SOLACE AU Study:
Interim Results at One Year of the Edwards SAPIEN XT™ Transcatheter Heart Valve in Intermediate Risk Patients with Severe Aortic Stenosis

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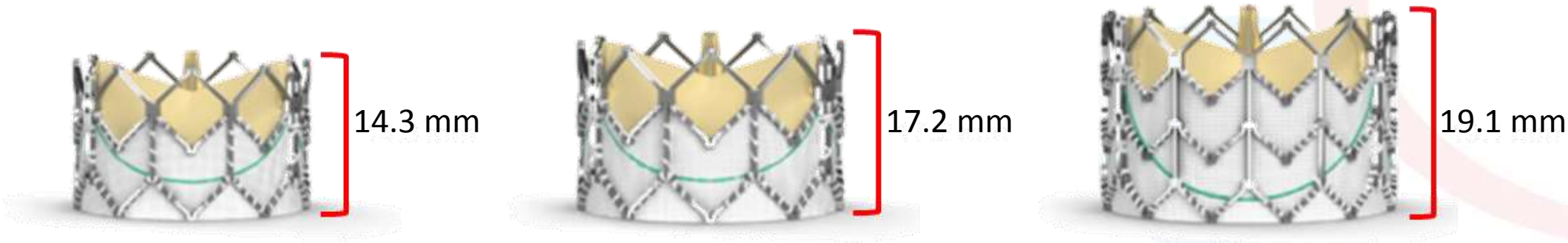
SOLACE AU

Background

We report the clinical outcomes of intermediate-risk patients at one year from the SOLACE AU Study who received the Edwards SAPIEN XT™ Transcatheter Heart Valve (THV).



Study Design

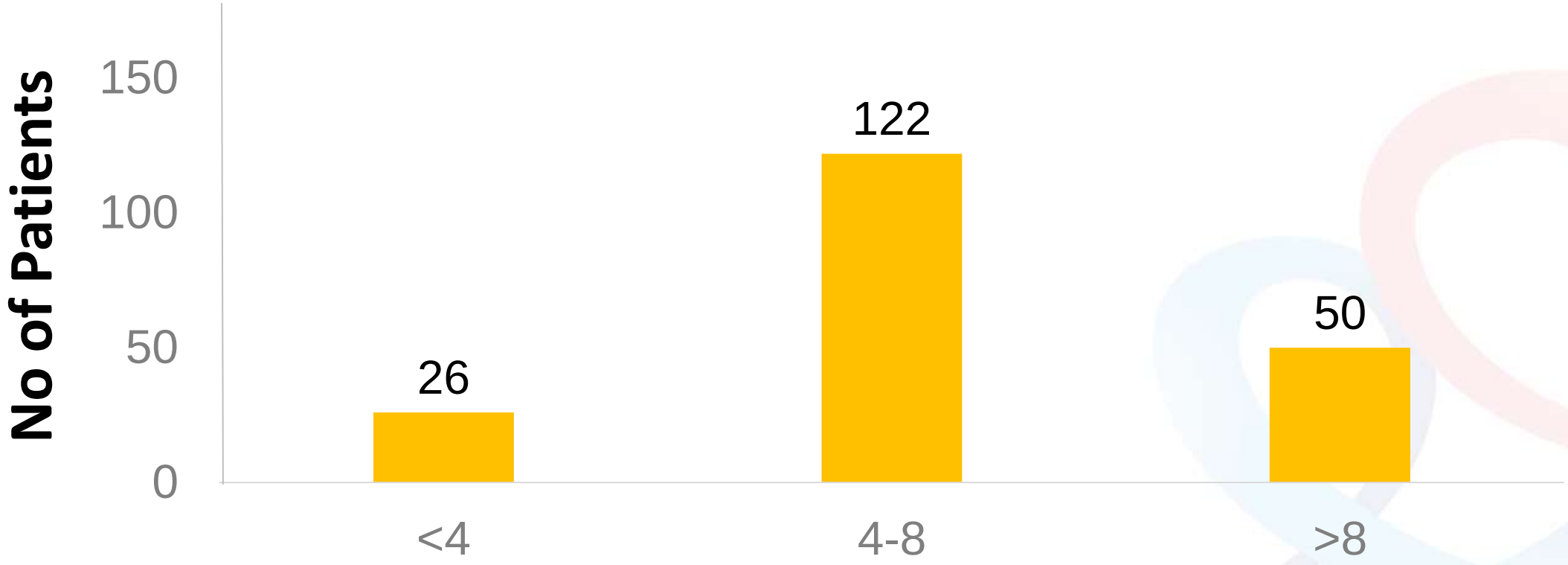
Study Design	Prospective, multi-centre safety and effectiveness clinical investigation
Access	Transfemoral
Enrollment Period	April 2012 - February 2016
Patients	198
Follow-Up Intervals	Hospital discharge, 30D, 6M, annually through 5Y
Organization	Steering Committee and Clinical Events Committee
Key Inclusion Criteria	• Severe AS: Echo-derived AVA < 1.0 cm^2 or mean AVG > 40 mmHg or iEOA < 0.5 cm^2/m^2 • Cardiac symptoms: NYHA functional class ≥ II • Intermediate surgical risk or greater
Primary Endpoint	VARC-2 Composite Combined Safety Endpoints at 30 days
Key Secondary Endpoints	• Extension of VARC-2 endpoints to 6M and 12M • NYHA functional status at 30 Days, 6M and 12M • Device Success • Quality of Life (all visits) • Hospital admissions and duration at 12M • Health care costs at 12M

