INSTITUT CARDIOVASCULAIRE PARIS SUD

Transcatheter Aortic Valve Implantation for Patients with Complex Valvular Disease: The bicuspid aortic valve.

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On behalf of ICPS Valve team

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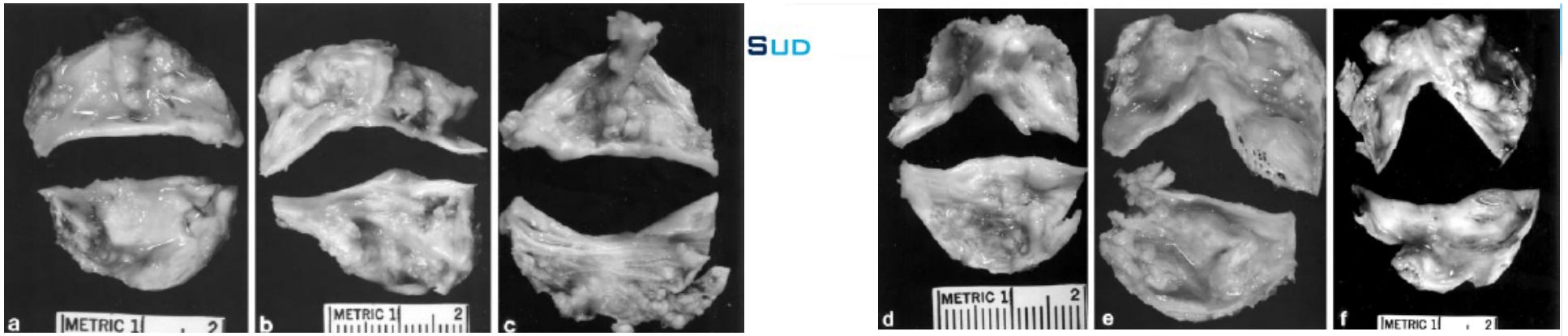
GÉNÉRALE DE SANTÉ

- In the last five years , I received research grants or speaker fees or I am/was consultant for: Abbott Vascular, Asahi, Astra Zeneca, AVI, Boston Scientific, Biotronik, Colibri, Cook, Cordis, Daichi-Sankyo, Eli-Lilly, Iroko, Medtronic, Terumo. I am currently minor shareholder & general mamager of CERC (CRO)



- 1 to 2% incidence, 2 to 4 times more frequent in men *(Tzemos et al. JAMA 2008; 300:1317-25.)*
- Could be an heritable condition – mutation of gene NOTCH1 *(Garg et al. Nature 2005; 437: 270-4)*

Frequency by Decades of Unicuspid, Bicuspid, and Tricuspid Aortic Valves in Adults Having Isolated Aortic Valve Replacement for Aortic Stenosis, With or Without Associated Aortic Regurgitation

William C. Roberts, MD; Jong M. Ko, BA

Background—Aortic valve stenosis (with
in the Western world has been cons
atherosclerotic disease.

Methods and Results—We examined ope
(mean±SD, 70±12), and none had associated mitral valve replacement or evidence of mitral stenosis: A total of 504 (54%) had congenitally malformed valves (unicuspid in 46 [unicommissural in 42; acommissural in 4] and bicuspid in 458); 417 (45%) had tricuspid valves (either absent or minimal commissural fusion); and 11 (1%) had valves of undetermined type. It is likely that the latter 11 valves also had been congenitally malformed. Of the 584 men, 343 (59%) had either a unicuspid or a bicuspid valve; of the 348 women, 161 (46%) had either a unicuspid or a bicuspid aortic valve.

Conclusions—The data from this large study of adults having isolated aortic valve replacement for aortic stenosis (with or without associated aortic regurgitation) and without associated mitral stenosis or mitral valve replacement strongly suggest that an underlying congenitally malformed valve, at least in men, is more common than a tricuspid aortic valve.
(*Circulation*. 2005;111:920-925.)

