

Safety and Efficacy of Transcatheter Aortic Valve Replacement using Sapien 3 Balloon-expandable Valve in Type 0 Bicuspid Aortic Valve Stenosis

A multicenter, retrospective study

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Disclosure of Relevant Financial Relationships

I, [Dejing Feng] DO NOT have any financial relationships to disclose.

Background & Purpose

- Available data regarding the performance of current devices in patients with type 0 BAV undergoing TAVR are scarce
- The proportion of BAV is very high (about 50%) in TAVR candidates in China and type 0 accounts for half of the proportion of BAV
- To investigate the procedural safety and efficacy of TAVR using Sapien 3 balloon-expandable valve in patients diagnosed with type-0 BAV stenosis

Study Methods

Key Inclusion Criteria

- Patients with native aortic stenosis (AS) accepted TAVR from September, 2021 to March 2023 in 28 centers in China were consecutively enrolled
- Patients with type-0 BAV anatomy confirmed by CT corelab in Fu Wai Hospital
- Patients with follow-up at least 30 days

Study Endpoints

Primary safety endpoint

- All-cause mortality or disabling stroke at 30-days

Primary efficacy endpoint

- Technical success (VARC-3)

Technical success (at exit from procedure room)

- Freedom from mortality
- Successful access, delivery of the device, and retrieval of the delivery system
- Correct positioning of a single prosthetic heart valve into the proper anatomical location
- Freedom from surgery or intervention related to the device* or to a major vascular or access-related, or cardiac structural complication

Key definitions

-High Implantation Depth: Defined by the core laboratory assessment of fluoroscopic images following successful valve deployment. High implantation was characterized by a ratio of the prosthetic valve aortic portion to the left ventricular outflow tract (LVOT) portion exceeding 8:2

-Valve Sizing Strategy:

- Annulus-Based Strategy: Valve selection according to manufacturer-recommended dimensions based on annular measurements.
- Supra-Annular Strategy: Selection of undersized valves relative to recommended dimensions, considering supra-annular constraints.

-Small Valve Implantation: Defined as the use of a prosthetic valve with a labeled diameter ≤ 23 mm

Description of calcification characteristics

-**Cross-Sectional View:** Calcification location relative to the leaflets was categorized as:

- Left (anterior) leaflet calcification
- Right (posterior) leaflet calcification
- Commissural calcification

-**Longitudinal View:** Calcification was classified based on distance from the annular plane:

- Leaflet basal calcification: ≤ 5 mm above the annulus
- Leaflet superior margin (free edge) calcification: > 5 mm above the annulus
- LVOT calcification: ≤ 5 mm below the annulus

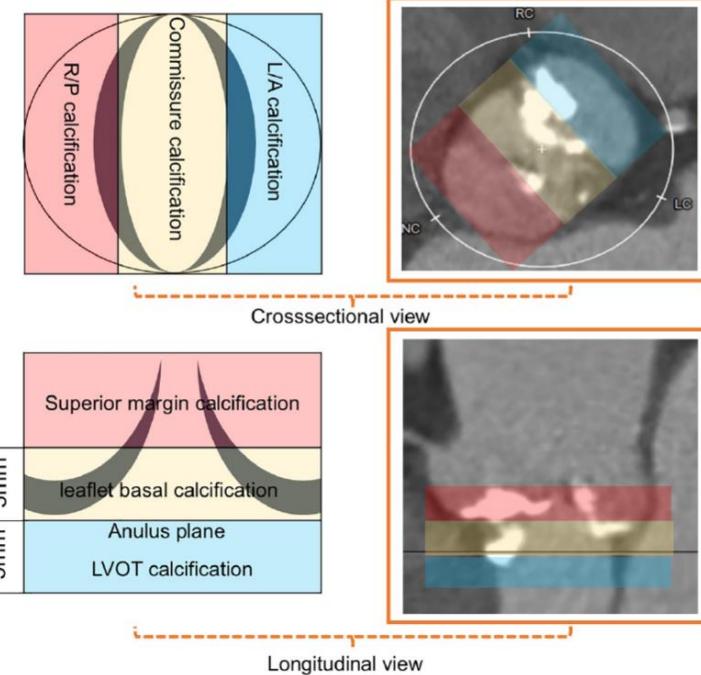


Fig. 1. Proposed qualitative assessment of calcification for Sievers type 0 BAV patients.

