

Cost-effectiveness of TAVI versus sutureless in low-medium risk patients

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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 28, 2016

VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

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CONCLUSIONS

In intermediate-risk patients, TAVR was similar to surgical AVR with respect to the primary end point of **death** or **disabling stroke**"

RESEARCH

the**bmj** | *BMJ* 2016;354:i5130 | doi: 10.1136/bmj.i5130





Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis

Reed A Siemieniuk,^{1,2} Thomas Agoritsas,^{1,3} Veena Manja,^{1,4,5} Tahira Devji,¹ Yaping Chang,¹ Malgorzata M Bala,⁶ Lehana Thabane,¹ Gordon H Guyatt¹

STUDY SELECTION:

Randomized trials of TAVI with SAVR in patients with a mean perioperative risk of death <8%

Trial	No randomized	Longest follow-up (months)	TAVI valve	Mean (SD) risk score*
STACCATO	72	3	Edwards SAPIEN balloon expanding	3.3 (1.4)
US Pivotal	795	36	Medtronic CoreValve self expanding	7.4 (3.1)
NOTION	280	24	Medtronic CoreValve self expanding	3.0 (1.6)
PARTNER 2A	2032	24	Edwards SAPIEN XT balloon expanding	5.8 (2.0)



RESEARCH

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Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis

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Outcomes favoring SAVR

Symptoms of heart failure
Aortic valve reintervention
Pacemaker insertion
Paravalvular Leakage

Outcomes favouring TAVI (TA-TF)

Bleeding
Atrial Fibrillation
Recovery time



RESEARCH

the**bmj** | *BMJ* 2016;354:i5130 | doi: 10.1136/bmj.i5130



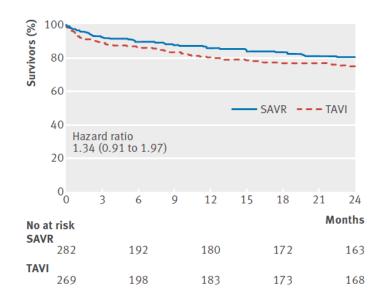


Transcatheter versus surgical aortic valve replacement in patients with severe aortic stenosis at low and intermediate risk: systematic review and meta-analysis

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Outcomes favoring TF over SAVR

Survival Acute Kidney injury









Patients at intermediate surgical risk undergoing isolated interventional or surgical aortic valve replacement for severe symptomatic aortic valve stenosis. One year results from the <u>German Aortic Valve Registry</u> (GARY).

Nicolas Werner, Ralf Zahn, Andreas Beckmann, Timm Bauer, Christian W. Hamm, Friedrich W. Mohr, Alexander Berkowitsch, Sandra Landwehr, Stephan Ensminger, Christian Frerker, Helge Möllmann, Thomas Walther, Steffen Schneider and Rüdiger Lange

on behalf of the GARY Executive Board.



Nicolas Werner Medical Clinic B, Klinikum Ludwigshafen, Germany.

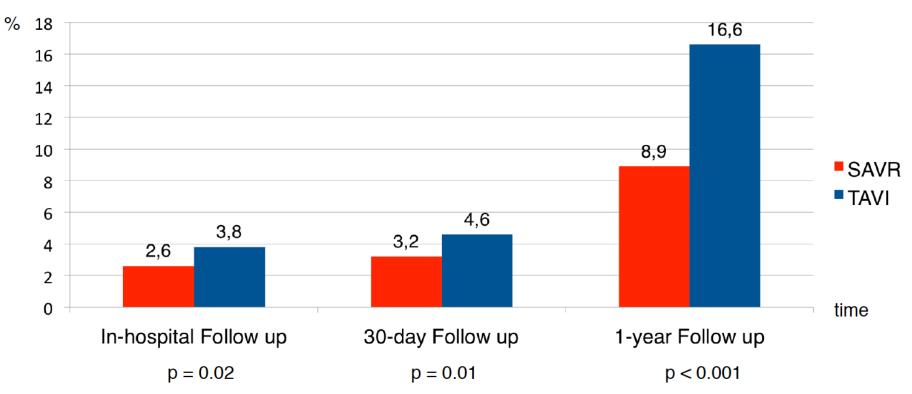
AHA's Scientific Sessions, Monday, November 14, 2016





Results III – Clinical outcome (all-cause mortality)

