



TIPS AND TRICKS FOR SUCCESSFUL TAVR WITH EDWARDS SAPIEN VALVE

Gerald Yong MBBS (Hons) FRACP FSCAI
Interventional Cardiologist
Royal Perth Hospital
Western Australia

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship

Grant/ Research Support:

Company

Consulting Fees/Honoraria:

Edwards Lifesciences (consultant & proctor)

Major Stock Shareholder/Equity Interest:

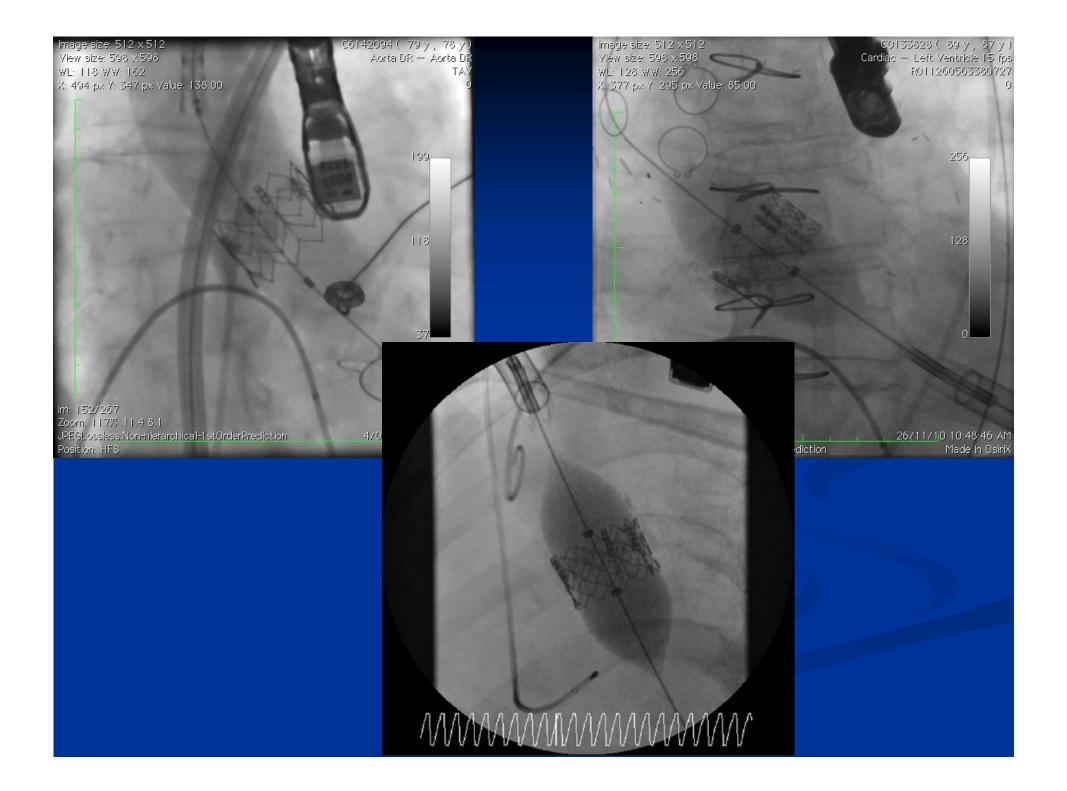
Royalty Income:

Ownership/Founder:

Salary:

Intellectual Property Rights:

Other Financial Benefit:



Keys to Success

PATIENT SELECTION

PROCEDURAL DETAILS

INTEGRATED MULTIDISCIPLINARY
 TEAM

Keys to Success

PATIENT SELECTION

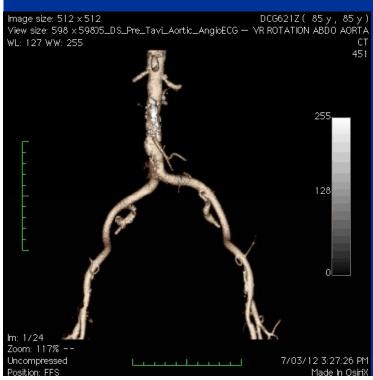
- PROCEDURAL DETAILS
- INTEGRATED TEAM MULTIDISCIPLINARY TEAM

