TAVI DURABILITY IN INTERMEDIATE RISK POPULATION

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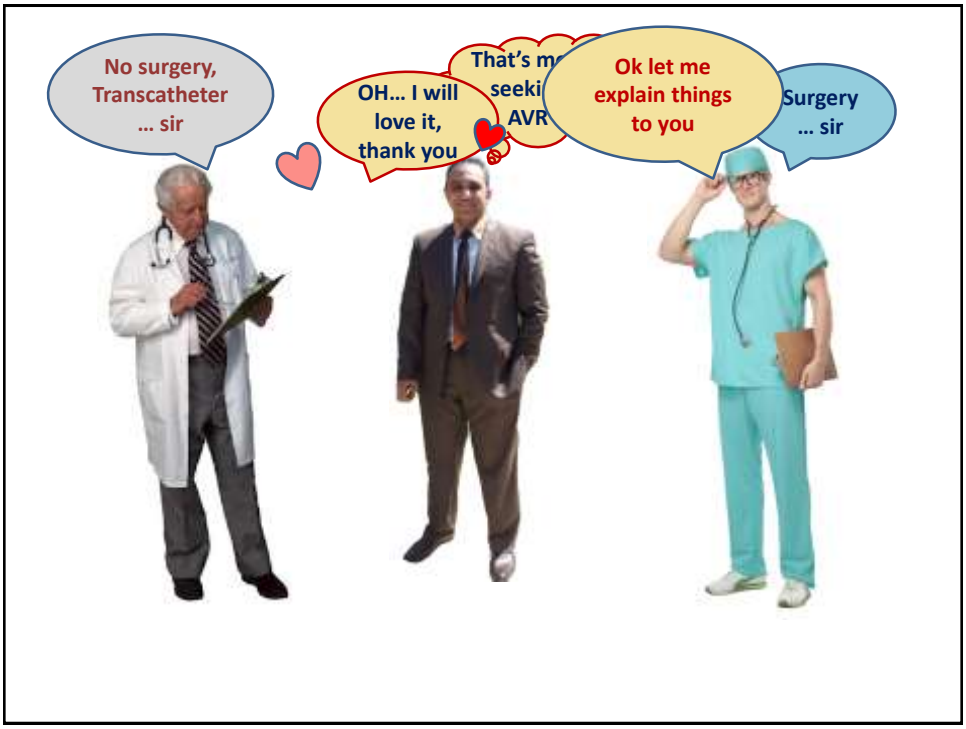
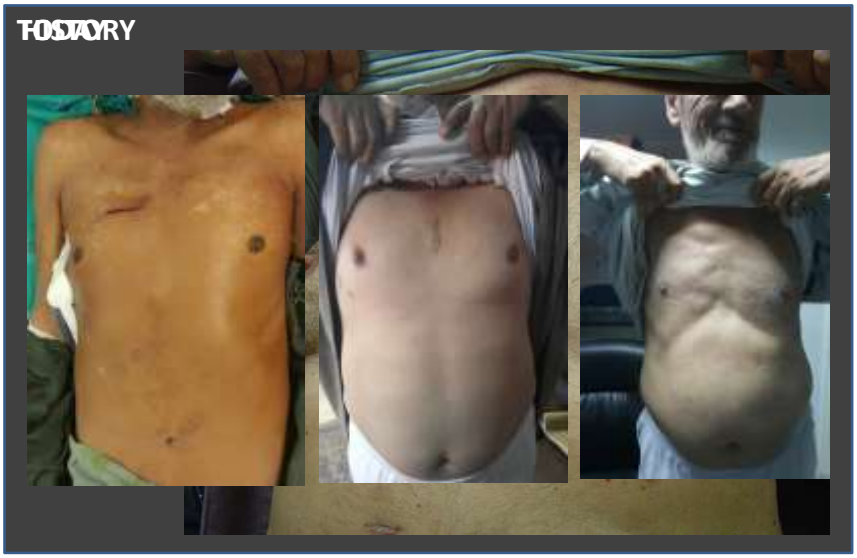
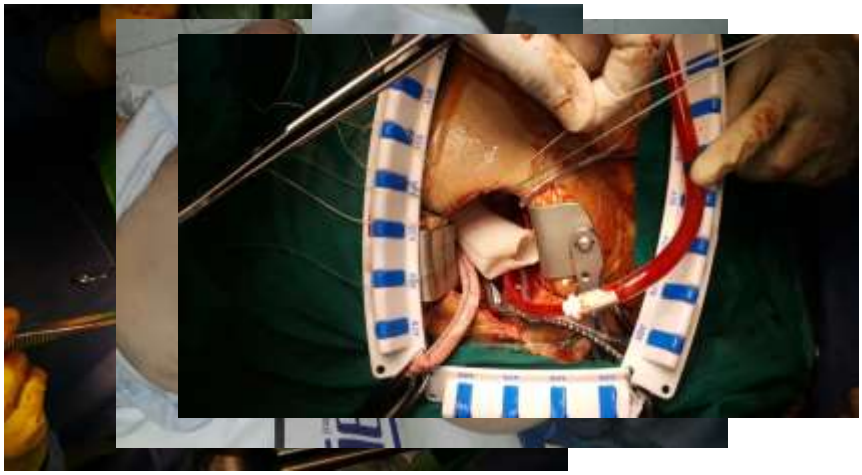