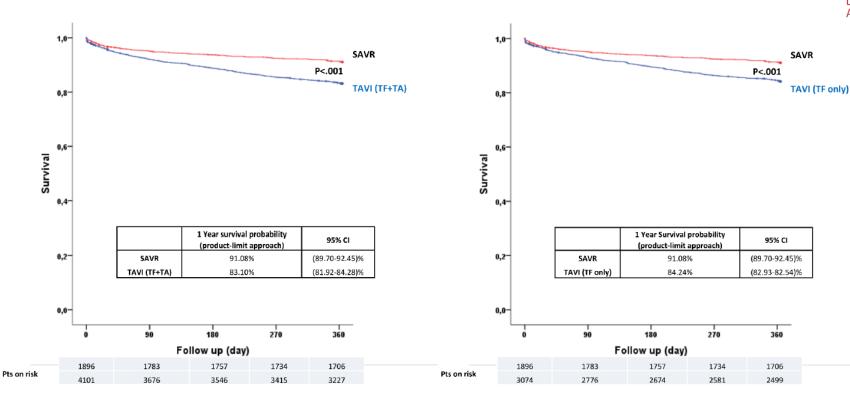






Unadjusted all-cause mortality (1-year FU)

(Completeness of data: TAVI 97.5%; SAVR 98.9%)





Deutsches

Aortenklappenregister

Propensity Score analysis



All cause one-year mortality rates for SAVR and TAVI according to propensity score quintile

SAVR vs. TAVI (transfemoral and transapical)

Stratified estimate for whole population		SAVR		TAVI	Difference; (95% CI)	p-value	
	Counts (n/N) Mortality (%)		Counts (n/N)	Mortality (%)			
Quintile 1	65/875	7.43%	14/326	12.58%	5.15%; (1.44-9.48)%	.004	
Quintile 2	47/551	8.53%	77/647	11.90%	3.37%; (-0.10-6.78)%	.067	
Quintile 3	33/289	11.42%	134/910	14.73%	3.31%; (-1.40-7.31)%	.158	
Quintile 4	17/141	12.06%	191/1059	18.04%	5.98%; (-0.79-11.00)%	.100	
Quintile 5	6/40	15.00%	236/1159	20.36%	5.36%; (-8.88-13.66)%	.379	
Stratified estimate		10.89%		15.52%	4.63%; (1.75-7.52)%	.002	



Propensity Score analysis



All cause one-year mortality rates for SAVR and TAVI according to propensity score quintile

SAVR vs. TAVI (transfemoral, only)

		SAVR	TAVI (tra	nsfemoral only)	Difference; (95% CI)	p-value
	Counts (n/N)	Mortality (%)	Counts (n/N)	Mortality (%)		
Quintile 1	65/875	7.43%	25/218	11.47%	4.04% (-0.03-9.19)%	.043
Quintile 2	47/551	8.53%	56/471	11.89%	3.36% (-0.35-7.19)%	.088
Quintile 3	33/289	11.42%	86/661	13.01%	1.59% (-3.21-5.81)%	.489
Quintile 4	17/141	12.06%	130/769	16.91%	4.85% (-2.02-10.06)%	.182
Quintile 5	6/40	15.00%	177/955	18.53%	3.53% (-10.73-11.88)%	.533
Stratified estimate		10.78%		14.26%	3.48%; (0.53-6.43)%	.021



Cite this article as: Gersak B, Fischlein T, Folliguet TA, Meuris B, Teoh KHT, Moten SC et al. Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an International Expert Consensus Panel. Eur J Cardiothorac Surg 2016;49:709–18.

Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an International Expert Consensus Panel

Borut Gersak^{a,*}, Theodor Fischlein^b, Thierry A. Folliguet^c, Bart Meuris^d, Kevin H.T. Teoh^e, Simon C. Moten^f, Marco Solinas^g, Antonio Miceli^h, Peter J. Oberwalderⁱ, Manfredo Rambaldini^j, Gopal Bhatnagar^k, Michael A. Borgerⁱ, Denis Bouchard^m, Olivier Bouchotⁿ, Stephen C. Clark^c, Otto E. Dapuntⁱ, Matteo Ferrarini^p, Guenther Laufer^q, Carmelo Mignosa^r, Russell Millner^s, Philippe Noirhomme^t, Steffen Pfeiffer^b, Xavier Ruyra-Baliarda^u, Malakh Shrestha^v, Rakesh M. Suri^w, Giovanni Troise^x, Anno Diegeler^y, Francois Laborde^z, Marc Laskar^{aa}, Hani K. Najm^{ab} and Mattia Glauber^p







A. B.

Sutureless aortic valve replacement: a systematic review and meta-analysis

Kevin Phan¹, Yi-Chin Tsai², Nithya Niranjan¹, Denis Bouchard³, Thierry P. Carrel⁴, Otto E. Dapunt⁵, Harald C. Eichstaedt⁶, Theodor Fischlein⁷, Borut Gersak⁸, Mattia Glauber⁹, Axel Haverich¹⁰, Martin Misfeld¹¹, Peter J. Oberwalder⁵, Giuseppe Santarpino⁷, Malakh Lal Shrestha¹⁰, Marco Solinas⁹, Marco Vola¹², Tristan D. Yan¹, Marco Di Eusanio¹³

