Issue of coronary obstruction in TAVI : Low height of coronary ostium &

Countermeasure

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Coronary Obstruction during TAVI



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Masson et al. **J Am Coll Cardiol**. 2009 Seipelt et al. **Inter CardioVasc and Thorac Surgery**. 2012

Coronary Obstruction during TAVI Incidence

Registries reported large variability regarding the incidence

Publication, Year	Valve	Number	Incidence
Webb et al. 2006	SAPIEN	1 / 18 patients	5.6%
Himbert et al. 2009	SAPIEN	0 / 160 patients	0.0%
Seipelt et al. 2012	SAPIEN XT	3 / 270 patients	1.11%
SOURCE registry, 2010	SAPIEN	6 / 1038 patients	0.58%
Canadian registry, 2010	SAPIEN, SAPIEN XT	3 / 345 patients	0.90%
Zierer et al. 2008	SAPIEN	2 / 26 patients	7.69%
Griese et al. 2013	SAPIEN, SAPIEN XT	2 / 411 patients	0.49%

Webb et al. Circulation. 2006 Seipelt et al. Inter CardioVasc and Thorac Surgery. 2012 Thomas M et al. Circulation 2010 Rodes-Cabau J et al. JACC 2010

Coronary Obstruction during TAVI

TABLE IV. Additional Complications Reported in Patients Undergoing TAVR

		Meta-analysis: TAVR
Complication		
Major vascular	%	6.60%
Complication	n/n total	234/3,559
	N studies	6
Cardiac tamponade		1.40%
		6/401
		3
Aortic dissection		0.71%
		9/1,270
		3
Aortic/annular		0.49%
Rupture		4/812
		4
Coronary		0.72%
Obstruction		12/1,675
Internet internet		4
Myocardial		0.56%
Infarction		5/900
		5
Blood		11.60%
Transfusion	149/1,282	
		2
Valve		0.56%
Embolization		10/1,770
		5
Paravalvular aortic regurgitation		11.6%
≥Moderate		80/692
		7
Endocarditis		0.39%
		2/514
		2

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Meta-analysis comparing SAVR vs TAVI

16 Studies with 5024 TAVI patients

Overall Incidence of Coronary Obstruction → 0.72%

Jilahawi et al. CCI 2012

Coronary Obstruction during TAVI Epidemiology

18 Publications between 2002-2012

- <u>Women 83%</u>
- Mean age 83±7 years
- Balloon expandable valve (Edwards) : 88%
- Self-expandable valve (CoreValve) : 12%

Incidence by vessels

- RCA : 12.5%
- <u>LCA : 83.3%</u>
- Both : 4.2%

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Coronary Obstruction during TAVI Clinical Presentation and Consequences

Clinical Presentations

- Severe Hypotension : 21 / 24 patients (87.5%)
- ST-segment change : 13 / 24 patients (54.2%)
- ST-segment elevation : 6 / 24 patients (25.0%)
- Ventricular arrhythmia : 6 / 24 patients (25.0%)

Consequences of the Events

- Need for "CPR" : 9 / 24 patients (37.5%)
- Need for Hemodynamic Support : 6 / 24 patients (25.0%)
- Conversion to Open heart surgery : 2 / 24 patients (8.3%)
- In-Hospital Death : 2 / 24 patients (8.3%)

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Coronary Obstruction during TAVI Consequences

		Clinical Presentation			Trea	Treatment					
Patient# (Ref#)	Coronary Obstruction	Severe Hypotension	ST-Segment Changes	Ventricular Arrhythmias or CPR	PCI	CABG	Successful PCI	Stent Type	Need for Hemodynamic Support	Hospital Stay (days)	In-Hospital Death
1 (9)	Both	Yes	Yes	No	Yes	No	Yes	BMS	No	11	No
2 (10)	LCA	Yes	No	No	No	No		1440	No	5	Yes
3 (11)	LCA	Yes	Yes	Yes	Yes	No	Yes	DES	No	5	No
4 (12)	LCA	Yes	Yes	Yes	Yes	No	Yes	BMS	Yes	13	No
5 (12)	RCA		9		Wee	N				12	No
6 (12)	RCA	PC	l was	attempte	d ir	n 23	case	s (9	95.8%)	14	No
7 (13)	LCA							- (-		4	No
8 (13)	LCA									0	Yes
9 (13)	LCA			Succes	s r	ates	: 91 3	%		5	No
10 (13)	LCA				510	aice	5 51.5	/0		4	No
11 (13)	LCA									3	No
12 (14)	LCA									_	No
13 (15)	LCA									5	No
14 (16)	LCA	Yes	No	Yes	Yes	No	Yes	BMS	No	5	No
15 (17)	RCA				1	- 114-				4	No
16 (18)	LCA			30-day m	ort	ality	/ rates	S			No
17 (19)	LCA									8	No
18 (20)	LCA			_	_					5	No
19 (21)	LCA			\rightarrow	8.3	3%				-	No
20 (22)	LCA	14 DAK	0.0000		19940	0969661	5254K	100000	11.0450	11	No
21 (23)	LCA	Yes	Yes	No	Yes	No	Yes	Both	No	_	No
22 (24)	LCA	No	Yes	No	Yes	No	Yes	BMS	No	-	No
23 (25)	LCA	No	No	No	Yes	No	Yes	BMS	No	-	No
24 (26)	LCA	Yes	No	Yes	Yes	No	Yes	DES	Yes		No

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Five Factors to Determine Coronary Obstruction [1] Height of Coronary Ostium