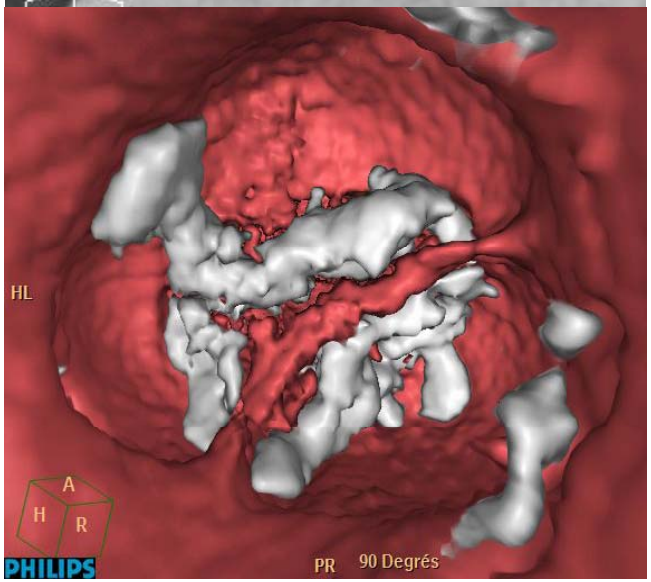
Bicuspid valve 62% <70 y & 38% > 80 y

TABLE 1. Aortic Valve Structure in 584 Men and 348 Women Aged 26 to 91 Years With Operatively Excised Stenotic Aortic Valves Unassociated With Mitral Valve Disease and Excised From 1993 to 2004

Aortic Valve Structure	Cases, n (%)	Ages (y) of Patients by Decades at Time of Aortic Valve Replacement							
		21–30	31–40	41–50	51–60	61–70	71–80	81–90	91–100
Men									
Unicuspid	34 (6)	3	4	11	8	4	4	0	0
					54	111	94	24	1
					4	50	119	51	0
					0	3	2	2	0
					(13)	168 (29)	219 (38)	77 (13)	1 (<1)
Women									
Unicuspid	12 (3)	1	2	3	1	4	1	0	0
Bicuspid	149 (43)	1	5	10	20	44	55	14	0
Tricuspid	183 (53)	0	0	2	11	43	79	47	1
Uncertain	4 (1)	0	0	1	0	0	3	0	0
Subtotals, n (%)	348 (100)	2 (<1)	7 (2)	16 (5)	32 (9)	91 (26)	138 (46)	61 (18)	1 (<1)

Values in parentheses are percentages.

- Bicuspidy is regarded as a relative contraindication to TAVI due to the risk of uneven expansion of the bioprosthesis.
- Not indicated in the IFU of approved devices
- Exclusion criteria in clinical trials
- Thus, the safety and efficacy of TAVI for this anatomic variation still remains unclear.



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Transcatheter Aortic Valve Implantation in Patients With Bicuspid Aortic Valve Stenosis

