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Background

A difficulty in treating patients with bicuspid aortic valve (BAV) is transcatheter heart valve (THV) sizing due to heterogeneity of bicuspid valve anatomy. In initial studies, this group had a higher rate of complication with more frequent aortic root injury and paravalvular leak (PVL).¹

THV sizing is routinely performed by following a recognised sizing algorithm based on CT-derived data. Complimentary to valve-sizing algorithms is the addition of individualised, patient-specific computer simulation using finite element modelling. This allows for prediction of PVL, conduction disturbance and may yield a different outcome when compared to an algorithmic sizing approach.

In this study we aimed to compare the results of the different algorithms in addition to computer modelling in a cohort of patients undergoing TAVI for BAV stenosis.

Methods

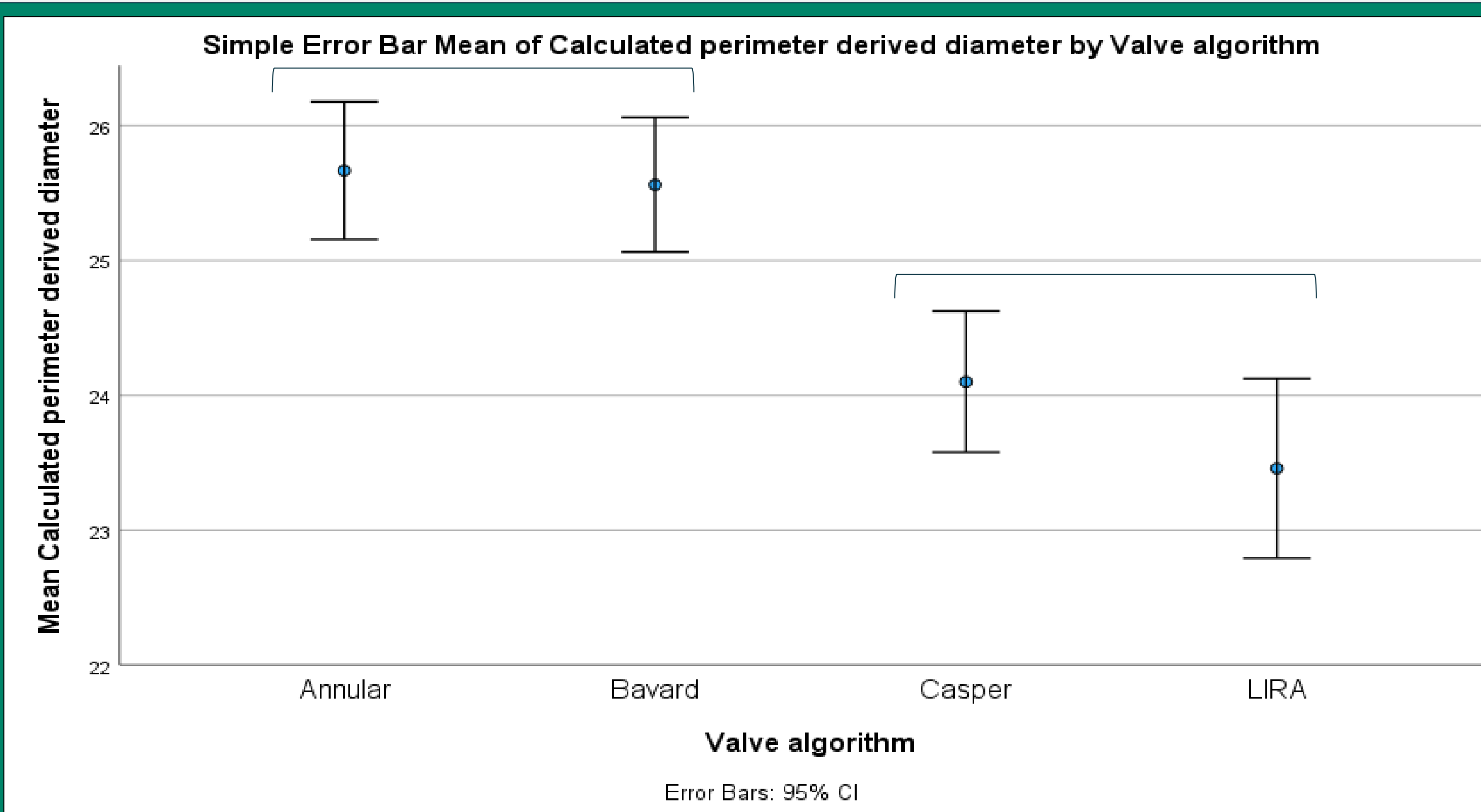
A retrospective study was performed on all patients assessed for transcatheter treatment of Sievers Type 1 BAV disease and who had undergone patient specific computer modelling using the FEops HEARTguide platform.

