

SYDNEY  
HEART  
TEAM

SUMMER  
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NEWSLETTER

## SYDNEY HEART TEAM TAVI UPDATE: Clinical Innovations and World-Leading Outcomes in TAVI

With the expansion of TAVI to lower risk patients, there continues to be rapid developments in the field. Prof Martin Ng (interventional cardiologist) and Prof Michael Wilson (cardiothoracic surgeon) of Sydney Heart Team continue to make significant contributions to TAVI practice, with global impact.

Notably, Profs Ng and Wilson have developed an innovative new pressure-regulated technique for valve deployment in TAVI that significantly improves procedural safety and efficacy.<sup>1</sup>

The development of such innovations, coupled with a highly experienced team have ensured excellent clinical outcomes in our TAVI program which we are delighted to share with you in this update.

### An Innovative New Technique for Safer and More Effective TAVI Outcomes

Prof Martin Ng and Prof Michael Wilson of Sydney Heart Team have recently described a new pressure-regulated method for deploying transcatheter aortic valves that improves the safety and efficacy of transcatheter aortic valve implantation (TAVI)<sup>1</sup>.



Prof Martin Ng  
interventional cardiologist



Prof Michael Vallely  
cardiothoracic surgeon



Prof Michael Wilson  
cardiothoracic surgeon



## Challenges in safe and effective valve deployment.

Successful TAVI depends on optimal deployment of a transcatheter heart valve (THV) relative to a patient’s aortic annulus. Excessive THV oversizing increases the risk for coronary artery obstruction and catastrophic annular rupture. In contrast, THV undersizing increases the risk for significant paravalvular regurgitation (PVR) which predisposes to heart failure and mortality. Unfortunately current methods for THV deployment are imprecise, resulting in wide procedural variations in practice, predisposing patients to inconsistent clinical outcomes.

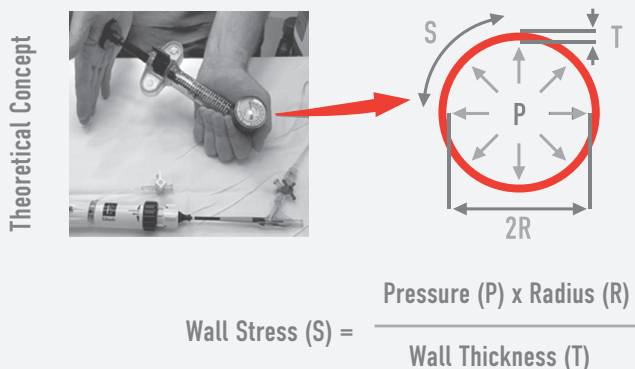
## Pressure-regulated TAVI – a Breakthrough for more Reproducible, Safer and more Effective TAVI Outcomes

We hypothesized that “pressure-regulated” deployment of balloon-expandable THVs will enable optimal apposition between the transcatheter valve and the aortic annulus, thereby minimizing PVR while also minimizing significant tissue injury (Figure 1).

In a groundbreaking study of 330 consecutive patients undergoing TAVI with the Sapien 3 valve (Edwards Lifesciences, Irvine, CA, USA), we identified for the first time, the ideal pressures required for optimal expansion of a THV that would eliminate PVR while also avoiding excessive THV oversizing which may predispose to annular injury. We found that patients who underwent THV deployment in optimal pressure range had outstanding outcomes, with no cases of  $\geq$  moderate PVR and no cases of annular injury (Figure 1).

Prof Ng and Prof Wilson’s innovation of pressure-regulated THV deployment was published as an Editorialised paper in the Journal of American College of Cardiology: Cardiovascular Interventions.<sup>1</sup> By providing a new, simple, reproducible, safe, and effective method for TAVI, this innovation led by members of the Sydney Heart Team has had global impact in further improving clinical outcomes for this revolutionary procedure.

