SHARE-TAVI Registry – TAVI outcomes in a low volume setting

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On behalf of the SHARE TAVI Investigators and all participating sites

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Cardiovascular Care – Meeting the Needs of Africa

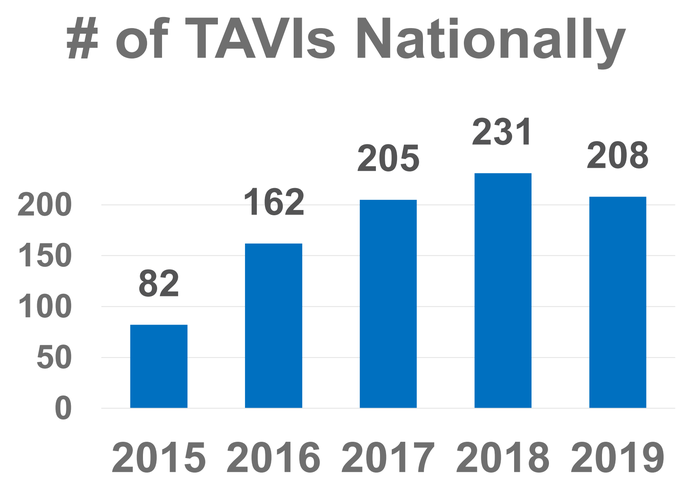
SHARE South African Heart Association Registry
TAVI
Shared experience, improved patient care

Purpose

SA Heart's prospective multi-centre observational registry, SHARE-TAVI, aims to capture data for all SA TAVI implants, to compare outcomes to international data, and define local variations in clinical presentation & outcomes, to improve patient care.

Access to tertiary cardiac services like TAVI is severely constrained in SA. Three Academic hospitals offer limited TAVI services to the Public sector through Public-Private partnerships.

Funding resistance in the Private sector has contributed to low volumes nationally since TAVI was introduced to SA in 2009. Funders have cited the technology learning curve, low volumes and a lack of local data as reasons for not supporting roll-out of TAVI, which has become a catch-22 situation.



Methods

- Capture per geographic site through a secure web-based registry interface.
- Capture compliance of 94% of all implants nationally is exceptional for a voluntary participation registry. Linking data entry with the funding application process incentivised capture.
- All 10 teams doing TAVI across 17 sites participate in the SHARE-TAVI registry.
- Outcomes at 30 days and annually for 5 years are reported according to VARC-2 criteria.
- Patient demographics comparable to international studies (GARY[1], SOURCE 3[2] and US Corevalve Pivotal[3])

Results - History and Risk Profile
30-day Outcomes Implant cohort (n=901)

Mean age:	79.90 ± 7.43 years	Male gender:	54.27% (n=489)

Risk profile:

Sector:	Private	Public
Dialysis	3.47%	0%
CVA/TIA	8.24%	3.23%
Frailty	27.54%	22.58%
Mean STS score:		6.50 ± 6.64%
Mean Log Euroscore:		22.87 ± 14.99
Mean Euroscore 2:		6.53 ± 5.81

Results

- 1254 patients were entered and evaluated for TAVI from Sept 2014 – Oct 2019.
- 163 patients still await funding decisions.
- Average wait in 2019 is 69 days, decreased from 180+ days in 2014.
- Funding decision time range 0-1176d.
- 160 patients exited after TAVI evaluation, 81% due to declined funding or death during the funding application process.
- Prolonged Funder application and decision times resulted in mortality for 33 patients (21% of exited patients) who awaited a Funder's response.
- A further 12 patients' health deteriorated to such an extent during the prolonged funder application period that they demised before an approved TAVI date.
- 29% of patients declined funding died within the first year.
- 911 entered patients received implants.
- 14% of TAVIs were done in the Public sector.

