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Outcomes Following Transcatheter Aortic Valve Implantation for Degenerative Stentless versus Stented Bioprostheses

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I do not have any potential conflict of interest

- Valve-in-valve (ViV) transcatheter aortic implantation (TAVI) is an alternative to redo surgery for patients with a failing aortic bioprosthesis.
- Stentless bioprostheses lack fluoroscopic markers and may be challenging for transcatheter treatment. A large comprehensive analysis of TAVI for failed stentless bioprostheses has not been described to date.

Methods: VIVID Registry

- Europe, North America, South America, Africa, Oceania, Middle East
- Data collected for cases 2007 - May 2016
- No restriction on aortic bioprosthesis type / size / TAVI device type
- Operation year, valve type, label size, internal diameter collected
- Baseline bioprosthetic valve area, peak/ mean gradient, AR from last echo before procedure
- Incidence of periprocedural device mal-position, need for second TAVI device, and coronary obstruction recorded
- Early post-implantation echo at 30-days and 1-year

Results: Demographics

- 1,598 ViV-TAVI procedures
- 291 stentless, 1307 stented bioprostheses
- types of failing bioprostheses



Valve Type	Frequency	%		Frequency	%
<i>Stentless</i>			<i>Stented</i>		
Homograft	77	26.5	Sorin Mitroflow	317	24.3
Medtronic Freestyle	75	25.8	Carpentier Edwards Perimount	288	22.0
St. Jude SPV Toronto	37	12.7	Medtronic Mosaic	161	12.3
Sorin Freedom	27	9.3	Carpentier Edwards	153	11.7
St. Jude Biocor	12	4.1	Medtronic Hancock	138	10.6
Cryolife O'Brien	11	3.8	St. Jude Epic / Biocor	73	5.6
Edwards Prima	10	3.4	Carpentier-Edwards Perimount Magna	36	2.7
Shelhigh Biostentless	10	3.4	Unknown	27	2.1
Unknown	7	2.4	Sorin Pericarbon	22	1.7
Vascutak Elan	6	2.1	Baxter-Edwards	16	1.2
BiValsalva	5	1.7	St. Jude Trifecta	15	1.2
Bravo Cardiovascular	4	1.4	Sorin Soprano	14	1.1
Stentless Xenograft	4	1.4	Carpentier-Edwards Perimount Magna	9	0.7
			Ease		
ATS 3F	3	1.0	Sorin Perceval	9	0.7
Braile Biomedica	2	0.7	Medtronic Intact	7	0.5
Baxter-Edwards	1	0.3	Labcor	6	0.5
			Vascutek Aspire	5	0.4
			Stented Xenograft / Xenomedica	4	0.3
			Braile Biomedica Stented	2	0.2
			Ionescu Shiley	2	0.2
			Biocardio	1	0.1
			Biotronik	1	0.1
			Sorin Carbomedics	1	0.1

Results: Demographics

	Stentless (n = 291)	Stented (n=1307)	P value
Age (years)	74.3±12.9	78.4±8.2	<0.001
Male (n,%)	173 (59.3)	748 (57.2)	0.41
Diabetes (n,%)	66 (22.6)	343 (26.3)	0.19
Peripheral vascular disease (n,%)	50 (17.1)	288 (22.1)	0.06
Renal impairment (GFR <60) (n,%)	140 (50.2)	640 (49.5)	0.84
Prior CVA/TIA (n,%)	43 (14.7)	172 (13.2)	0.49
Chronic lung disease (n,%)	40 (19.4)	194 (21.5)	0.51
Previous permanent pacemaker (n,%)	31 (12.8)	156 (13.6)	0.79
Logistic EuroSCORE II	13.6±9.0	14.7±8.5	0.065
STS-PROM Score	9.0±7.9	9.4±8.2	0.44

