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Is TAVI appropriate for South Africa?

1-year outcomes in a resource-constrained economy

EAPCI SASCI SA Heart PCR

Background / Study objective

- The uptake and outcomes for TAVI in emerging and threshold economies are less well explored than developed economies, and concerns have been raised that standards of care in a resource-constrained economy may not be comparable.

- 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.
- Procedural, 30-day and 1-year outcomes are reported as defined by the VARC-2 criteria

Patients

Study period: September 2014 to November 2017

Patients enrolled into registry	n = 592	
Approved for TAVI by a Heart Team	n = 579	Awaiting Heart Team decision (n=5) Reasons for exit (n=8) 6 referred for conventional surgery 2 referred for medical treatment
Patients proceeding to TAVI	n = 416 (study cohort)	Reasons for not proceeding (n=163) 80 Awaiting funding decisions 6 Approved awaiting TAVI date 13 Mortality while waiting for decision 9 Mortality, funding approved, before TAVI 18 Mortality after funding declined 17 Funding declined 1 Mortality, Other exit reason 17 Other exit reason

Study cohort (n=416)

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=394)	
Transfemoral access	89.34 % (n=352)
Overall procedural success	92.39 %
Immediate peri-procedural complications (≤72 hours)	
Mortality	3.3 %, n=13
Myocardial infarction	0.51 %, n=2
Stroke	0.51 %, n=2
Bleeding complications	6.6 %, n=26
Vascular complications	7.36 %, n=29
Valve in Valve	3.81 %, n=15
New PPM implantation (at 30d)	6.09 %, n=24

Results 2 – Outcomes at 1-year

1-Year Outcomes (n=248)	
Mean ICU stay	2.37 ±1.89 days
Mean high care stay	0.77 ±1.50 days
Mean ward stay	1.93 ±2.38 days
Total LOS	5.07 ±4.09 days
Thirty day all cause mortality	6.45% (n=16 patients)
One year all cause mortality	14.11% (n=35 patients)
Cardiac related re-admissions during follow up at 30 days (total re-admissions n=23)	3.23% (n=8 patients)
Cardiac related re-admissions during follow up at 1 year (total re-admissions n=27)	7.26% (n=18 patients)

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 92.39%, peri-operative mortality was 3.3%
- 30day All-cause mortality was 6.45% [compared to 6.5% for PARTNER A, 3.4% in US Corevalve and 5.6% for GARY].
- 1-year mortality was 14.1% [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 (1.79±1.95 days) and the Private sector (2.48±1.86 days) as was total length of stay (State 4.52±3.37, Private 5.17±4.20 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%].
- 62% of patients in NYHA Class III/IV at baseline, 93.0% 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.