PATIENT SELECTION

- Indication
 - Symptomatic severe aortic stenosis
 - High risk for surgical AVR
- Suitable anatomy left ventricle, aortic root, aortic annulus, peripheral vessels
- Other high risk clinical features to be aware
 - Severe MR
 - Severe LVF
 - Irrevascularised CAD
 - Pulmonary hypertension









High Risk For Surgical AVR

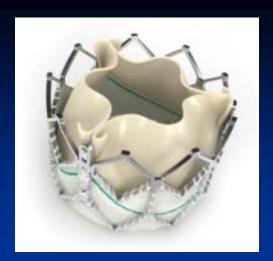


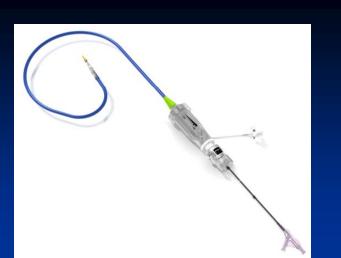
3 Keys to Success

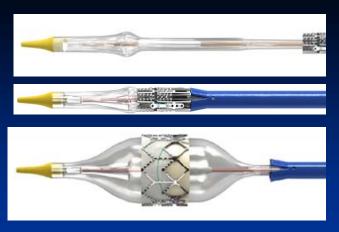
PATIENT SELECTION

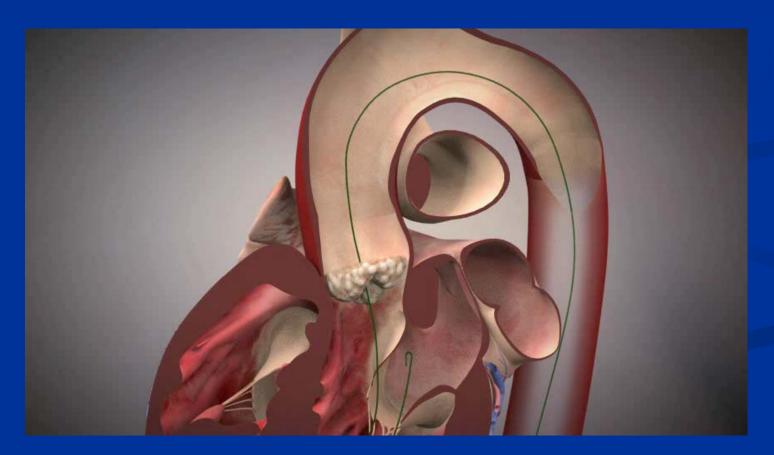
PROCEDURAL DETAILS

■ INTEGRATED TEAM APPROACE









TRANSFEMORAL TAVI PROCEDURAL STEPS

- Vascular access and insertion of large 18 / 19F sheath
- Insertion of pacing wire for rapid ventricular pacing
- Insertion of pigtail catheter for guiding aortography
- Cross aortic valve and insertion Amplatz Extra-stiff wire
- Balloon aortic valvuloplasty
- Insertion of valve assembly and NovaFlex, align valve, cross arch and aortic valve
- Valve positioning and deployment
- Removal of NovaFlex and balloon catheter
- Removal of large sheath and vascular closure