Procedural outcomes
30-day Outcomes Implant cohort (n=901)

Transfemoral access	91.12% n=821		
Overall procedural success	94.7%		
Immediate peri-procedural complications (≤72 hours)			
Mortality	2.35% n=21	MI	0.33% n=3
Conversion to open heart	1.0% n=9	Bleeding	4.88% n=44
Valve in Valve (unplanned)	2.0% n=18	Vascular complications	7.77% n=70

Hospital stay (days):

Sector:	Private	Public
Mean ICU stay	2.66 ±4.63	1.20 ±1.32
Total LOS	5.00 ±5.60	4.90 ±4.05
Procedural success:	94.72%	94.35%

New PPM at 30d	**7.8% n=70/901**
Stroke at 30d	**3.66% n=33/901**
30-day all-cause mortality	**4.88% n=44**

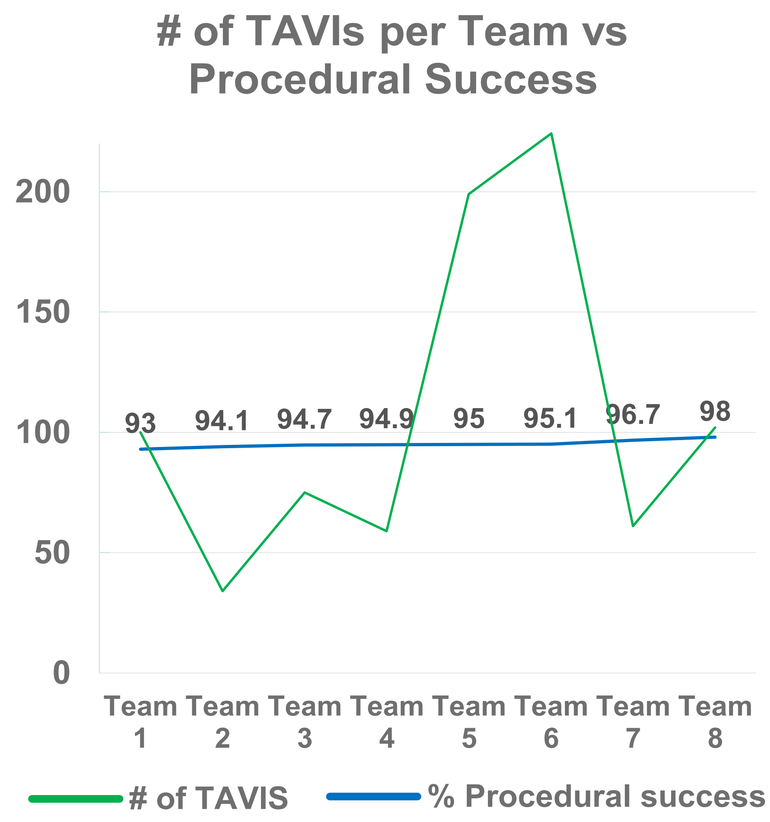
1-Year Outcomes (n=658)

New PPM at 1-yr	10.33% (n=68)
Stroke at 1-yr	3.95% (n=26)
1-year all-cause mortality	**10.03% (n=66) Private: 10.02% Public: 10.1%**
Cardiac : Non-cardiac mortality	**68 : 32% (Non-cardiac n=21 patients)**

- All-cause mortality at 1-year is similar in Private and Public sectors and compares favourably to published TAVI populations [14,2% US Corevalve[3], 12.6% SOURCE 3[2], 20% GARY[1]].
- State and Private care offer similar procedural success and hospital stays in the 30-day outcome cohort.

Results

- Only 2 teams do >40 implants annually, 4 teams do <15 each p.a.
- Procedural success in 8 teams even at the lowest volume centres is >93%
- 2 teams excluded from results due to incomplete records and new team
- 51% of implants are with newer generation devices and procedural success for these is 97.4%
- 98.98% procedural success for implants done in 2019



Conclusions

All SA TAVI teams would be considered low volume by International standards, however their **procedural success is consistently high independent of procedure volume.** The average of all teams' success rates is comparable to high-volume international centres. TAVI volumes remain low nationally primarily due to funding resistance.

Approximately one third of the appropriately selected patients who were declined funding demised within a year of their consultation for TAVI evaluation.

A high proportion of patients demise during the unnecessarily lengthy and cumbersome funding application process. Teams may need to routinely consider interim Balloon Valvuloplasty for severely symptomatic patients during the funding application period.

The SHARE-TAVI registry offers independent local data that confirms that TAVI in local low volume settings compares favourably to international best practice standards, in both the Public and Private sectors.

References

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Declaration of Interest: The authors have no conflicts of interest to declare.

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