SAPIEN XT: Study Baseline Comparisons

	Source XT (n=1685)[1]	PARTNER II Cohort A (n=1011)[2]	SOLACE AU (n = 198)
Age (mean yr)	82.1	81.5	**85.5**
Male (%)	35.6	54.2	**44.9**
STS (mean)	8.0	5.8	**7.1**
EuroSCORE (mean)	19.8	NR*	**18.6**
CAD (%)	39.6	69.2	**61.1**
PCI (%)	10.1	27.1	**20.2**
Myocardial Infarction (%)	12.2	18.3	**16.2**
Renal Insufficiency/Failure or Dialysis (%)	28.9	5.0	**4.5**
Prior Aortic Valvuloplasty (%)	NR*	5.0	**32.3**

*NR = Not Reported; [1]Schymik G et al., J Amer Col Card, 2015. **6**(5): 657-669; [2]Leon L et al., N Engl J Med, 2016. **374**(17):1609-120

SOLACE AU: STS Score Frequency (n=198)

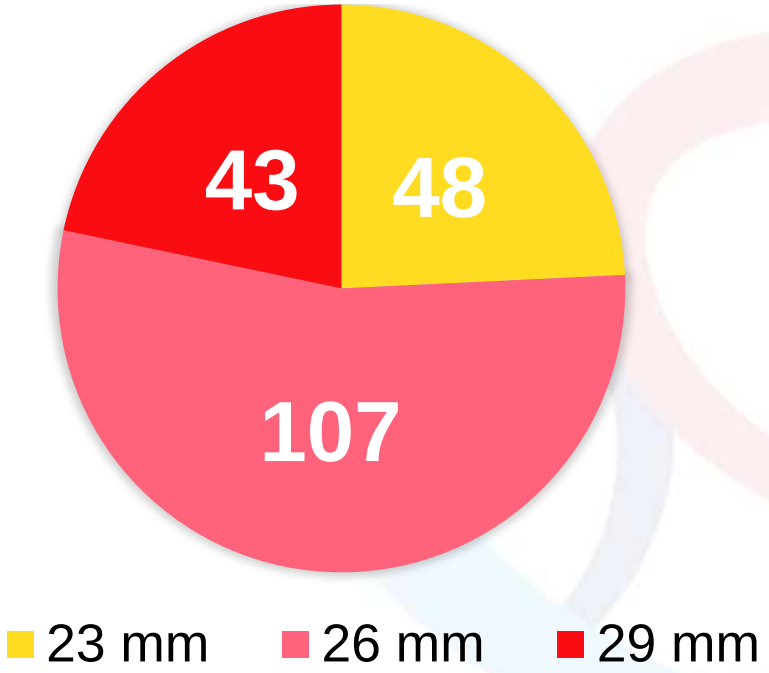


SOLACE AU: Procedural Summary (n=198)

