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Funding resistance and 1-year outcomes in SHARE-TAVI, a local South African TAVR/TAVI registry

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Purpose

Access to tertiary cardiac services is severely constrained in South Africa (SA).

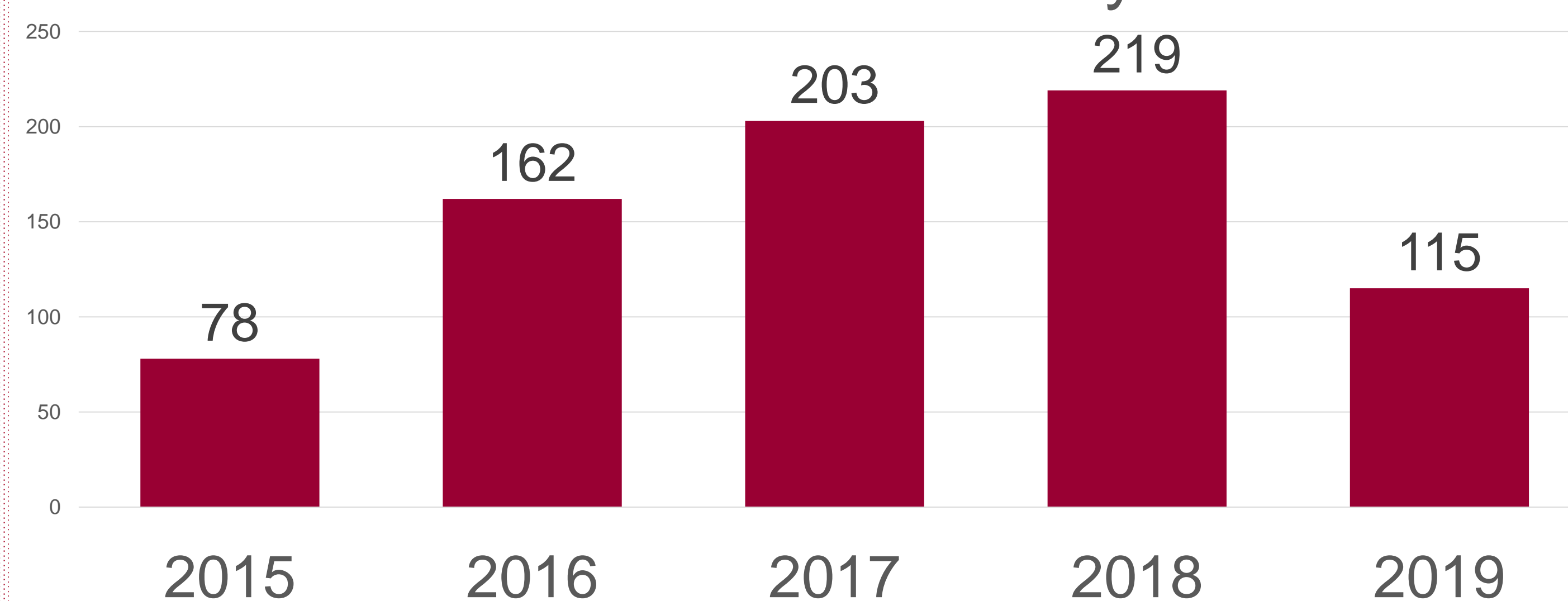
State-provided healthcare focuses on primary healthcare and communicable diseases (HIV, TB) and serves 84% of the population.

Funding resistance in the Private sector has contributed to low volumes nationally since TAVI was introduced in 2009. Funders have cited a lack of local data as one of the reasons for not supporting roll-out of TAVI.



SHARE-TAVI aims to capture data for all SA TAVI patients, to compare outcomes to international data, and define local variations in clinical presentation & outcomes, to improve patient care.

of TAVIs Nationally



Methods

- Linking data entry with the funding application process incentivised capture in this voluntary participation registry, with 93% capture compliance of all implants, and all 9 teams doing TAVI across 12 sites participating in the SHARE-TAVI registry.
- Data collection: web-based registry at each site and encrypted and saved on a central server.
- Outcomes at 30 days and annually thereafter for 5 years are reported according to VARC-2 criteria.

