  - Survival analysis to evaluate composite endpoint of freedom from recurrent AI, reoperations, or death
  - Studied 170 patients from 2007-2016 with mean ages 63.8 (BB), 45.5 (MB), and 49.2 (VSRR)

Results:

In elective cases, increased length of stay in the BB and MB for the immediate post-op period

Follow up period showed a trend for decreased composite endpoint even in VSRR compared to MB and a significant difference compared to BB

Clinical outcomes of patients undergoing the Bentall procedure vs valve-sparing aortic root replacement*

Variable	Bioprosthetic Bentall	Mechanical Bentall	VSRR	*P* value
All patients	36	63	71	
Reexploration for bleeding	2 (6%)	6 (10%)	1 (1%)	0.09
Prolonged ventilator >24 h	2 (6%)	10 (16%)	1 (1%)	**0.005**
New dialysis required	1 (3%)	3 (5%)	0	0.16
Permanent neurologic dysfunction	0	1 (2%)	0	0.58
Pacemaker implantation	1 (3%)	5 (8%)	3 (5%)	0.56
Length of stay (days)	6 (0–17)	6 (2–42)	5 (3–35)	**0.0001**
Operative mortality	3 (8%)	2 (3%)	0	**0.04**
Elective only	30	49	68	
Re-exploration for bleeding	2 (7%)	2 (4%)	1 (2%)	0.29
Prolonged ventilator >24 h	2 (7%)	4 (8%)	1 (2%)	0.19
New dialysis required	1 (3%)	2 (4%)	0	0.21
Permanent neurologic dysfunction	0	1 (2%)	0	0.54
Pacemaker implantation	1 (4%)	4 (9%)	3 (5%)	0.63
Length of stay (days)	6 (4–17)	6 (4–42)	5 (3–35)	**0.001**

Hamandi, M., Nwafor, C. I., Baxter, R., Shinn, K., Wooley, J., Vasudevan, A., Harrington, K., Schaffer, J., Moore, D., DiMaio, J. M., Ryan, W. H., & Brinkman, W. T. (2020). Comparison of the Bentall procedure versus valve-sparing aortic root replacement. *Proceedings (Baylor University. Medical Center)*, *33*(4), 524–528. https://doi.org/10.1080/08998280.2020.1771163