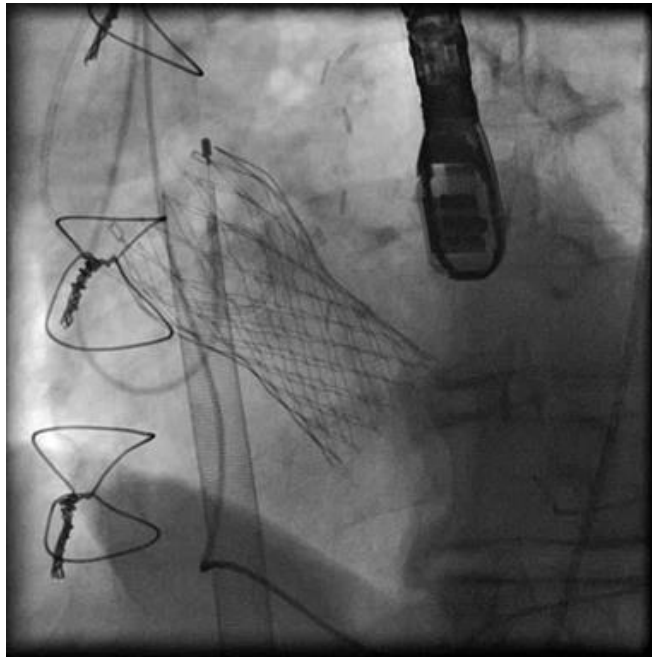
Results: Demographics

- failing stentless bioprosthesis
 - younger (74.3 ± 12.9 vs. 78.4 ± 8.2 years, $p < 0.001$)
 - more likely to be in NYHA Class IV (33.3% vs. 24.7%, $p = 0.005$)
 - undergone more previous cardiac surgical procedures ($p = 0.009$)
 - failed earlier than stented devices
 - stentless: median 9 years, IQR 6 – 12 years
 - stented: median 12 years, IQR 8 – 15 years; $p < 0.001$)
 - Logistic EuroSCORE and STS risk scores were similar between stentless and stented groups.
- AVR failure due to AR in 56% stentless vs. 20% stented devices

	Stentless (n = 291)	Stented (n=1307)	P value
Femoral Access (%)	207 (71.1)	970 (74.2)	0.81
TAVI device type (n,%)			0.029
CoreValve/Evolut R	163 (56.0)	629 (48.1)	
SAPIEN/SAPIEN XT/SAPIEN 3	116 (39.9)	590 (45.1)	
Others	12 (4.1)	88 (6.7)	
TAVI device size implanted (mm)	26.4±2.5	24.3±1.8	<0.001
No vascular complication (n,%)	265 (91.1)	1179 (90.2)	0.71
Major bleeding (n,%)	13 (4.9)	77 (6.1)	0.69
Major stroke (n,%)	3 (1.0)	18 (1.4)	0.65
Acute kidney injury (≥Stage 2) (n,%)	21 (8.0)	71 (5.6)	0.13
Permanent Pacemaker (n,%)	15 (5.7)	79 (6.8)	0.39

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Permanent Pacemaker (n,%)	15 (5.7)	79 (6.8)	0.39
Initial device mal-position (n,%)	29 (10.3)	77 (6.2)	0.014
2 nd prosthesis required (n,%)	23 (7.9)	44 (3.4)	<0.001
Coronary obstruction (n,%)	17 (6.0)	19 (1.5)	<0.001
Paravalvular leak (>mild) (n,%)	165 (56.7)	501 (38.6)	<0.001
Duration of hospital stay (days)	7 (5-12)	7 (5-11)	0.53
30-day mortality (n,%)	19 (6.6)	55 (4.4)	0.12
1 year mortality (n,%)	46 (15.8)	165 (12.6)	0.15