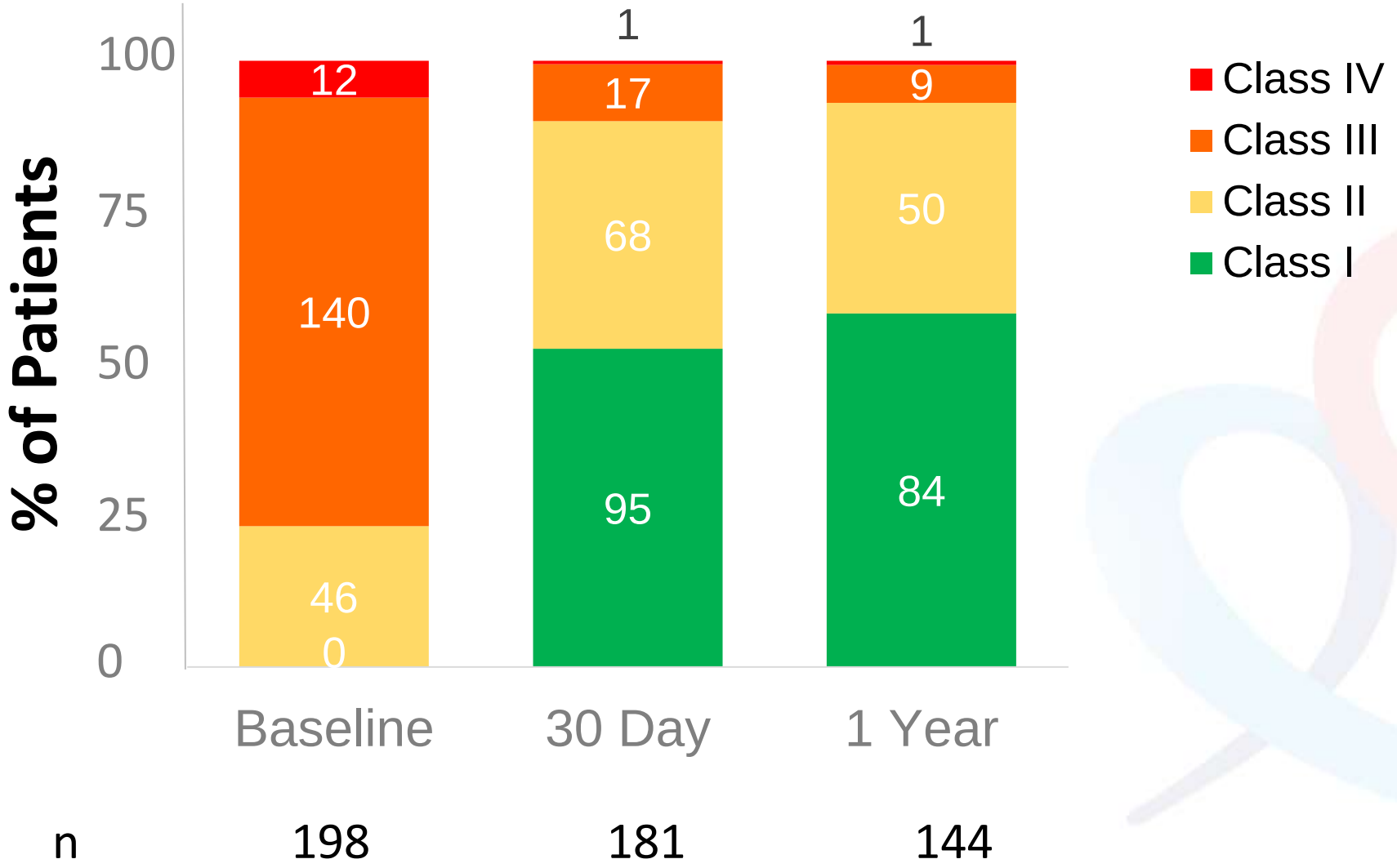
Valve Deployment Position

Position	% Patients
Acceptable	98.5
Too aortic	1.5
Too ventricular	0.0
Conversion to AVR	0.0