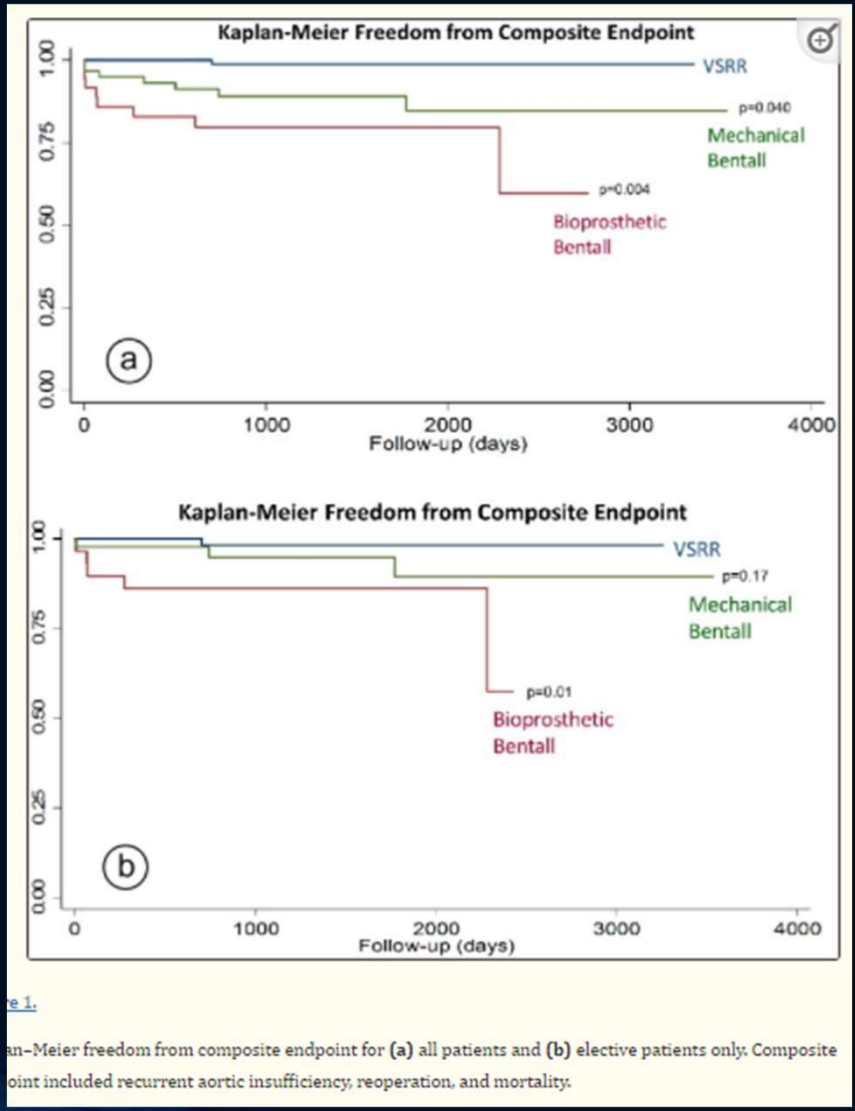
Further comparison

- 1990 – 2010: 616 patients younger than 70 years old
  - Elective surgery
  - VSRR, BM, BB
  - Mean age 46
  - Mean follow up was 9.8 years
- Results:
  - VSRR = higher proportions of Marfans (4470) and lower rate of bicuspid AV (10%)
  - MB had higher incidence of previous cardiac surgery (432)
  - Similar CPB and cross clamp times
  - In-hospital mortality (0.3%) and CVA (1.3%) similar
  - MB had a higher incidence of PPM (7%)

Ouzounian M, Rao V, Manlhiot C, Abraham N, David C, Feindel CM, David TE. Valve-Sparing Root Replacement Compared With Composite Valve Graft Procedures in Patients With Aortic Root Dilation. J Am Coll Cardiol. 2016 Oct 25;68(17):1838-1847. doi: 10.1016/j.jacc.2016.07.767. PMID: 27765186.

Comparison Results

- Long-term; VSRR conveys a statistically improved freedom from cardiac mortality and valve related morbidities compared to BB and MB



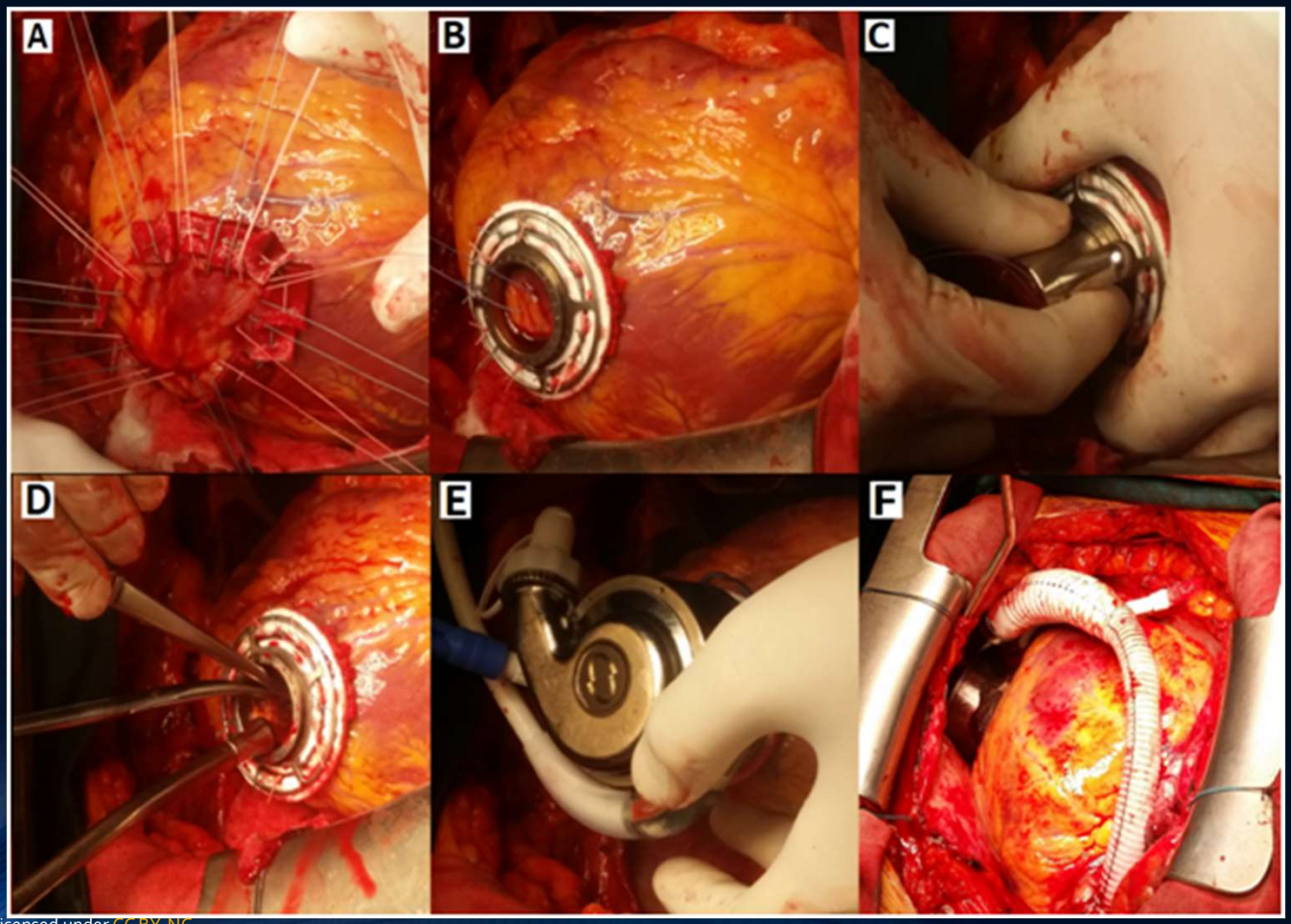
e 1.