Results

- Patient demographics comparable to international studies (GARY¹, SOURCE 3², and US Corevalve Pivotal³).
- 1093 patients From Sept 2014 – June 2019 were evaluated for TAVI.
- 145 patients still await funding decisions, decision time range 0-1176d.
- Average wait in 2019 is 70 days, decreased from 180+ days in 2014.
- 134 patients exited during/after TAVI evaluation, 81% due to declined funding or death during the funding application process.
- 20% of exited patients demised during funding application process.
- 8% of exited patients demised with TAVI approved, before TAVI date.
- 29% of patients declined funding died within the first year (n=21/72).
- 798 patients received implants, 15% were done in the State sector.

History and Risk Profile Implant cohort (n=798)

Mean age: 80.01 ± 7.2 years Male gender: 54.1%(n=432)

Contra-indications to surgery:

Frailty	27.7% (n=221)	Porcelain aorta	7.3% (n=58)
Hostile thorax	3.1% (n=25)	Patent LIMA graft	10.7% (n=85)

Risk profile:

Dialysis	2.6%	Diabetes	23.6%
Previous CVA/TIA	7.39%	Chronic lung disease	17.2%
Extracardiac arteriopathy	18.4%	Mean Euroscore 2	6.6 ± 5.9
Mean STS score:	6.8 ± 7.0%	Mean Log Euroscore:	23.2 ± 15.4

Procedural outcomes (n=782)

Transfemoral access 91.7 % n=697
Overall procedural success 94.6 %

Immediate peri-procedural complications (≤72 hours)

Mortality	2.69% n=21	MI	0.38% n=3
Stroke	1.41% n=11	Bleeding	5.20% n=41
Valve in Valve (unplanned)	2.30% n=18	Vascular complications	7.67% n=60

New PPM implantation (at 30d) 7.42% n=58/663

1-Year Outcomes (n=557)

Mean ICU stay	2.47 ± 4.16 days	Mean high care	0.73 ± 1.28 days
Mean ward stay	2.20 ± 2.63 days	Total LOS	5.19 ± 5.30 days
30-day all-cause mortality	5.4 % (n=30 patients)		
1-year all-cause mortality	10.6 % (n=59 patients)		
Cardiac/Non-cardiac mortality	69 / 31% (Non-cardiac n=18 patients)		

Results

- All-cause mortality of 10.6% (n=59/557) at 1-year compares favourably to published TAVI populations [14.2% US Corevalve³, 12.6% SOURCE 3², 20% GARY¹].
- 31% of 1-year all-cause mortality is non-cardiac, mostly attributable to cancer, pneumonia and renal failure.
- Only 2 teams do >40 implants annually, 3 teams do <15 each p.a.
- Procedural success even at the lowest volume centres is >90% over the 2 years 2016-2017, which included the learning curve period.
- State and Private care offer similar procedural success in the 30-day outcome cohort (State 93.1%, Private 94.7%), and hospital stays - mean ICU [State 1.24±1.35d, Private 2.59±3.95d] & total length of stay [State LOS 4.91±4.15d, Private LOS 5.04±4.99d].

Conclusions

All SA TAVI teams would be considered low volume by International standards, however their procedural success is still favourable and the average of all centres' success rate is comparable to high-volume international centres.

Nationally volumes remain low, primarily due to funding resistance, with approximately a third of the appropriately selected patients who were declined funding demising within a year of their consultation for TAVI evaluation, and a high proportion of patients demising during the unnecessarily lengthy and cumbersome funding application process.

The SHARE-TAVI registry offers independent local data in both the State and Private sectors that confirms that TAVI in local resource-constrained settings compares favourably to international best practice standards, even with relatively low volumes at both State and Private centres.

References

- The German Aortic Valve Registry (GARY): in-hospital outcome. Christian W. Hamm. Euro Heart J. 2014; 35, 1588–1598
- 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.
- Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis. David H. Adams. N Engl J Med 2014; 370:1790-1798

Declaration of Interest

The authors have no conflicts of interest to declare.