Valve Distribution



SOLACE AU: NYHA Functional Assessment



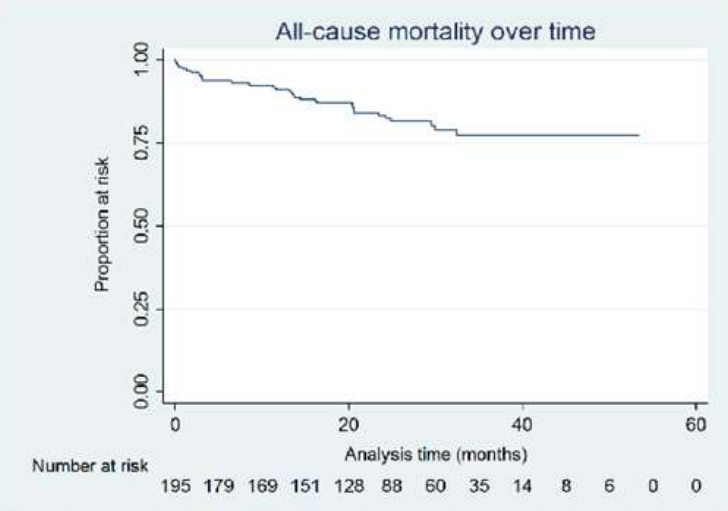
SAPIEN XT: Study Outcome Comparisons

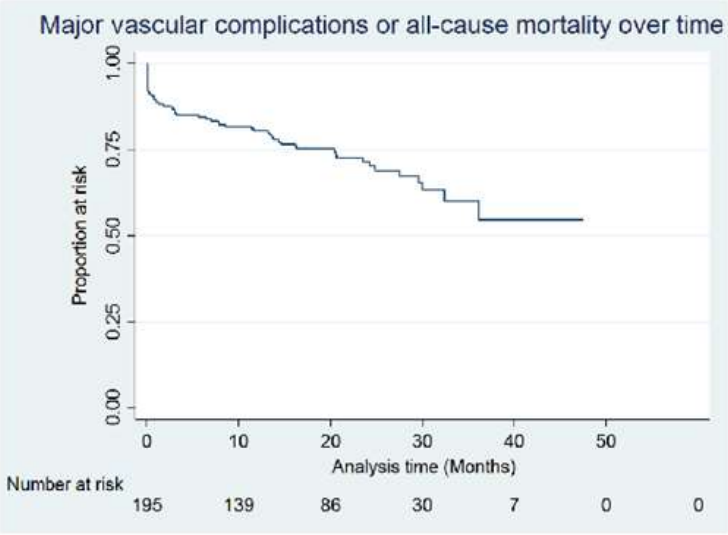
	Kaplan-Meier Event Rate (30 D)			Kaplan-Meier Event Rate (1 Yr)		
Event*	SXT (n=1685)[1]	PIIA (n=1011)[2]	SAU (n=198)	SXT (n=1685) [1]	PIIA (n=1011) [2]	SAU (n=198)
Death	4.2	3.9	2.6	15.0	12.3	9.7
All Stroke	3.4	5.5	2.0	5.6	8.0	4.3
Pacemaker	8.7	8.5	4.6	10.0	9.9	4.6
Vascular - Major	7.9	7.9	3.0	8.3	8.4	3.0
Life-threatening or Disabling Bleeding	3.8	10.4	0.5	4.5	15.2	1.1
Reintervention	NA	0.4	1.5	NA	1.2	1.5
Acute Kidney Injury	11.9	1.3	NA	14.7	3.4	NA
Acute Kidney Injury – III	NA	NA	0	NA	NA	1.3
Myocardial Infarction	0.4	1.2	NA	1.5	2.5	NA
Peri-procedural MI	NA	NA	0	NA	NA	0