Parameter	Events/total	N	Weighted pooled proportion	н	eterogeneity
Faranieter	Everits/total	IN	(%) or estimate (95% CI)	I^2	P value
Early outcomes					
30 day mortality	22/940	10	2.1 (1.1-3.3)	11	0.341
Strokes	12/562	7	1.9 (0.8-3.4)	0	0.632
vavi Zesturabes ir	nd#ded	6	2.3 (0.5-5.1)	52	0.062
Paravalvular leak	41/940	10	4.3 (2.2-6.9)	60	0.007
Renal failure	8/244	4	3.1 (1.0-6.0)	0	0.856
Up to 1-year follow-up	L				
AP-103 Zait patient	S 57/926	10	4.9 (2.7-7.7)	59	0.007
Strokes	16/844	8	1.5 (0.4-3.1)	43	0.092
Valve degeneration/dislocation	1/438	4	0.4 (0-1.4)	0	0.79
Paravalvular leak	33/960	10	3.0 (1.0-5.8)	72	<0.001
Permanent pacemaker	38/627	5	5.6 (3.5-8.0)	25	0.256
Renal failure	3/260	2	1.2 (0-4.1)	52	0.012
Endocarditis	26/1,032	10	2.2 (0.8-4.1)	58	0.012
CPB, cardiopulmonary bypass; AVR	, aortic valve replacen	nent; N, nu	mber of studies; CI, confidence inte	erval.	

SUTURELESS VS STENTED

Aortic Valve Replacement Through Right Anterior Minithoracotomy: Can Sutureless Technology Improve Clinical Outcomes?

Daniyar Gilmanov, MD, Antonio Miceli, MD, Matteo Ferrarini, MD, Pierandrea Farneti, MD, Michele Murzi, MD, Marco Solinas, MD, and Mattia Glauber, MD

Department of Adult Cardiac Surgery, G. Pasquinucci Heart Hospital, Gabriele Monasterio Foundation, Massa; and Humanitas Clinical and Research Center, Rozzano, Italy

A Randomized Multicenter Trial of Minimally Invasive Rapid Deployment Versus Conventional Full Sternotomy Aortic Valve Replacement

Michael A. Borger, MD, PhD, Vadim Moustafine, MD, Lenard Conradi, MD, Christoph Knosalla, MD, PhD, Markus Richter, MD, PhD, Denis R. Merk, MD, Torsten Doenst, MD, PhD, Robert Hammerschmidt, MD, Hendrik Treede, MD, PhD, Pascal Dohmen, MD, PhD, and Justus T. Strauch, MD

University of Leipzig, Leipzig; University Hospital of the Ruhr University of Bochum, North Rhine-Westphalia; University Heart Center Hamburg, Hamburg, German Heart Institute Berlin, Berlin; and Jena University Hospital, Jena, Germany

The Perceval S Aortic Valve Has the Potential of Shortening Surgical Time: Does It Also Result in Improved Outcome?

Giuseppe Santarpino, MD, Steffen Pfeiffer, MD, Giovanni Concistré, MD, Irena Grossmann, MD, Martin Hinzmann, MD, and Theodor Fischlein, MD

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Better Short-Term Outcome by Using Sutureless Valves: A Propensity-Matched Score Analysis

Francesco Pollari, MD,* Giuseppe Santarpino, MD,* Angelo Maria Dell'Aquila, MD, Laszlo Gazdag, MD, Husam Alnahas, MD, Ferdinand Vogt, MD, Steffen Pfeiffer, MD, and Theodor Fischlein, MD

Department of Cardiac Surgery, Klinikum Nürnberg, Paracelsus Medizinischen Privatuniversität, Nuremberg; and Department of Cardiac Surgery, Universitätsklinikum Münster, Münster, Germany

Aortic valve replacement through full sternotomy with a stented bioprosthesis versus minimally invasive sternotomy with a sutureless bioprosthesis

Magnus Dalénaha, Fausto Biancari, Antonino S. Rubino, Giuseppe Santarpino, Natalie Glasera, Herbert De Praetere, Keiichiro Kasama, Tatu Juvonen, Wanda Deste, Francesco Pollari, Bart Meuris, Theodor Fischlein, Carmelo Mignosa, Giuseppe Gatti, Aniello Pappalardo, Peter Svenarudah, and Ulrik Sartipyah.