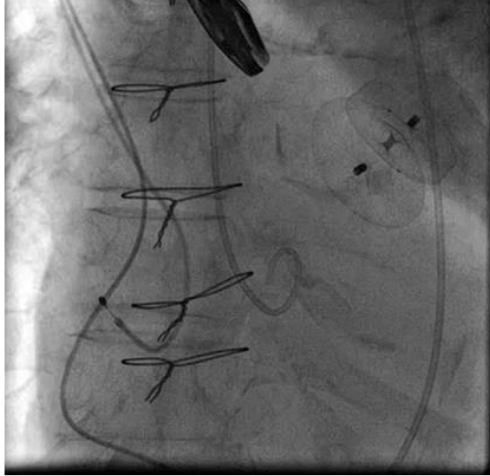
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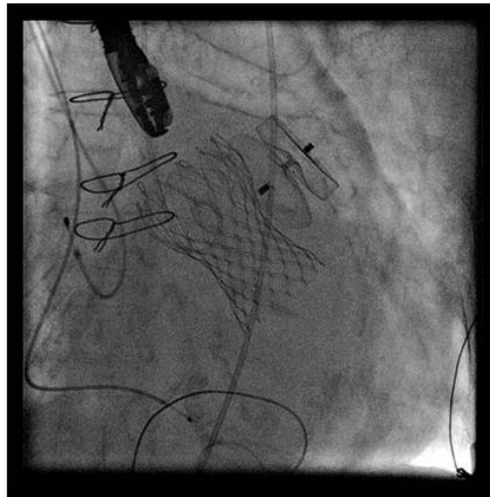
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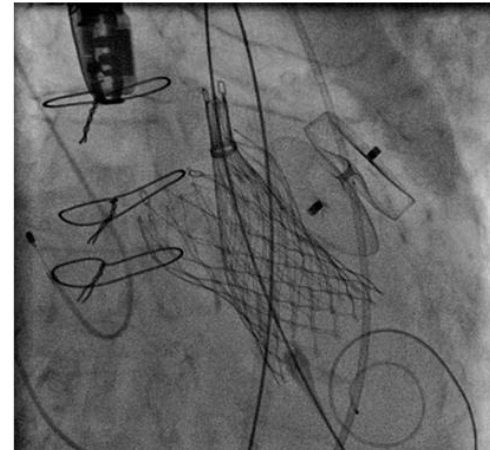
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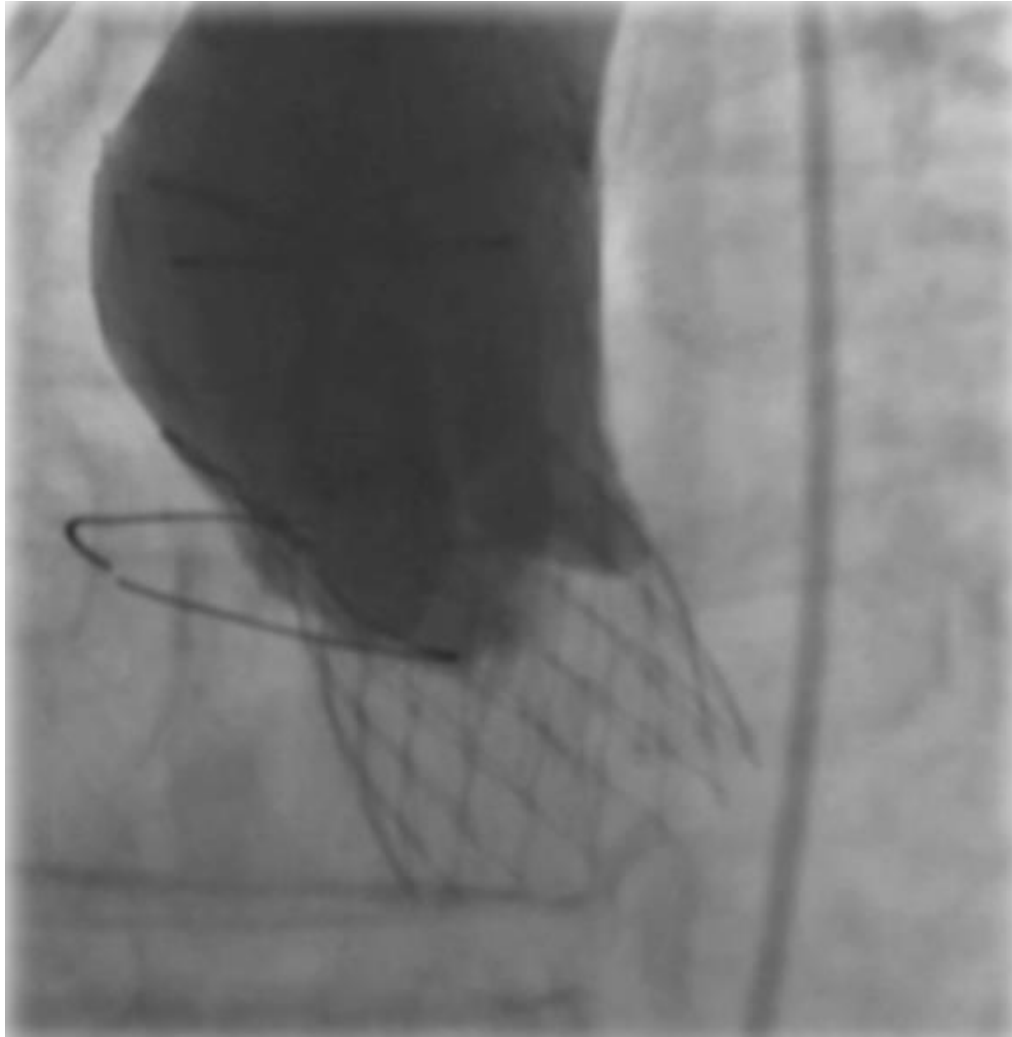