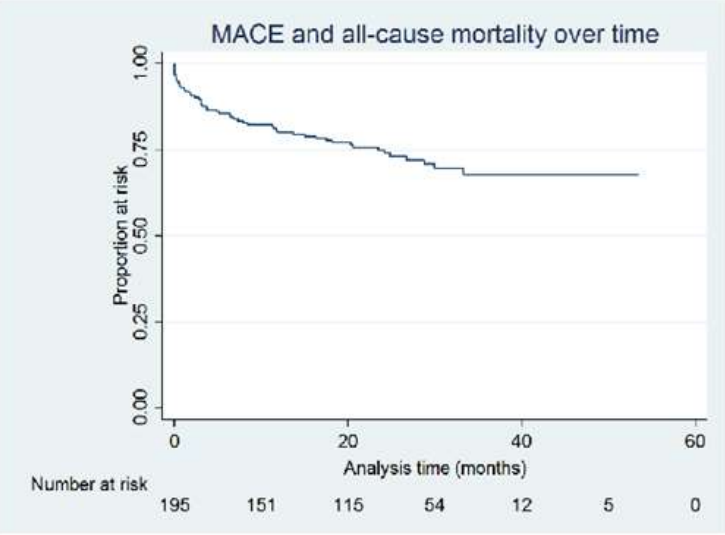
Note: SXT = Source XT Registry; PIIA = PARTNER II Cohort A; SAU = SOLACE AU, NA = Not Available; *Definitions of events may vary between studies

[1]Schymik G et al., J Amer Col Card, 2015. **6**(5): 657-669; [2]Leon L et al., N Engl J Med, 2016. **374**(17):1609-120

