

Conflict of Interest: None

7th Iranian Joint Cardiovascular Congress

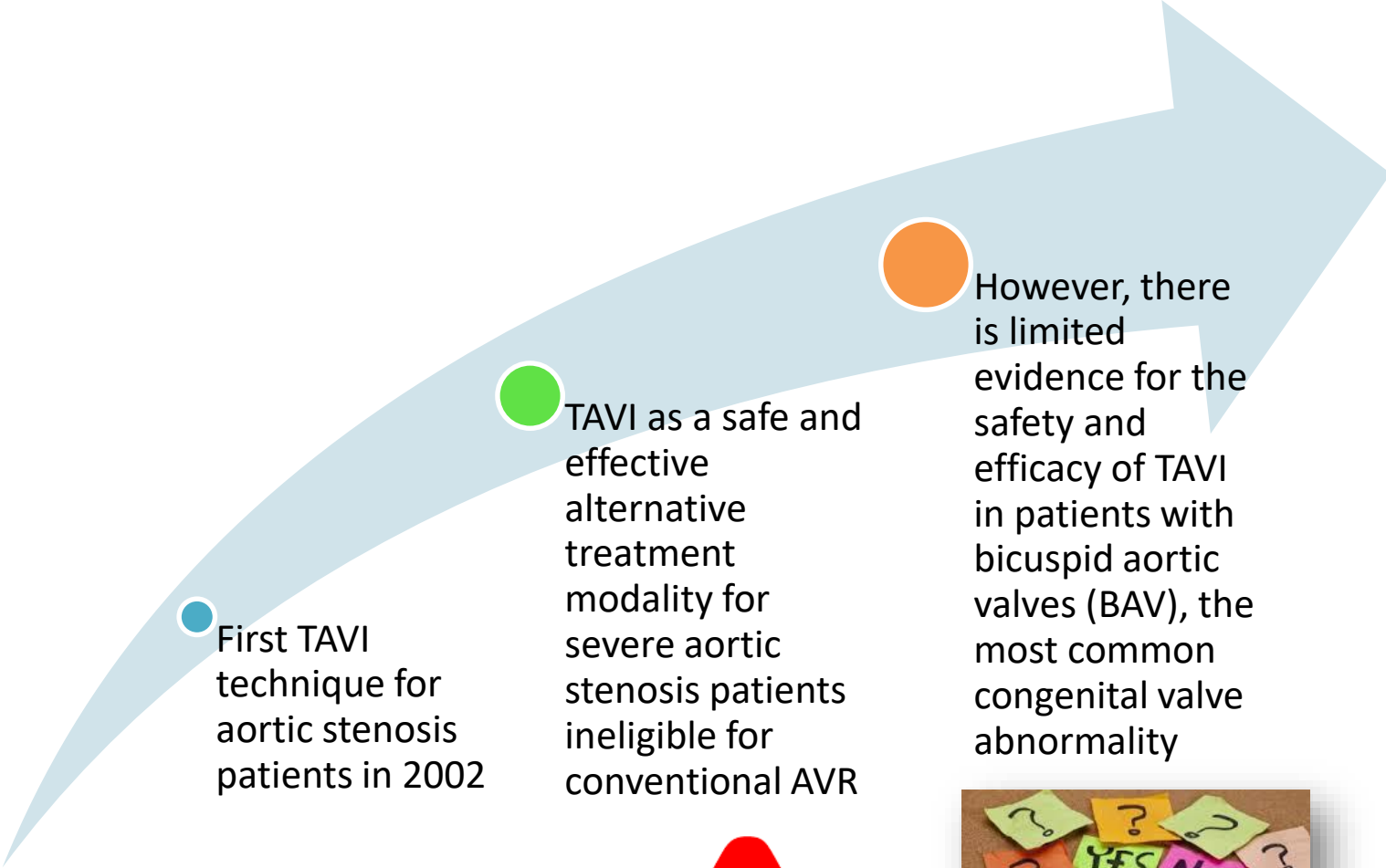
Bicuspid Aortic Valve

Any Room for TAVI?



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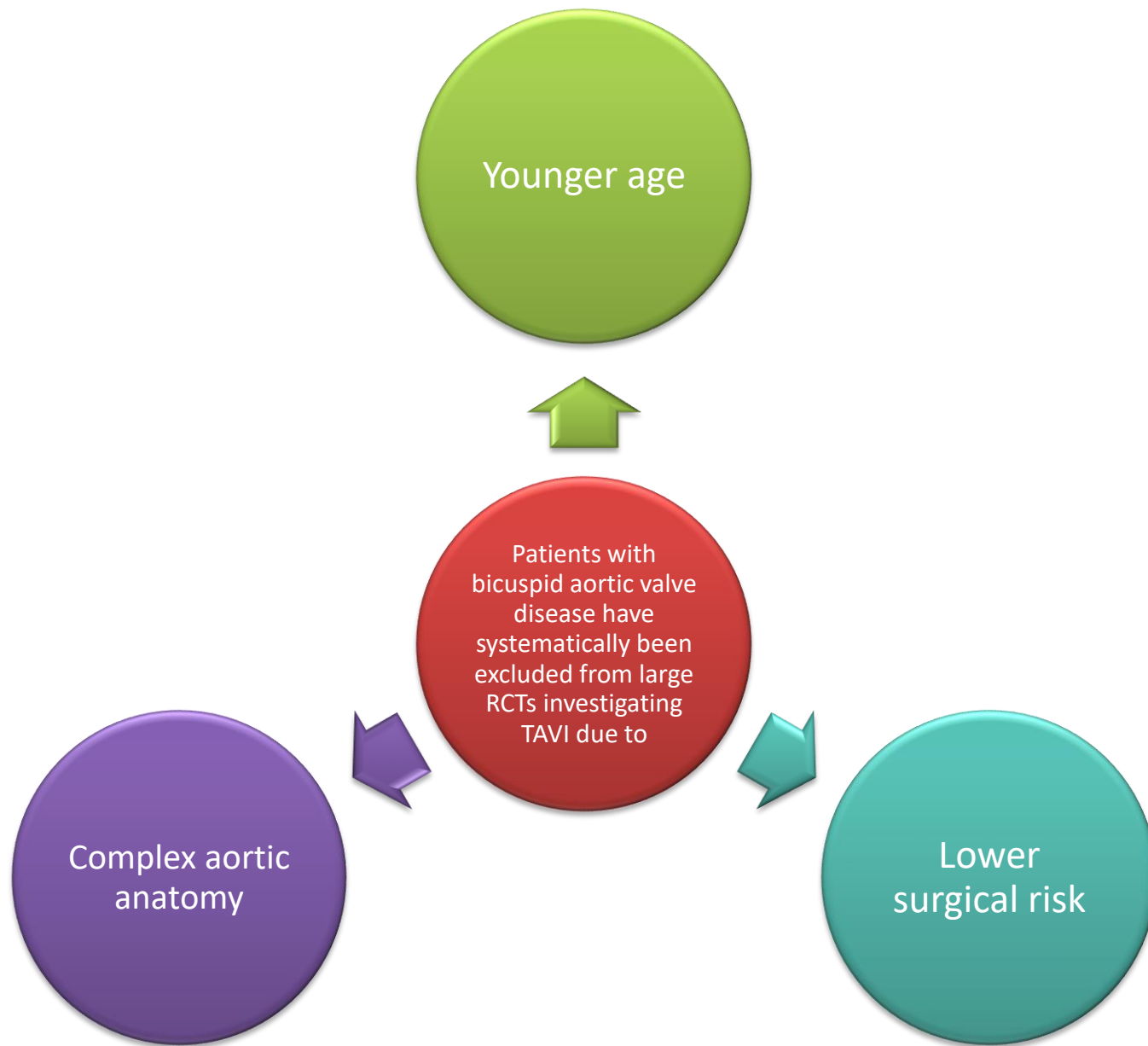
First TAVI
technique for
aortic stenosis
patients in 2002