Sutureless Perceval Aortic Valve in Comparison with the Stented Carpentier-Edwards Perimount Aortic Valve

Karl Christian König, Thorsten Wahlers, Maximilian Scherner, Jens Wippermann

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REDUCTION OF CROSS CLAMP TIME AND CPB TIMES

KEY POINTS

COST-EFFECTIVENESS analysis:

- is a form of economic analysis that compares the relative costs and outcomes (effects) of different courses of action.
- How to evaluate the COST- EFFECTIVENESS?
 - TAVI
 - Sutureless

Intermediate / low risk Patients

1. Effectiveness

- Mortality and Adverse event rates



Journal of Cardiology 67 (2016) 504–512



Contents lists available at ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc



Original article

Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation: A meta-analysis of comparative studies



Hisato Takagi (MD, PhD)*, Takuya Umemoto (MD, PhD) for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group



Study	Pre	dicted mortali	ty (%)	
	Score	Sutureless AVR	TAVI	p value
Miceli 2015* [5]	Logistic EuroSCORE I	16.1 ± 11	15.7 ± 8.5	< 0.0001
Kamperidis 2015 [6]	Logistic EuroSCORE I	$\boxed{15.9\pm10.6}$	15.5 ± 8.4	0.85
Biancari 2015 [*] [7]	Logistic EuroSCORE II	4.1 ± 3.2	3.6 ± 2.6	0.117
D'Onofrio 2012 [8]	Logistic EuroSCORE I	13.7 ± 7.2	14.8 ± 7.5	0.47
Doss 2012 [9]	Logistic EuroSCORE I	13.7 ± 6.3	35.3 ± 4.2	< 0.004
Muneretto	Logistic EuroSCORE I/	16 ± 11.7	20.4 ± 12.7	N/R
2015 [10]	STS-PROM	5.4 ± 6.8	6 ± 3.6	
Santarpino 2014 [11]	Logistic EuroSCORE I	18.1 ± 1.9	20.6 ± 2.2	0.81

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	Sutureless		TAV	-		Odds Ratio Odds Ratio			
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
Biancari 2015* [7]	2	144	10	144	22.4%	0.19 [0.04, 0.88]	- •		
D'Onofrio 2012 [8]	0	38	2	38	5.6%	0.19 [0.01, 4.08]			
Doss 2012 [9]	3	27	5	29	22.4%	0.60 [0.13, 2.80]			
Kamperidis 2015 [6]	1	48	10	221	12.3%	0.45 [0.06, 3.59]			
Miceli 2015* [5]	0	37	3	37	5.9%	0.13 [0.01, 2.64]	· · · · · · · · · · · · · · · · · · ·		
Muneretto 2015 [10]	3	53	6	55	25.5%	0.49 [0.12, 2.07]	- +		
Santarpino 2014 [11]	0	37	3	37	5.9%	0.13 [0.01, 2.64]	•		
Total (95% CI)	2.5 %	384	7.3 %	∕ ₀ 561	100.0%	0.33 [0.16, 0.69]	•		
Total events	9		39						
Heterogeneity: Tau ² =	0.00; Chi ² =	2.31, d	f = 6 (P =	= 0.89	$I^2 = 0\%$		1000		
Test for overall effect:							0.005 0.1 1 10 200 Favors sutureless AVR Favors TAVI		



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	Suture	less AVR	TAV	'I		Odds Ratio	Odds Ratio
Study or Sub	group Event	s Total	Events	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Biancari 2015	* [7]	3 144	0	144	9.6%	7.15 [0.37, 139.65]	-
D'Onofrio 201	.2 [8]	2 38	1	38	13.2%	2.06 [0.18, 23.68]	
Kamperidis 20	015 [6]	0 40	2	40	9.1%	0.19 [0.01, 4.09]	•
Miceli 2015* [[5] 1	1 37	4	37	30.7%	3.49 [1.00, 12.24]	
Muneretto 20	15 [10]	4 53	5	55	28.1%	0.82 [0.21, 3.22]	
Santarpino 20	14 [11]	0 37	2	37	9.1%	0.19 [0.01, 4.08]	•
Total (95% CI	5.7	% ₃₄₉	4 %	351	100.0%	1.36 [0.50, 3.74]	
Total events	2	0	14				
Heterogeneity	$r: Tau^2 = 0.45; Ch$	$i^2 = 7.11, c$	df = 5 (P =	= 0.21)	$I^2 = 30\%$		0.005 0.1 1 10 200
Test for overa	II effect: Z = 0.60	(P = 0.55)					0.005 0.1 1 10 200 Favors sutureless AVR Favors TAVI





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	Sutureless	AVR	TAV	ı		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
Biancari 2015* [7]	16	144	22	144	30.8%	0.69 [0.35, 1.38]	
D'Onofrio 2012 [8]	2	38	2	38	14.5%	1.00 [0.13, 7.49]	
Doss 2012 [9]	0	27	1	29	7.4%	0.35 [0.01, 8.85]	· · ·
Kamperidis 2015 [6]	1	40	3	40	12.3%	0.32 [0.03, 3.18]	
Miceli 2015* [5]	2	37	0	37	8.1%	5.28 [0.24, 113.87]	-
Muneretto 2015 [10]	1	53	14	55	14.1%	0.06 [0.01, 0.45]	
Santarpino 2014 [11]	4	37	1	37	12.7%	4.36 [0.46, 41.06]	
Total (95% CI)	6.9 %	376	12.1	% 80	100.0%	0.66 [0.24, 1.78]	
Total events	26		43				
Heterogeneity: Tau ² = 0 Test for overall effect: 2			df = 6 (P	= 0.10	0); $I^2 = 44$	%	0.005 0.1 1 10 200 Favors surureless AVR Favors TAVI