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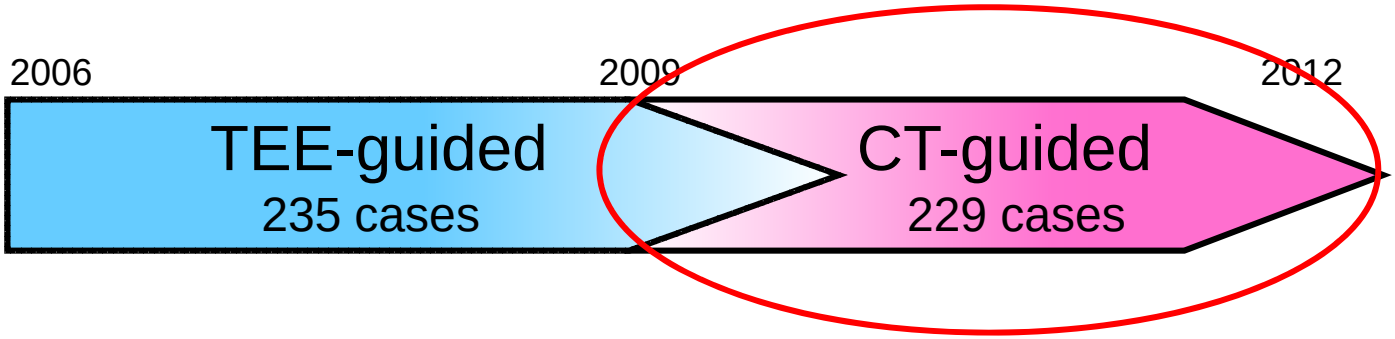
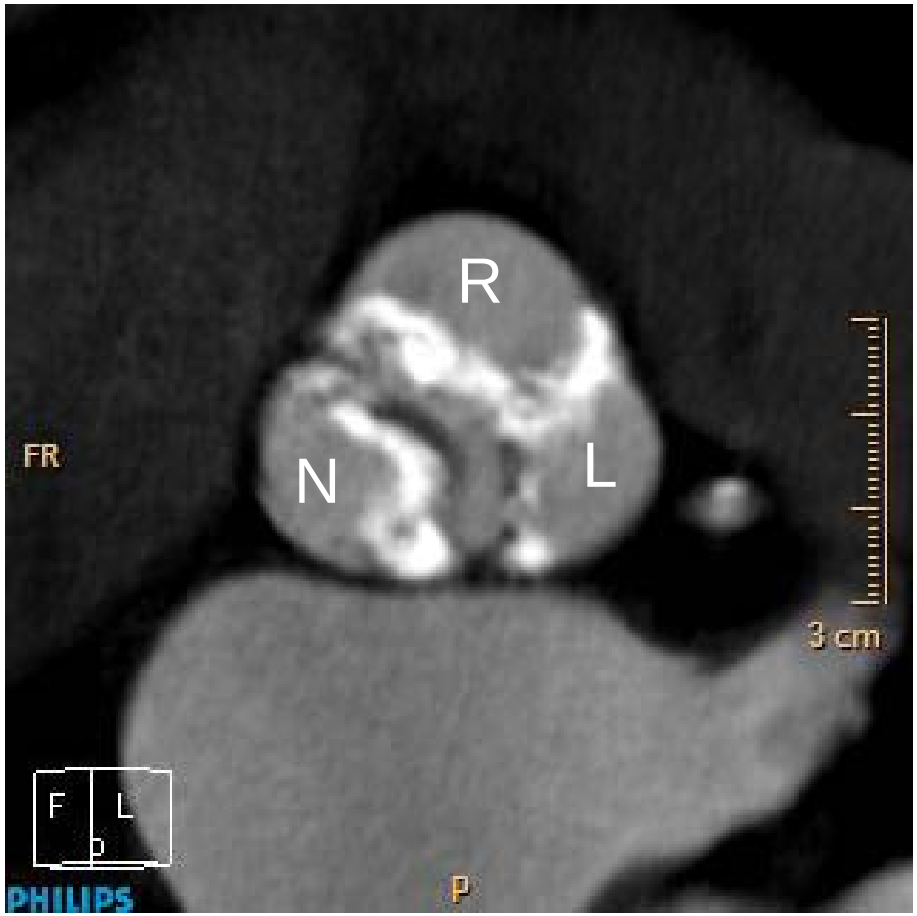
- 11 patients in 3 centres – STS 4,4%
- Sapien in all pts
- Mean gradient 13 mmHg
- 2 deaths @ 30 d in TA
- 1 late conversion to SAVR

Study Design



- October 2006 – January 2012
- 470 high-risk patients with severe aortic stenosis were treated with TAVI
- 6 patients who did not receive TAVI were excluded.
- 235 patients who did not undergo CT were excluded.
- The remaining 229 patients are the subject of the analysis presented here
- We compared clinical outcomes in patients with vs. without bicuspidy