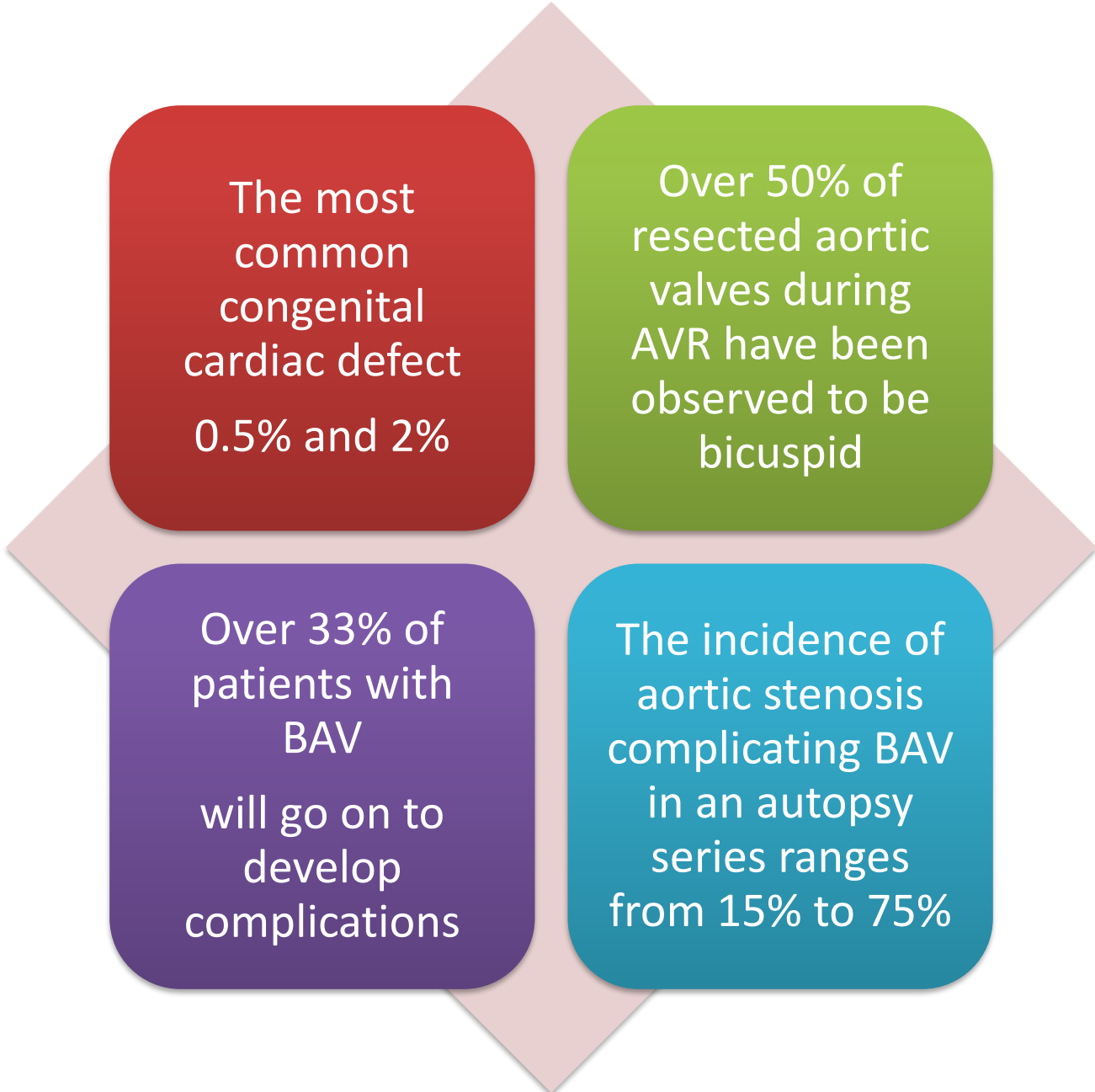
TAVI as a safe and
effective
alternative
treatment
modality for
severe aortic
stenosis patients
ineligible for
conventional AVR

However, there
is limited
evidence for the
safety and
efficacy of TAVI
in patients with
bicuspid aortic
valves (BAV), the
most common
congenital valve
abnormality

SAFE







The most
common
congenital
cardiac defect
0.5% and 2%

Over 50% of
resected aortic
valves during
AVR have been
observed to be
bicuspid

Over 33% of
patients with
BAV
will go on to
develop
complications

The incidence of
aortic stenosis
complicating BAV
in an autopsy
series ranges
from 15% to 75%



challenges

The asymmetric nature + heavy regional calcification

Positioning

expansion

Risk of TAVI-related complications

coronary occlusion

aortic dissection and annular rupture

Achilles Heel

PVL

PPM need



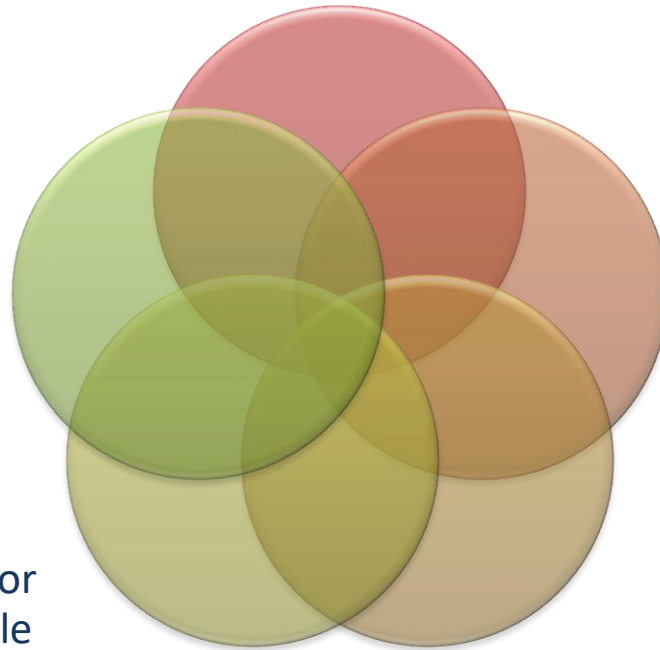
Surgical AVR Remains
the standard approach
with proven Durability
an safety for most
patients

Even for
Intermediate risk
group

TAVI is
Transformative

Good Alternative for
High risk inoperable
group

Cardiologist and
patients Want This



NEW Guidelines 2017

SAVR or TAVR for
patients at
Intermediate risk



CLASS II A



CLASS I

EDITORIAL COMMENT

Transcatheter Aortic Valve Replacement for Bicuspid Aortic Stenosis

Are We Ready for the Challenge?*

Raj Makkar, MD,^a Tarun Chakravarty, MD,^a Hasan Jilaihawi, MD^b



There will be **zero tolerance** for adverse outcomes with TAVR for bicuspid AS in intermediate and low-risk patients, as these patients continue to be excellent candidates for surgery.

As we await FDA approval of TAVR for the younger intermediate-risk population,

Start studies for low risk TAVR, the potential patient population with bicuspid AS requiring TAVR is likely to grow significantly.

The specific concerns regarding TAVR for BAV include:

specific concerns

1. An elliptically shaped annulus that may impair valve positioning and sealing.

2. Asymmetrical and heavy calcification of leaflets may impede valve expansion and valve hemodynamics

3. Presence of aortic disease increases the risk of dissection or rupture during valvuloplasty, post dilatation, or implantation of balloon-expandable valves.

4. Fused commissures are susceptible to disruption during balloon valvuloplasty, resulting in severe aortic regurgitation.

5. Underexpansion and/or a non-circular shape of the transcatheter heart valve may affect long-term durability.

1st



Transcatheter Aortic Valve Implantation in Patients With Bicuspid Aortic Valve Stenosis

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Vancouver, British Columbia, Quebec City, Quebec, and Hamilton, Ontario, Canada

Objectives We evaluated transcatheter aortic valve implantation (TAVI) in high-risk patients with bicuspid aortic valve (BAV) stenosis.

Background TAVI shows promise in the treatment of severe stenosis of tricuspid aortic valves, especially in high-risk patients. However, BAV stenosis has been considered a contraindication to TAVI.

Methods Eleven patients (age 52 to 90 years) with symptomatic severe BAV stenosis underwent TAVI at 3 Canadian tertiary hospitals between May 2006 and April 2010. All patients were considered high risk for surgical aortic valve replacement. Edwards-SAPIEN transcatheter heart valves (Edwards Lifesciences, Inc., Irvine, California) were used. Transfemoral or transapical access was selected, depending on the adequacy of femoral access.

Results Access was transfemoral in 7 patients and transapical in 4 patients. There were no intraprocedural complications. Significant symptomatic and hemodynamic improvement was observed in 10 of 11 patients. Baseline aortic valve area of $0.65 \pm 0.17 \text{ cm}^2$ and mean transaortic pressure gradient of $41 \pm 15 \text{ mmHg}$ were reduced to $1.5 \pm 0.4 \text{ cm}^2$ and $18 \pm 10 \text{ mmHg}$, respectively. All patients were discharged home on oral anticoagulation. Systemic embolism, stroke, or death was not observed. Valve regurgitation was mild to moderate in 10 patients and moderate to severe in 1 patient.