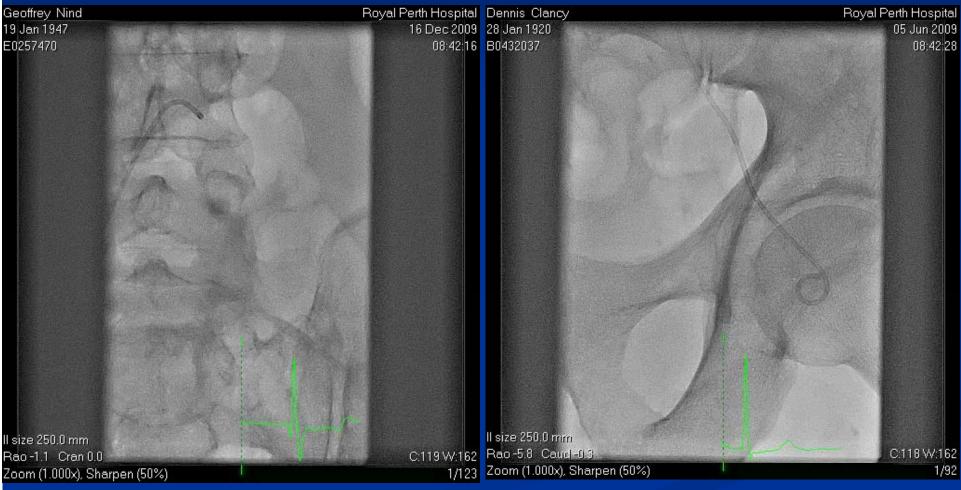
TRANSFEMORAL TAVI PROCEDURAL STEPS

- Vascular access and insertion of large 18 / 19F sheath
- Insertion of pacing wire for rapid ventricular pacing
- Insertion of pigtail catheter for guiding aortography
- Cross aortic valve and insertion Amplatz Extra-stiff wire
- Balloon aortic valvuloplasty
- Insertion of valve assembly and NovaFlex, align valve, cross arch and aortic valve
- Valve positioning and deployment
- Removal of NovaFlex and balloon catheter
- Removal of large sheath and vascular closure

Common Femoral Artery Puncture

- It is vital to puncture at the anterior wall of the common femoral artery of the side for large sheath
- Ideally avoid calcified plaques (seen on fluroscopy)
- Options
 - Ultrasound guidance
 - Puncture of contralateral side first, then guide arterial puncture of side selected for large sheath by
 - Antegrade angiography
 - Cross-over pigtail

Common Femoral Artery Puncture



Contralateral antegrade AG

Cross-over pigtail marking CFA

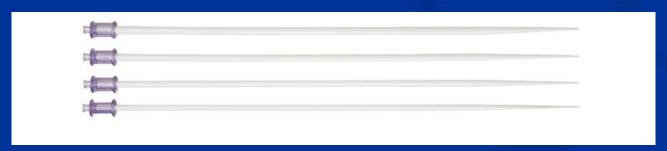
NovaFlex Introducer Sheath Set

Hydrophilic coating designed for easy insertion



Tri-seal valve technology designed for hemostasis

4 stepped dilators for arterial expansion



Hydrophilic coating and tapered distal segment for smooth arterial dilation

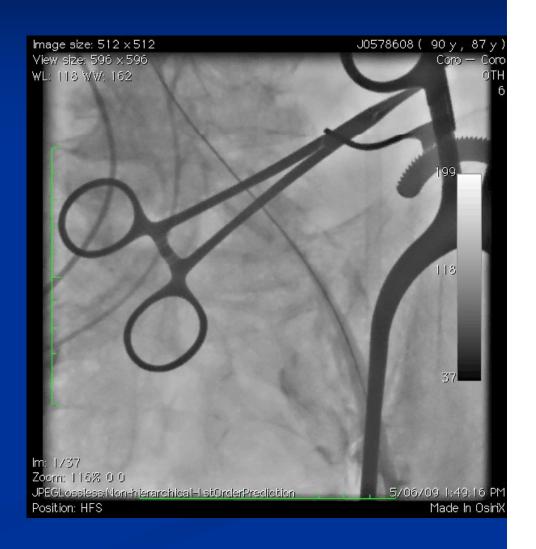
Large Sheath Insertion

- Fluroscopy all large dilators and sheath insertion
- Over stiff wire
- Pass smaller dilators
 - Pass at least one dilator past aortic bifurcation or areas of smallest diameter
- Rotate dilators & sheath when inserting
 - Exception E-sheath
- Know position of final sheath tip