A VIEW OF AORTIC SURGERY



EVEN OTHER TYPES OF SURGERIES

MVR **MV Repair** **MIDCAB** **ASD** **BENTALL**



WHERE TAVI STANDS

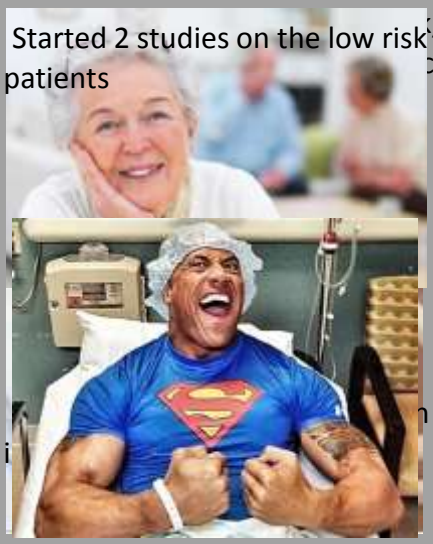
- **INDICATIONS**
- **TODAY**
- **TOMORROW**

The U.S. Food And Drug Administration Approved On 18th Of August 2016, For

PARTNER III, SABIEN3 in low Risk
CoreValve Evolute R in low Risk
Both will include 4d CT scans for valve thrombosis

SURTAVI for CoreValve system next year

- Started 2 studies on the low risk patients



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PARTNER II DETAILS

Table 2. Clinical End Points at 30 Days, 1 Year, and 2 Years.*

End Point	At 30 Days			At 1 Year			At 2 Years		
	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value	TAVR (N=1011)	Surgery (N=1021)	P Value
	no. of patients (%)			no. of patients (%)			no. of patients (%)		
Death from any cause or disabling stroke	82 (8.1)	80 (8.0)	0.11	145 (14.5)	160 (16.4)	0.24	192 (19.3)	202 (21.1)	0.33
Death									
From any cause	39 (3.9)	43 (4.1)	0.78	123 (12.3)	124 (12.9)	0.69	168 (16.7)	170 (18.0)	0.45
From cardiac causes	33 (3.3)	32 (3.2)	0.92	70 (7.1)	77 (8.1)	0.40	97 (10.1)	104 (11.1)	0.38
Not from cardiac causes	6 (0.6)	9 (0.9)	0.41	53 (5.6)	47 (5.1)	0.71	69 (7.4)	65 (7.0)	0.98
Neurologic event									
Any event	64 (6.4)	65 (6.5)	0.94	98 (10.1)	93 (9.7)	0.76	121 (12.7)	103 (11.0)	0.25
Transient ischemic attack	9 (0.9)	4 (0.4)	0.17	23 (2.4)	18 (1.9)	0.55	34 (3.7)	20 (2.3)	0.09
Any stroke	55 (5.5)	62 (6.1)	0.57	78 (8.0)	79 (8.1)	0.88	91 (9.5)	85 (8.9)	0.67
Disabling stroke	32 (3.2)	43 (4.3)	0.20	49 (5.0)	56 (5.8)	0.46	59 (6.2)	61 (6.4)	0.83
Nondisabling stroke	23 (2.3)	18 (1.8)	0.43	30 (3.0)	24 (2.5)	0.44	33 (3.4)	27 (2.9)	0.51
Rehospitalization	64 (6.3)	63 (6.5)	0.99	142 (14.8)	135 (14.7)	0.92	183 (19.6)	156 (17.1)	0.22
Death from any cause or rehospitalization	99 (9.8)	101 (10.2)	0.78	234 (23.4)	225 (23.3)	0.97	301 (33.5)	281 (29.6)	0.67
Death from any cause, any stroke, or rehospitalization	140 (13.9)	153 (15.3)	0.37	274 (27.4)	276 (28.3)	0.64	344 (34.6)	326 (33.9)	0.75
Myocardial infarction	12 (1.2)	19 (1.9)	0.22	24 (2.5)	29 (3.0)	0.47	33 (3.6)	37 (4.1)	0.56
Major vascular complication	80 (7.9)	51 (5.0)	0.008	84 (8.4)	54 (5.3)	0.007	86 (8.6)	55 (5.5)	0.006
Life-threatening or disabling bleeding	185 (18.6)	442 (43.4)	<0.001	151 (15.2)	460 (45.5)	<0.001	169 (17.3)	471 (47.0)	<0.001
Acute kidney injury	13 (1.3)	31 (3.1)	0.006	32 (3.4)	48 (5.0)	0.07	36 (3.8)	57 (6.2)	0.02
New atrial fibrillation	91 (9.1)	265 (26.4)	<0.001	100 (10.1)	272 (27.3)	<0.001	110 (11.3)	273 (27.3)	<0.001
New permanent pacemaker	85 (8.5)	68 (6.9)	0.17	98 (9.9)	85 (8.9)	0.43	114 (11.8)	96 (10.1)	0.29
Endocarditis	0	3	—	7 (0.8)	6 (0.7)	0.84	11 (1.2)	6 (0.7)	0.22
Aortic valve reintervention	4 (0.4)	0	0.05	11 (1.2)	4 (0.5)	0.10	13 (1.4)	5 (0.6)	0.09
Coronary obstruction	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53	4 (0.4)	6 (0.6)	0.53