Original article

Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation: A meta-analysis of comparative studies



Hisato Takagi (MD, PhD)*, Takuya Umemoto (MD, PhD) for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

	Sutureless	AVR	TAV	1		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight I	IV, Random, 95% CI	IV, Random, 95% CI
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D'Onofrio 2012 [8]	6	38	17	38	24.5%	0.23 [0.08, 0.68]	
Doss 2012 [9]	0	27	4	29	7.2%	0.10 [0.01, 2.01]	
Kamperidis 2015 [6]	2	40	9	40	17.0%	0.18 [0.04, 0.90]	
Miceli 2015* [5]	0	37	10	37	7.5%	0.03 [0.00, 0.62]	
Muneretto 2015 [10]	1	53	5	55	11.5%	0.19 [0.02, 1.70]	
Santarpino 2014 [11]	0	37	5	37	7.3%	0.08 [0.00, 1.48]	
Total (95% CI)	3.4 %	376	33.1	% 80	100.0%	0.09 [0.04, 0.23]	•
Total events	13		126				
Heterogeneity: Tau ² =	0.52; Chi ² =	10.12,	df = 6 (P	0.12	2); $l^2 = 419$	%	
Test for overall effect:	Z = 5.24 (P <	< 0.000	01)				0.01 0.1 1 10 100 Favors sutureless AVR Favors TAVI



KEY POINTS

COST-EFFECTIVENESS analysis:

- is a form of economic analysis that compares the relative costs and outcomes (effects) of different courses of action.
- How to evaluate the COST- EFFECTIVENESS?
 - TAVI
 - Sutureless

Intermediate / low risk Patients

1. Effectiveness

- Mortality and Adverse event rates
- Quality of Life



EFFECTIVENESS: Quality of life



Quality of Life measured with KCCQ (Kansas City Cardiomyopathy Questionnaire)

No difference TAVI and SAVR at 1 and 2-year in Intermediate - risk patients



KEY POINTS

COST-EFFECTIVENESS analysis:

- is a form of economic analysis that compares the relative costs and outcomes (effects) of different courses of action.
- How to evaluate the COST- EFFECTIVENESS?
 - TAVI
 - Sutureless

Intermediate / low risk Patients

- 1. Effectiveness
- 2. **Cost**
 - Costs
 - Quality Adjusted life Year (QALY), Life Year Gained (LYG)
 - Incremental cost effectiveness ratio (ICER)

COSTS

Clinical Outcome and Cost Analysis of Sutureless Versus Transcatheter Aortic Valve Implantation With Propensity Score Matching Analysis

Giuseppe Santarpino, MD^{a,*}, Steffen Pfeiffer, MD^a, Jürgen Jessl, MD^b, Angelo Dell'Aquila, MD^c, Ferdinand Vogt, MD^a, Che von Wardenburg, MD^a, Johannes Schwab, MD^b, Joachim Sirch, MD^a, Matthias Pauschinger, MD^b, and Theodor Fischlein, MD^a

Patients in the sutureless group endure more hospital complications, but TAVI entails a higher follow-up mortality (PVL occurred more frequently in patients from the TAVI group p < 0.001 with an impact on follow-up survival rate)

Variable mean (SD)	Sutureless	TAVI	P value
	(n=102)	(n=102)	
OR costs including anaesthesia	* 5,076 ± 1,399	$4,312 \pm 1,362$	0.004
Hospital stay costs including ICU	* 9,188 ± 9,590	$5,714 \pm 4,055$	0.009
Diagnostics*	$1,883 \pm 1,887$	* $4,137 \pm 3,128$	< 0.001
Total costs - excluding the device	$16,148 \pm 11,704$	$14,164 \pm 6,148$	0.217
Mean cost of the device (min; max)	6,303 (3,600 - 7,214)	18,712 (17,050 - 22,015)	
Total costs - including the device	$22,451 \pm 11,704$	$32,877 \pm 6,148$	< 0.001

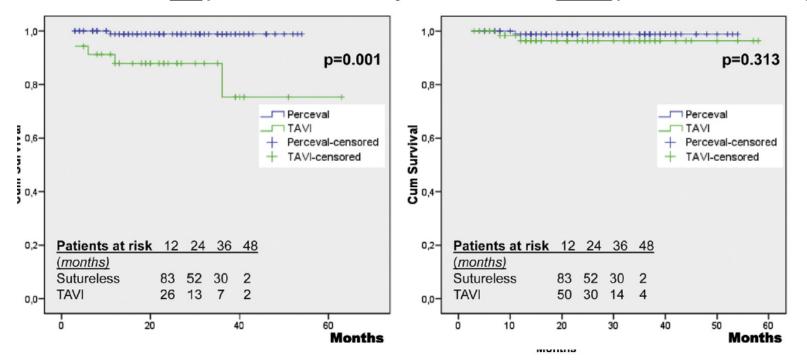
^{*} Diagnostics includes radiology laboratory, cardiac diagnostic therapy, endoscopic diagnostics, and other diagnostics.