Large Sheath Insertion Issues

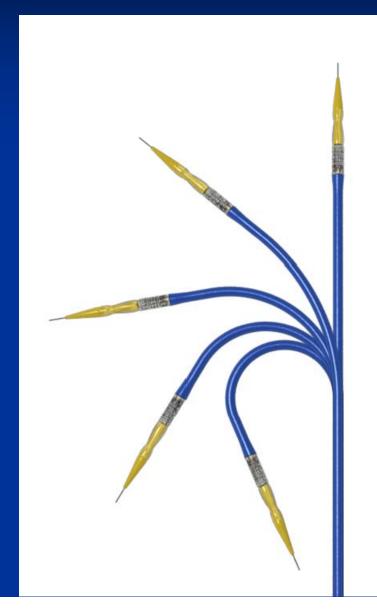
- Do not force sheath
- Watch movement of vessel calcium on fluroscopy
- Watch BP
- If vascular complications or rupture
 - Occlusion balloon
 - Insert dilator to tamponade



TRANSFEMORAL TAVI PROCEDURAL STEPS

- Vascular access and insertion of large 18 / 19F sheath
- Insertion of pacing wire for rapid ventricular pacing
- Insertion of pigtail catheter for guiding aortography
- Cross aortic valve and insertion Amplatz Extra-stiff wire
- Balloon aortic valvuloplasty
- Insertion of valve assembly and NovaFlex, align valve, cross arch and aortic valve
- Valve positioning and deployment
- Removal of NovaFlex and balloon catheter
- Removal of large sheath and vascular closure

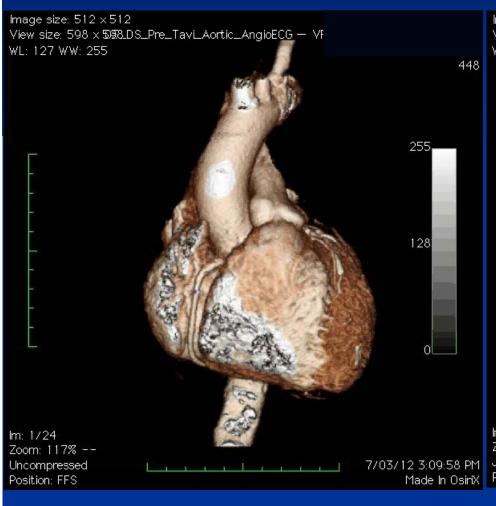
Crossing Arch

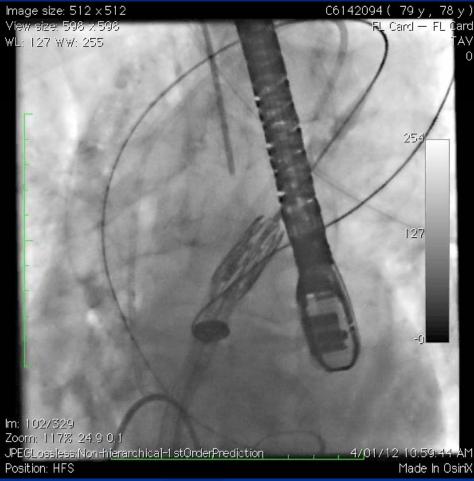


- Rotate flex wheel and fully flex by the time
 THV reach arch
- In resistance or unfolded aorta Ensure maximal flexion and tension on wire