an–Meier freedom from composite endpoint for **(a)** all patients and **(b)** elective patients only. Composite oint included recurrent aortic insufficiency, reoperation, and mortality.

Discussion

- Complex surgeries difficult to reproduce results (IE Ross procedure)
- Only 5% of cardiac surgery programs perform >16 root surgeries annually and median is 2 procedures
- Consider in young Marfan patients.

Mechanical Circulatory Support in the Modern Era

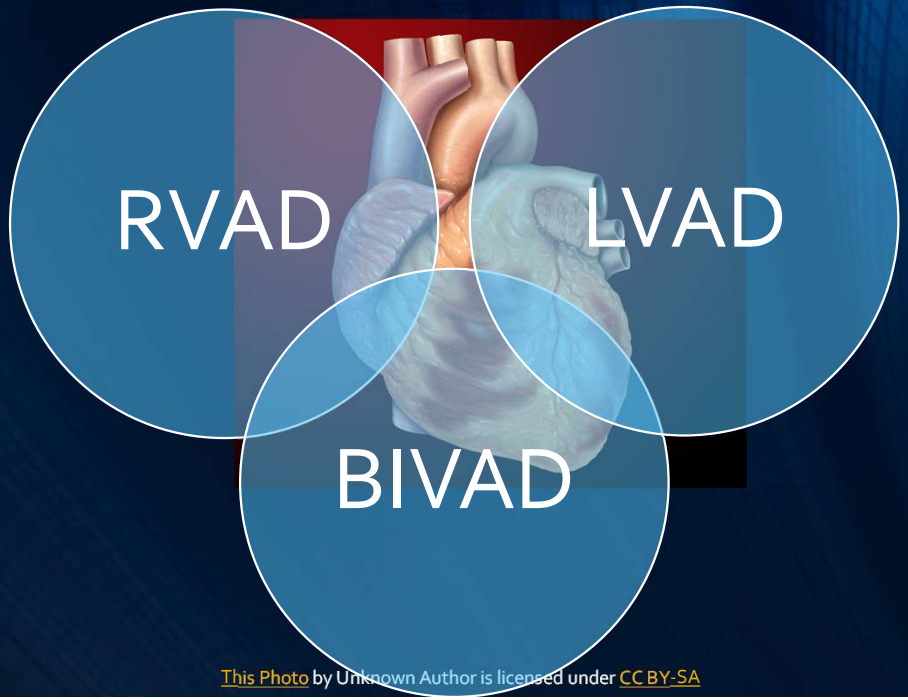





NYHA CLASS I	CLASS II	CLASS III	CLASS IV
No symptoms or activity limitations	Slight activity limitations	Significant activity limitations	Unable to carry on any physical activity without symptoms

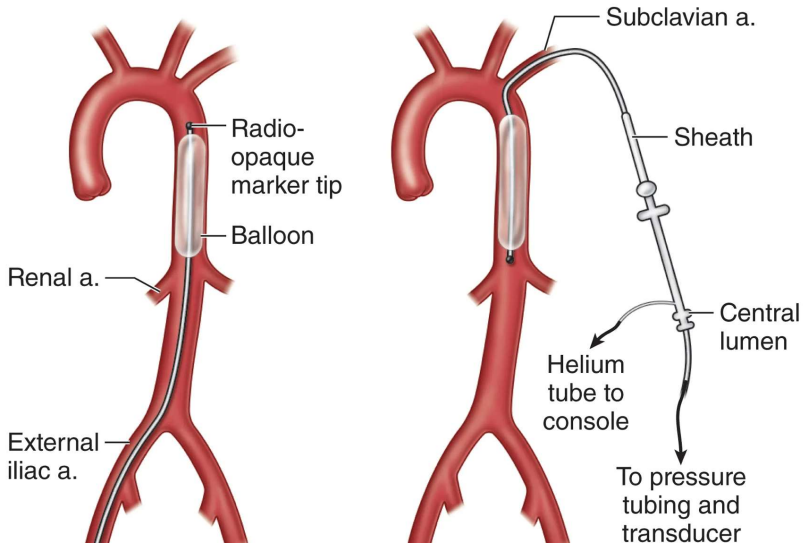
Mechanical Circulatory Support - Development