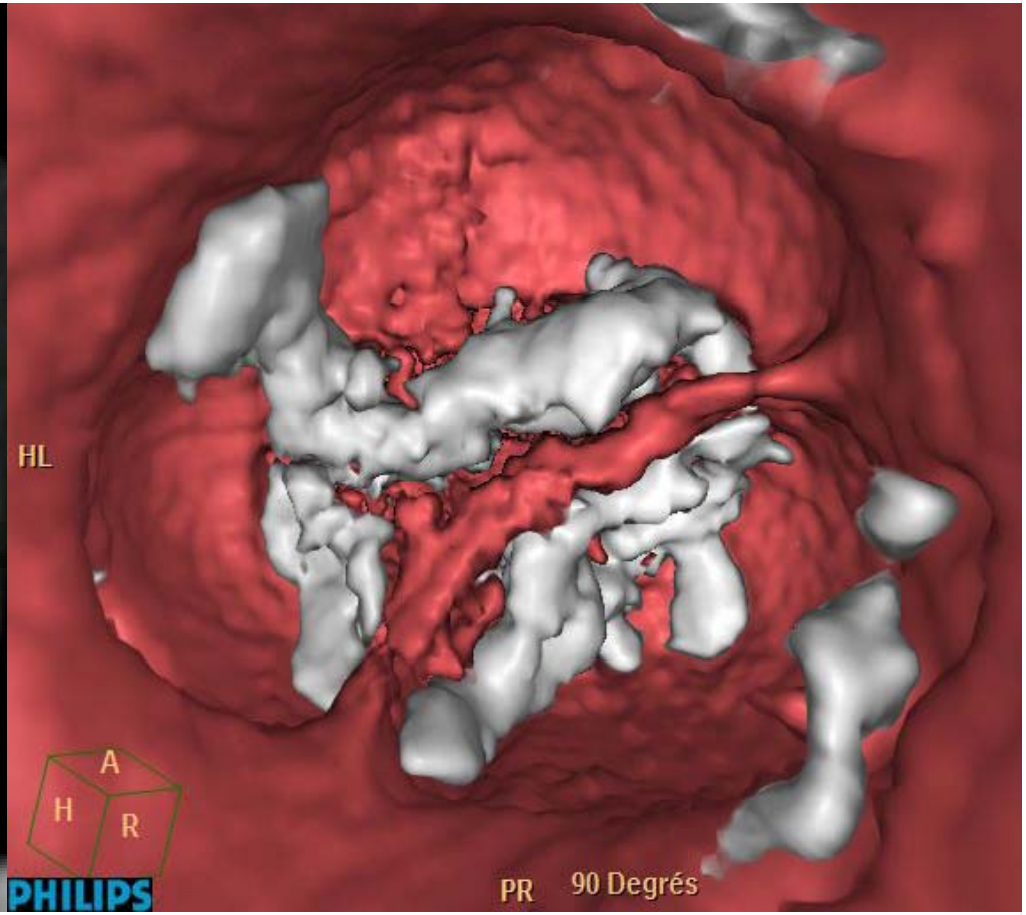
CT Findings



Total:	21
•Type 1 L-R:	16
•Type 1 L-N:	1
•Type 1 R-N:	1
•Type 2 L-R + L-N:	3

* Of 21 cases, 15 (71.4%) were not diagnosed as bicuspid valve by echocardiography

Bicuspid Valve



Baseline characteristics

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Age, years	82.0 ± 7.0	83.2 ± 6.5	0.43
Male gender	12 (57.1%)	111 (53.4%)	0.74
NYHA class III / IV	19 (90.5%)	183 (88.0%)	0.74
Coronary artery disease	10 (47.6%)	121 (58.2%)	0.35
Previous CABG	2 (9.5%)	28 (13.5%)	0.61
Peripheral artery disease	5 (23.8%)	68 (32.7%)	0.41
Cerebrovascular disease	1 (4.8%)	13 (6.2%)	0.79
COPD	5 (23.8%)	50 (24.0%)	0.98
eGFR <60 ml/min.	12 (57.1%)	124 (59.6%)	0.83
Logistic EuroSCORE, %	19.9 ± 11.9	20.1 ± 11.4	0.95