NovaFlex to Cross Unfolded Aorta

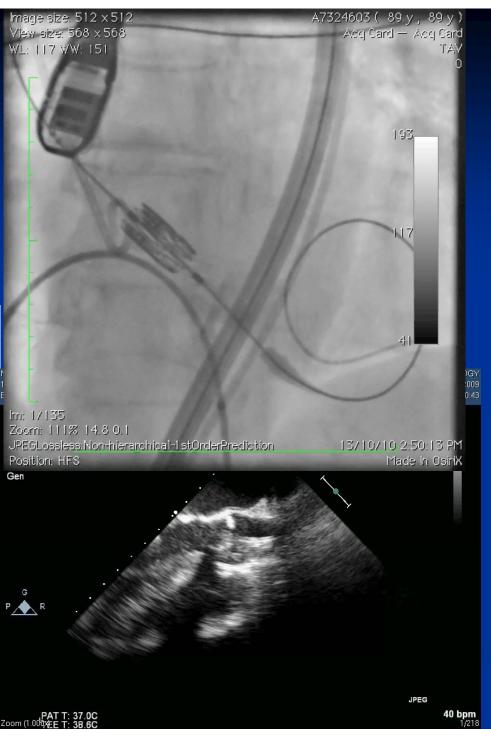
Maximal Flexion and Tension on Wire





TRANSFEMORAL TAVI PROCEDURAL STEPS

- Vascular access and insertion of large 18 / 19F sheath
- Insertion of pacing wire for rapid ventricular pacing
- Insertion of pigtail catheter for guiding aortography
- Cross aortic valve and insertion Amplatz Extra-stiff wire
- Balloon aortic valvuloplasty
- Insertion of valve assembly and NovaFlex, align valve, cross arch and aortic valve
- Valve positioning and deployment
- Removal of NovaFlex and balloon catheter
- Removal of large sheath and vascular closure

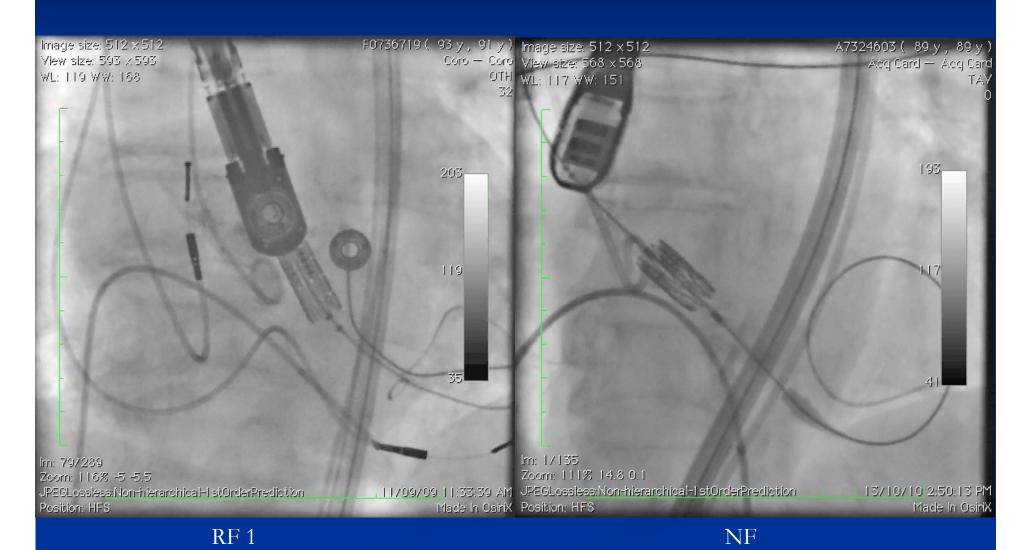


Positioning and Deployment

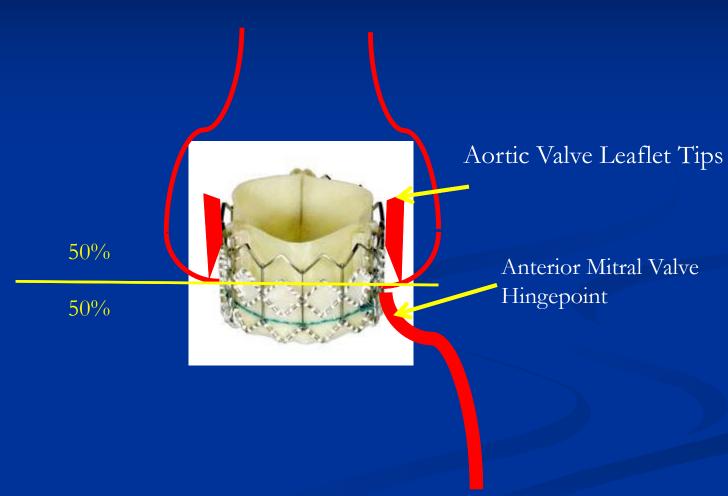
- Under aortography & TEE
- Valve deployment projection
- Position 50-60%ventricular
- Take your time but watch hemodynamics
- Useful to do aortogram
 while burst rapid pacing
 prior to deployment
- Hold inflation 3 sec

