

Prospective observational study on the accuracy of predictors of high-grade atrioventricular CONDUCTION block after TAVI (CONDUCT-TAVI): Background, trial protocol and significance

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Background

High-grade atrioventricular block (HGAVB) is common after TAVI occurring in up to 26% of cases. Patients are typically monitored for 48 hours post-TAVI, however 40% of HGAVB occurs after discharge (delayed).

Delayed HGAVB can cause syncope or sudden unexplained cardiac death in a vulnerable elderly population, and no accurate methods currently exist to identify patients at risk.

Protocol

CONDUCT-TAVI is an **open-label, prospective observational trial** taking place at Royal North Shore and North Shore Private Hospitals in Sydney, Australia [ANZCTR ID: ACTRN12621001700820]

Inclusion Criteria: Consecutive patients for elective TAVI, without prior aortic valve prosthesis or pacemaker

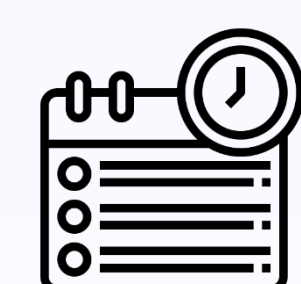
Recruited patients undergo **targeted electrophysiology study**, including pre and post-TAVI measurement of His-Ventricular (HV) interval and AV Wenckebach cycle length; and receive an implantable loop recorder (ILR) prior to discharge

Objectives and Methods

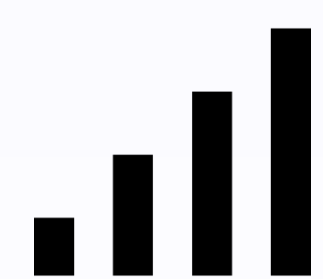
1. Primary objective: Evaluate the diagnostic utility of both novel and previously published electrophysiological predictors of HGAVB, particularly increase in AV Wenckebach cycle length and HV interval following TAVI
2. Secondary objectives: evaluation of other predictors of HGAVB including ECG parameters, calcium volume, membranous septum length and fluoroscopic implantation depth



Planned sample size: 205 patients

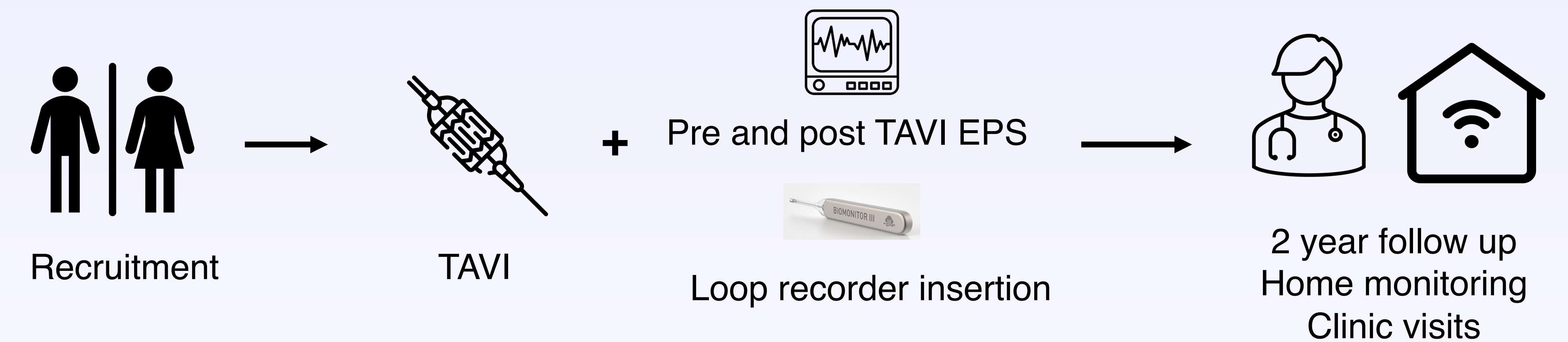


Follow up: 2 years, with continuous cardiac rhythm monitoring via implantable loop recorders (home monitor)



Current status: Recruitment has commenced and is due for completion by mid-2023. 71 patients recruited so far.

Interventions	Admission for TAVI	Post-TAVI Visits (28 days, 6 months, 12 months and 24 months after TAVI)
Informed Consent	✓	
Inclusion / Exclusion criteria	✓	
Demographics	✓	
Medical History	✓	✓
Medications List, Height, Weight, Vitals	✓	✓
Echocardiogram	✓	✓
Pre-procedure CT parameters	✓	
12 Lead ECG	✓	✓
Rapid Atrial Pacing	✓	
Measurement of HV Interval	✓	
Loop recorder implantation	✓	
Loop recorder or PPM interrogation		✓



Significance

- CONDUCT-TAVI will improve our prediction algorithm for patients at risk of HGAVB and pacemakers after TAVI
- Streamline and optimise TAVI and help shift towards “minimalist TAVI”
- Reduce hospital lengths of stay and improve cost-effectiveness of the procedure
- Improve overall patient outcomes.



Royal North Shore and North Shore Private Hospitals, Australia