Echocardiographic Findings

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Aortic valve area, cm^2	0.67 ± 0.11	0.65 ± 0.14	0.56
Mean pressure gradient, mmHg	47.8 ± 18.6	48.1 ± 17.0	0.94
LVEF <40%	6 (28.6%)	54 (26.0%)	0.80
Aortic annulus size (TEE), mm	23.4 ± 2.7	22.5 ± 1.9	0.15
Aortic regurgitation (0-4)	0.95 ± 0.74	0.83 ± 0.70	0.47
Mitral regurgitation (0-4)	0.74 ± 0.87	0.82 ± 0.67	0.62

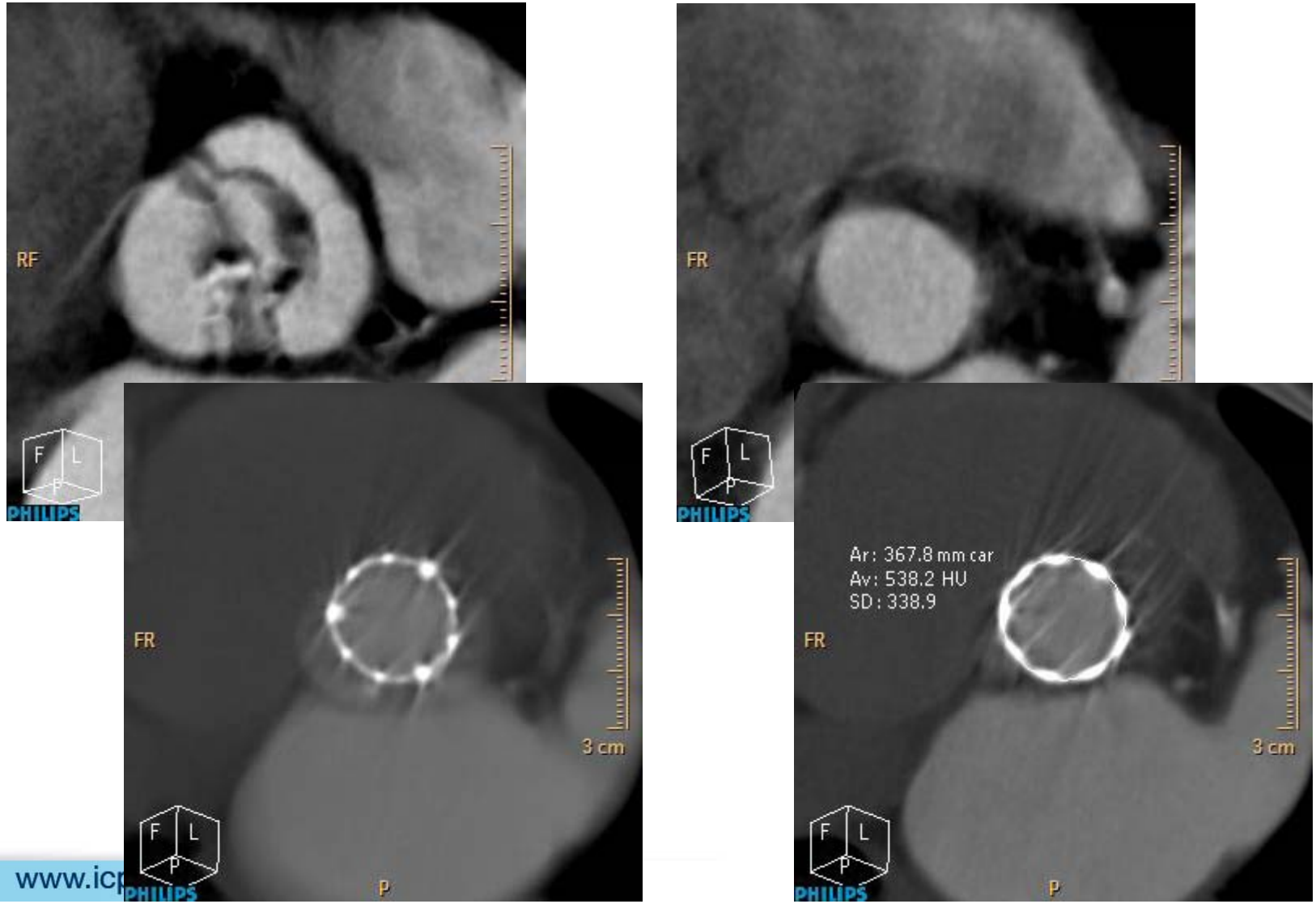
CT Findings

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Mean annulus size (CT), mm	**24.7 ± 3.0**	**23.7 ± 1.9**	**0.14**
Short-axis annulus size (CT), mm	22.7 ± 2.8	21.9 ± 1.9	0.21
Long-axis annulus size (CT), mm	**27.4 ± 3.1**	**26.4 ± 2.5**	**0.08**
Long/short Diam-CT ratio	1.21 ± 0.07	1.21 ± 0.08	0.89

