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Patient and Device Selection for ViV TAVR: The Good, the Bad, and the Ugly

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Disclosures

Physician name

Company

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4tech Cardio, Abbott, Ablative Solutions, Ancora Heart, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, CGuard, Comed B.V., Contego, CVRx, Edwards, Endologix, Hemoteq, InspireMD, Lifetech, Maguet Getinge Group, Medtronic, Mitralign, Nuomao Medtech, Occlutech, pfm Medical, Recor, Renal Guard, Rox Medical, Terumo, Vascular Dynamics, Vivasure Medical, Venus, Veryan

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Bioprosthetic Aortic Valves do not function forever



- They may fail due to stenosis, insufficiency or a combination of both
- The risk of failure is higher in younger patients

Rahimtoola S. Choice of prosthetic heart valve in adults An Update. J Am Coll Caridiol 2010;55:2413-26.; Bonow R, Carabello B, Chatterjee K, et al. ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease J Am Coll Cardiol 2006;48:1-148.; Mosaic® aortic bioprosthesis. Medtronic, Inc. 2014 UC201503587EN

Patient selection for Valve in Valve



Prosthetic Aortic Valve Failure

 For severely symptomatic patients with bioprosthetic aortic valve stenosis or regurgitation judged by the heart team to be at high or prohibitive risk for surgical therapy, in whom improvement in hemodynamics is anticipated, a transcatheter valve-in-valve procedure is reasonable

Class IIa LOE B-NR

Θ EΔCTS Management of prosthetic valve dysfunction (continued)



Recommendations	Class	Level
Bioprosthetic failure		
Reoperation is recommended in symptomatic patients with a significant increase in transprosthetic gradient (after exclusion of valve thrombosis) or severe regurgitation.		с
Reoperation should be considered in asymptomatic patients with significant prosthetic dysfunction, if reoperation is at low-risk.	lla	с
Transcatheter valve-in-valve implantation in aortic position should be considered by the Heart Team depending on the risk of reoperation and the type and size of prosthesis.	lla	с

TAVI for Bioprosthetic Stenosis/Regurgitation



- Failed SAVR (n=365)
 - Initial Registry (n=96)
 - Continued Access (n=269)
 - Mean age: 78.9
 - Mean STS score: 9.1%
 - Device Type: Sapien XT
- Surgical implant >10yr: 66.3%
- All-cause mortality
 - 30 days: 2.7%
 - 1 year: 12.4%
- Major stroke:
 - 30 days: 2.7%
 - 1 year: 4.5%
- New PPM at 30-days: 1.9%

TAVI for Bioprosthetic Stenosis/Regurgitation



• CoreValve U.S Study

30 days: 8.1% 1 year: 11.0%

Deeb GM, et al. JACC Cardiovasc Interv. 2017 May 22;10(10):1034-1044

Surgical Valves



Dvir D, Webb J. Circulation. 2013

Mechanism of valve failure

Stenosis

Regurgitation

Pannus



Thrombus



Calcification



Wear & Tear (int.)

Wear & Tear (ext.)

Endocarditis







Which TAVI valves have been used for ViV ?



SAPIEN XT

CoreValve

SAPIEN 3

Evolut R

Danny Dvir, CSI 2018



Danny Dvir, CSI 2018

Valve selection and sizing

- Check type and the inner diameter of the surgical valve
 - OR reports and IFU or information from the manufacturer
- Use CT scan!
 - Inner diameter may be smaller due to leaflet thickening and calcification
 - Distance to the coronary arteries
- Use the ViV App!



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Hancock II

CoreValve Ideal Placement

Stented

If recommendation is two sizes, choose the valves size depending on size of sinus of valsalva. Place CoreValve 4mm below the fluoroscopic marker in the sewing ring





Valve-in-Valve Positioning Considerations

Location of Angiographic Markers in Surgical Valves Varies



What are the challenges?

- Make sure there is no paravalvular (surgical) leak
- Crossing the bioprosthetic valve may be more difficult
- Introducing the TAVI valve into a bioprostesis may be more difficult
- Positioning may be very difficult in stentless values with severe regurgitation
- Higher stroke risk
- Patient prosthesis mismatch of the surgical valve
- High residual gradient
- Higher risk of coronary obstruction with some of the surgical valves

Are there any good news?

- Sizing is easier
- Positioning the valve is very easy in stented valves
- No paravalvular leaks
- Lower risk of need for permanent pacemaker
- No risk of anulus rupture

Residual stenosis due to initial patient prosthesis mismatch + the additional material of the TAVI valve

Supra-anular valve design (CoreValve) may be better than intra-anular design (Sapien, Portico)



Dvir D et al. JAMA. 2014;312(2):162-170.

Position of the valve is important

Smaller valve area and higher gradient if the CoreValve is placed too low



Simonato M. EuroIntervention 2016

If there is a residual gradient:

- Post dilate!
 - it leads to compression of the bioprosthesis leaflets which may add 1mm
- Consider bioprosthetic valve ring fracture (BVF)

Bioprosthetic Valve Ring Fracture (BVF)





Jens Erik Nielsen-Kudsk. et al. Circ Cardiovasc Interv. 2015

Bioprosthetic Valve Ring Fracture



Complications of Bioprosthetic Valve Ring Fracture

- N = 74 (21 centers)
 - 2 embolic stroke
 - 1 flail anterior MV leaflet –required surgery
 - 2 severe AI from TAVR valve treated with 2nd valve
- Potential complications
 - Aortic root or annulus rupture
 - Coronary occlusion
 - AV block

Adnan Chhatriwalla et al.

Not all surgical valves can be fractured!

Manufacturer/ Brand	Valve Size	Bard TRU Balloon Fracture/Pressure	Bard Atlas Gold Balloon Fracture/Pressure	Appearance After Fracture
St. Jude Trifecta	19 mm	NO	NO	
	21 mm	NO	NO	
St. Jude Biocor Epic				-
	21 mm	YES / 8 ATM	YES / 8 ATM	\bigcirc
Medtronic Mosaic	19 mm	YES / 10 ATM	YES / 10 ATM	1 0 1
	21 mm	YES / 10 ATM	YES / 10 ATM	4
Medtronic Hancock II				
	21 mm	NO	NO	
Sorin Mitroflow			and the same	
	19 mm	YES / 12 ATM	YES / 12 ATM	A
	21 mm	YES / 12 ATM	YES / 12 ATM	-
Edwards MagnaEase				, 1
	19 mm	YES / 18 ATM	YES / 18 ATM	1
	21 mm	YES / 18 ATM	YES / 18 ATM	
Edwards Magna				1 0
	19 mm	YES / 24 ATM	YES / 24 ATM	
	21 mm	YES / 24 ATM	YES / 24 ATM	

Keith Allen et al. Annals of thoracic surgery 2017

Coronary obstruction

Incidence of Coronary Obstruction According to the Type of Surgical Bioprosthesis



BASILICA



D Devir, TCT 2017

Other problems

Some valves (like Labcor) are not well visible on fluoro



Difficulties to cross

- Degenerated bioprosthetic valve
- Horizontal aorta
- Venus valve could not be introduced into the LV



- Snare
 - Contralateral femoral artery or brachial/radial
- Valve delivery system has to go through snare



- Venus valve lifted away from the frame of the bioprosthetic valve
- Stepwise advancement of the Venus valve



• Snare released



Snare removal





• Valve implantation



• Final angio



In Summary

- Aortic value in value procedures can be performed safely and with results at least comparable to redosurgery
- There are ways to prevent problems like residual gradients in small valves, coronary obstruction and other complications
- Valve in valve instead of redo surgery should be considered at least in high risk patients