



# Purpose

Access to TAVI and other tertiary cardiac services is severely constrained in South Africa (SA), the State provides healthcare to >80% of the population and focuses mainly on primary healthcare and communicable diseases.

The SHARE-TAVI registry aims to improve patient care through increasing access to aortic stenosis treatment, by providing locally collected outcomes data which can be used to support locally relevant evidence-based decision making and policy development.

The registry captures data for all SA TAVI patients, to compare outcomes to international data, and define local variations in clinical presentation & outcomes in different regional, funding, and clinical environments.



### Methods

- 16 TAVI Sites implant all TAVIs in SA and represent both Private and State sectors, in the 4 Provinces where TAVI is available. All sites, representing 14 implanting teams, participate voluntarily in the registry, achieving 93% capture compliance. Linking data entry with the funding application process incentivised capture in the registry.
- Data collection: web-based registry accessed by each site with a unique code, data is encrypted and saved on a secure central server.
- Outcomes according to VARC-2 criteria are reported at 30 days and annually thereafter for 5 years for patients who receive TAVIs. Patients who do NOT proceed with TAVI are followed up for 1 year.
- Patient demographics and risk profile comparable to international studies (GARY<sup>1</sup>, SOURCE 3<sup>2</sup>, and US Corevalve Pivotal<sup>3</sup>).

# 2-Year Outcomes of TAVI in South Africa from the SHARE-TAVI Registry

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### On behalf of the SHARE TAVI Investigators and all participating sites

2019.

**Risk profile:** 

Previous CVA/TIA

Mean STS score:

Dialysis

June 2021 to 377 in October 2021.

died prior to an approved TAVI date.

Age at Procedure  $79.83 \pm 7.41$  years

Extracardiac arteriopathy 18.63%

# Results



2.641%

7.81%

22							
	Transfemoral access			91.71 % n=763			
	Overall procedural success			95.07 %			
	30-day All-cause mortality			5.53 % n=46/832			
	Mean ICU stay	2.68 ±4.10	) days	Mean high care	0.81 ±1.	41 days	
	Total LOS	5.14 ±5.15	5 days	Mean ward stay	2.19 ±2.	54 days	
	New PPM implantation (at 30d)			8.05% n=67/832			
	NYHA Class (III+IV) at Evaluation			67.7% of patients			
	NYHA Class (III+IV) at 30-days			6.53% of patients			
Immediate peri-procedural complications (VARC ≤72 hours)							
	Mortality	2.52%	n=21	MI	0.36%	n=3	
	Stroke	1.56%	n=13	Bleeding	5.17%	n=43	
	Valve in Valve (unplanned)	2.16%	n=18	Vascular complications	7.57%	n=63	

2021



1. The German Aortic Valve Registry (GARY): in-hospital outcome. Christian W. Hamm. Euro Heart J. 2014; 35, 1588–1598 2. SOURCE 3: 1-year outcomes post-transcatheter aortic valve implantation using the latest generation of the balloon-expandable transcatheter heart valve. Wendler O. Eur Heart J. 2017 Sep 21;38(36):2717-2726. 3. Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis. David H. Adams. N Engl J Med 2014; 370:1790-1798

1870 patients From Sept 2014 – Jun 2021 were evaluated for TAVI. 1277 patients received implants, 13% were done in State sector. • Funding decision times range 0-1095d, average wait decreased from 180+ days in 2014, to 49 days in 2019, but in the first half of 2021 had increased to 84 days, and number of patients awaiting decisions increased from 326 in

• 22.1% of exited patients demised during funding application process, 8%

The 2-year outcomes cohort consists of 832 implant records to end June

History and Risk profile and 30-day outcomes validated on 832 patients.

### History and Risk Profile 2-year Implant cohort (n=832)

Male	gender:
	genaen

54.21 (n=451)

Diabetes	23.68%
Chronic lung disease	17.31%
Mean Euroscore 2	$6.65 \pm 5.92$

6.72 ± 6.88% Mean Log Euroscore: 22.97 ± 15.21

### **Procedural outcomes (n=832)**



- invalid.

## Late Outcomes in the 2-year Cohort

Outcome 1-year All-cause mortality 2-year All-cause mortality Stroke at 1-year Stroke at 2-year PPM Implantation at 1-year PPM Implantation at 2-year

The Covid pandemic has been disruptive globally at every level of healthcare provision. Routine clinical care has been affected by lockdowns. Elective surgery has been reduced or suspended during lockdowns, patients have feared attending hospitals for routine visits due to concerns of Covid infection, and other businesses supporting healthcare provision have had absenteeism and restrictions on staffing for social distancing. This disruption in service affected TAVI implantations and funding applications too, this resulted in an increase in the waiting time for funding decisions and the highest proportion of patients paused in the capture stage of Evaluation since the registry was initiated.

The availability of local data to benchmark against international study populations and guidelines is possible, as shown in the Perioperative and 30-day outcomes herein, as the demographics and risk profile of the patients is similar to other registry and trial data. However outcomes comparison at 1-year and 2-year is currently temporarily confounded by incomplete data where capture has been disrupted due to both personnel restraints during the Covid pandemic, and interruption of follow up visits due to patient unwillingness to visit hospitals in the pandemic for routine care.

A strategy has been developed to assist sites with this interrupted data capture and this outcomes data will be available in the near future.



## Results

• In the 2-year cohort (n=832), the VARC 2 measures at 30-days such as Bleeding and Vascular complications, Procedural success, Mortality (periprocedural, and 30d), Hospital Length of Stay, unplanned Valve-in-Valves, and NYHA class improvement post-TAVI all compare favourably to published TAVI populations such as US Corevalve, SOURCE3 and GARY. • 1- and 2-year follow up data were unavailable for 230/832 records due to

• Only 602 records then available for 2-year outcomes measures. • The effect of the base rate fallacy is particularly evident when observing the Mortality outcomes at 1- and 2-years between the limited data of the 602/832 patients in comparison to the full 832 records.

• 1-year All-cause mortality in both the n=832 (12.86%) and the n=602 (17.28%) both fall within the comparable populations of [14,2% US Corevalve<sup>3</sup>, 12.6% SOURCE 3<sup>2</sup>, 20% GARY<sup>1</sup>], but comparisons are rendered

> n=832 12.86% 18.75% 4.09% 4.57% 9.98% 10.34%

n=602 17.28% 25.25% 4.82% 5.48% 10.8% 11.3%

# Conclusions