



Is TAVI appropriate for South Africa?

1-year outcomes in a resource-constrained economy

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ON BEHALF OF THE SHARE-TAVI INVESTIGATORS



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I do not have any potential conflict of interest

Background / Study objective

The uptake and outcomes for TAVI in emerging and threshold economies are less well explored than developed economies.

The national SHARE-TAVI registry (South African Heart Association Registries – TAVI registry) aims to report on local outcomes and benchmark them to registries in the developed world.



Methods

- The SHARE - TAVI registry is a prospective multicentre registry.
- It is designed to capture data for **all** patients undergoing TAVI across South Africa in a dedicated web-based database.
- The registry was launched in September 2014.
- All eleven centres performing TAVI in South Africa are actively capturing data into the registry.
- Three centres being initiated in 2018
- Procedural, 30-day and 1-year outcomes are reported as defined by the VARC-2 criteria

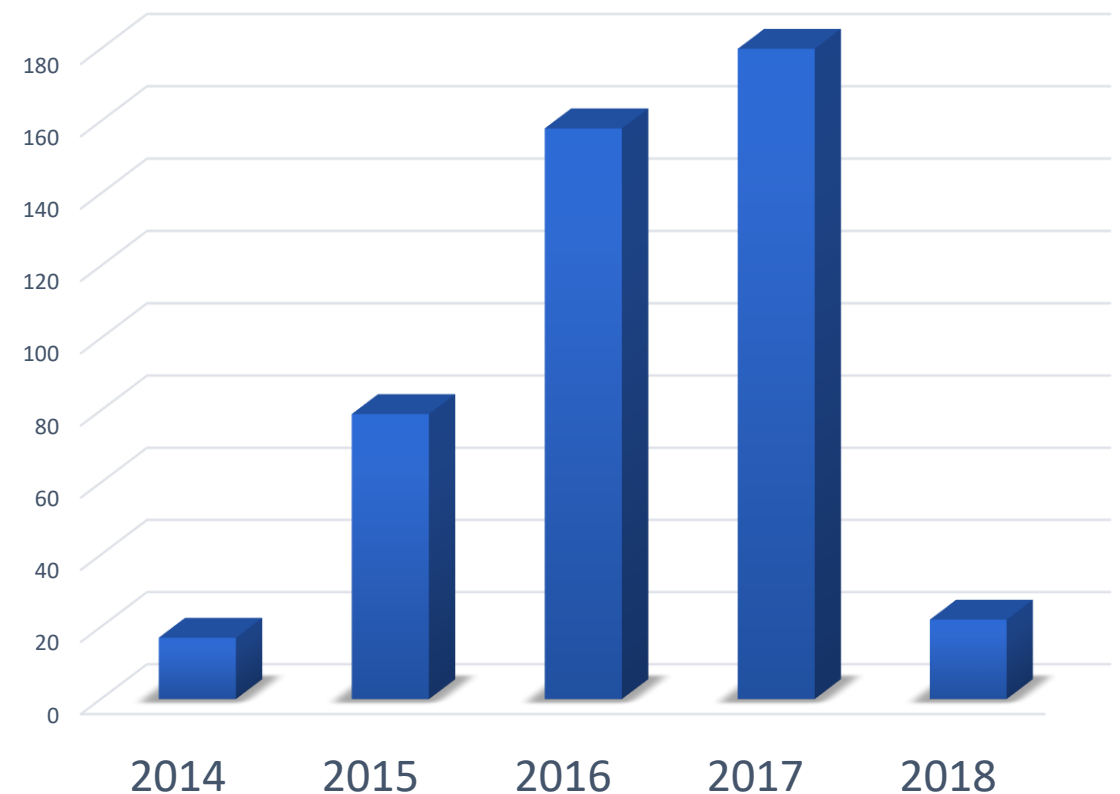


Enrolment breakdown

Entry status	Number
Total enrolled	644
Non-TAVI	8
Awaiting Heart Team decision	11
Approved for TAVI	625
TAVI Completed	456
TAVI Funding Application	77
TAVI approved awaiting date	7
TAVI not done - Exited	83
TAVI Aborted	2