Conclusions TAVI in selected high-risk patients with severe BAV stenosis can be successfully performed with acceptable clinical outcomes but will require further evaluation. (J Am Coll Cardiol Intv 2010;3:1122–5) © 2010 by the American College of Cardiology Foundation

Sapien valves were implanted successfully in 11 patients,

significant haemodynamic improvement

However, 2 patients (18.2 %) had moderate paravalvular leak.

2 deaths at the 30-day

One conversion to open surgery.

Transcatheter Aortic Valve Implantation for Patients With Severe Bicuspid Aortic Valve Stenosis

Kentaro Hayashida, MD, PhD, FESC; Erik Bouvier, MD; Thierry Lefèvre, MD, FSCAI, FESC; Bernard Chevalier, MD, FSCAI, FESC; Thomas Hovasse, MD; Mauro Romano, MD; Philippe Garot, MD, FESC; Yusuke Watanabe, MD; Arnaud Farge, MD; Patrick Donzeau-Gouge, MD; Bertrand Cormier, MD; Marie-Claude Morice, MD, FESC

(*Circ Cardiovasc Interv.* 2013;6:284-291.)



21 patients with bicuspid AS

CoreValve (Medtronic) was used more frequently in the bicuspid AS group (47.6 % versus 16.3 %; $p=0.002$).

There was no significant difference in aortic regurgitation \geq grade 2 (19.0 % versus 14.9 %; $p=0.54$)

30-day mortality (4.8 % versus 8.2 %; $p=1.00$)

Device success rate (100 % versus 92.8 %; $p=0.37$).

Acceptable outcomes similar to those in non-BAV patients

Transcatheter Aortic Valve Replacement in Bicuspid Aortic Valve Disease



Darren Mylotte, MB, MD,*† Thierry Lefevre, MD,‡ Lars Søndergaard, MD,§ Yusuke Watanabe, MD,‡

Large cohort (n=139) of bicuspid aortic valve stenosis using the first-generation (Sapien [Edwards]; n=48) or self-expanding valves (CoreValve [Medtronic]; n=91).

Mean age was 78.0 ± 8.9 , and 56.1 % of patients were male with a mean Society of Thoracic Surgeons (STS) score of 4.9 ± 3.4 , indicating intermediate surgical risk.

The type of bicuspid aortic valve was available in 120 patients; type 0 in 26.7 %, type 1 in 68.3 %, and type 2 in 5.0 %.

Paravalvular leak \geq grade 2 occurred in 28.4 % of patients (19.6 % Sapien versus 32.2 % CoreValve; $p=0.11$).

A new pacemaker was implanted in 23.2 % of patients (16.7 % Sapien versus 26.7 % CoreValve; $p=0.21$).

One-year mortality was 17.5 %, without significant difference between the valves (20.8 % Sapien versus 12.5 % CoreValve; $p=0.12$).

TAV-in-BAV is feasible with encouraging short- and intermediate-term clinical outcomes

Bicuspid Aortic Valve Stenosis



Favorable Early Outcomes With a Next-Generation Transcatheter Heart Valve in a Multicenter Study

Gidon Y. Perlman, MD,^a Philipp Blanke, MD,^a Danny Dvir, MD,^a Gregor Pache, MD,^b Thomas Modine, MD,^c

TABLE 4 30-Day Clinical Events (N = 51)*

Mortality	2 (3.9)
Myocardial infarction	0 (0)
Stroke, total events	1 (1.9)
Disabling stroke	0 (0)
Nondisabling stroke	1 (1.9)
Bleeding, total events	14 (27.5)
Life-threatening	2 (3.9)
Major	3 (5.9)
Minor	9 (17.6)
Vascular complications, total events	7 (13.7)
Major	2 (3.9)
Minor	5 (9.8)
Acute kidney injury ≥ 2	1 (1.9)
New permanent pacemaker†	12 (23.5)
Device 30-day safety endpoint	6 (11.7)



Transcatheter Aortic Valve Implantation (TAVI) in Patients With Bicuspid Aortic Valve Stenosis – Systematic Review and Meta-Analysis

Kevin Phan^{a,c,d,e}, Sophia Wong^b, Steven Phan^c, Hakeem Ha^d,
Pierre Qian^e, Tristan D. Yan^{a,f*}

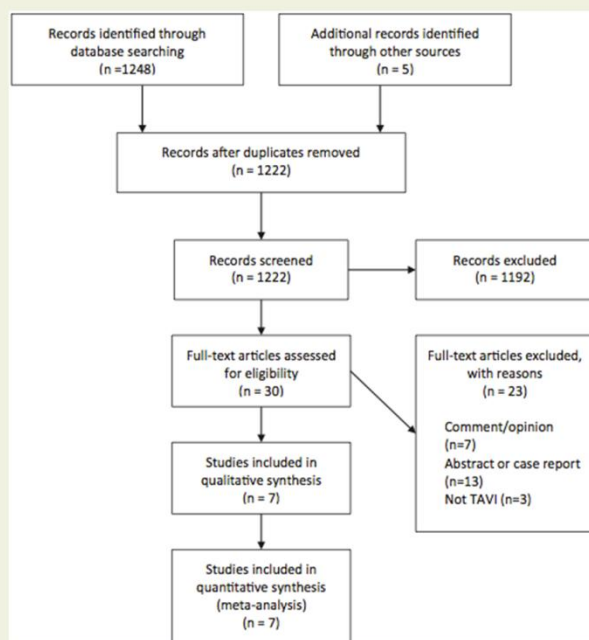


Figure 1 PRISMA flow-chart for systematic literature search of studies investigating transcatheter aortic valve implantation in patients with bicuspid aortic valves.

30 day Mortality 1 year Mortality

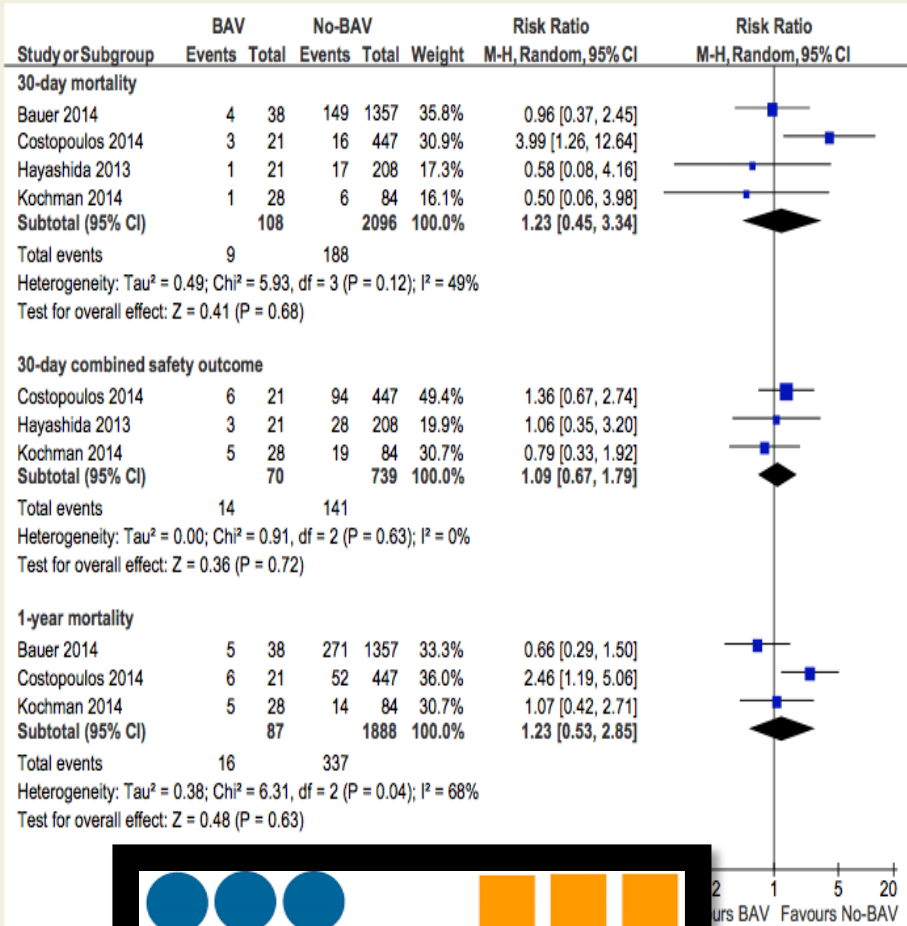


Figure 2 Forest plot showing summary relative risk (RR) using a scale where values between 0.5 and 2.0 indicate no significant difference, and values outside this range indicate a significant difference.