NovaFlex System

- Easier to achieve co-axial alignment
- Does no move much during valve deployment

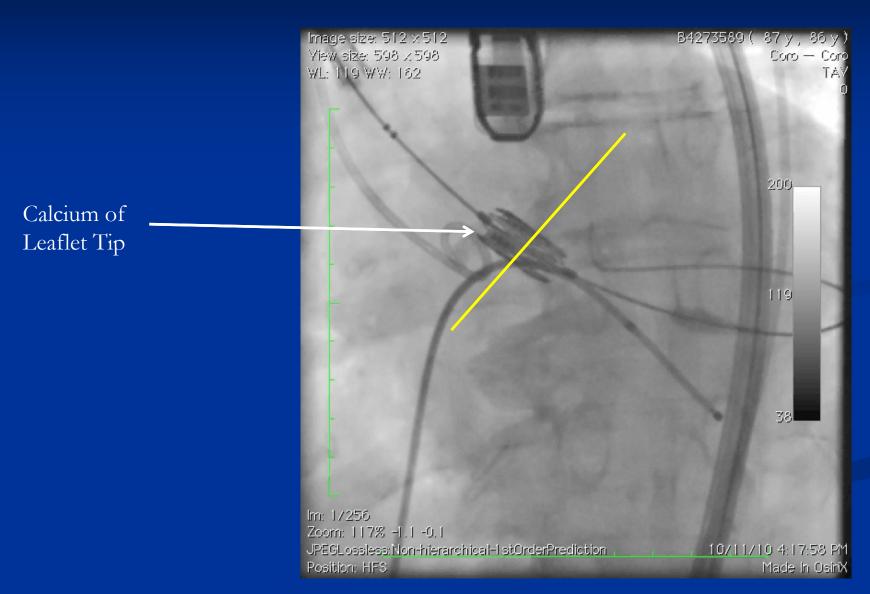


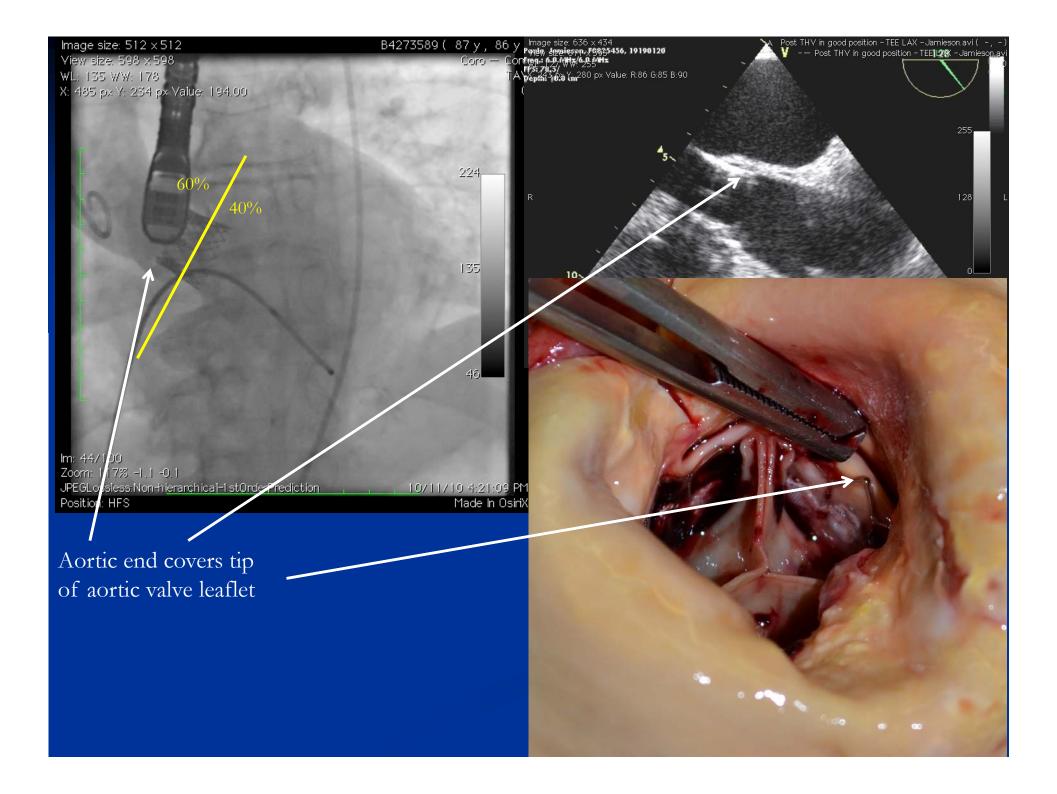
Ideal Final Position



Not always possible to satisfy all these

Using Leaflet Tip Ca to Help Positioning





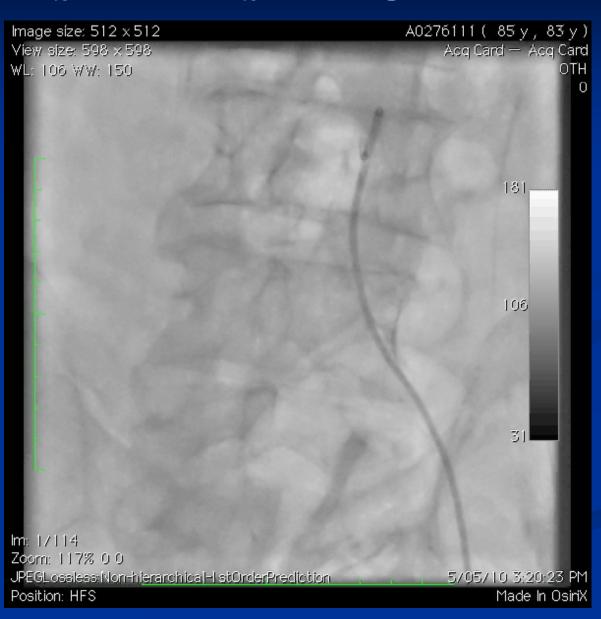
TRANSFEMORAL TAVI PROCEDURAL STEPS

- Vascular access and insertion of large 18 / 19F sheath
- Insertion of pacing wire for rapid ventricular pacing
- Insertion of pigtail catheter for guiding aortography
- Cross aortic valve and insertion Amplatz Extra-stiff wire
- Balloon aortic valvuloplasty
- Insertion of valve assembly and NovaFlex, align valve, cross arch and aortic valve
- Valve positioning and deployment
- Removal of NovaFlex and balloon catheter
- Removal of large sheath and vascular closure

Removal Of Large Sheath