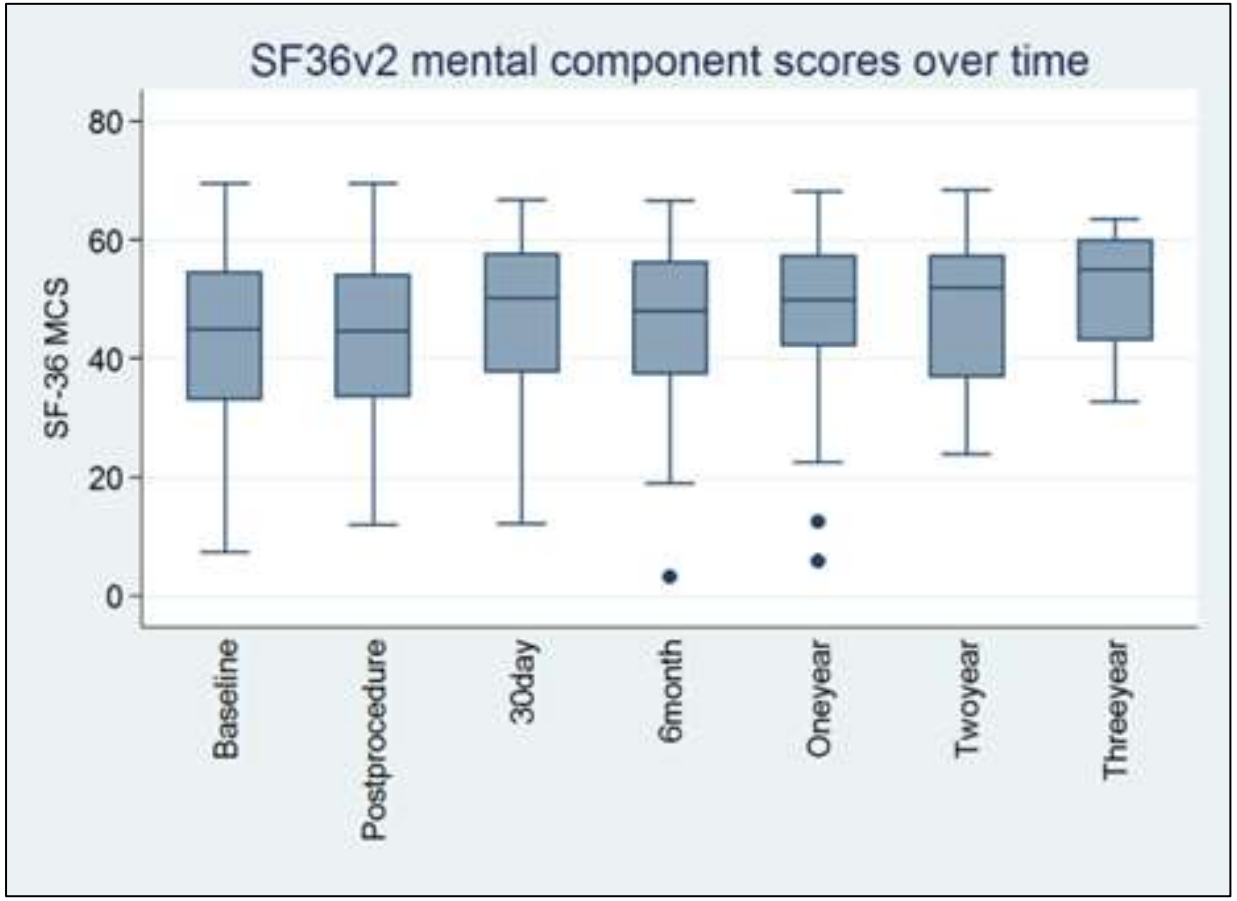
Solace AU Long term outcomes

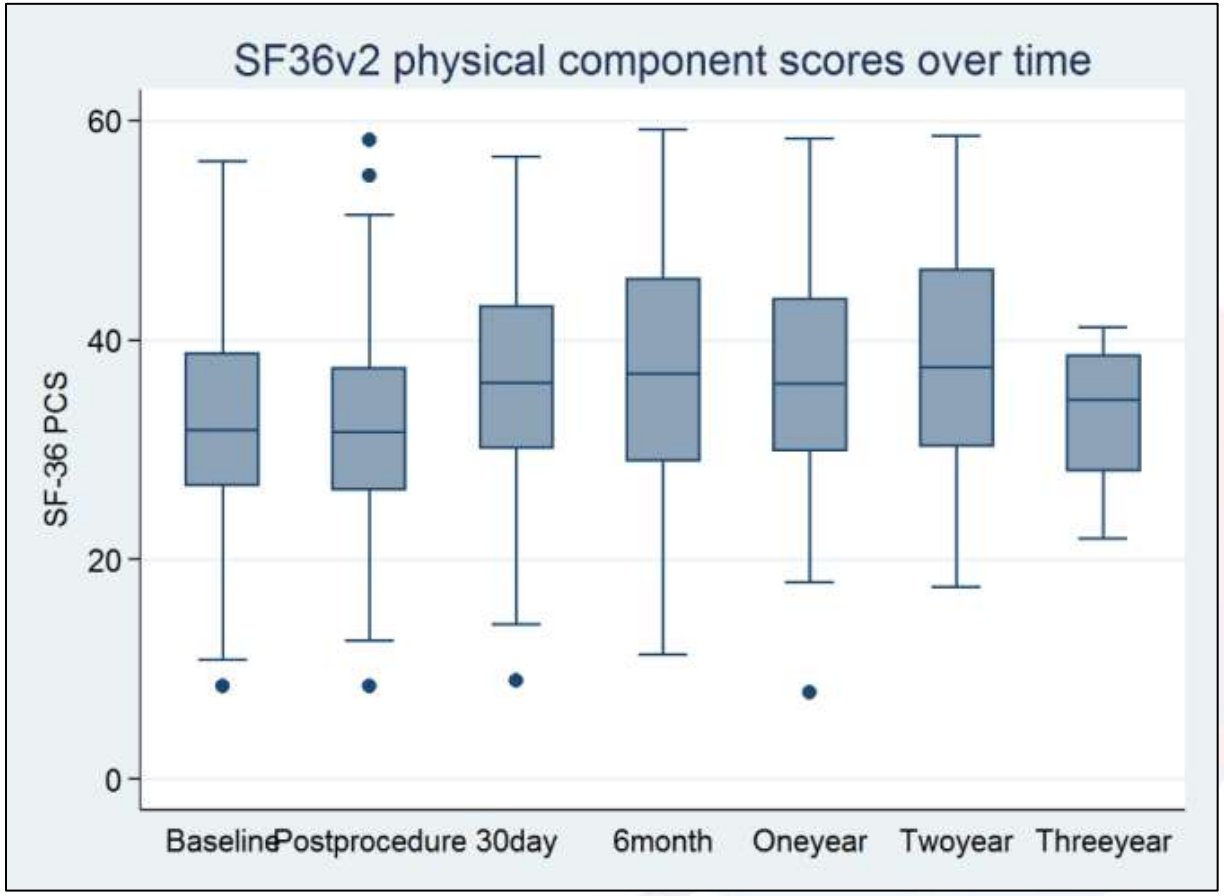






Quality of Life





Cost utilisation economic analysis

	Index hospitalisation cost	
	SOLACE-AU (mean,SD)	SOLACE-AU (mean, SD)
	Low Volume Centres	High Volume Centres
TAVI-TF	$23,480 ($12,798)	$20,439 ($4,284)
SAVR	$48,655.34	
Non prosthetic cost difference	25,175	28,216.34

SAVR PROSTHESIS COST	$6,000-8,000
TAVR PROSTHESIS COST	$33,000
Price margin eligible break even	$27,000

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Conclusions

- In this cohort of intermediate risk patients undergoing TAVI with the SAPIEN XT, we demonstrated excellent one year outcomes with high rates of optimal deployment and low rates of morbidity and mortality.

- These outcomes compare well to the transfemoral cohort in the larger PARTNER II SAPIEN XT cohort.
- Improvement in quality of life are sustained over 2-3 years
- TAVI is significantly less expensive than S AVR in Australia

- **In conclusion, the SOLACE AU trial provides strong support for the extension of TAVI into the intermediate risk patient cohort in Australia.**

ANZ experience

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Initial experience with the balloon expandable Edwards-SAPIEN Transcatheter Heart Valve in Australia and New Zealand: The SOURCE ANZ registry: Outcomes at 30 days and one year☆,☆☆

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ABSTRACT