* All percentages are Kaplan–Meier estimates at the specific time point and thus do not equal the number of patients divided by the total number of patients in the treatment group. P values are for point-in-time comparisons.

Contemporary Real-World Outcomes of Surgical Aortic Valve Replacement in 141,905 Low-Risk, Intermediate-Risk, and High-Risk Patients

Vinod H. Thourani, MD, Rakesh M. Suri, MD, DPhil, Rebecca L. Gunter, MD, Shubin Sheng, PhD, Sean M. O'Brien, PhD, Gorav Ailawadi, MD, Wilson Y. Szeto, MD, Todd M. Dewey, MD, Robert A. Guyton, MD, Joseph E. Bavaria, MD, Vasilis Babaliaros, MD, James S. Gammie, MD, Lars Svensson, MD, PhD, Mathew Williams, MD, Vinay Badhwar, MD, and Michael J. Mack, MD

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(Ann Thorac Surg 2015;99:55–61)

- **4% to 8% (group 2,n [19,769),**

PARTNER II vs REAL WORLD

ITEMS	PARTNER II TAVR	PARTNER II SAVR	REAL WORLD SAVR
PATIENTS	1011	1021	**19769**
MEDIAN AGE	81.5±6.7	81.7±6.7	77.2 ±9.9 Median 80.0
MORTALITY	3.9%	4.1%	5.1%
ANY STROKE	5.5%	6.1%	**2.3%**
LIFE THREATNING BLEEDING	10.4%	43.4%	**4.7%**
PERM. PACING	8.5%	6.9%	**5%**

DURABILITY OF PROSTHESES FOR TAVR

- Review was Published 7 April 2016 by Department Cardiac Surgery, Kerckhoff Heart Center, Germany.
- Reliable long-term data for transcatheter aortic valve implantation (TAVI) devices are currently available only for up to 5 years
- The durability of biological prostheses, conventional xenografts, or TAVI prostheses depends on multiple, and sometimes unique, factors. factors that must be considered include ***patient age***, *comorbidities* (such as renal failure), *infections*, and *procedural factors* during implantation.

DURABILITY OF PROSTHESES FOR TAVR

continue

- Owing to the slow development of SVD, early valve failure from SVD is quite rare (<1% after 5 years, and still only 10% after 10 years). However, these rates apply only to patients aged >65 years because SVD is highly age-dependent. The highest rates of SVD have been identified in patients aged <35 years, because younger patients have increased metabolic rates and higher competence of their immune systems.