Post op TAMG

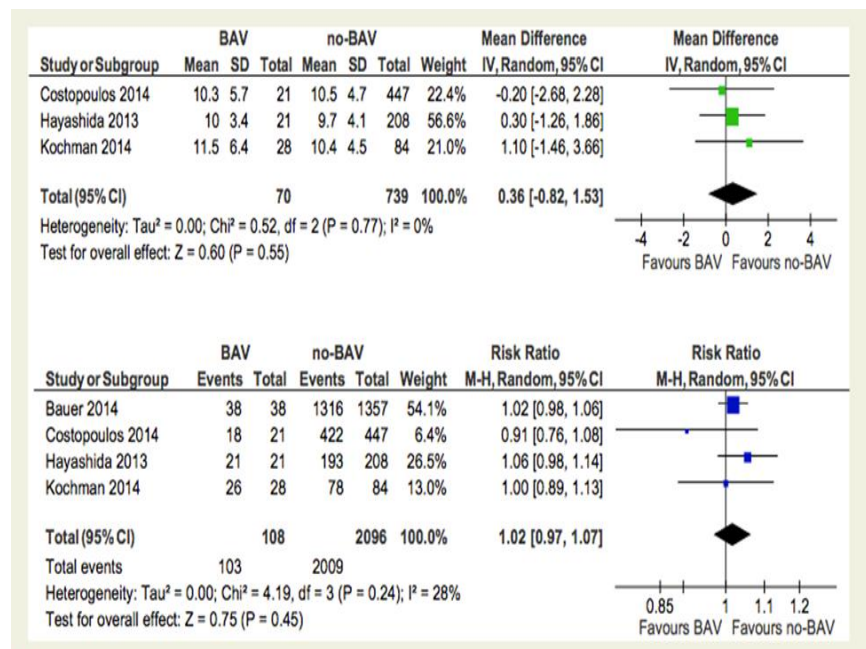
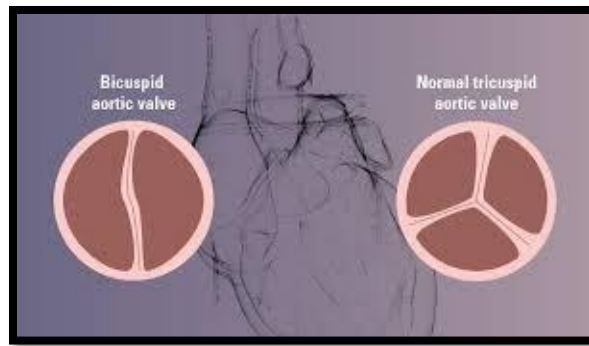


Figure 3 Forest plot showing summary relative risk (RR) using a scale where values between 0.85 and 1.2 indicate no significant difference, and values outside this range indicate a significant difference.



No difference in Short term mortality (8.3% & 9%)

Success rate

Conversion to open Surgery

No difference in Long term mortality (18.4% & 17.8%)

PPM

Major Bleeding



Study limitations

TAVI in BAV is

Feasible
Safe & Efficacious
In Selected patients

Small sample sizes of the BAV cohorts

Lack of randomization

Lack of long-term safety and durability data

Heterogeneity of TAVI prosthesis and routes

Heterogeneity of BAV types (functional bicuspid valves rather than true bicuspid disease).

Bicuspid Aortic Valve Stenosis

Favorable Early Outcomes With a Next-Generation Transcatheter Heart Valve in a Multicenter Study



Gidon Y. Perlman, MD,^a Philipp Blanke, MD,^a Danny Dvir, MD,^a Gregor Pache, MD,^b Thomas Modine, MD,^c

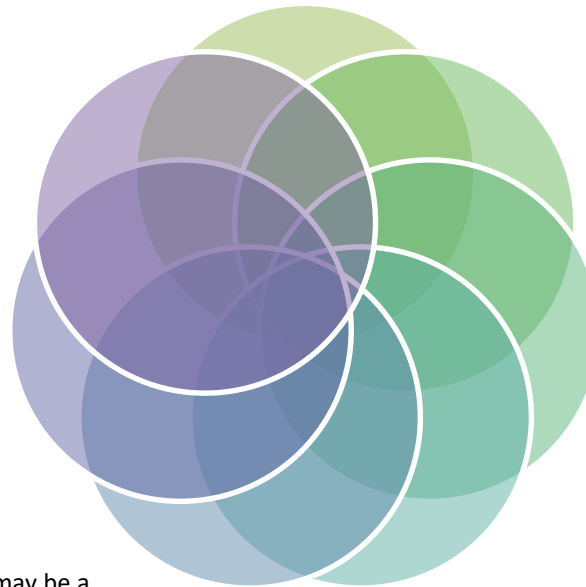
A 51 new-generation balloon-expandable valve (Sapien 3)

Future studies can clarify the association of valve haemodynamics and selection of device size.

None had second valve implantation or paravalvular leak \geq moderate.

However less oversized devices could be a potential cause of future deterioration in valve function.

PPM need in 23.5 %, a relatively higher rate than in tricuspid AS.



Less oversized devices may be a reasonable option because of no moderate or greater paravalvular leak was observed in this study, and the fact that using more oversizing devices may carry the risk of annulus rupture or aortic injury,

Less oversized devices (area oversizing $<$ 10 %) tended to have more frequent paravalvular leak $>$ mild (48%)



Original article

The feasibility of transcatheter aortic valve implantation using the Edwards SAPIEN 3 for patients with severe bicuspid aortic stenosis

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ABSTRACT

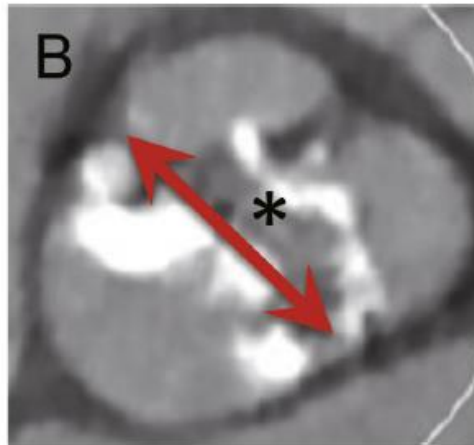
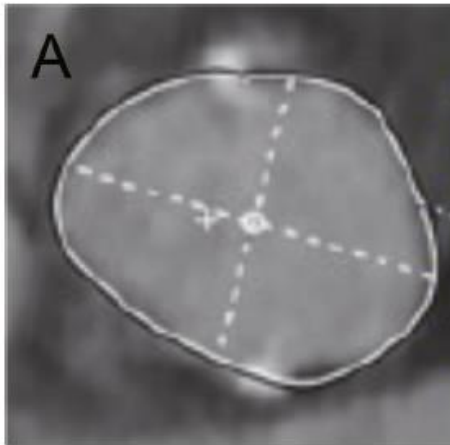
Background: There are currently only limited data focusing on transcatheter aortic valve implantation (TAVI) for bicuspid aortic valves (BAV) patients using the Edwards SAPIEN (Irvine, CA, USA) 3 (S3) valve. The aim of this study was to evaluate the feasibility and efficacy of TAVI using the S3 in patients with BAV.

Methods: A total of 153 TAVI cases performed with the S3 were included. BAV was detected by multidetector computed tomography (MDCT) in 10 (7%) patients. The other patients had tricuspid aortic valves (TAV). The BAV and TAV groups were compared.

Results: Patient age and logistic EuroSCORE were similar in the BAV and TAV groups. The calculated annulus average diameter (CAAD) by MDCT was significantly larger in the BAV group (26.5 mm vs 23.7 mm, $p = 0.036$) as was the annular area by MDCT (562 mm² vs 446 mm², $p = 0.033$). On the other hand, the valve diameter/CAAD ratio was significantly lower in the BAV group (1.01 vs 1.06, $p = 0.010$) as was the annular area oversizing percentage (3% vs 11%, $p = 0.033$). There were no significant differences between the two groups regarding the frequency of paravalvular aortic leakage (PVL) ≥ 2 (0% vs 6%, $p = 0.492$) and the 30-day mortality rate (0% vs 1%, $p = 0.799$).

Conclusions: Although TAVI for BAV tended to be carried out with a less oversized valve compared to TAVI for TAV, the frequency of post-procedural PVL ≥ 2 was similarly low in the two groups. TAVI using the S3 in patients with BAV seems to be feasible.

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A total of 153 TAVI cases performed with the S3

Table 1
Baseline clinical characteristics.