Background: We report the findings of the SOURCE-ANZ registry of the clinical outcomes of the Edwards SAPIEN ™ Transcatheter Heart Valve (THV) in the Australian and New Zealand (ANZ) clinical environment.
Methods: This single arm registry of select patients treated in eight centres, represent the initial experience within ANZ with the balloon expandable Edwards SAPIEN THV delivered by transfemoral (TF) and transapical (TA) access.
Results: The total enrolment for the study was 132 patients, 63 patients treated by TF, 56 by TA, and 2 patients were withdrawn from the study. The mean ages: 83.7 (TF) and 81.7 (TA), female: 34.3% (TF) and 61.3% (TA), logistic EuroSCORE: 26.8% (TF) and 28.8% (TA), and with procedural success (successful implant without conversion to surgery or death): 92.4% (TF) and 87.1% (TA) ($p = 0.32$). Outcomes were not significantly different between TF and TA implants. These included one year mortality of 13.6% (TF) and 21.7% (TA) ($p = 0.24$), MACCE: 16.7% (TF) and 28.3% (TA) ($p = 0.12$), pacemaker: 4.6% (TF) and 8.3% (TA) ($p = 0.39$), and VARC major vascular complication of 4.6% (TF) and 5.0% (TA) ($p = 0.91$).
Conclusion: TAVI in the ANZ clinical environment has demonstrated excellent outcomes for both the TA and TF approaches in highly selected patients. These results are consistent with those demonstrated in European, Canadian registries and the pivotal US clinical trials. ACTRN12611001026910.

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ORIGINAL ARTICLE

Mid-term Outcomes in Patients Following Transcatheter Aortic Valve Implantation in the CoreValve Australia and New Zealand Study