Results & baseline characteristics

	All patients(n=131)
Age (mean±SD)	69.8 ±7.5
Female (%)	62 (47.3)
BMI (mean±SD)	23.2 ±3.5
BSA (mean±SD)	1.7 ±0.2
NYHA class III/IV (%)	81 (61.9)
Smoker (n, %)	33 (25.2)
Hypertension (n, %)	48 (36.6)
Diabetes (n, %)	26 (20.0)
Hyperlipidemia (n, %)	25 (19.5)
Coronary artery disease (n, %)	36 (27.5)
Stroke history (n, %)	3 (2.3)
Permanent pacemaker implantation (n, %)	1 (0.8)

- Young AS population**
- Hypertension, diabetes mellitus, and coronary artery disease were the most prevalent comorbidities**
- Left ventricular ejection fraction (LVEF) was preserved in the majority of patients**

LVEDD (mean±SD)	48.4 ±6.9
LVEF (mean±SD)	59.3 ±10.9
Peak velocity (mean±SD)	4.8 ±1.1
Mean gradient (mean±SD)	60.0 ±20.2

Results & baseline characteristics

	All patients (n=131)
anulus mean (mean±SD)	24.7 ±2.5
Small annuli (n, %)	64 (48.9)
Annular perimeter (mean±SD)	78.2 ±7.8
Annular area (mean±SD)	476.1 ±99.2
LVOT perimeter (mean±SD)	80.1 ±9.6
LVOT area (mean±SD)	488.4 ±119.2
STJ mean diameter (mean±SD)	32.5 ±5.1
STJ height (mean±SD)	24.4±5.1
Left coronary height (mean±SD)	16.7±3.6
Right coronary height (mean±SD)	17.7±3.2
Ascending aorta mean diameter at 50mm (mean±SD)	42.5±5.7

- *Latero-lateral type was the predominant*
- *Concomitant ascending aortic dilatation was common*
- *Overall calcification burden was considerable*

Calcium volume (HU 850) (mean±SD)	912.2 ±1436.2
Latero-lateral type (n, %)	113 (86.3)
Severe calcification (n, %)	64 (48.9)
Leaflet upper half calcification (n, %)	82 (62.6)
Leaflet lower half calcification (n, %)	45 (34.4)
LVOT Calcification (n, %)	22 (16.8)
Commissure calcification (n, %)	38 (29.0)

Results & Procedure details

	All patients (n=131)
General anesthesia (n, %)	106 (80.9)
Transfemoral access (n, %)	131 (100.0)
Predilation (n, %)	109 (83.2)
Postdilation (n, %)	30 (22.9)
High Implantation (n, %)	105 (80.2)
Valve size (n, %)	
20	6 (4.6)
23	59 (45.0)
26	52 (39.7)
29	14 (10.7)
Oversize (%), mean±SD)	2.0 ± 12.0

- 80.2% patients received TAVR with High valve implantation depth**
- Nearly half (50.0%) received prostheses sized ≤23 mm**
- Annulus-based valve sizing was implemented in only 33.6% of cases**

Small valve implantation (≤23mm) (n, %)	65 (49.6)
Annular sizing	44 (33.6)
Post procedure peak velocity (mean±SD)	2.59 (1.08)
Post procedure mean gradient (mean±SD)	14.55 (6.84)