Significantly Smaller Height of Coronary Ostium than

1. Patients undergoing TAVI due to AS

2. Patients without AS

Current Safety Cut-Off ≥ 10mm Is Safe ?? → 60% of cases with coronary obstruction → Had ostial height > 10mm

Mean Coronary Ostial Height : 10.3 mm

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Five Factors to Determine Coronary Obstruction [2] Aortic Root Size and Space of Sinus Valsalva



Significantly Smaller Aortic Root Size than

1. Patients undergoing TAVI due to AS

2. Patients without AS

Mean Aortic Root Size : 27.8 mm

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Five Factors to Determine Coronary Obstruction [3] Length of Aortic Valve Leaflet Currently, No available data regarding the association between length of native valve leaflet

and the risk of coronary obstruction



40 post-mortem heart harvested from the TAVI patients 72.5% of coronary ostium were located below the ST junction

Longer leaflet may more easily cover the ostium (personal thought)

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Zheng-Fu et al. J Thrac Dis. 2014

Five Factors to Determine Coronary Obstruction [4] Presence of Calcium Chunk on Valve Leaflet



None of previous study quantitatively measured the volume of leaflet calcium chunk

But, we already know that "Heavy" Calcium Chunk in Leaflet will "Obstruct" the Ostium

Currently, There was No cases of coronary obstruction related to the struts of valve frame or to the cuff/leaflet of prosthetic valve

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Saia et al. J Invasive Cardiol 2011 Ribeiro et al. JACC intervention 2013

Five Factors to Determine Coronary Obstruction [5] Self-expandable vs. Balloon-expandable

Study (Ref. #)	n	Valve/Approach	TF	ТА	All Procedures	Cases SAPIEN	Cases CoreValve
ADVANCE (3)	996	CoreValve	0.1%		0.1%	-	1
Canadian (4)	345	Cribier-Edwards, SAPIEN, SAPIEN XT/49% TF, 51% TA	0.6%	1.1%	0.9%	3	÷
FRANCE (2)	244	SAPIEN or CoreValve/66% TF, TS 5%, 29% TA	SAPIEN (2.1%) 0% CoreValve (1.5%)		1.2%	2	1
German (8)	670	SAPIEN or CoreValve/96% TF, 4% TA			0.1%		÷
SOURCE (6)	1,038	SAPIEN/45% TF, 55% TA	0.7%	0.5%	0.6%	6	<u> </u>
PARTNER (5)	348	SAPIEN/70.1% TF, 29.9% TA	0%	0%	0%	-	
Source XT (7)	2,600	SAPIEN XT/63% TF, 34% TA	0.3%	0.3%	0.3%	8	<u></u>
Pooled studies			13/3,726 (0.35%)	8/1,833 (0.44%)	22/6,241 (0.35%)	19	2
SAPIEN					19/4,497 (0.42%)		
CoreValve					2/1.074 (0.19%)		

ADVANCE = Medtronic CoreValve study; FRANCE = FRench Aortic National CoreValve and Edwards registry; PARTNER = Placement of Aortic Transcatheter Valve trial; SOURCE = SAPIEN aortic bioprosthesis European outcome registry; TAVI = transcatheter aortic valve implantation; other abbreviations as in Table 1.

Overall incidence from the largest registry and RCT <u>SAPIEN → 0.42 %</u> <u>CoreValve → 0.19%</u>

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- 65 YO FeMale , 147.2 Cm, 50.8 Kg, BMI : 23.44
- Chief complaint> Dyspnea on exertion (NYHA III), 2YA
- Present Illness>
 DOE since 2YA → Local hospital Echo → Dxed as AS
 → Other Tertiary Center → F/U with Echo
 → Recent F/U Echo : Severe AS
 → Referred for TAVI
- Patient strongly refused surgical AVR.



- ✓ Severe AS with Severe Valvular Calcification
- Trans AV mean Pr gradient = 86.6 mmHg, AV Vmax = 5.75 m/s
- ✓ AVA = 0.65 cm^2
- ✓ Normal LV cavity size and normal systolic function
 - LVEDD/ESD 38/24, LVEF 60%, LA size 40mm
- ✓ Dilated ascending aorta (40mm)
- ✓ Increased LV wall thickness, RWMA (-)







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Five Factors to Determine Coronary Obstruction [1] Height of Coronary Ostium

RCA

LCA



Significantly Lower RCA ostial height

Five Factors to Determine Coronary Obstruction [2] Aortic Root Size and Width of Sinus Valsalva

Aortic Root Size

Sinus Valsalva Width



Smaller Annulus Size Sufficient Space of Sinus Valsalva

Five Factors to Determine Coronary Obstruction [3] Length of Aortic Valve Leaflet



Relatively longer Rt. Leaflet Length Than RCA ostial height

Five Factors to Determine Coronary Obstruction [4] Presence of Calcium Chunk on Valve Leaflet



Extremely Heavy Calcification in Rt. leaflet



RCA obstruction during BAV





Implantation of CoreValve 23 mm Under engagement of guiding catheter into RCA



No obstruction of coronary artery. Discharged at POD #5 without Any Complication

Conclusions Coronary Obstruction During TAVI

- Rare but Fatal Complication : Overall Mortality 8.3%
- Meticulous Pre-TAVI Planning is Essential to "Do No Harm"
- Five Factors Predisposing This Detrimental Complications
 - Coronary Ostial Height
 - Space of Sinus of Valsalva
 - Length of Leaflet
 - Calcium Chunk on Leaflet
 - Balloon-expandable Valve
- If worrisome factor is present, test during BAV before valve implantation
- If coronary obstruction suspected → engage guiding catheter, then implant prosthetic valve