	BAV (n = 10)	TAV (n = 143)	p-value
Baseline characteristics			
Age, years	81.3 ± 5.1	82.6 ± 6.2	0.547
Gender, male	6 (43%)	7 (7%)	0.046
BMI (kg/m ²)	24.6 ± 5.2	26.5 ± 5.4	0.316
BSA (m ²)	1.57 ± 0.61	1.74 ± 0.22	0.439
NYHA classification (III/IV)	9 (90%)	142 (99%)	0.723
Prior PCI, n	1 (10%)	21 (15%)	0.731
Prior CABG, n	1 (10%)	9 (6%)	0.575
Prior stroke, n	1 (10%)	1 (1%)	0.409
Diabetes mellitus, n	2 (20%)	37 (26%)	0.809
Hypertension, n	8 (80%)	100 (70%)	0.138
Dyslipidemia, n	3 (30%)	66 (46%)	0.475
COPD, n	0 (0%)	3 (3%)	0.663
Logistic EuroSCORE, %	19.0 ± 12.5	18.1 ± 11.0	0.840
Creatinine clearance (ml/min)	54.0 ± 26.7	62.5 ± 29.4	0.402
Echocardiographic data			
LVEF, %	52.6 ± 18.5	56.4 ± 13.0	0.566
AVA (cm ²)	0.67 ± 0.16	0.65 ± 0.14	0.707
Mean gradient (mmHg)	46.4 ± 20.0	48.3 ± 13.5	0.789
AR grade (0–4)	1.00 ± 0.86	1.02 ± 0.57	0.912
PAP (mmHg)	41.2 ± 18.6	44.2 ± 14.3	0.576

Table 3

Post-procedural characteristics.

	BAV (n = 10)	TAV (n = 143)	p-value
Post-procedural variables			
Procedural success	10 (100%)	141 (98%)	0.737
30 day mortality	0 (0%)	1 (1%)	0.799
30 day combined safety endpoint	0 (0%)	9 (7%)	0.462
Major stroke	0 (0%)	0 (0%)	–
AKI	0 (0%)	2 (2%)	0.736
Major vascular complication	1 (10%)	7 (5%)	0.425
Life-threatening bleeding	0 (0%)	1 (1%)	0.813
Annulus rupture	0 (0%)	1 (1%)	0.813
Pacemaker implantation	0 (0%)	12 (8%)	0.394
2 valve implantation	0 (0%)	1 (1%)	0.813
Post AR \geq grade 2	0 (0%)	8 (6%)	0.492

Values are number (%) or mean \pm SD.
BAV, bicuspid aortic valve; TAV, tricuspid aortic valve; AKI, acute kidney injury; AR, aortic regurgitation.

Retrospective observational study

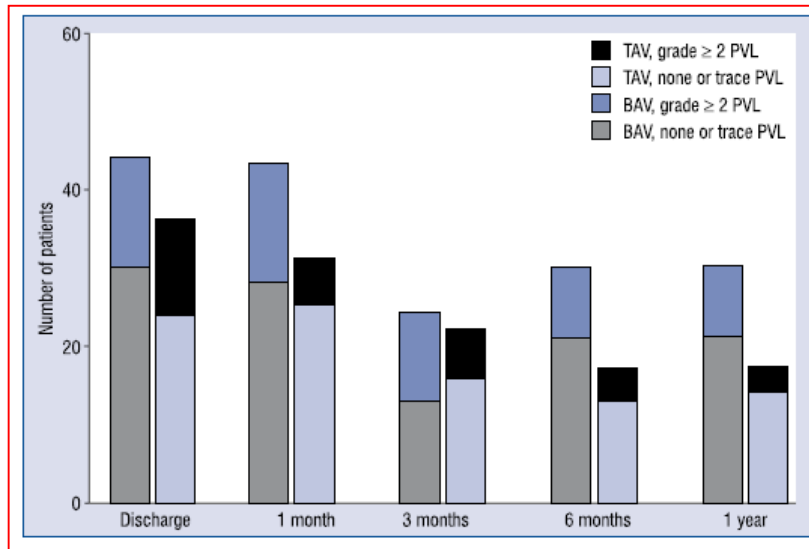
Mean follow-up period was 41 days

85
 patients
 Corevalve

Hemodynamic changes after transcatheter aortic valve implantation during sequential follow-ups in patients with bicuspid aortic valve compared with tricuspid aortic valve

Tian-Yuan Xiong, Ming-Xia Zheng, Xin Wei, Yi-Jian Li, Yan-Biao Liao, Zhen-Gang Zhao, Yuan-Ning Xu, Hong Tang, Yuan Feng, Mao Chen

Department of Cardiology, West China Hospital, Sichuan University, China



In this cohort, BAV does not seem to alter hemodynamic changes when compared with its TAV counterparts after TAVI with the self-expanding THV

ORIGINAL INVESTIGATIONS

Outcomes in Transcatheter Aortic Valve Replacement for Bicuspid Versus Tricuspid Aortic Valve Stenosis



Sung-Han Yoon, MD,^a Sabine Bleiziffer, MD,^b Ole De Backer, MD,^c Victoria Delgado, MD,^d Takahide Arai, MD,^e

546 pairs of patients with bicuspid and tricuspid AS
were created for propensity matched score

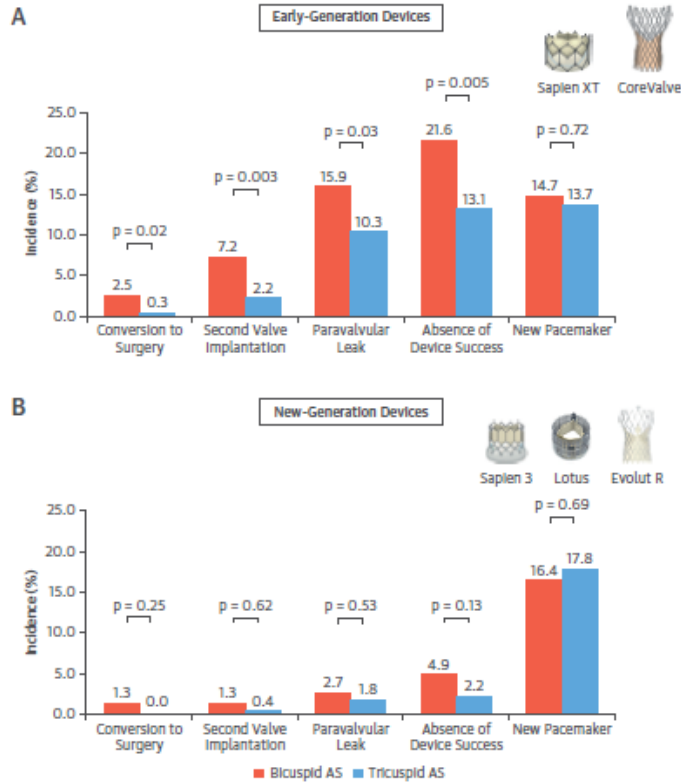
TABLE 2 Procedural and Clinical Outcomes

	Propensity Score Matched Cohort			
	Bicuspid AS (n = 546)	Tricuspid AS (n = 546)	p Value	OR (95% CI)
Procedural outcomes				
Procedure-related death	7 (1.3)	6 (1.1)	>0.99	1.17 (0.39-3.47)
Conversion to surgery	11 (2.0)	1 (0.2)	0.006	11.00 (1.42-85.20)
Coronary obstruction	5 (0.9)	3 (0.5)	0.73	1.67 (0.40-6.97)
Aortic root injury	9 (1.6)	0 (0.0)	0.004	–
Implantation of 2 valves	26 (4.8)	8 (1.5)	0.002	3.71 (1.61-8.56)
New permanent pacemaker	84 (15.4)	84 (15.4)	>0.99	1.00 (0.72-1.39)
Echocardiographic findings				
Mean gradient, mm Hg	10.8 ± 6.7	10.2 ± 4.4	0.18	
LVEF, %	54.2 ± 13.6	54.7 ± 13.9	0.79	
Moderate or severe paravalvular leak	57 (10.4)	37 (6.8)	0.04	1.61 (1.04-2.48)
Device success	466 (85.3)	499 (91.4)	0.002	0.54 (0.37-0.80)
All-cause mortality				
All-cause mortality	20 (3.7)	18 (3.3)	0.87	1.11 (0.59-2.10)
Stroke				
Stroke	16 (2.9)	10 (1.8)	0.33	1.60 (0.73-3.53)
Nondisabling				
Nondisabling	7 (1.3)	6 (1.1)	>0.99	1.17 (0.39-3.47)
Disabling				
Disabling	9 (1.6)	4 (0.7)	0.27	2.25 (0.69-7.31)
Bleeding				
Major				
Major	20 (3.7)	22 (4.0)	0.88	0.91 (0.50-1.67)
Life-threatening				
Life-threatening	11 (2.0)	19 (3.5)	0.20	0.58 (0.28-1.22)
Major vascular complication				
Major vascular complication	16 (2.9)	16 (2.9)	>0.99	1.00 (0.50-2.00)
Acute kidney injury (stage 2 or 3)				
Acute kidney injury (stage 2 or 3)	11 (2.0)	5 (0.9)	0.21	2.20 (0.77-6.33)