COSTS

Clinical Outcome and Cost Analysis of Sutureless Versus Transcatheter Aortic Valve Implantation With Propensity Score Matching Analysis

Giuseppe Santarpino, MD^{a,*}, Steffen Pfeiffer, MD^a, Jürgen Jessl, MD^b, Angelo Dell'Aquila, MD^c, Ferdinand Vogt, MD^a, Che von Wardenburg, MD^a, Johannes Schwab, MD^b, Joachim Sirch, MD^a, Matthias Pauschinger, MD^b, and Theodor Fischlein, MD^a

Sutureless vs TAVI with para-valvular insufficiency Sutureless vs TAVI without para-valvular insufficiency





A cost-utility analysis of transcatheter **OPEN** aortic valve implantation in Belgium: focusing on a well-defined and identifiable population

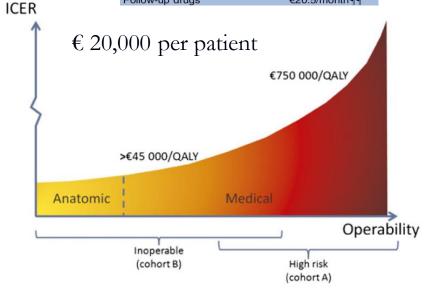
Mattias Neyt, Hans Van Brabandt, Stephan Devriese, Stefaan Van De Sande

Similar Mortality

2 fold increased risk of Stroke

Conclusions: It is inappropriate to consider reimbursement of TAVI for high-risk operable patients. Reimbursing TAVI in inoperable patients in essence is a political decision. From an economic perspective, it would be prudent to first target patients that are inoperable because of anatomical prohibitive conditions. In the search for evidence, the authors identified non-published negative results from a randomised controlled TAVI trial. The study sponsor should be more willing to share this information to allow balanced evaluations and policy recommendations. Payers should require these data before taking reimbursement decisions.

Table 2 Overview of cost data	
Variable	Mean
TAVI (high-risk operable patients)	
TF	€40917
TA	640.700
IA	€49799
All	€43571†
TAVI (inoperable patients)	€40 057‡
Standard therapy	€3170§
AVR	€23749¶
Polloon portio valvulanlastv	£400++
Balloon aortic valvuloplasty Repeat hospitalisation	€489†† €5983
Trepeat Trospitalisation	C3300
Stroke	
Minor	€4679‡‡
Major	€12493‡‡
TIA	€3946
LIA	C3340
Follow-up fees	€43.2/month§§
Follow-up drugs	€20.5/month¶¶



COSTS

Systematic review of the cost-effectiveness of transcatheter aortic valve implantation

Praveen Indraratna, MBBS, ^{a,b} Su C. Ang, MBBS, ^{a,b} Hemal Gada, MD, ^a Tristan D. Yan, MBBS, PhD, ^{a,c} Con Manganas, MBBS, ^b Paul Bannon, MBBS, PhD, ^{a,c} and Christopher Cao, MBBS, BSc (Med) ^{a,b}

ICER: Incremental cost effectiveness ratio → cost required to gain 1 additional QALY

TABLE 3. Projected raw costs of incremental cost-effectiveness ratio of transcatheter aortic valve implantation versus surgical aortic valve replacement

	QALYs gained	Projected m	ean raw cost	Discounting	ICER (local	ICER	WTPT	Probability of
Investigator	by TAVI	TAVI	AVR	rate (%)	currency PQG)	(\$US PQG)*	(\$US PQG)*	cost-effectiveness
Neyt et al ⁴	0.03	EUR 43,571	EUR 23,749	3.0	EUR 750,000	975,697	47,141	NR
Doble et al ⁷	-0.102	CAD 85,755	CAD 74,602	5.0	Dominated by AVR	NA	48,672	0.116
Gada et al ⁸	0.06	USD 59,503	USD 56,339	5.0	USD 52,773	52,773	100,000	NR
	(reference case)							
Gada et al ⁸	0.01 (PARTNER	USD 85,513	USD 82,989	5.0	USD 252,400	252,400	100,000	NR
	scenario)							
Gada et al ⁸	0.06 (combined)	USD 81,446	USD 79,526	5.0	USD 32,000	32,000	100,000	NR
Osnabrugge et	al ⁹ 0.068†	EUR 46,217	EUR 35,511	NA	EUR 157,441	204,819	NR	NR
Reynolds et al	0.027 (TF- and	USD 100,504	USD 98,434	NA	USD 76,877	76,877	50,000	0.438