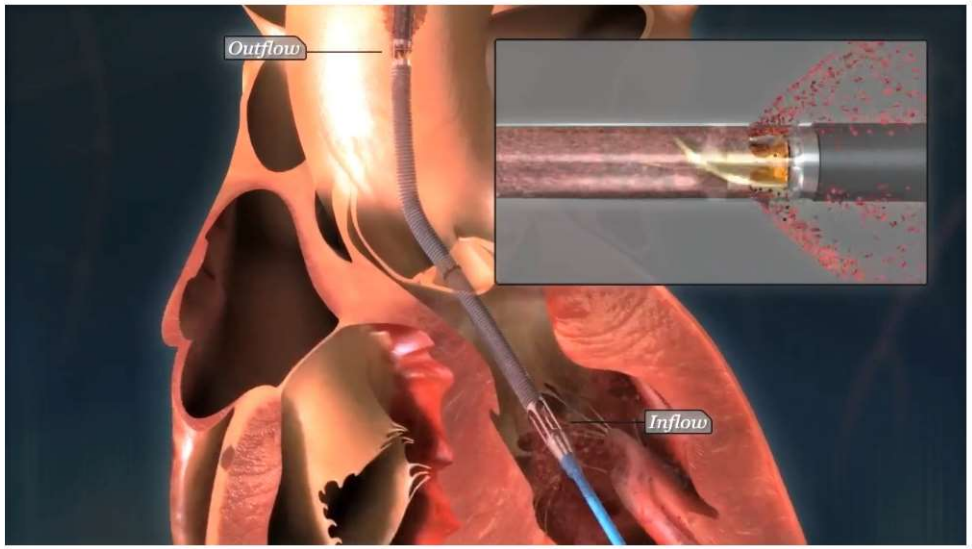
THE DEVELOPMENT OF ELECTROMECHANICAL DEVICES TO SUPPORT CIRCULATION HAVE HAS BEEN USED TO PROVIDE TEMPORARY AS WELL AS LONG TERM SUPPORT FOR THE FAILED HEART.