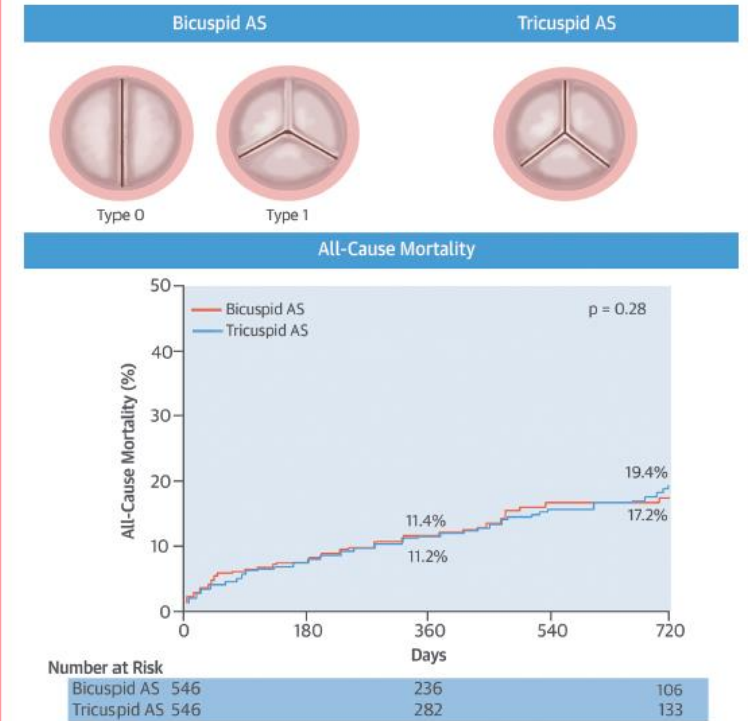
Values are n (%) or mean ± SD, unless otherwise indicated.

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

FIGURE 2 Procedural Outcomes in Bicuspid and Tricuspid AS With Early- and New-Generation Devices



CENTRAL ILLUSTRATION TAVR for Bicuspid Versus Tricuspid Aortic Valve Stenosis



Yoon, S.-H. et al. *J Am Coll Cardiol*. 2017;69(21):2579-89.

(Top) Schematic presentations of bicuspid and tricuspid aortic valves. Type 0 and 1 indicate bicuspid aortic valve with no raphe, and 1 raphe, respectively. (Bottom) Cumulative all-cause mortality rates in patients with bicuspid AS (orange) and tricuspid AS (blue) in a propensity score matched cohort. Event rates were compared using the win ratio test. AS = aortic valve stenosis.

CONCLUSION

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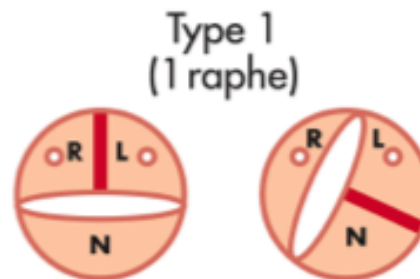
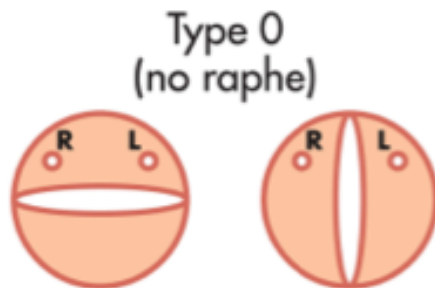
Compared with tricuspid AS, TAVR in bicuspid AS was associated with a similar prognosis, but lower device success rate.

Procedural differences were observed in early-generation devices,

no differences were observed in new-generation devices.

Dose the BAV type affect the outcome?

CLASSIFICATION SYSTEMS FOR BICUSPID AORTIC VALVE DISEASE Sievers and Schmidtke;



higher rates of PVL
in Sievers type 1
morphology
(34.2%) than in
Sievers type 0
(13.3%)

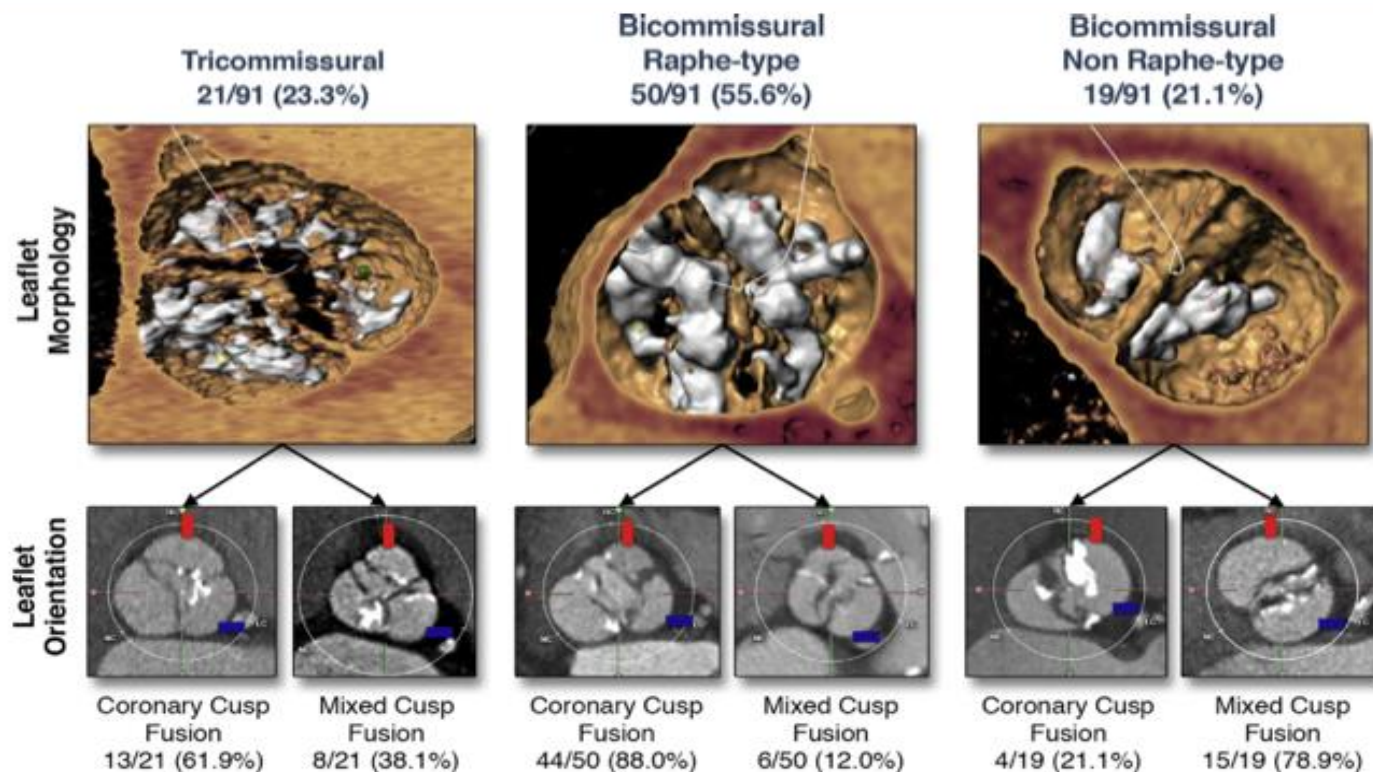
FIGURE 2 | The Sievers and Schmidtke classification system for bicuspid aortic valve [Adapted from Sievers et al. (33)].

