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Safety and efficacy of the ACURATE neo2 in bicuspid aortic stenosis: the Neo2 BAV Study

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PCR EAPCI European Society of Cardiology KAROLINSKA UNIVERSITY HOSPITAL

Potential conflicts of interest

Speaker's name: Andreas Rück

☑ I have the following potential conflicts of interest to report

- Receipt of grants / research supports - Boston Scientific
- Receipt of honoraria or consultation fees - Boston Scientific
- Receipt of grants / research supports - Edwards Lifesciences
- Receipt of honoraria or consultation fees - Edwards Lifesciences
- Receipt of honoraria or consultation fees - Other

Why this study?

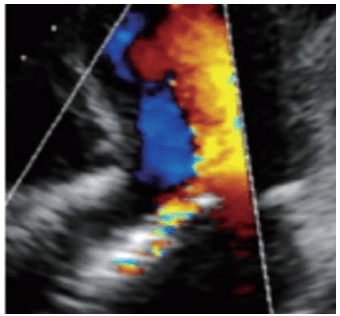
- The ACURATE neo2 (Boston Scientific) is indicated for tricuspid aortic stenosis
- Bicuspid anatomy can be associated with worse outcomes after TAVI
- Studies of the ACURATE neo2 in bicuspid patients are lacking

What did we study?

- Investigator initiated European registry, PI Darren Mylotte
- 181 consecutive patients with bicuspid anatomy (by CT)
- Treated with ACURATE neo2 (sizes 23-25-27 mm)

Center	Site PI	n
Karolinska, Stockholm	Andreas Rück	72
Kerkhoff Klinik, Bad Nauheim	Won-Keun Kim	53
San Raffaele, Milano	Matteo Montorfano	16
German Trias I Pujos, Badalona	Xavier Carrillo Suarez	9
St Johannes, Dortmund	Helge Möllmann	7
Monzino, Milano	Federico de Marco	7
Galway University Hospital	Darren Mylotte	7
Padova	Giuseppe Tarantini	6
Galeazzi-Sant'Ambrogio, Milano	Alfonso Ileasi	2
San Marco, Catania	Marco Barbanti	2

How was the study executed?



Corelab for Echo, CT, implantation fluoroscopy:

CORRIB, Galway, Prof Soliman

Baseline data	N=181
Age	78
Female	58%
eGFR ml/min	59
Prior pacemaker	7%
STS-PROM score	2.3%
Mean gradient aorta	47
AVA cm2	0.7
Bicuspid type 0/1/2	8%/91%/1%
Agatston score aortic valve	2963
Raphe length mm	7.7
Calciphied raphe	76%

Procedural data, complications

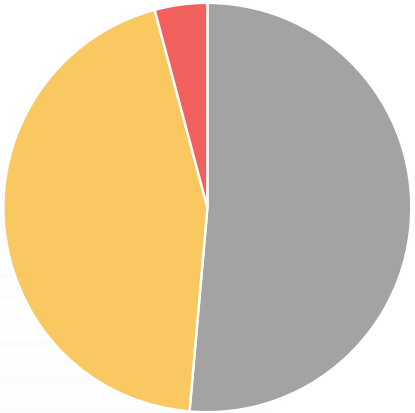
Procedural data	N=181
Transfemoral access	99%
Predilatation	100%
Predilatation NC balloon	51%
Predilatation balloon undersizing to annulus	1.9 mm
Postdilatation	58%
Annulus size mm	24.7

Complications	N=181	n
Need for second valve	2.2%	4
Annular rupture	1.1%	2
Procedural death	1.1%	2
Coronary obstruction	0%	0
Valve embolization	1.6%	3
Conversion to surgery	1.6%	3
Not technical success	*4.4%*	*8*
Technical success	**95.6%**	**173**

Results

Clinical outcomes at 30 days	N=181
Device success	**90.6%**
Death	2.3%
All stroke	1.6%
Major vasc complication	2.9%
New pacemaker	6.1%
Myocardial infarction	0%
Valve reintervention	0%
Acute kidney injury	0%

Postprocedural PVL:



Echo at 30 days	N=164
LVEF	57%
AVA cm^2	2.0
Mean gradient mmHg	6.5
Patient prosthesis mismatch moderate	11.4%
Patient prosthesis mismatch severe	0.6%

Results in perspective

	This study (ACURATE neo2 in bicuspid)	Early neo2 (ACURATE neo2 in 98% tricuspid AS)[2]	BIVOLUT X (Evolut-R/PRO in bicuspid)[3]	PARTNER 3 Bicuspid registry (Sapien 3)[4]
N	**181**	554	149	169
PVL > mild %	**4.3%**	2.8%	11.3%	1.9%
30 d mortality	**2.3%**	1.3%	3.9%	0%
30 d stroke	**1.6%**	2.7%	4.6%	1.4%
New pacemaker	**6.1%**	6.2%	19.5%	6.1%
Mean Agatston score	**2963**	?	?	?
Mean gradient preop	**47**	43	45	49

References: [2] Rück et al, JAHA 2023:12:e029464, [3] Tchétché et al, EuroIntervention 2023:19:502-511 [4] Williams et al, JACC CVI 2022:15:523

The essentials to remember

- The ACURATE neo2 was evaluated in 181 bicuspid patients

- Good echo results (4.3% moderate PVL, mean gradient 6.5 mmHg)
- High technical success (96%) and 30 day device success (91%)

- Similar results as with other platforms in bicuspid patients
- Case selection: yes, but probably as other bicuspid registries

Simultaneous publication

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TAVI with the ACURATE *neo*2 in severe bicuspid aortic valve stenosis: the Neo2 BAV Registry

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