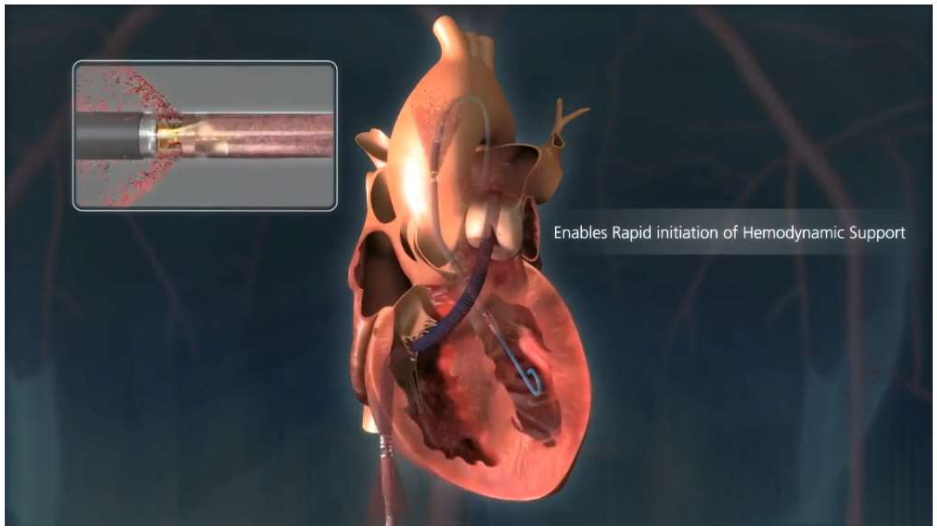


Mechanical Circulatory Support – Types of Devices

IABP
IMPELLA
ECMO/CARDIOHELP
DURABLE LVAD,
CENTRIMAG,
ROTAFLOW
TOTAL ARTIFICIAL HEART





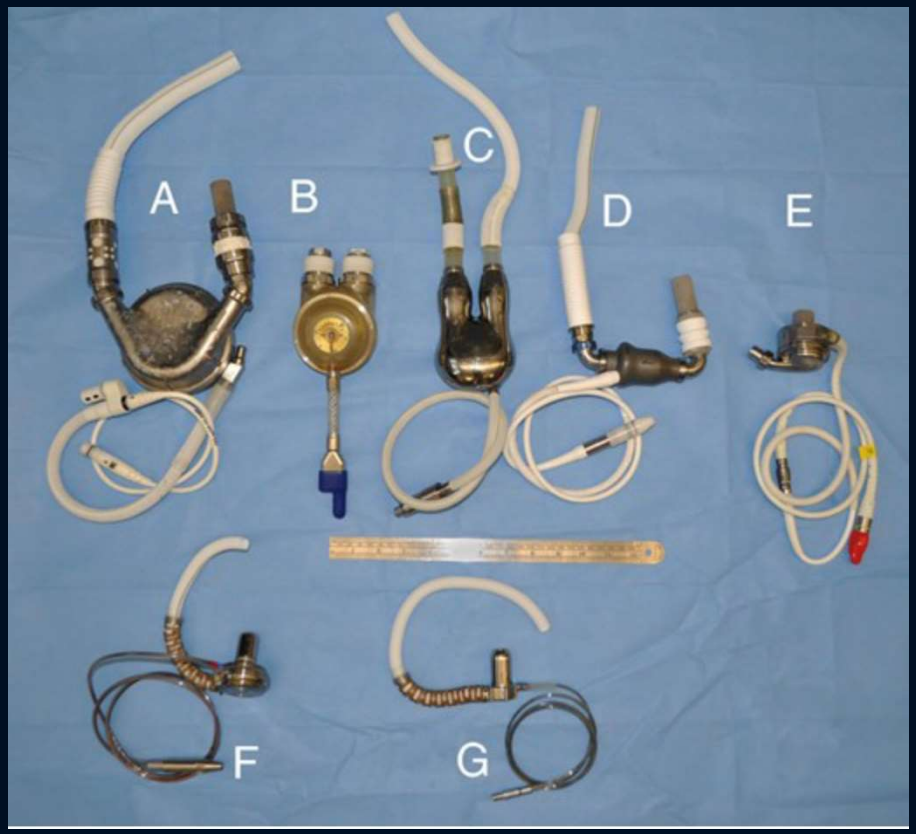


Designed for long duration support

- Patient ambulation
- Ceramic bearings
- No pigtail

Mechanical Circulatory Support - LVAD History

- 1953 first clinical use of cardiopulmonary bypass (Philadelphia)
- 1963 first implant of an air powered LVAD (Baylor)
- 1966 first successful outcome of LVAD therapy (Baylor)
- 1967 first human heart transplant (Cape Town)
- 1988 First long term implant (Boston Children's)
- 1994 FDA approves HeartMate I



Mechanical Circulatory Support - Trials

Randomized evaluation of mechanical assistance of the treatment of congestive heart failure (REMATCH Trial)