Results & Procedure Results

	All patients (n=131)
Surgery Conversion (n, %)	2 (1.5)
Annular rupture (n, %)	1 (0.8)
Valve Embolization (n, %)	0 (0)
Coronary obstruction (n, %)	1 (0.8)
Moderate PVL (n, %)	0 (0)
Second valve implantation	0 (0)
Major vascular complication (n, %)	1 (0.8)
Major Bleeding (n, %)	0 (0)
Technical success (n, %)	129 (98.5)

- *The overall technical success rate was 98.5%,*
- *2 cases conversion to surgery : one case of coronary obstruction and one case of annular rupture*
- *0 case of valve embolization or moderate/severe paravalvular regurgitation*

Results & 30-day outcomes

	All patients (n=131)
All-cause Mortality or disabling stroke (n, %)	1 (0.8)
All-cause Mortality	1 (0.8)
All Stroke (n, %)	4 (3.1)
Disabling stroke (n, %)	0 (0)
Pacemaker Implantation (n, %)	3 (2.3)

- *The mortality rate was 0.8%*
- *Four patients occurred Stroke, all of which were non-disabling*
- *Three permanent pacemaker implantations (PPI)*

Results & hemodynamic assessment

Post-procedure unfavorable hemodynamics were defined as a mean trans-valvular gradient greater than 15 mmHg measured by transthoracic echocardiography (TTE)

	Univariate	p	multivariate	p
Age	0.99 (0.94-1.04)	0.622	0.98 (0.89-1.07)	0.653
Male	1.69 (0.76-3.71)	0.190	0.54 (1.28-2.06)	0.383
BSA (per 1 dm² increase)	1.01 (0.99-1.03)	0.521	1.05 (1.01-1.10)	0.016
Latero-lateral type	1.13 (0.40-3.38)	0.819	0.43 (0.08-2.09)	0.288
Baseline mean gradient	1.02 (1.00-1.04)	0.093	1.02 (0.99-1.06)	0.167
Small valve implantation	3.64 (1.63-8.42)	0.002	22.3 (4.52-153.3)	<0.001
Postdilation	0.44 (0.16-1.15)	0.106	0.08 (0.01-0.44)	0.009
Supra-annular sizing	0.95 (0.41-2.16)	0.903	0.29 (0.05-1.48)	0.147
Severe calcification	1.07 (0.49-2.34)	0.871	0.48 (0.12-1.72)	0.263
STJ mean diameter	1.02 (0.94-1.10)	0.672	1.13 (1.01-1.29)	0.036
Oversize (per 1% increase)	0.98 (0.91-1.05)	0.548	0.95 (0.81-1.10)	0.484

Results & hemodynamic assessment

Patients receiving small-sized valves exhibited worse hemodynamics, particularly when severe calcification was present (mean gradient: 17.5 ± 9.1 mmHg)