Regulate Deployment Pressure to Control Annular Wall Tension During Expansion  
 → Optimize Prosthesis-Annulus Apposition while Preventing Annular Injury



Wall Stress >3 MPa associated with Reduced Post-Dilatation and Final PVR (TTE)  
 Wall Stress >3.5 MPa Associated with Increased Risk of Annular Rupture

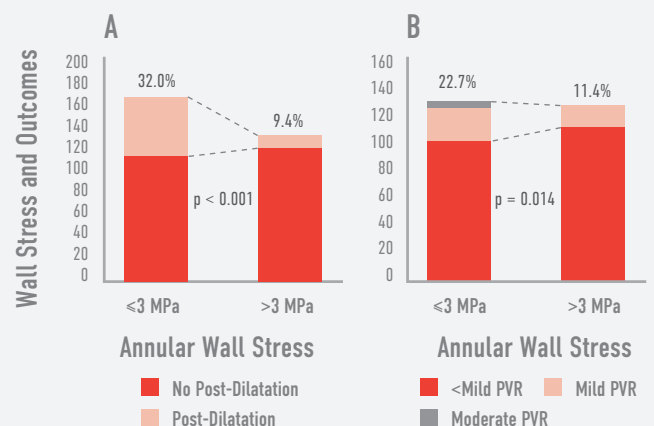


Figure 1. Pressure-Regulated Transcatheter Heart Valve Deployment

## Sydney Heart Team: A Volume TAVI Service with Outstanding Outcomes.

### A High Volume and Highly Experienced TAVI Heart Team

Sydney Heart Team comprises a high-volume, highly experienced interdisciplinary TAVI practice between Prof Ng (interventional cardiologist) and Prof Wilson (cardiac surgeon) where each operator undertakes over 100 TAVI procedures a year with a long-term track record of excellent clinical short and long-term outcomes.

Indeed, TAVI outcomes are highly correlated with operator volume, with data from the U.S. Transcatheter Valve Therapy Registry<sup>2</sup> showing that high-volume TAVI proceduralists ( $\geq 70$  cases per annum) have significantly lower mortality than low-volume TAVI operators (Figure 2).

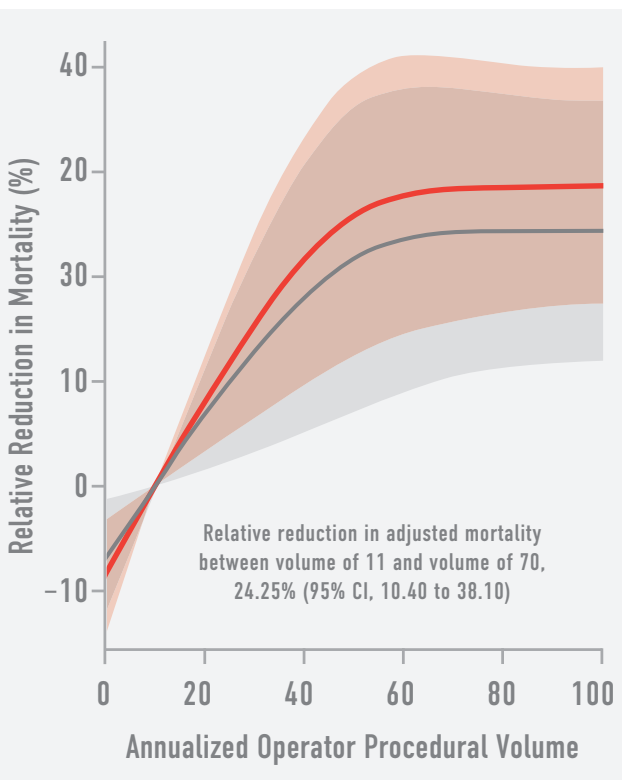


Figure 2. Relationship between TAVI Operator Volume and Mortality

### Excellent Clinical Outcomes in TAVI

Over the last 2 years, the clinical outcomes from our TAVI service at Macquarie University Hospital (MUH) have been excellent. Sydney Heart Team's TAVI outcomes over a two-year period from 1st July 2021 to 30th June 2023 have been independently audited and reviewed by Prof David Gillatt, Director of Medical Services at MUH. During this 2-year period, we performed TAVIs on 215 patients at MUH. The mean age of patients was  $81.8 \pm 6.7$  years, with 60.9% patients being male. The mean predicted mortality from cardiac surgery by the Society for Thoracic Surgery (STS) score for these patients is 3.5%. 98.1% percent of patients underwent TAVI by transfemoral approach with the remainder of patients (1.9%) requiring transaxillary TAVI.