THV sizing was compared using an annular-based sizing algorithm and three BAV sizing algorithms; the Level of Implantation at the Raphe (LIRA), Calcium Algorithm Sizing for Bicuspid Evaluation with Raphe (CASPER) and Bicuspid Aortic Valve Anatomy and Relationship with Devices (BAVARD), yielding both an algorithm-derived diameter and a resulting valve size.²⁻⁴ THV selection was made using the Evolut self-expanding platform, therefore the circle method was not applied.

Patient-specific computer modelling was performed with FEops HEARTguide (FEops, nv, Ghent, Belgium) allowing the selection of the THV which gave the smallest predicted rate of paravalvular leak (PVL).

Baseline patient characteristics

| BASILINE CHARACTERISTICS | N = 73 |
|---|--------------|
| Age, years | 78.1±9.5 |
| male | 48/73 (65.8) |
| BMI, kg/m ² | 25.6±6.7 |
| NYHA class III or IV | 52/73 (71.2) |
| Diabetes Mellitus | 15/73 (20.5) |
| Known atrial fibrillation | 25/73 (34.2) |
| Left ventricular ejection fraction, % | 51±14.1 |
| EuroSCORE II, % | 3.5±3.1 |
| STS mortality, % | 2.9±1.6 |
| Presence of coronary artery disease | 11/73 (15.1) |
| Prior PCI | 8/73 (11.0) |
| Prior CABG | 0/73 (0) |
| prior PPM | 12/73 (16.4) |
| Values are mean±standard deviation or n/N (%) | |



Results

A total of 73 patients were included in this study.

The mean algorithm-derived diameter for each method was: annular 25.67 mm (25.16-26.18 mm), BAVARD 25.56 mm (25.05-26.06 mm), CASPER 24.1 mm (23.58-24.62 mm) and LIRA 23.46 mm (22.79-24.12 mm).

One-way ANOVA demonstrated a significant difference in algorithm-derived diameter ($p < 0.01$), with annular and BAVARD sizing giving a larger diameter than CASPER and LIRA.

THV sizing ranged from 23 mm to 34 mm valves. The mean THV size for annular sizing was 31.05 mm (30.34-31.77), BAVARD 30.99 mm (30.27-31.7 mm), FEops 30.27 mm (29.62-30.93 mm), CASPER 29.01 mm (28.34-29.68 mm) and LIRA 28.36 mm (27.58-29.13 mm)

One-way ANOVA showed a significant difference in THV sizing ($p < 0.01$), forming 3 groups; group 1: Annular, BAVARD and FEops, group 2: FEops and Casper, and group 3: CASPER and LIRA. Group 1 resulted in the largest THV size and group 3 the smallest.

In 74% of patients (n=54) there was variation in THV sizing across the different algorithms.

In 14.2% of patients (n=11) there was a difference of 2 THV sizes between algorithms.