Patients enrolled n= 644
TAVIs captured n= 456

TAVIs captured



Exit after funding application

Exit after funding application	n=83
Mortality during funding application process	(24)
Mortality – Prior to approved procedure	9
Mortality - While waiting for funding response	15
Funding declined	(39)
Alive	20
Mortality	19
Other exit reason (e.g. patient declined, condition deteriorated, referred for surgery, other)	(19)
Alive	18
Mortality	1

AWAITING FUNDING DECISIONS April 2015 - Present

Median wait for funding decision (was 180d) 92 d

Median days to procedure from Consult 83d

1-yr Mortality of patients declined funding – 49%
24 patients died during the funding application process

Funding

TAVI = Yes



TAVI Funding n= 456	%
Blank	26
Medical aid approval - Full amount	35
Medical aid approval - Partial amount	26
Medical aid declined - Patient Self-funded	3
State-funded	10

Average co-pay for partially funded procedures **R 112 000.00**

Patient characteristics

Study period: September 2014 to March 2018

Study cohort (n=456)

Mean age:	80.44 ±7.23 years	Male gender:	52.89% (n=220)
Mean STS score:	6.25 ±5.55	Mean Log Euroscore:	21.98 ±14.24
Contra-indications for surgery:			
Frailty	33.65 % (n=140)		
Porcelain aorta	7.21 % (n= 30)		
Patent LIMA graft	11.78 % (n=49)		
Hostile thorax	2.4 % (n=10)		

Results 1 – Procedural outcomes

Procedural outcomes (n=441)	
Transfemoral access	88.0 % n=388
Overall procedural success	92.29 %
Immediate peri-procedural complications (≤72 hours)	
Mortality	2.9 %, n=13
Myocardial infarction	0.68 %, n=3
Stroke	0.91 %, n=4
Bleeding complications	6.35 % n=28
Vascular complications	6.57 %, n=29
Valve in Valve	3.62 %, n=16
New PPM implantation (at 30d)	7.9 %, n=35

Results 2 – Outcomes at 1-year

1-Year Outcomes (n=284)

Mean ICU stay	2.32 ±1.83 days
Mean high care stay	0.79 ±1.47 days
Mean ward stay	1.91 ±2.31 days
Total LOS	5.02 ±3.94 days
Thirty day all cause mortality	6.3 % (n=18 patients)
One year all cause mortality	12.7 % (n=36 patients)
Cardiac related re-admissions during follow up at 30 days (total re-admissions n=26)	2.8 % (n=8 patients)
Cardiac related re-admissions during follow up at 1 year (total re-admissions n=49)	5.6% (n=16 patients)