Conclusions: Depending on the ICER threshold selected, TAVI is potentially justified on both medical and economic grounds compared with medical therapy for patients deemed to be surgically inoperable. However, in the high-risk surgical patient cohort, the evidence is currently insufficient to economically justify the use of TAVI in preference to AVR. (J Thorac Cardiovasc Surg 2014;148:509-14)

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER

COSTS

VOL. 67, NO. 1, 2016 ISSN 0735-1097/\$36.00

http://dx.doi.org/10.1016/j.jacc.2015.10.046

Cost-Effectiveness of Transcatheter Aortic Valve Replacement With a Self-Expanding Prosthesis Versus Surgical Aortic Valve Replacement



The economic impact of patient recovery

ICU and Hospital stay

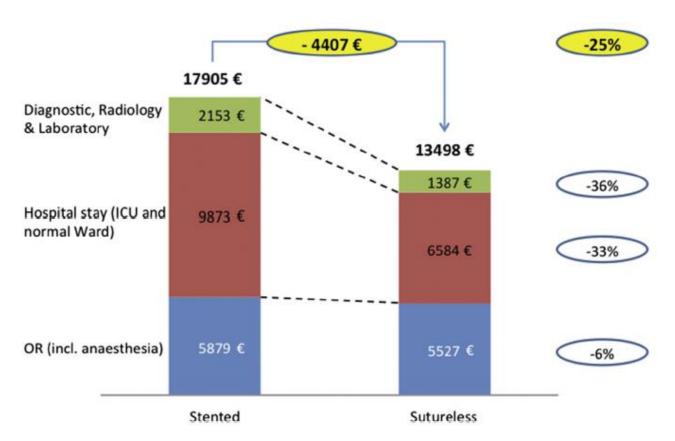
Matthew R. Reynolds, MD, MSc,*† Yang Lei, MSc,‡§ Kaijun Wang, PhD,‡ Khaja Chinnakondepalli, MS,‡ Katherine A. Vilain, MPH,‡ Elizabeth A. Magnuson, ScD,‡|| Benjamin Z. Galper, MD, MPH,¶ Christopher U. Meduri, MD, MPH,# Suzanne V. Arnold, MD, MHA,‡|| Suzanne J. Baron, MD, MSc,‡|| Michael J. Reardon, MD,** David H. Adams, MD,†† Jeffrey J. Popma, MD,‡‡ David J. Cohen, MD, MSc,‡|| on behalf of the CoreValve U.S. High Risk Pivotal Trial Investigators

As expected, we found that procedural costs were substantially higher with TAVR than with SAVR, and that those costs were offset by savings from shortened hospital length of stay and a reduced need for post-discharge residential care. In this trial, those offsets were not sufficient for TAVR to achieve overall cost neutrality relative to SAVR, either in the short- or long-term. The conclusion that TAVR is nonetheless a reasonable value consequently hinges on the observed clinical benefits. These findings have important implications, as TAVR is evaluated in lower-risk AS patients. At current valve prices, length of stay would likely need to be at least 5 to 6 days shorter with TAVR than with SAVR in order to approach cost neutrality.

Better Short-Term Outcome by Using Sutureless Valves: A Propensity-Matched Score Analysis

Francesco Pollari, MD,* Giuseppe Santarpino, MD,* Angelo Maria Dell'Aquila, MD, Laszlo Gazdag, MD, Husam Alnahas, MD, Ferdinand Vogt, MD, Steffen Pfeiffer, MD, and Theodor Fischlein, MD

Department of Cardiac Surgery, Klinikum Nürnberg, Paracelsus Medizinischen Privatuniversität, Nuremberg; and Department of Cardiac Surgery, Universitätsklinikum Münster, Münster, Germany





Ann Thorac Surg 2014;98:611-7

MINIMALLY INVASIVE AVR

Minimal Access Aortic Valve Replacement: Is It Worth It?

Bari Murtuza, PhD, FRCS, John R. Pepper, FRCS, Rex DeL Stanbridge, FRCS, Catherine Jones, BSc, MBBS, Christopher Rao, MBBS, Ara Darzi, KBE, FRCS, and Thanos Athanasiou, PhD, FETCS

Departments of Cardiothoracic Surgery and Surgical Oncology and Technology, St. Mary's Hospital, Faculty of Medicine, Imperial College, and Department of Cardiothoracic Surgery, Royal Brompton Hospital, Faculty of Medicine, Imperial College, London, England

Controversy surrounds the use of minimal access aortic valve replacement (AVR). This meta-analytical study quantified the effects of minimal access AVR on morbidity and mortality compared with conventional AVR and evaluated study heterogeneity and robustness of the findings using sensitivity analysis. Overall, meta-analysis suggested marginal benefits in perioperative mortality (4,667 patients; odds ratio, 0.72; 95% confidence interval, 0.51-1.00; p = 0.05), intensive care unit stay, total hospital stay, and ventilation time in the minimal access

AVR group, although cross-clamp, cardiopulmonary bypass, and total operation times were longer. Study heterogeneity and apparent benefits in perioperative mortality were related to study quality, athough results for intensive care unit and hospital stay were maintained according to the sensitivity analysis. This suggests that minimal access AVR can be offered on the basis of patient choice and cosmesis rather than evident clinical benefit.

