Optimal Valve Choice in Various TAVR: A Complex Equation to Select One

Alan C. Yeung, MD Li Ka Shing Professor of Medicine Medical Director, Cardiovascular Health Stanford University School of Medicine Stanford Hospital and Clinic



How Many TAVRs Do We Need?





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HERZZENTRUM LEIPZIG

SOLVE-TAV

A 2x2 Randomized Trial of Self-Expandable vs Balloon-Expandable Valves and General vs Local Anesthesia in Patients Undergoing Transcatheter Aortic Valve Implantation

1-year Results

Hans-Josef Feistritzer, MD, PhD On behalf of the SOLVE-TAVI Investigators



SOLVE-TAVI – 2 x 2 Factorial Design

SOLVE-TAV





Flow Chart – Valve Strategy





30-Day Primary Endpoint – Valve Strategy

All-cause mortality, stroke, moderate or severe prosthetic valve regurgitation, permanent pacemaker implantation at 30 days



SOLVE-TAV



TCT CONNECT

1-year Outcomes – Valve Strategy

	Evolut R	Sapien 3	p-value	Cause specific HR (95% CI)	
	n (%)	n (%)	Gray's test		
Composite endpoint*	87 (41.9)	85 (40.4)	0.76	0.95 (0.71-1.28)	
All-cause mortality	34 (17.6)	33 (17.0)	0.88	0.96 (0.60-1.55)	
Cardiovascular mortality	1 (0.5)	4 (1.8)	0.19	3.89 (0.44-34.67)	
Stroke	2 (1.0)	14 (6.9)	0.002	7.13 (1.62-31.32)	
Moderate/severe PVL	14 (7.0)	9 (4.5)	0.35	0.63 (0.27-1.45)	
Permanent pacemaker implantation	54 (24.7)	44 (20.2)	0.25	0.79 (0.53-1.16)	
Time-related safety (VARC-2)	45 (15.6)	64 (20.8)	0.10	1.36 (0.93-1.99)	

*Composite of all-cause mortality, stroke, moderate/severe PVL, and permanent pacemaker implantation

1-year Outcomes – Valve Strategy



Stroke

All-cause mortality



TCT CONNECT



Echocardiographic Findings – Valve Strategy

	Evolut R		Sapien 3		Difference		o voluo
	Median	IQR	Median	IQR	Median	95%CI	p-varue
AVA, cm ²	1.9	(1.6, 2.3)	1.7	(1.5, 2.0)	-0.2	-0.3 to 0	0.063
AVA index, cm ² /m ²	1.0	(0.9, 1.2)	1.1	(0.8, 1.3)	0	-0.1 to 0.2	0.75
Mean aortic valve gradient, mmHg	6	(4, 8)	10	(8, 12)	4	3 to 5	<0.001
Max. aortic valve gradient, mmHg	12	(8, 16)	19	(13, 24)	7	5 to 9	<0.001



By and Large, Equivalent!

- Similar composite end points (death, stroke, m/sPVL and pacemakers
- More strokes in BEV
- Better hemodynamics in SEV



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- Nuance driven!



My Equations !



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• Sapien=
$$(x + a)^n = \sum_{k=0}^n \binom{n}{k} x^k a^{n-k}$$

• Evolut Pro =
$$(x + b)^n = \sum_{i=0}^n \binom{n}{i} x^i b^{n-i}$$



Anatomical	Sapien 3	Evolut Pro
Access Size	5.0mm	5.5mm
Tortuous Iliacs	++	+++
Calcified Iliacs	Possible	Better
Annular Sizing	742mm2 (+4cc)	94.2mm (perimeter)
Outflow Track Ca++	Avoid	OK
Septal Bulge	OK	OK
Heavy Valve Calcification	Pre-dilate	Pre and Post-dilate



Subsets	Sapien 3	Evolut Pro
Bicuspid	OK	OK
Low Risk	OK (SEV in BEV)	OK (SEV/BEV in SEV)
Al large component (or minimal calcification)	Avoid	Better
Coronary Access (now or future)	Straight Forward	More Difficult
Valve in Valve	Larger Valve OK	Better hemo
Small Annulus	Avoid 20mm	Better hemo
Decrease LV Function	Rapid pacing needed	Avoid long pacing
Low Flow, Low Gradient	OK	May be better



REPRODUCIBILITY OF CUSP OVERLAP TECHNIQUE TO REDUCE PERMANENT PACEMAKER IMPLANTION WITH EVOLUT – THE LATIN AMERICAN EXPERIENCE

<u>Hemal Gada, MD, MBA;</u> Amit N. Vora, MD, MPH; Oscar Millan Iturbe, MD; Matias Sztejfman, MD; Lucas Gerbaudo, MD; Alejandro Alverez Iorio, MD; Rogerio Tumelero, MD; Luis Gutierrez Jaikel, MD

University of Pittsburgh Medical Center Pinnacle, Wormleysburg, PA; Hospital de Cardiologia, UMAE, Mexico City, Mexico; Sanatorio Finochietto, Buenos Aires, Argentina; Sanatorio del Salvador, Cordoba, Argentina; Hemodinamia del Sur, Bahia Blanca, Argentina; Hospital Sao Vicente de Paulo, Rio de Janeiro, Brazil; Hospital Clinica Biblica, San Jose, Costa Rica



CUSP OVERLAP HIGHLIGHTS

The cusp overlap view isolates the NCC by overlapping the RCC and LCC and is generally in the RAO imaging plane.



This view provides a good anatomical reference for deployment depth at the point of contact (NCC) as it:

- Maintains basal plane alignment of coronary cusps
- Elongates the outflow tract in a long axis view
- Reduces or removes parallax in the marker band
- Assists with depth visualization near the non-right commissure and membranous septum during deployment
- Provides a favorable root viewing angle inclusive of anatomies with root angulation approaching 70°

To have an efficient, scripted procedure, you require a high quality gated CT with contrast; free from motion artifact and slice misregistration.

PROCEDURAL MODIFICATIONS

1. Start Higher



2. Allow the Valve to Descend



3. Control Pace to Point of No-Recapture



PROCEDURAL MODIFICATIONS

4. Confirm Depth and Performance





5. Release Slowly and Methodically



RESULTS

- Fourteen implanting physicians from 7 different countries performed consecutive procedures on 114 patients
- Each physician implanted 22.6±10.9 THVs the previous year, with a lifetime experience of 129±110 THVs
- Of the 114 patients, 105 (92%) did not have prior PPI
- The in-hospital rate of new PPI post-THV was 5.7%
 - No use of a second valve
 - True cusp overlap achieved in 98.2% of cases
- 30-day follow-up data was only present for 85 patients in the series; none of these had a new PPI





Ochiai T et al. JACC Cardiovasc Intv 2020;13:693-705

Results of Modified "3 O'Clock" Flush Port Insertion Technique

- Experience thus far: 240 consecutive cases since 3/2019-7/2020
 - # of catheter rotation in descending aorta to make "Hat" marker outer curve: <10%</p>
- "Hat" at OC/CF increased from 70% to 93% (p<0.0001)
- Severe coronary overlap (versus "12 o'clock"):
 - I or both coronaries reduced from to 38.0% to 20.8% (p=0.006)
 - LM from 31.4% to 14.2% (p=0.002)
 - RCA from 20.7% to 11.7% (p=0.027)
 - Both coronaries from 14% to 5.0% (p=0.004)

My Equations !

Sapien= Experience with Sapien

Evolut Pro = Experience with Evolut Systems