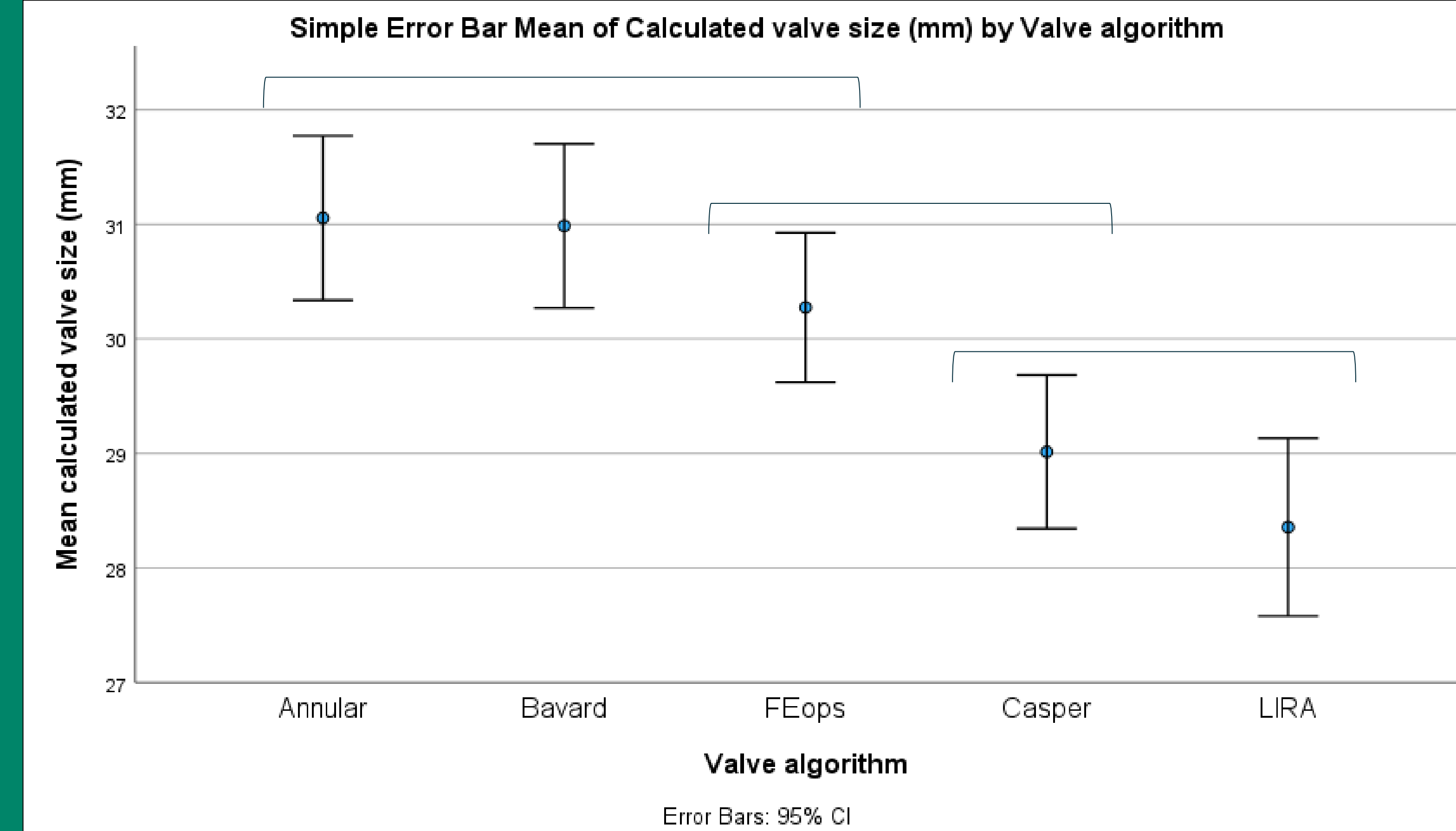
Conclusions

This study demonstrates that discrepancy in THV sizing is evident when applying different sizing algorithms and computer modelling for BAV. The application of different algorithms resulted in THV size variation in 74% of cases and a difference in 2 sizes in 14.2% of cases.

Larger THV sizes are implanted when using annular, BAVARD and patient-specific methods and smaller when applying CASPER and LIRA methods.

