TAVI in South Africa's resource-constrained economy: the role of local data in overcoming funding resistance

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On behalf of the SHARE TAVI Investigators and all participating sites

SHARE South African Heart Association Registry
TAVI
Shared experience, improved patient care

Purpose

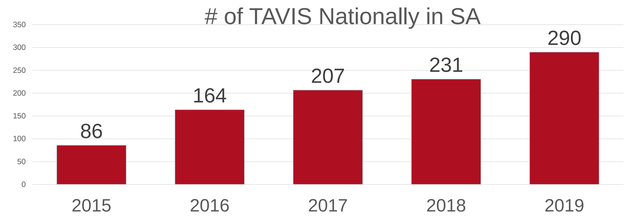
Access to TAVI and other tertiary cardiac services is severely constrained in South Africa (SA), the State provides healthcare to >80% of the population and focuses mainly on primary healthcare and communicable diseases.



The small Private Funding sector has largely resisted funding TAVIs since 2009, due to the perceived high cost of the technology, and Funders have cited a lack of local data as the main reason for not supporting TAVI implantation. Funders resist the introduction of newer generation devices citing poorer outcomes during learning curves and unnecessary increased costs for benefits that are perceived as insignificant.

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 funding 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[1], SOURCE 3[2], and US Corevalve Pivotal[3]).

Results

- 1375 patients From Sept 2014 – Jan 2020 were evaluated for TAVI.
- Funding decision times range 0-1176d, average wait in 2019 is 70 days, decreased from 180+ days in 2014.
- 23% of exited patients demised during funding application process, 6% died prior to an approved TAVI date.
- 998 patients received implants, 13% were done in State sector, and 6.2% of State sector (teaching hospitals) implants were 2nd generation devices such as the Edwards Sapien 3 & Medtronic Evolut R and PRO. Funding policies leave patients with unaffordable co-pays (>€ 5 500) for 2G devices and in 2019 30% of all implants were still 1st generation devices such as the Sapien XT.

History and Risk Profile Implant cohort (n=998)

Mean age:	79.71 ± 7.46 years	Male gender:	54.5%(n=544)
Risk profile:			
Dialysis	3.01%	Diabetes	23.75%
Previous CVA/TIA	7.62%	Chronic lung disease	18.2%
Extracardiac arteriopathy	17.84%	Mean Euroscore 2	6.51 ± 5.74
Mean STS score:	6.43 ± 6.49%	Mean Log Euroscore:	22.37 ± 14.84

Procedural outcomes (n=982)

Transfemoral access		91.1 % n=895	
Overall procedural success		95.1 %	
30-day All-cause mortality		4.68 % n=46	
Mean ICU stay	2.43 ±4.25 days	Mean high care	0.72 ±1.42 days
Total LOS	4.88 ±5.31 days	Mean ward stay	1.99 ±2.53 days
New PPM implantation (at 30d)		7.23% n=71/982	
Immediate peri-procedural complications (VARC ≤72 hours)			
Mortality	2.24% n=22	MI	0.31% n=3
Stroke	3.36% n=3	Bleeding	4.89% n=48
Valve in Valve (unplanned)	2.43% n=19	Vascular complications	8.04% n=79

1-Year Outcomes (n=721)

1-year All-cause mortality	**11.37 %**	**n=82**
Cardiac : Non-cardiac mortality	68 : 32%	n=26 Non-cardiac
Cardiac-Related admissions to 1yr	4.58%	n=33
Cardiac : Non-cardiac admissions	38 : 62%	n=53 patients Non-cardiac

- All-cause mortality of 11.37% (n=82/721) at 1-year compares favourably to published TAVI populations [14,2% US Corevalve[3], 12.6% SOURCE 3[2], 20% GARY[1]].
- 32% of 1-year All-cause mortality is non-cardiac, mostly attributable to cancer, pneumonia and renal failure.
- <5% of patients require cardiac-related admissions in Year-1 post TAVI

Results

- Bleeding complications, Procedural success, Mortality (peri-procedural, 30d and 1-Yr), Hospital Length of Stay, unplanned Valve-in-Valves, and NYHA class all show improved outcomes in the 2G devices over the 1G devices used in South Africa, but the difference between generations of devices in cardiac-related hospital admissions post-TAVI is negligible.

Outcome comparison
1st and 2nd generation devices (1G & 2G)

Outcome	n =	1G devices	2G devices
Procedural success	973	94.04%	97.50%
Periprocedural mortality	973	3.09%	1.15%
Mortality at 30d	973	5.96%	3.46%
Mortality at 1-year	713	12.96%	9.25%
Hospital Length of Stay (LOS)	713	5.51d	4.25d
ICU Length of Stay	713	2.44d	2.33d
Unplanned Valve-in-valve	973	3.31%	0.77%
Bleeding complications <72hours	973	5.52%	4.04%
NYHA class (III+IV) at evaluation	973	72.1%	63.5%
NYHA class (III+IV) at 1-year post-TAVI	973	9.45%	4.32%
Cardiac readmissions at 1-year post-TAVI	713	4.76%	4.48%

Conclusions

Funding decision waiting periods were reduced through processes initiated by interaction and sharing of local pre-TAVI mortality data with Funders.
Locally-collected data showed comparable mortality and procedural success as well as other VARC2-defined measured outcomes when benchmarked to international data.
The SA TAVI programme provides quality of care and outcomes equivalent to international best-practice standards despite low volumes and resource limitations. The locally-relevant data can be used by stakeholders to motivate for increased access to funding for TAVI.
As in international data, local data supports the superiority of 2G over 1G devices, with procedural success and mortality outcomes improved despite the learning curve with the newer devices.
This refutes Funder's assertions that there is insignificant benefit to newer generation devices and that the outcomes will be poorer due to the learning curve. Patients should therefore not be forced to tender large co-payments for appropriate treatment.
Local data may be used to support calls for preferential use of the newer generation devices. The standard of care available in the State sector is considered the minimum standard for provision of care amongst the Private funders, thus the availability of newer generation devices in the State sector should drive the revision of Private Funders treatment protocols.

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References

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