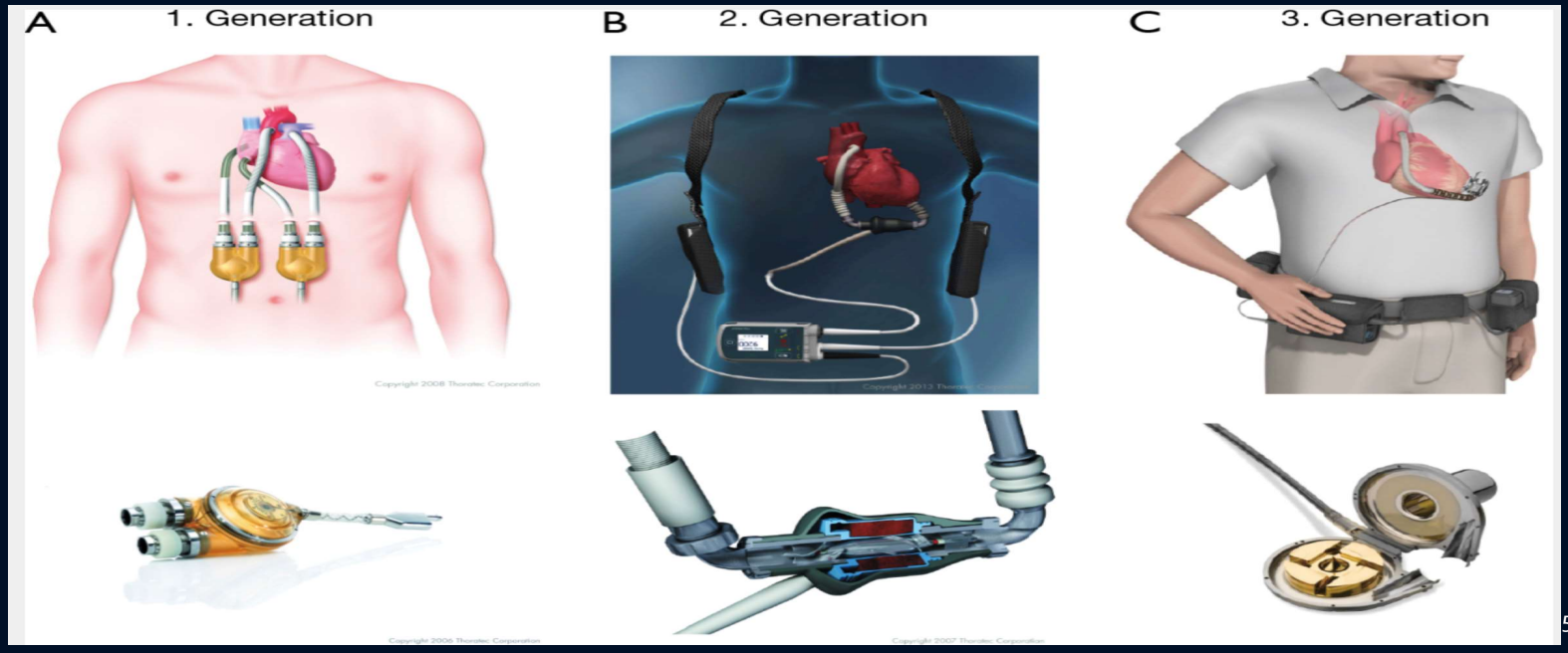
- 1998-2001
- FDA approval of BTT 2001, DT 2003
- Demonstrated 81% improvement in 2-year survival compared to medical therapy (23% vs 8%)

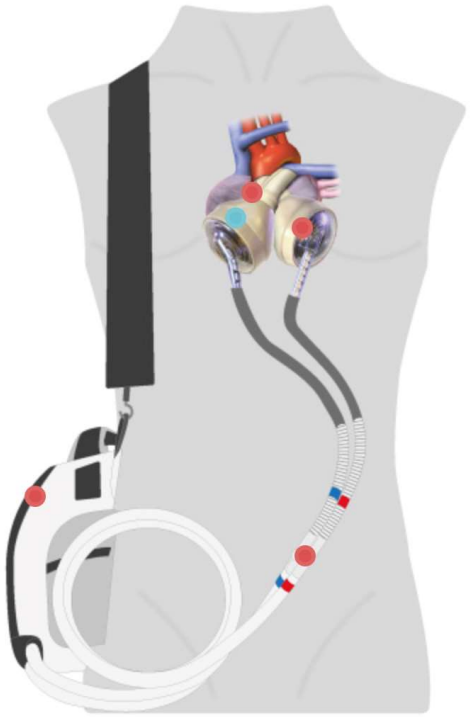
LVAD design after REMATCH

Heartmate I
- Pulsatile

Heartmate II
- Continuous Flow

Heartmate III
- Suspended Centrifugal impellar





Trial - Adverse Outcomes

Adverse event	HeartMate II BTT trial (2007)[87]	HVAD BTT trial (2012)[88]
Bleeding	72 (26)	20 (14.3)
Replacement	4 (1)	3 (2.1)
Infection	41 (14)	17 (12.1)
Stroke	24 (8)	18 (12.8)

Adverse event rates for HeartMate II and HVAD for their respective initial clinical trials reported as *N* (%).