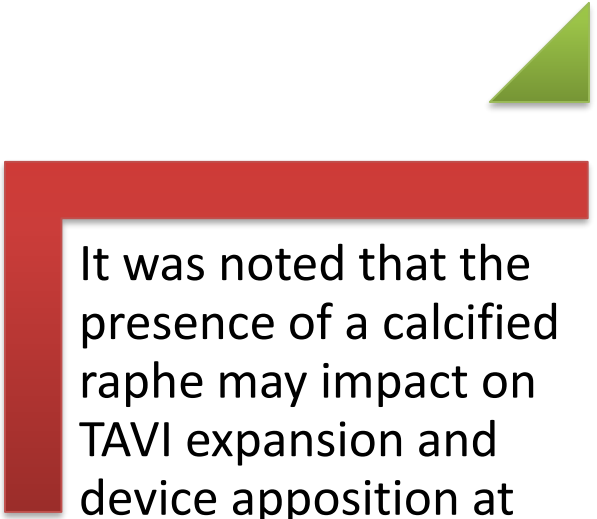
A Bicuspid Aortic Valve Imaging Classification for the TAVR Era



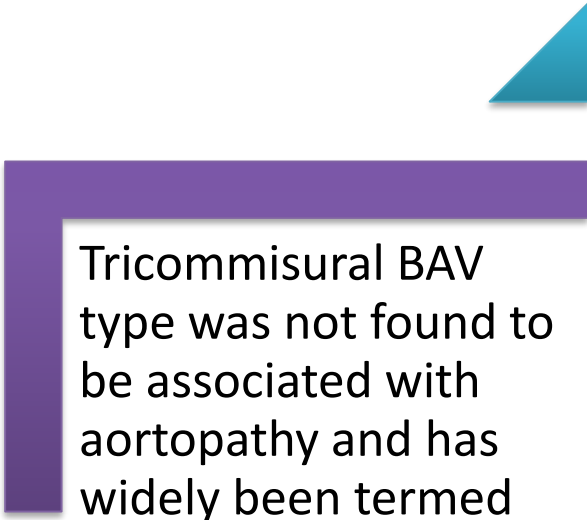
Hasan Jilalihawi, MD,^a Mao Chen, MD,^b John Webb, MD,^c Dominique Himbert, MD,^d Carlos E. Ruiz, MD,^e

FIGURE 1 Proposed TAVR-Specific BAV Classification

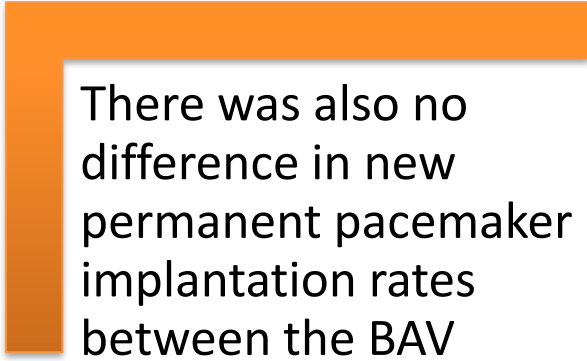




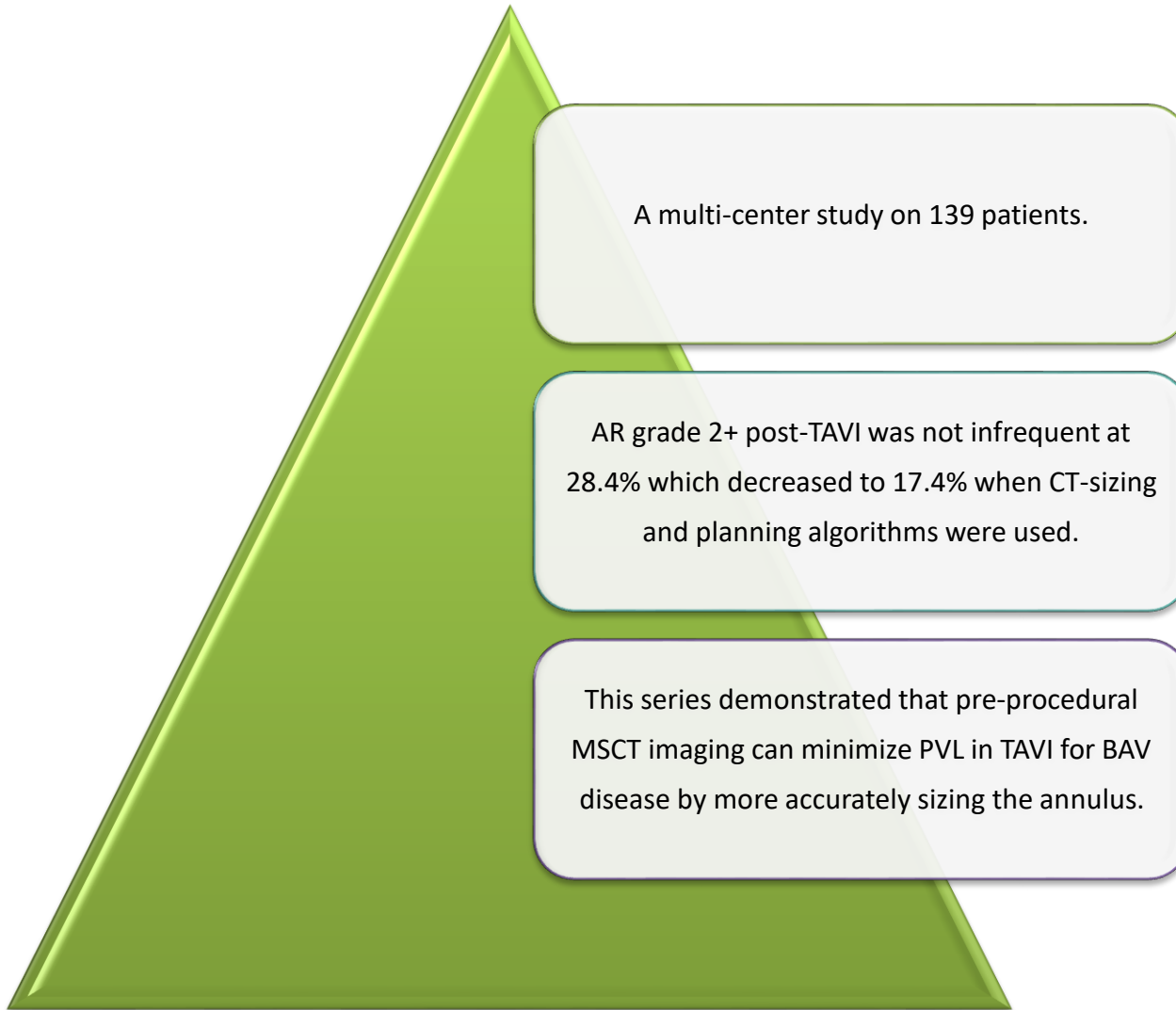
It was noted that the presence of a calcified raphe may impact on TAVI expansion and device apposition at the annulus.



Tricommissural BAV type was not found to be associated with aortopathy and has widely been termed functional or acquired BAV disease



There was also no difference in new permanent pacemaker implantation rates between the BAV subtypes.



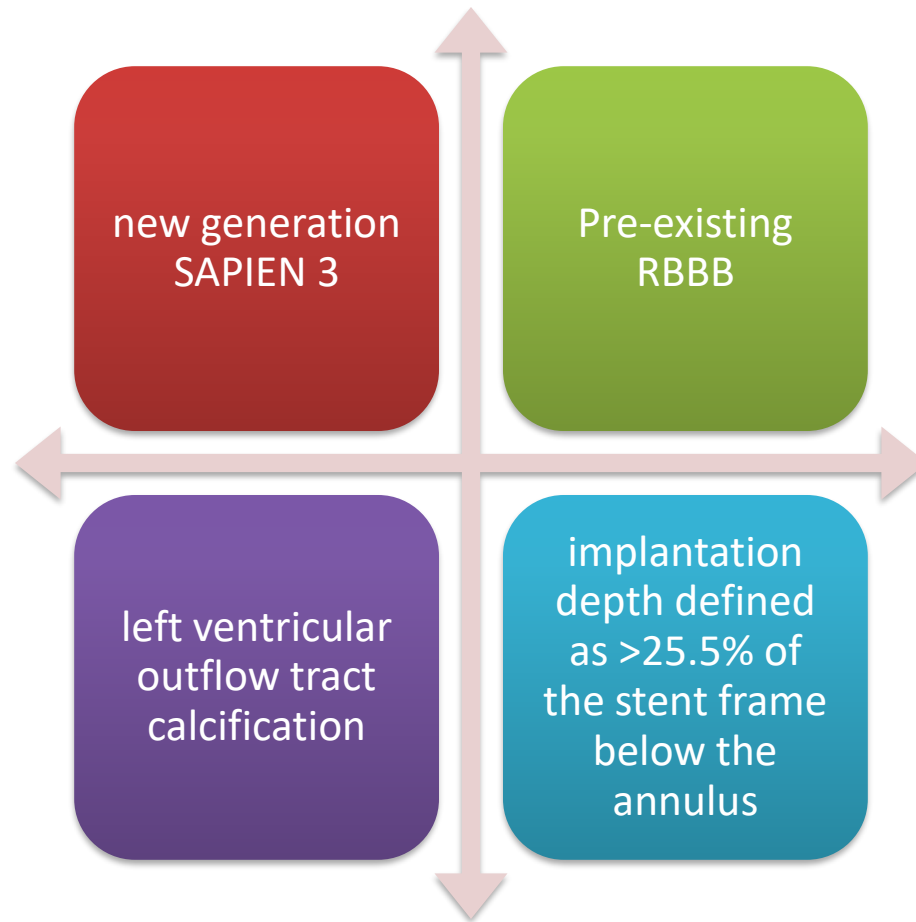
PROSTHESIS CHOICE IN BICUSPID VALVE?!