- Aim for short dwell time
 - ie. Remove sheath as soon as valve function verified
- Contrast injection during sheath removal
 - Contralateral catheter / pigtail
 - Pre-emptive cross-over sheath with balloon inflation
- Leave guidewire in-place until haemostasis secured if preclosure
- Watch BP during sheath removal
- Ready large dilator or occlusion balloon to tamponade any perforation

Abrupt hypotension post-large sheath removal

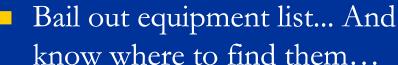




Be Prepared for All Emergencies

Preferably with pre-defined & discussed protocol....

- What to do when BP falls
- Peripheral perforation
- Pre-closure fail
- Coronary occlusion
- Severe AR
- Embolised valve
- Valve malposition





Hypotension Emergency Treatment

■ Pressors +/- fluid

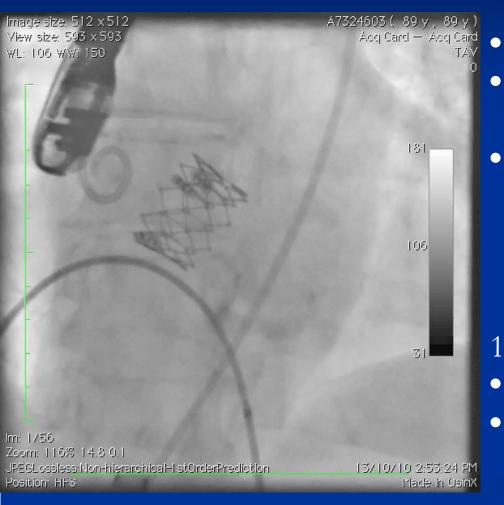
Consider early cardiopulmonary bypass if not responsive