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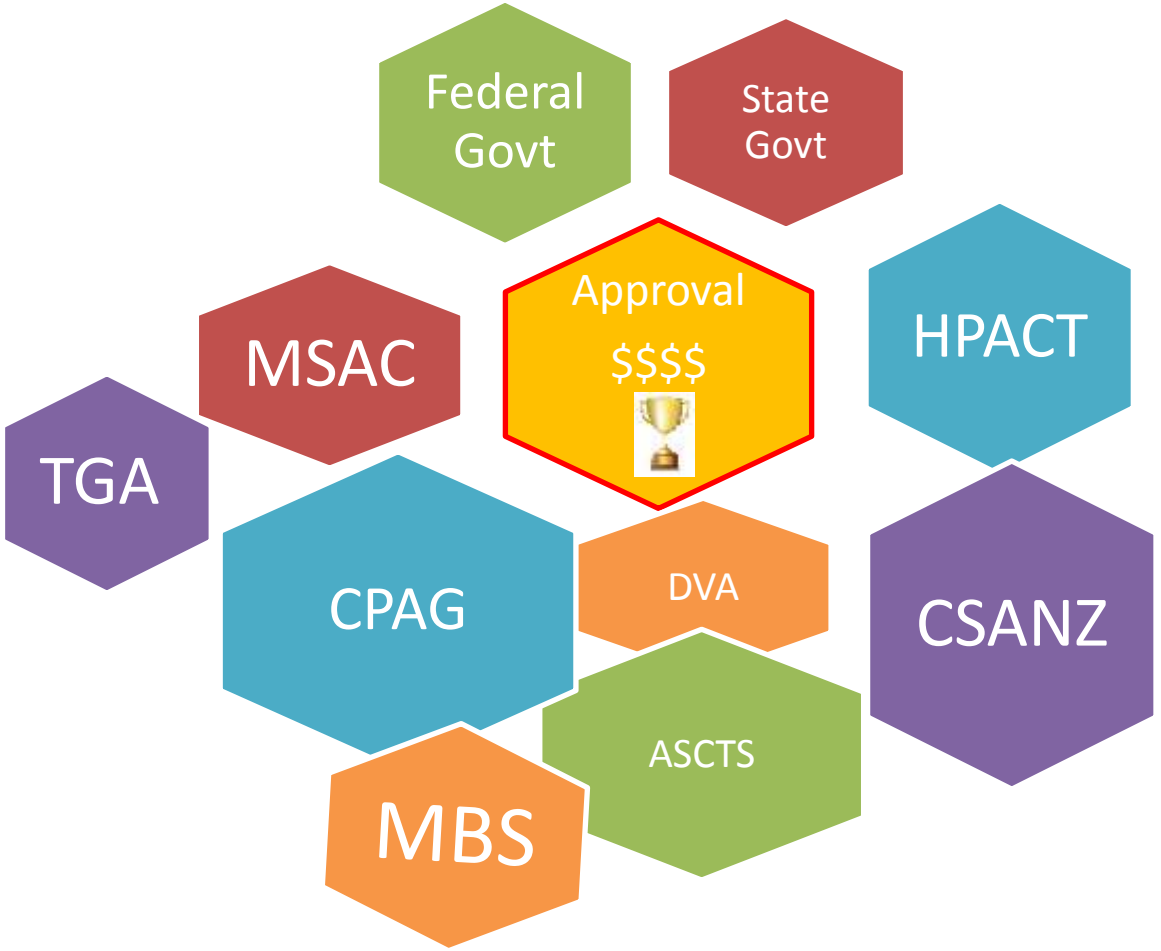
Transcatheter Aortic Valve Replacement for Severe Symptomatic Aortic Stenosis Using a Repositionable Valve System

30-Day Primary Endpoint Results From the REPRISE II Study

Ian T. Meredith AM, MBBS, PhD,* Darren L. Walters, MBBS, MPHIL,† Nicolas Dumonteil, MD,† Stephen G. Worthley, MD,‡ Didier Tchétché, MD,‖ Ganesh Manoharan, MD,¶ Daniel J. Blackman, MD,# Gilles Rioufol, MD, PhD,** David Hildick-Smith, MD,†† Robert J. Whitbourn, MBBS,‡‡ Thierry Lefèvre, MD,§§ Rüdiger Lange, MD,‖‖ Ralf Müller, MD,¶¶ Simon Redwood, MD,## Dominic J. Allocco, MD,*** Keith D. Dawkins, MD***

innovation and collaboration

Approval In AUS the breakdown



TAVI in AUS *Go Live Nov 2017*

MBS reimbursement items numbers linked to indication for the procedure

- High risk SAVR
- Heart team review
- Accredited team Q4 2017

Nationally Mandated Data base

modelled on TVT USA Registry

Accredited centres- Conjoint Committee CSANZ on TAVI

Thank You