Balloon-expandable valves have greater radial force and may circularize the native annulus minimizing potential sites for paravalvular leaks.

A greater incidence of PVL ≥ 2 with self-expanding valves (19.6% with Sapien XT and 32.2% with CoreValve).

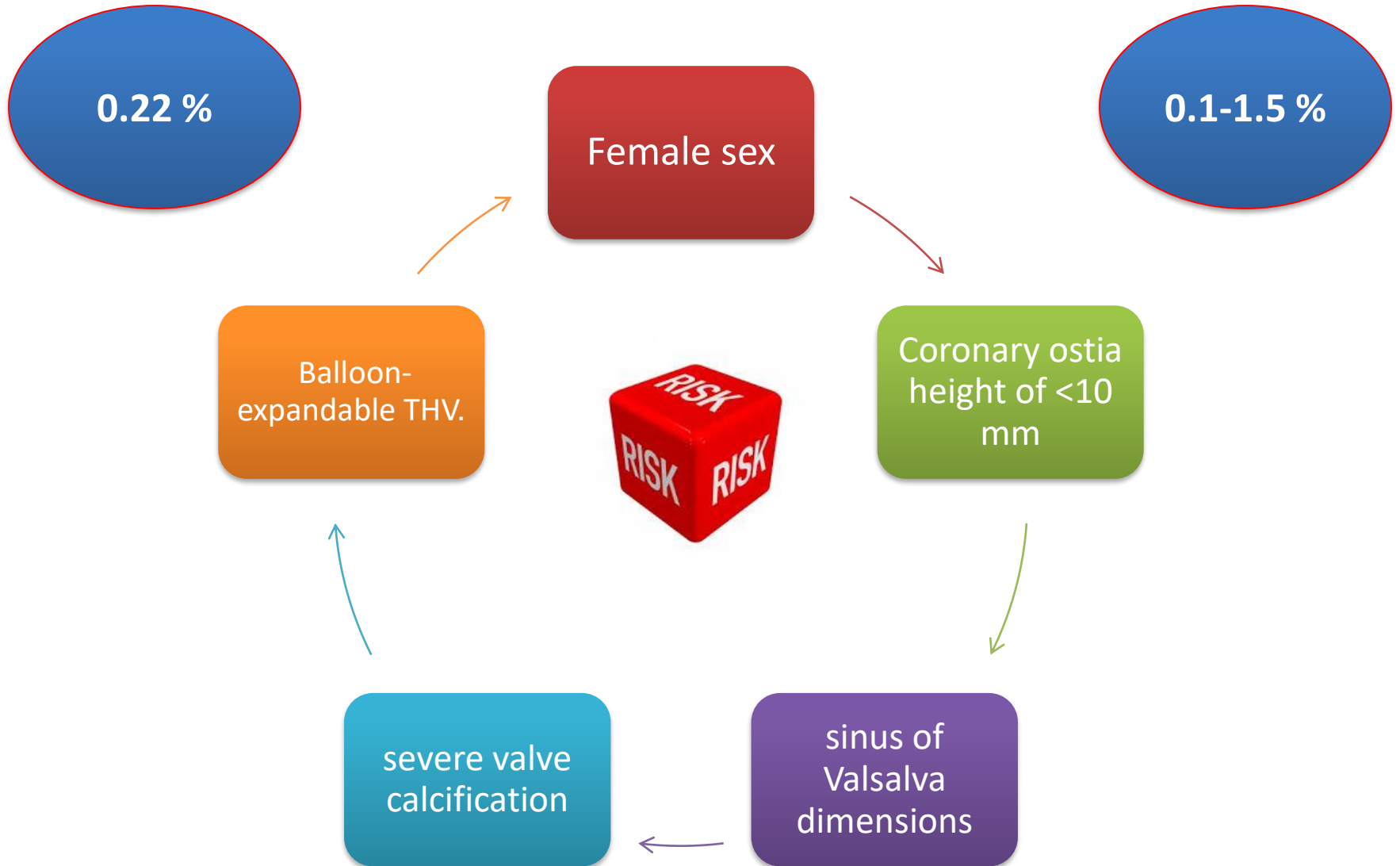
Conversely, no significant differences between the new generation

Predictors for New PPM



Balance these with the risk of THV embolization with higher implants

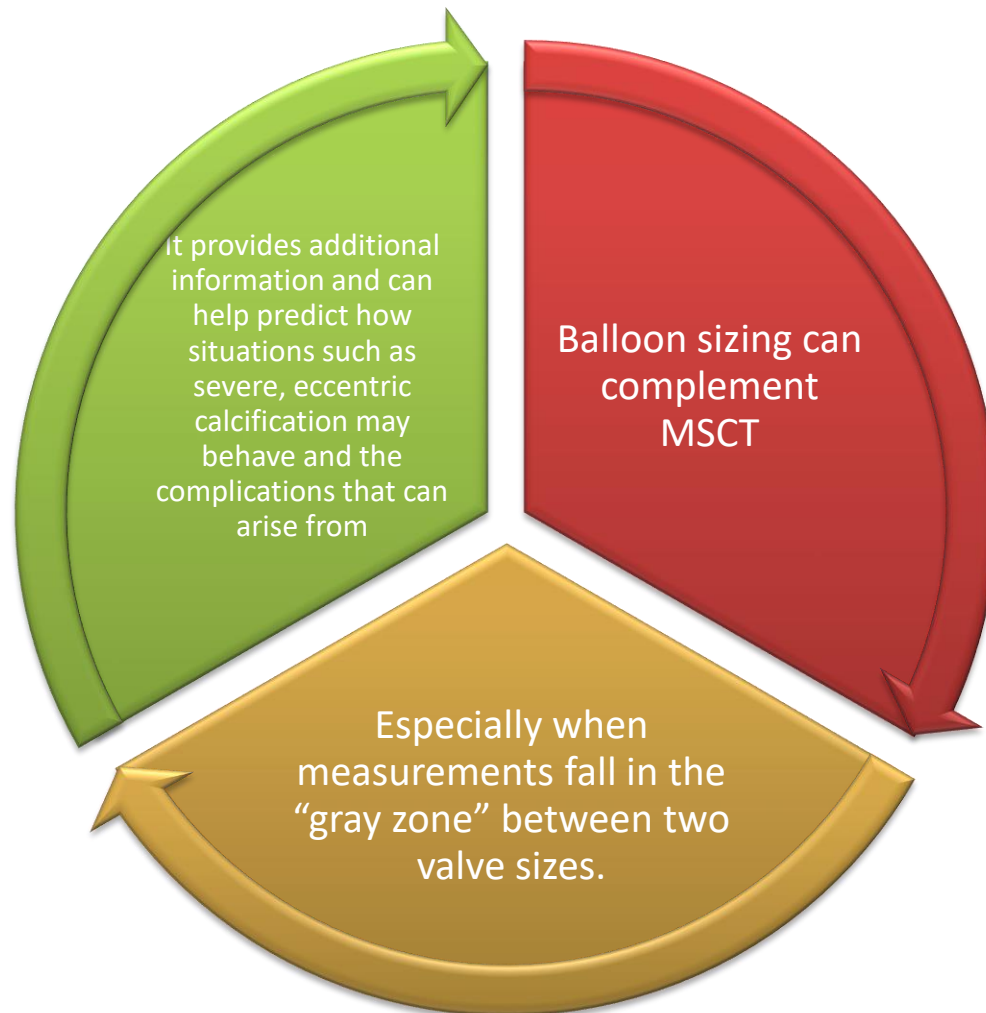
CORONARY OCCLUSION AND ANNULAR RUPTURE



TECHNICAL CONSIDERATIONS FOR TAVI IN BAV

Adversely affect valve
hemodynamics and
durability

Balloon sizing





**Take
home message*

WHAT IS KNOWN? Bicuspid aortic valve stenosis is often considered a relative contraindication to transcatheter aortic valve implantation. Initial reports have shown feasibility, but higher rates of paravalvular regurgitation than observed for tricuspid aortic valves.

WHAT IS NEW? Implantation of a new-generation device was associated with minimal paravalvular regurgitation and good clinical outcomes.

WHAT IS NEXT? Rates of pacemaker implantation after TAVR in bicuspid AS were relatively high and require further study to understand the mechanism.