Confirm diagnosis depending on circumstance & context

Hypotension Consider circumstances

- At sheath insertion / removal
 - Peripheral perforation
 - → Early angiography
- After stiff wire passage to LV
 - Severe MR; Tamponade
 - \rightarrow Echo
- Post-BAV
 - Severe AR; Tamponade
 - → Echo, Aortogram
- Post-THV deployment
 - Severe AR (valvular / paravalvular); Coronary occlusion; Tamponade
 - → Echo & Aortogram, then coronary angiogram

Hypotension post-TAVI



- Post-TF TAVI
- Heparin reversed with protamine
- 18Fr Sheath removed successfully & hemostasis confirmed

10 minutes post sheath removal

- Severe hypotension
- CVP **^**



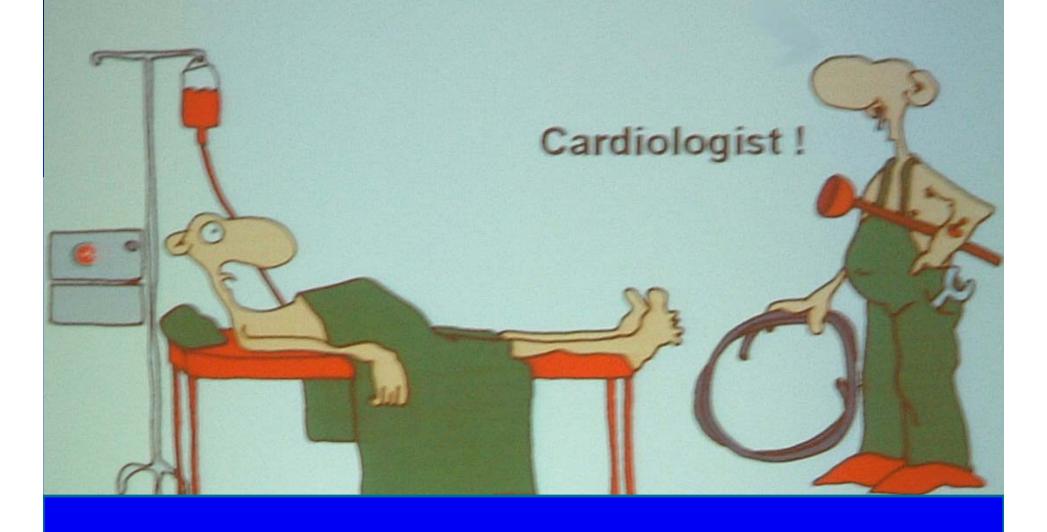


3 Keys to Success

- PATIENT SELECTION
- PROCEDURAL DETAILS

INTEGRATED MULTIDISCIPLINARY
TEAM

Are you the guy for the valve job?



Geriartrician

Cardiac Imaging

Nephrologist

Interventional cardiology

Cardiac surgery

Cardiac cathlab

TAVR Program

Intensivist

Vascular Surgery

Program Co-ordinator

Cardiac Anesthetist

Hybrid OR

Wards – ICU / CCU / Cadiac / CTS ward



Conclusion

- TAVR is a unique procedure...
- Low volume (~60-100/yr in "expert centers")
- Highly challenging procedure (despite mininally invasive)
 - Crucial part of procedure over in short time
 - No / Minimal options for "re-do"
 - Multiple operators & support staff must act in co-ordinated manner
- High risk patient subset minimal reserve for errors

Keys To Success In A TAVR Program

- Proper patient selection
- Attention to technical details
 - Do the same steps all the time
 - Diligent monitoring of patient from start (puncture or cut) to finish (sheath removed and closed)...
 - Develop action plans for disasters
 - Be prepared to handle the unexpected
 - Same operators / procedural support staff
- Well trained and experienced multidisciplinary team
 - Supports procedure
 - Supports pre-TAVI and post-TAVI care