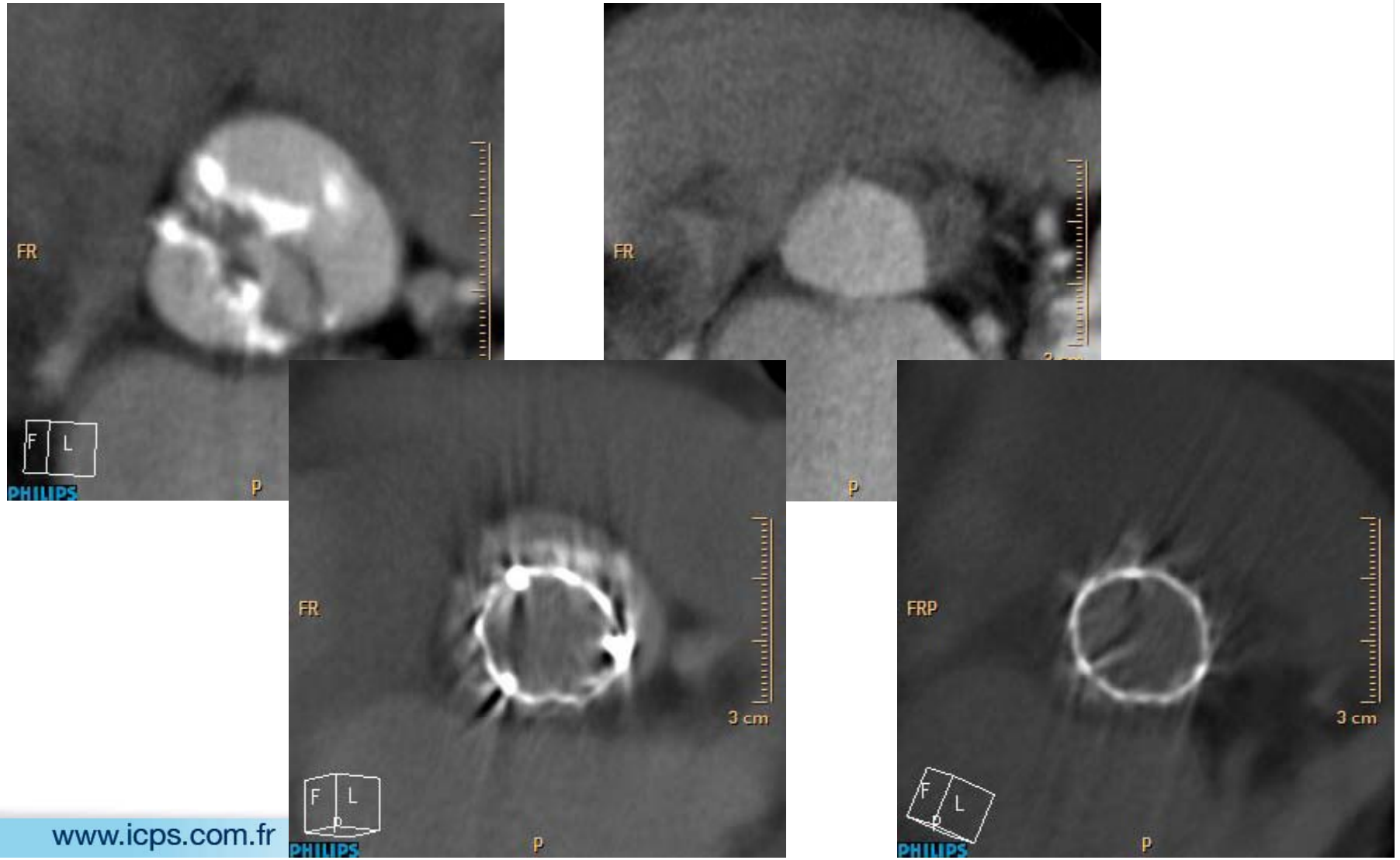
Procedural Characteristics

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Edwards	11 (52.4%)	174 (83.7%)	<0.01
Transfemoral	5 (23.8%)	79 (38.0%)	0.93
Transapical	3 (14.3%)	37 (17.8%)	
Transaortic	3 (14.3%)	58 (27.9%)	
CoreValve	10 (47.6%)	34 (16.3%)	<0.01
Transfemoral	8 (38.1%)	26 (12.5%)	0.71
Transsubclavian	0	3 (1.4%)	
Transaortic	2 (9.5%)	5 (2.4%)	
Valve size, mm	27.8 ± 3.0	26.4 ± 2.1	0.07