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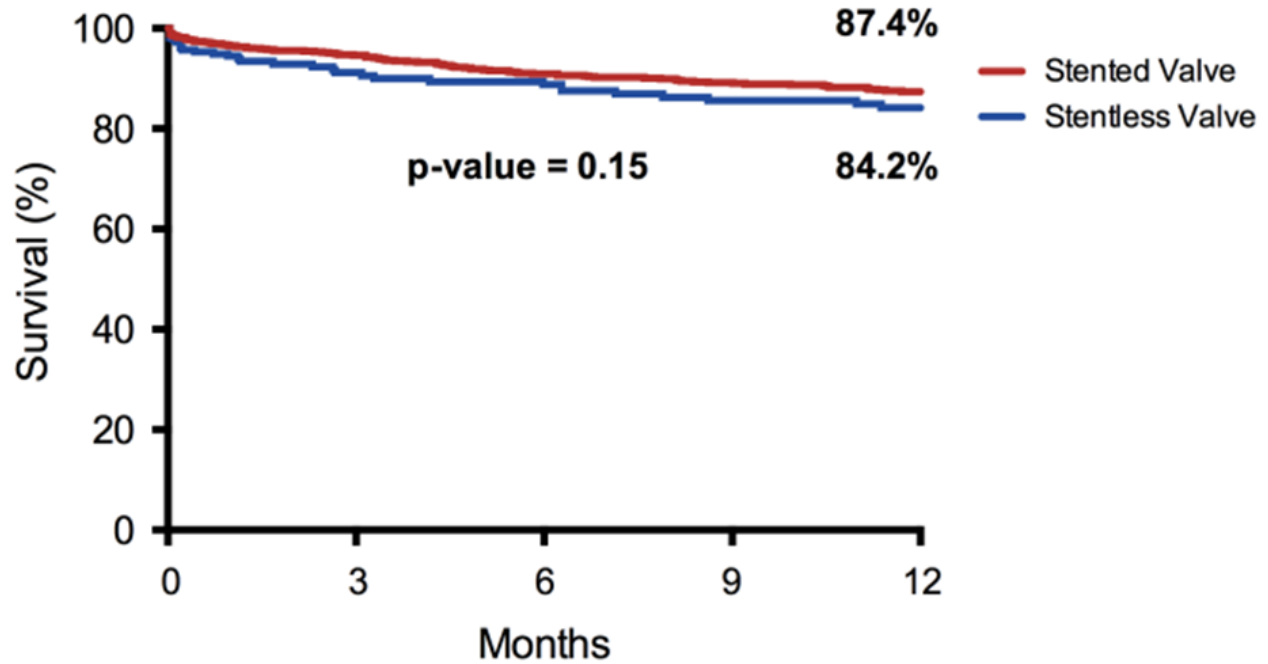


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Survival - Stented vs. Stentless Valves



Patients at risk

Stented	1235	784	666	582	488
Stentless	260	156	145	129	110

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30-day mortality (n,%)	19 (6.6)	55 (4.4)	0.12
1 year mortality (n,%)	46 (15.8)	165 (12.6)	0.15
1-year aortic valve area (cm ²)	1.7±0.6	1.4±0.4	<0.001
1-year peak aortic valve gradient (mmHg)	22±12	33±16	<0.001
1-year mean aortic valve gradient (mmHg)	12±7	19±10	<0.001

- **Stentless ViV-TAVI is associated with greater peri-procedural complications**
- **initial device malposition, second transcatheter device, coronary obstruction, paravalvular leak**
- **better device haemodynamics post-implantation**

Conclusions

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