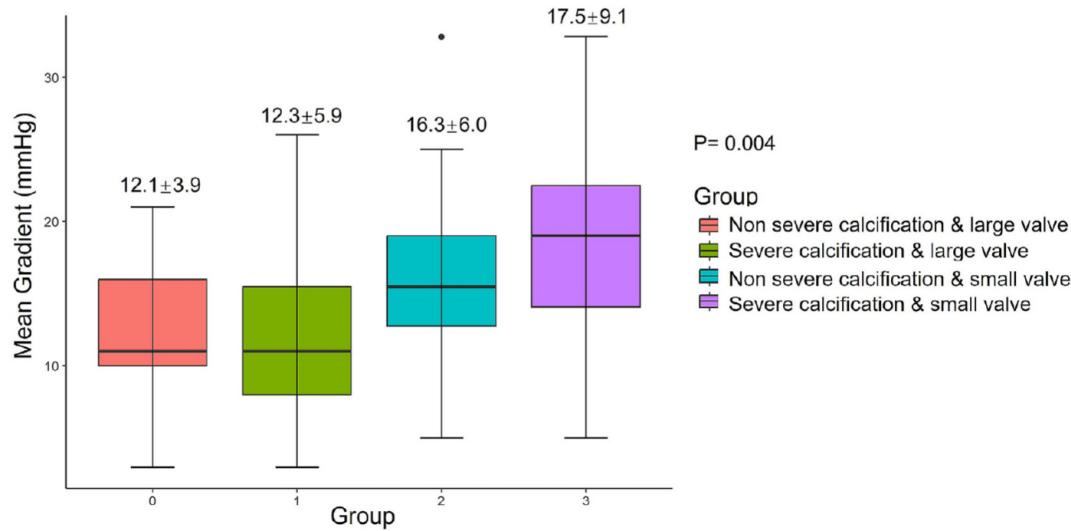


Fig. 2. Post-procedure mean gradients among patients with different morphological characteristics.

Results & hemodynamic assessment

Mean pressure gradient did not differ significantly between the two sizing strategy groups

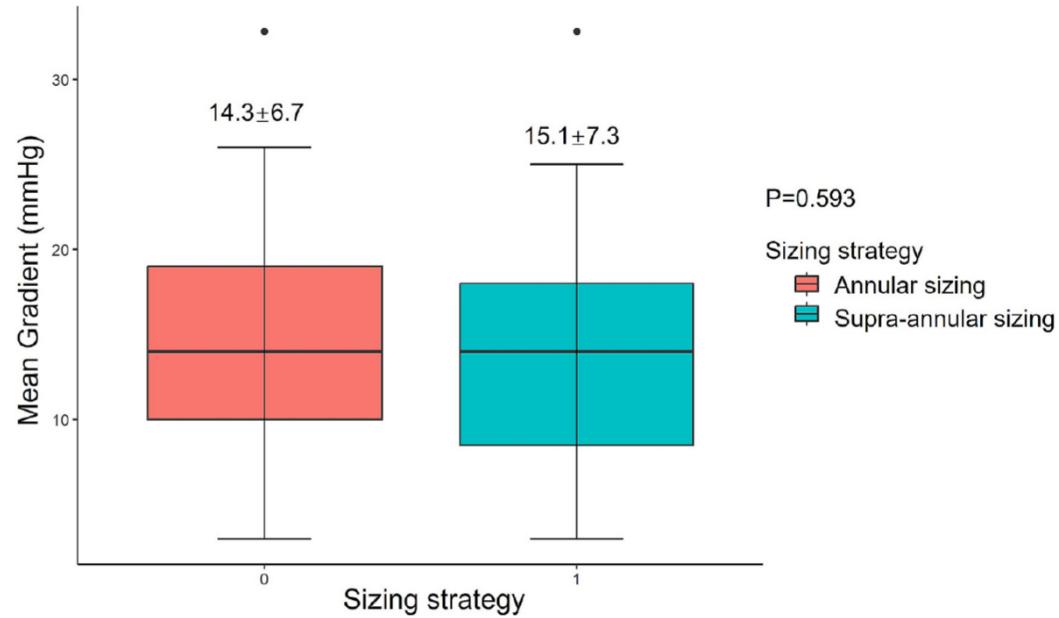


Fig. 3. Post-procedure mean gradients among patients with different sizing strategies.

Conclusion

- *The results demonstrate that BEV implantation in type-0 BAV patients achieved high levels of safety and efficacy, particularly regarding immediate technical success and reduced paravalvular regurgitation*
- *Regarding hemodynamic outcomes, implantation of a small sized valve was identified as the primary factor influencing postoperative hemodynamics, with severe calcification further exacerbating hemodynamic impairment in recipients of small valves*

Limitations

- *The sample size remains relatively limited. Validation of our conclusions requires future large-scale prospective cohort studies.*
- *The majority of enrolled patients underwent pre-procedural screening selection, caution is warranted when generalizing these findings to broader populations.*
- *The follow-up duration was relatively short, and the lack of 30-day postoperative echocardiographic data precludes a definitive assessment of hemodynamic changes following BEV implantation. Continued longitudinal follow-up of this cohort is planned to obtain more comprehensive data.*