There was no inpatient mortality amongst the 215 patients undergoing TAVI by Sydney Heart Team. The 30-day mortality rate was 0.9%. The rate of major vascular complications was 1.9%. The rates of non-disabling and disabling stroke were 0.47% and 0.93%, respectively. The rate of new permanent pacemaker implantation was 7%. Only one patient (0.5%) had at least moderate aortic regurgitation post TAVI.

### Sydney Heart Team TAVI Outcomes Exceed International Benchmarks and National Guidelines

Sydney Heart Team TAVI outcomes compare favourably with published international benchmarks in similar patient cohorts. For example, the NOTION trial studied patients with a mean age of  $79.2 \pm 4.9$  years with a mean STS score of 2.9%<sup>3</sup>.

The 30-day mortality amongst TAVI patients in this study was higher at 2.1%. Furthermore rates of major complications in this study are higher than for Sydney Heart Team's outcomes including total stroke (2.8%), major vascular complications (5.6%) and new PPM implantation (34.1%).

Sydney Heart Team's TAVI results are also well within with the outcome requirements of the current Position Statement on the Operator and Institutional requirements for a TAVI program in Australia which require a 30-day mortality of <5%, a major vascular complication rate of <5% and a 30-day cerebrovascular event rate of <5%<sup>4</sup>.

**Table 1. Sydney Heart Team TAVI Outcomes at Macquarie University Hospital**

| COMPLICATIONS/<br>OUTCOMES      | MUH-MN<br>(n=215) |
|---------------------------------|-------------------|
| <b>IN HOSPITAL</b>              |                   |
| New PPM - n(%)                  | 15 (6.97)         |
| Stroke - no. (%)                | 3 (1.39)          |
| a. Disabling - no. (%)          | 2 (0.93)          |
| b. Non-disabling - no. (%)      | 2 (0.93)          |
| Major Vascular - no. (%)        | 4 (1.9)           |
| Minor Vascular - no. (%)        | 9 (4.2)           |
| ≥Moderate AR - no. (%)          | 1 (0.5)           |
| <b>MORTALITY</b>                |                   |
| In-hospital mortality - no. (%) | 0 (0)             |
| 30-Day mortality - no. (%)      | 2 (0.9)           |

## CONCLUSIONS

The development of a new Pressure-regulated valve deployment technique by Prof Ng and Prof Wilson highlights the ongoing international leadership within Sydney Heart Team to further improving patient safety and outcomes in TAVI. Leadership in procedural innovation, coupled with deep experience and high clinical volumes, have been pivotal in delivering outstanding clinical outcomes in our TAVI program, as evidenced in the audit of our patient outcomes over the last 2 years.

For practitioners who are interested in more information beyond what has been presented in this update, please don't hesitate to contact us at:

✉ [referrals@sydneyheartteam.com.au](mailto:referrals@sydneyheartteam.com.au)

**References:**1. Snir A, Wilson MK, Ju LA et al. Novel Pressure-Regulated Deployment Strategy for Improving the Safety and Efficacy of Balloon-Expandable Transcatheter Aortic Valves. *JACC Cardiovascular interventions* 2021;14:2503-2515. 2. Vemulapalli S, Carroll JD, Mack MJ et al. Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England journal of medicine* 2019;380:2541-2550. 3. Thyregod HG, Steinbruechel DA, Ihlemann N et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. *Journal of the American College of Cardiology* 2015;65:2184-94.4. Bennetts J, Sinhal A, Walters D et al. 2021 CSANZ and ANZSCTS Position Statement on the Operator and Institutional Requirements for a Transcatheter Aortic Valve Implantation (TAVI) Program in Australia. *Heart Lung Circ* 2021;30:1811-1818. ■

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