Table 2 | **Age-dependent durability of conventional xenograft valves**

Valve type	Model	Follow-up (years)	Age (years)	Freedom from SVD (%)	Study
Stented bioprostheses					
Porcine	St. Jude Biocor™ (St. Jude Medical, USA)	20	73 (mean)	61.1 ± 8.5	Myken et al. (2009)[18]
			≤50	37.7 ± 5.8	
			51–60	60.7 ± 10.3	
			61–70	81.0 ± 5.1	
			71–80	97.3 ± 1.2	
			>80	100	
Porcine	Medtronic Hancock® II (Medtronic CV Luxembourg S.a.r.l., Luxembourg)	15	<60	70.4 ± 7.5	Rizzoli et al. (2006)[19]
			≥60	96.5 ± 1.3	
			≥65	96.9 ± 1.4	
Porcine	Medtronic Hancock® II	10	<40	88.9 ± 5.8	Une et al. (2014)[17]
			40–49	96.4 ± 4.9	
			50–59	93.5 ± 2.4	
		20	<40	14.1 ± 6.7	
			40–49	14.7 ± 3.8	
			50–59	17.5 ± 5.8	
Stentless bioprostheses					
Porcine	St. Jude Toronto SPV® (St. Jude Medical, USA)	12	65 (mean)	89 ± 4.0	David et al. (2003)[12]
			≤65	52 ± 5.0	
			>65	85 ± 4.0	
Porcine	Medtronic Freestyle® (Medtronic CV Luxembourg S.a.r.l., Luxembourg)	9	73 (mean)	92.4 ± 7.4	Emiker et al. (2009)[16]
Porcine	Medtronic Freestyle®	15	<60	62.6	Mohammadi et al. (2012)[13]
			≥60	88.4	

DURABILITY OF PROSTHESES FOR TAVR

continue

- For example, the Ionescu–Shiley pericardial tissue valve (Shiley, USA) had promising initial results and haemodynamics. However, suture fixation of the leaflets ultimately resulted in cusp tear and aortic regurgitation by 5–6 years after implantation, with a freedom from reoperation of only 38% after 13 years
- Mitroflow® pericardial valve (Sorin Group, Canada), first introduced in 1982 (REF. 17). The first generation of the valve had a freedom from SVD of 96.9% after 5 years, but only 39.2% at 10 years

SO TAVR MIGHT HAVE A GREATER DURABILITY.?

- Leaflet and valve design might further affect TAVI valve durability. Although the tissue used for TAVI prostheses is the same as, or similar to, that for surgical bioprostheses, the ***mechanical stress*** placed on TAVI valves is ***higher*** as a result of the way in which the tissue is mounted to a rigid ring, compared with in conventional xenografts where there is usually some residual flexibility in the stent.
- TAVI devices can also undergo ***underexpansion*** and ***overexpansion*** of the stent. Improper expansion causes ***changes in valve geometry*** that affect the mechanical stresses on leaflet tissue. With variations in mechanical stress between SAVR and TAVI, variations in durability of the respective valves should be expected.

SO TAVR MIGHT HAVE A GREATER DURABILITY.? *CONTINUE*

- In an effort to reduce vascular complications, ***sheath sizes*** are continuously being reduced — a design element that requires increasingly thinner leaflet material. ***Thinner leaflet*** material might have shorter durability compared with the regular-thickness bovine pericardium used in many conventional xenografts (thickness of TAVI leaflets is ~0.25 mm compared with ~0.4 mm in surgical valve leaflets). The reduction of sheath sizes also necessitates additional ***crimping*** of the leaflets. Although an association between crimping and SVD has not been demonstrated clinically, bench studies have ***detected microscopic tissue damage*** on the valve surface layers40. These injuries might predispose to thrombus formation and affect TAVI durability.

EuroPCR 2016: Study casts doubt on long-term TAVR durability

- The study looked at 704 patients who had a TAVR procedure between April 2002 and May 2011, following 378 of them for up to 10 years. In the 100 patients who survived for at least 5 years, there were 35 cases of valve degeneration, with a significant number showing deterioration between 5 and 7 years after TAVR implantation.
- The study's authors estimated that the 8-year rate of degeneration was roughly 50%.

EuroPCR 2016: Study casts doubt on long-term TAVR durability *CONTINUE*

- "Physicians performing [TAVR] in younger patients and in those expected to survive long after the procedure should be aware that the long-term rate of [transcatheter heart valve] degeneration is not negligible, at least for first-generation THV devices,"

author Dr. Danny Dvir, of Vancouver's St. Paul's Hospital

CONCLUSION

- TAVR IS A PROMISING ALTERNATIVE TO SAVR IN HIGH RISK PATIENTS
- TAVR MAY BE SUITABLE IN INTERMEDIATE RISK PATIENTS WITH LESS OUTCOMES THAN SAVR
- CONCERNING TAVR IN INTERMEDIATE RISK PATIENTS SHOULD BE RESERVED FOR AGE ABOVE 75 AND PREFERABLY OCTOGENERIANS
- SHOULD NOT APPLY FOR LOW RISK POPULATION EXCEPT AFTER LONG TERM FOLLOWUP RESEARCH