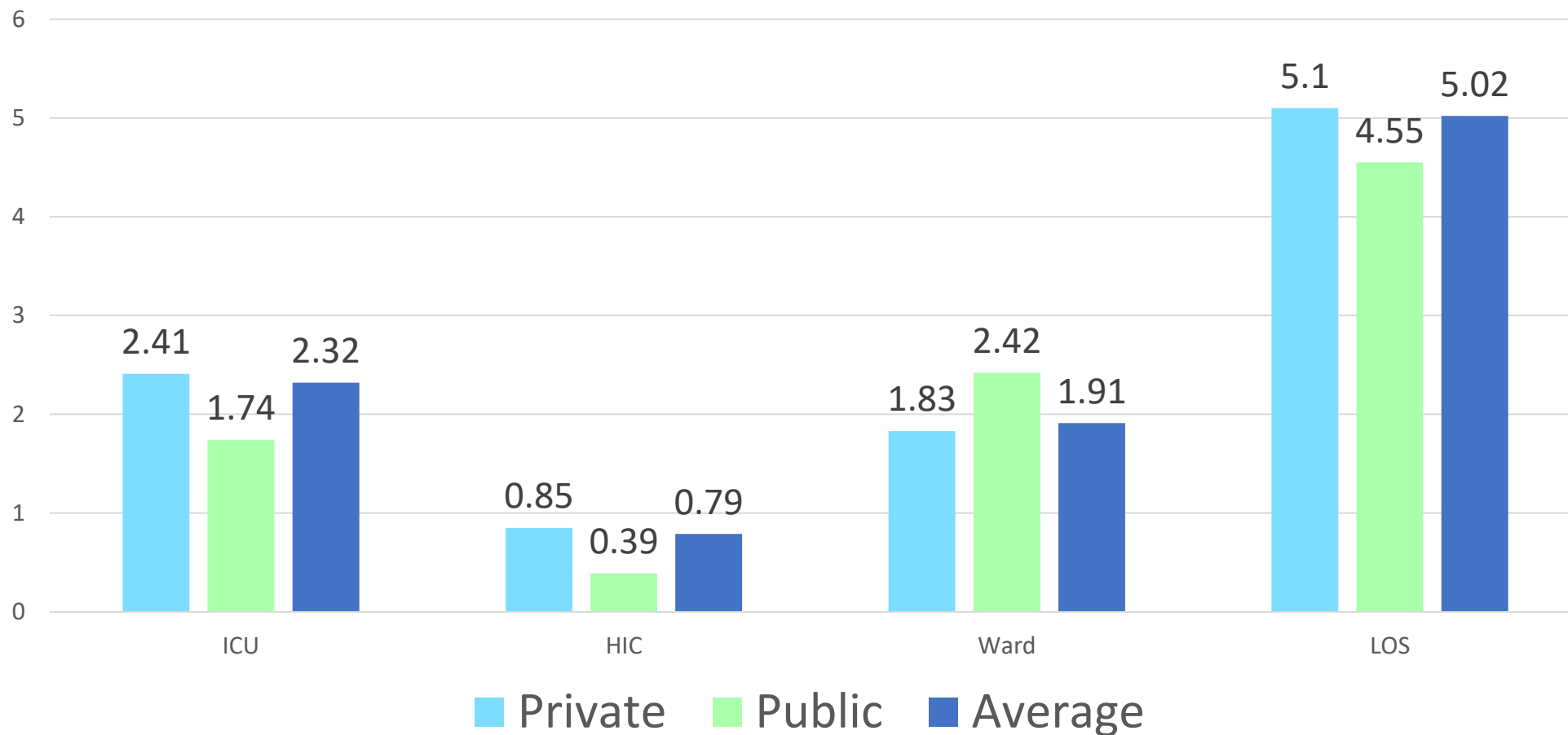
30-d All-cause Mortality

SHARE	6.3%
PARTNER A	6.5%
CoreValve US pivotal	3.4%
PARTNER 2	4.0%
SOURCE	8.5%
GARY	5.6%

1-yr All-cause Mortality

SHARE	13 %
PARTNER A	24 %
CoreValve US pivotal	14 %
PARTNER 2A	12 %
SOURCE	24 %
GARY	21%

LOS in days – Private and Public sectors



Results

- Age, gender and mean risk prediction values in the SHARE-TAVI cohort were comparable to US Corevalve Pivotal trial population, SOURCE XT, and German Aortic Valve registry [GARY].
- Overall procedural success was 92.29%, peri-operative mortality was 2.9%
- 30day All-cause mortality was 6.3% [compared to 6.5% for PARTNER A, 3.4% in US Corevalve and 5.6% for GARY].
- 1-year mortality was 12.7% [compared to 14.2% in US Corevalve, 19.4% in SOURCE XT, and 20.7% for GARY].
- Mean ICU stay was similar in both the State (1.74 ± 1.90 days) and the Private sector (2.41 ± 1.81 days) as was total length of stay (State 4.55 ± 3.29 , Private 5.1 ± 4.04 days).
- 1-year pacemaker implantation [7.6%] was lower than comparable registries, strokes [4.8%] comparable to GARY [4.8%] and SAPIEN XT [6.3%].
- 67% of patients in NYHA Class III/IV at baseline, 92.0% patients at NYHA Class I/II at 1-year.

Conclusions

- Early data suggests that both State and Private South African TAVI centres provide favourable early and mid-term outcomes, comparable to those seen in developed economies
- TAVI should be considered an appropriate option to treat patients suffering from severe aortic stenosis in South Africa, as per the SA Heart TAVI guidelines.
- In resource-constrained economies, funding remains a major challenge for widespread and appropriate use of TAVI.
- Reporting outcomes through national registries could aid in addressing these constraints.

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