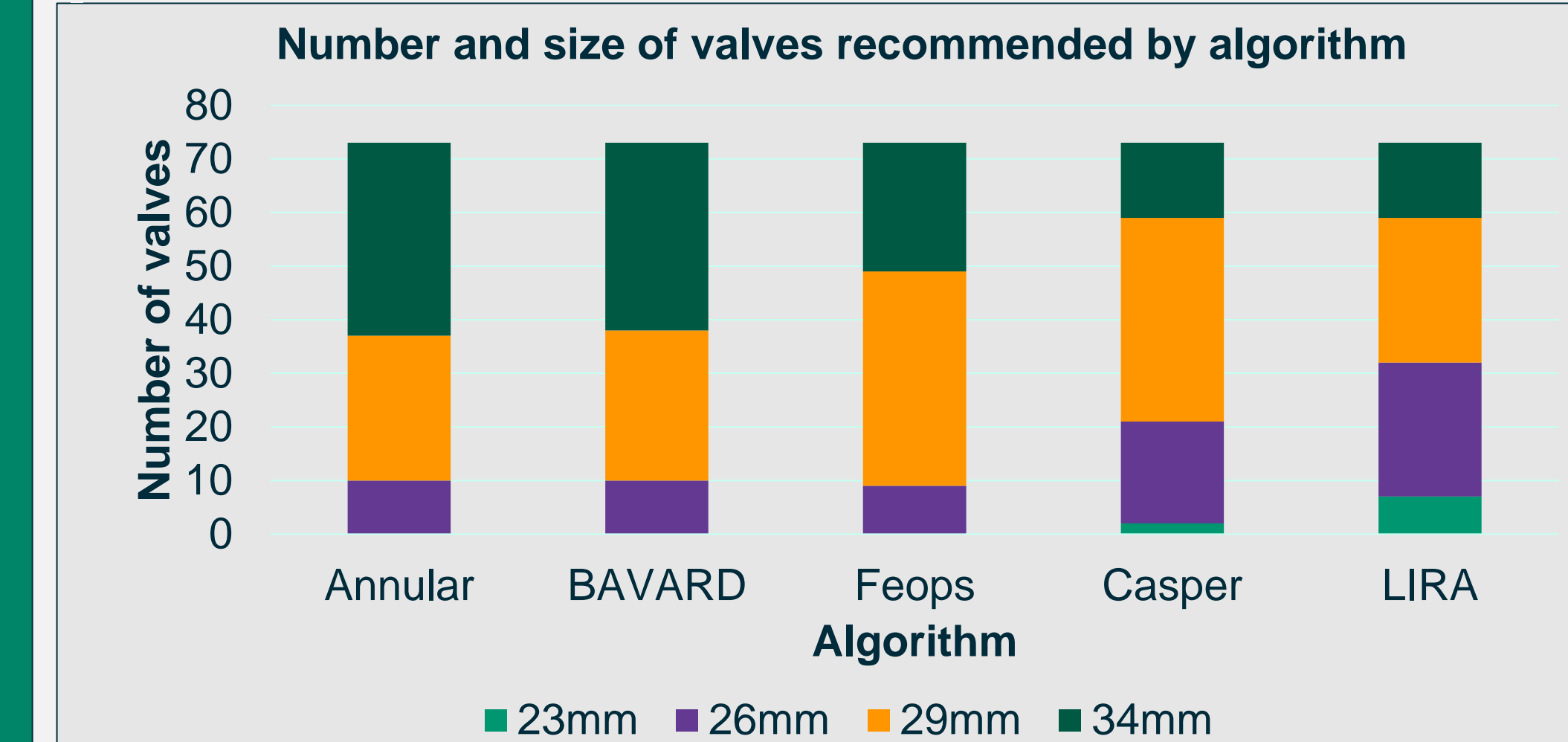
These size differences may affect long-term patient outcomes however a limitation is that this study has not focused on clinical outcomes following valve implantation.

Despite technological and procedural advances, meta-analyses have shown continued elevated complication rates in bicuspid aortic valve TAVI with increased risk of PVL and aortic root injury. It is hypothesised that improvements in valve-sizing could reduce these complications and warrants further investigation.



Results table 2

| CT ANALYSIS | N = 73 |
|---|---------------|
| Morphology | |
| R-N | 11/73 (15.1%) |
| R-L | 61/73 (83.6%) |
| N-L | 1/73 (1.37%) |
| Aortic annular area, mm ² | 498.2±99 |
| aortic annular perimeter derived diameter, mm | 25.67±2.19 |
| Inter-commisural distance, mm | 27.6±2.67 |
| calcium quantification, mm ³ | 699.3±548.2 |
| raphe length, mm | 11.86±2.93 |
| LIRA plane perimeter derived diameter, mm | 23.5±2.92 |
| Complete agreement in sizing | 19/73 (26%) |
| Variation in sizing recommendation | 54/73 (74%) |
| 2 or more difference in valve | 11/73 (14.2%) |
| Values are mean±standard deviation or n/N (%) | |



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Disclosures

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Figure 1: demonstrating a worked example of application of the different valve algorithms and patient-specific computer simulation