> (Ann Thorac Surg 2008;85:1121-31) © 2008 by The Society of Thoracic Surgeons



HOW TO INCREASE COST EFFECTIVENES



- Better clinical outcomes
- Less Pain
- Faster recovery

MIAVR AND SUTURELESS



- Reduce Hospital stay
- Reduce complications



Minimally invasive aortic valve replacement with Perceval S sutureless valve: Early outcomes and one-year survival from two European centers

Antonio Miceli, MD, PhD, a,b Giuseppe Santarpino, MD, Steffen Pfeiffer, MD, Michele Murzi, MD, Daniyar Gilmanov, MD, Giovanni Concistré, MD, Eugenio Quaini, MD, Marco Solinas, MD, Marco Solinas, MD, Marco Solinas, MD, Giovanni Concistré, MD, Eugenio Quaini, MD, Marco Solinas, MD, Marco MD, Marco MD, Marco MD, Marco



CPB - 40% Xclamp - 38 %

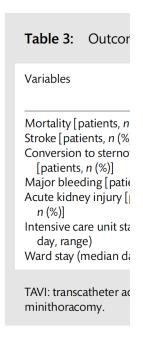


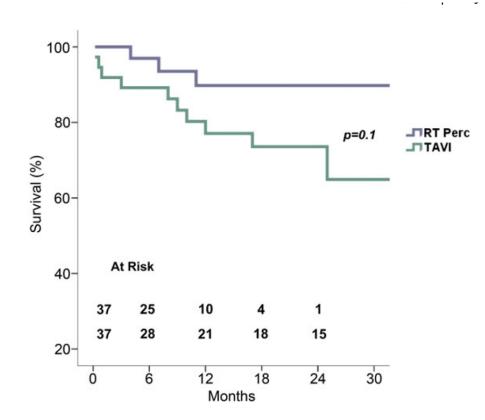
- 35% - 43%



Cite this article as: Miceli A, Gilmanov D, Murzi M, Marchi F, Ferrarini M, Cerillo AG *et al.* Minimally invasive aortic valve replacement with a sutureless valve through a right anterior mini-thoracotomy versus transcatheter aortic valve implantation in high-risk patients. Eur J Cardiothorac Surg 2015; doi:10.1093/ejcts/ezv210.

Minimally invasive aortic valve replacement with a sutureless valve through a right anterior mini-thoracotomy versus transcatheter aortic





7)	TAVI (n = 37)	Р
9	19.7 ± 5.4	0.26
7	10.1 ± 3.4	0.17
	0	0.5
	30 (81.1)	< 0.001
	6 (12.2)	
	14 (37.8)	
	10 (27)	
	0 ,	

EDITORIAL: ACQUIRED: AORTIC VALVE

Minimally invasive aortic valve replacement with sutureless valve is the appropriate treatment option for high-risk patients and the "real alternative" to transcatheter aortic valve implantation

Mattia Glauber, MD, and Antonio Miceli, MD, PhD

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Received for publication Oct 7, 2015; accepted for publication Oct 8, 2015; available ahead of print Nov 19, 2015.

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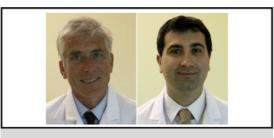
J Thorac Cardiovasc Surg 2016;151:610-3

0022-5223/\$36.00

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Mattia Glauber, MD, and Antonio Miceli, MD, PhD

Central Message

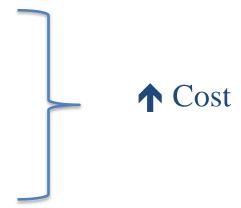
Minimally invasive aortic valve replacement with a sutureless valve is the first-line treatment option for operable high-risk patients.

Heart Team for a Tailored approach



CONCLUSIONS

- TAVI is a cost effectiveness procedure in inoperable patients
- There is no evidence that TAVI is a cost effectiveness procedure compared to conventional AVR in high risk operable patients (trend of benefit in Trans femoral approach)
- No data is reported in medium-low risk patients on cost effectiveness
- Major issues:
 - Stroke
 - Paravalvular leakage
 - Pacemaker implantation
 - Durability
 - Thrombosis





CONCLUSIONS

- Sutureless Valves have shown excellent clinical results
- Sutureless valves in combination with minimally invasive approach might be **the real cost effectiveness** procedure in medium —low risk patients
- •Randomized trials are required!

THANK YOU