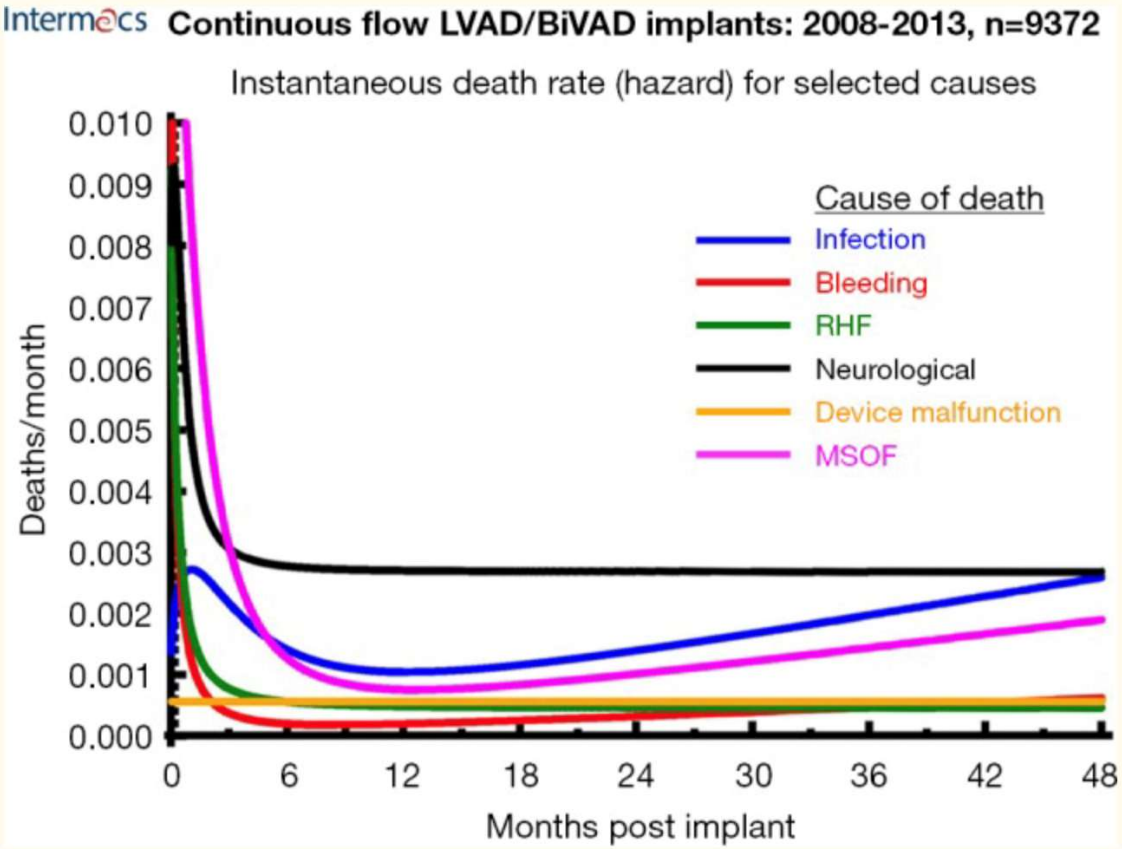


Figure 2

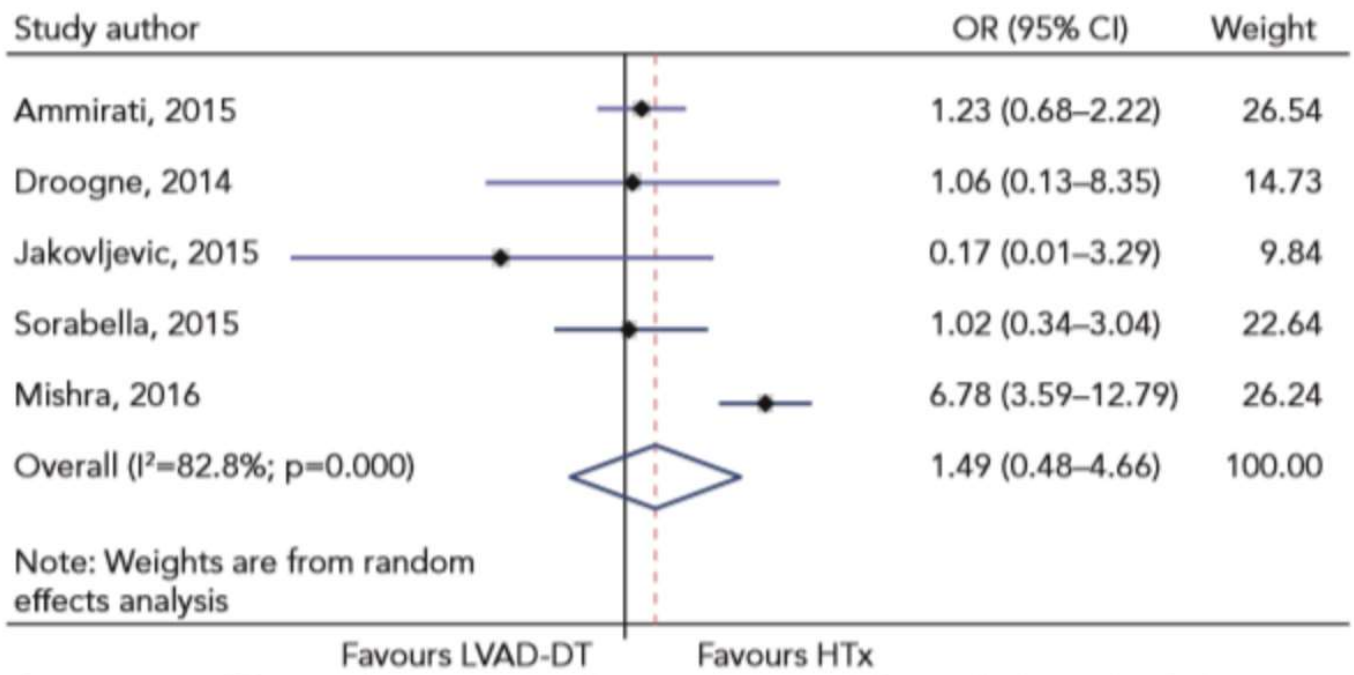
Hazard unction for mortality following primary implantation for continuous-flow devices broken down by causative mortality between 2008 to 2013 in the INTERMACS registry. RHF, right heart failure; MSOF, multi-system organ failure; LVAD, left ventricular assist device; BiVAD, bi-ventricular assist device; INTERMACS, interagency for mechanically assisted circulatory support.