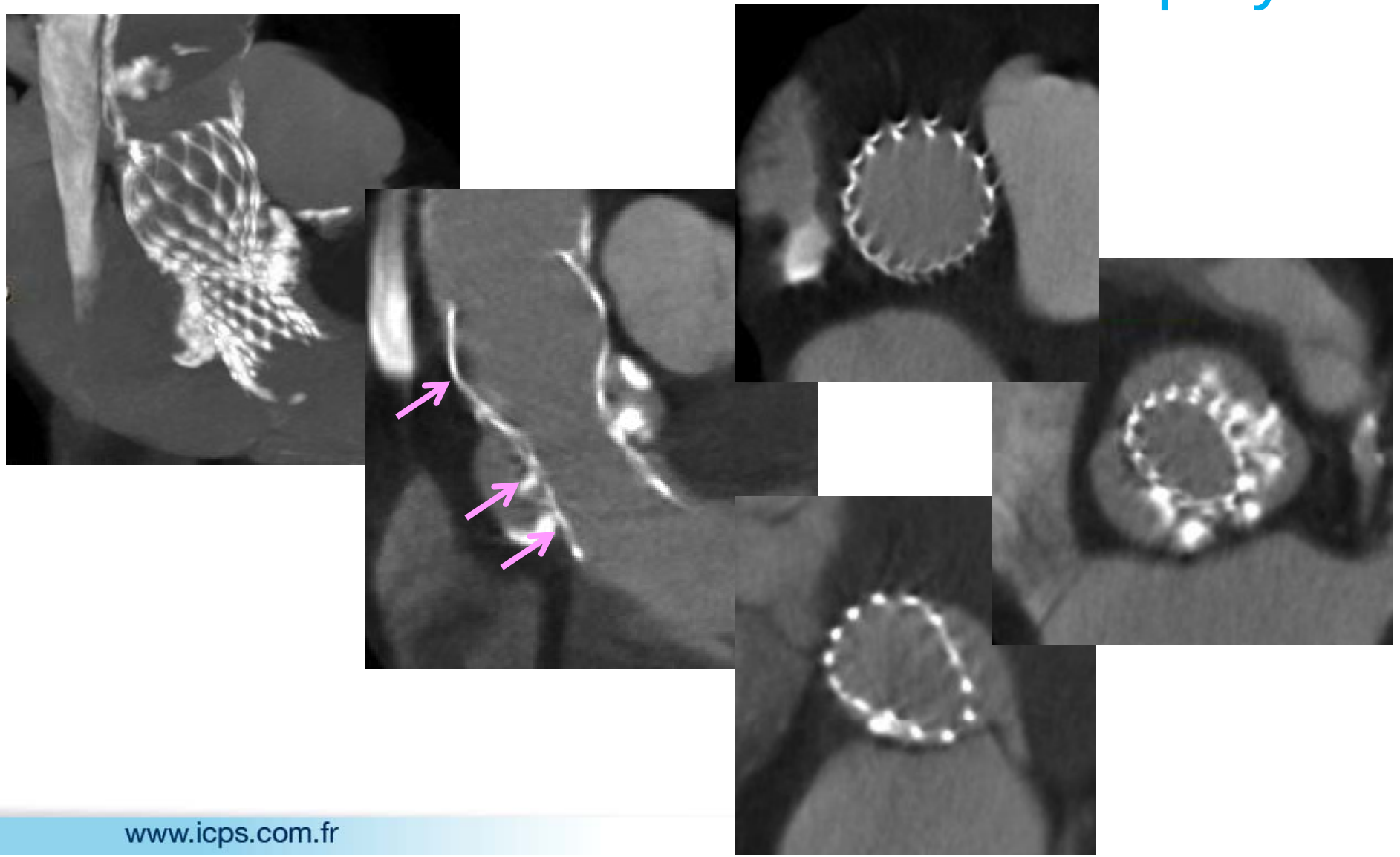
Edwards Valve in bicuspidy #1



Edwards Valve in bicuspidy #2



CoreValve in bicuspidy



Clinical Outcomes

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Mean pressure gradient, mmHg	**10.0 ± 3.4**	**9.7 ± 4.1**	**0.78**
LVEF, %	53.2 ± 15.1	54.4 ± 12.2	0.67
Aortic regurgitation ≥2	**4 (19.0%)**	**31 (14.9%)**	**0.54**
Aortic regurgitation ≥3	0	2 (1.0%)	0.83
Annulus rupture	0	3 (1.4%)	0.75
Valve migration	0	3 (1.4%)	0.75
Coronary occlusion	1 (4.8%)	4 (1.9%)	0.39
Major vascular complication	1 (4.8%)	9 (4.3%)	0.63
Acute kidney injury	1 (4.8%)	23 (11.1%)	0.33
New pacemaker	3 (14.3%)	15 (7.2%)	0.22

Clinical Outcomes

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Device success	21 (100%)	193 (92.8%)	0.23
30-day mortality	1 (4.8%)	17 (8.2%)	0.49
30-day combined safety point	3 (14.3%)	28 (13.5%)	0.56
ICU stay, days	4.5 ± 3.6	4.1 ± 4.2	0.70
Hospital stay, days	8.5 ± 3.6	11.0 ± 6.2	0.08

Conclusions

- CT was more sensitive than echo to detect bicuspid valve.
- Type 1 L-R was the most common type in this cohort.
- A trend towards larger aortic annulus in bicuspid valve requiring larger bioprosthesis size
- Similar device success (Gradient, post-procedural AR) was achieved without increase in adverse events.
- Although longevity of prostheses in non-circulatory expansion should be explored, indication of TAVI might be extended to this type of anatomy in the future.