Mechanical Circulatory Support - Survival Advantages

Heart transplant vs Destination therapy

- 8281 patients end stage HF 2010-2014
  - 1 year survival 87.7% vs 76.4% respectively
  - 5 year survival 72.1 vs 36.1% respectively

Figure 1: Forest Plot of the Odds Ratios for 1-year Mortality Between Cardiac Transplant and Left Ventricular Assist Device Destination Therapy

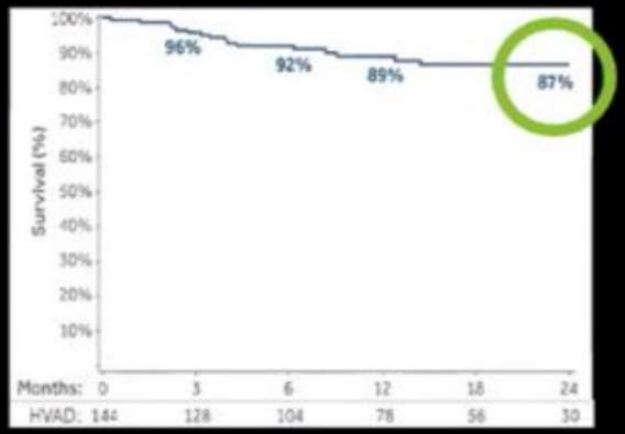


There was no difference in 1-year mortality rates between left ventricular assist device as destination therapy (LVAD-DT) and cardiac transplant (HTx) among the five studies. Source: Theochari et al. 2018.[13] *Reproduced with permission from AME Publishing Company.*

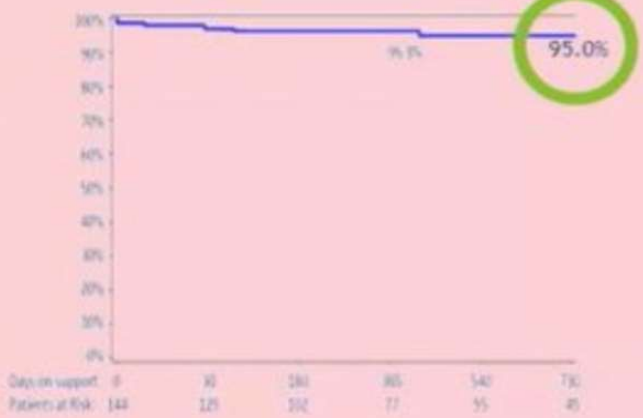
Future of MCS

RESULTS OF LATERAL TRIAL

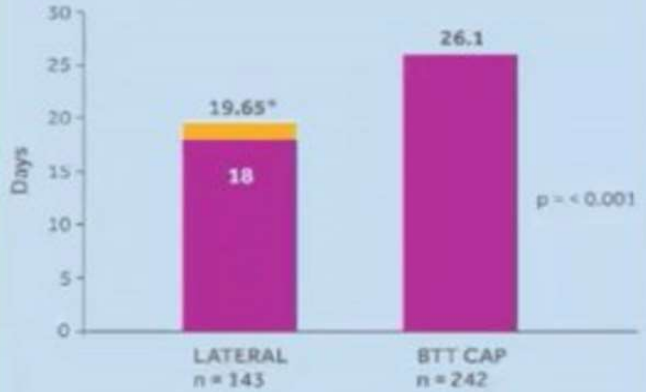
87% survival at 2 years



95% freedom from disabling stroke at 2 years



30% reduced length of stay



Future of MCS

- Size reduction
- Fully implantable devices
- Durability
- Reduction of blood trauma