

CONVENTIONAL SURGERY, SUTURELESS VALVES AND TRANS-APICAL AORTIC VALVE REPLACEMENT:

WHAT IS THE BEST OPTION IN PATIENTS WITH AORTIC VALVE STENOSIS?

A MULTICENTER, PROPENSITY-MATCHED ANALYSIS

A. D'Onofrio, G. Rizzoli, A. Messina, O. Alfieri, R. Lorusso, S. Salizzoni, M. Glauber, R. Di Bartolomeo, L. Besola, M. Rinaldi, G. Troise and G. Gerosa

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Disclosure: G. Gerosa and A. D'Onofrio: TA-TAVR proctors for Edwards Lifesciences, M. Glauber: educational activity for Sorin Perceval, G. Troise: Sutureless proctor for Sorin

Background

- Surgical aortic valve replacement (SAVR) is the treatment of choice in patients suffering from severe symptomatic aortic valve stenosis since it is reproducible, its results are well established and its complications are well known
- During the last few years, new alternative therapeutic strategies have been introduced into clinical practice
 - ***Sutureless aortic valve replacement (SU-AVR)***
 - ***Trans-catheter aortic valve replacement (TAVR)***

Background-2 AATS 2012

Sutureless aortic valve replacement as an alternative treatment for aortic stenosis in patients with aortic valve regurgitation and multiple comorbidities.

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Dr D'Onofrio. I want to answer your second question first. We are now designing a new study considering all 3 groups—trans-catheter, sutureless, and surgical aortic valve. I hope it will be done in the very near future.

Objective

- Aim of this multicenter, propensity-matched study, was to compare hospital clinical and hemodynamic outcomes of SAVR, TA-TAVR and SU-AVR

Patients

- TA-TAVR:

- 566 patients (I-TA registry)
- April 2008-May 2011



- SU-AVR:

- 38 patients (3 Italian centers)
- March-September 2011



- SAVR:

- 349 consecutive patients (University of Padova)
- January 2009-December 2011



Analysis

- Patients were initially classified as receiving
 - TA-TAVR
 - “OPEN HEART SURGERY” (OHS)
 - SAVR
 - SU-AVR
- Within OHS we further analyzed
 - SAVR
 - SU-AVR

Propensity score analysis

- Stratification in 17 blocks
- 1:1 matching
 - 286 patients (143 TA-TAVR, 143 OHS)
- Psmatch2 common support region
 - 633 patients (490 TA-TAVR; 143 OHS)

End-points

- All-cause 30-day mortality
- Disabling stroke
- Permanent pace-maker implantation
- Renal replacement therapy
- Peri-procedural acute myocardial infarction
- Aortic regurgitation at discharge ($\geq 1+/3+$)
- Trans-aortic gradient at discharge

Cohorts

Continuous variables

Pre-match

Variable	OHS	TA-TAVR	p-value
PRE-MATCHING (n=953) OHS: n=387; TA-TAVR: n=566			
Age (years)	72,7±10,1	80,6±6,8	<0,001
BSA (m ²)	1,8±0,2	1,7±0,2	<0,001
Logistic Euroscore (%)	14,2±11,2	25,5±15	<0,001
LVEF (%)	59,1±10,6	52,7±13,6	<0,001
AVAi (cm ² /m ²)	0,51±0,1	0,55±0,2	0,001
POST-MATCHING COMMON SUPPORT (N=633) OHS: n=143; TA-TAVR: n=490			
Age (years)	73,5±12,6	80,4±7	<0,001
BSA (m ²)	1,8±0,3	1,7±0,2	0,001
Logistic Euroscore (%)	18,3±14,6	24,5±14,1	<0,001
LVEF (%)	58,1±10,9	53,4±13,6	<0,001
AVAi (cm ² /m ²)	0,55±0,2	0,54±0,2	0,93
POST-CALIPER MATCHING (n=286) OHS: n=143; TA-TAVR: n= 143			
Age (years)	73,5±12,6	77,6±9	0,003
BSA (m ²)	1,8±0,3	1,7±0,2	0,12
Logistic Euroscore (%)	18,3±15,6	20,2±12,5	0,22
LVEF (%)	58,1±10,9	56,1±13	0,15
AVAi (cm ² /m ²)	0,55±0,2	0,55±0,2	0,93

Post-match

Cohorts

Categorical variables

Pre-match

Variable	OHS	TA-TAVR	p-value
<i>PRE-MATCHING (n=953) OHS: n=387; TA-TAVR: n=566</i>			
Male Sex (%)	48,3	40,8	0,02
NYHA ≥3 (%)	33,1	83,4	<0,001
PVD (%)	36,7	51,2	<0,001
COPD (%)	20,9	35,7	<0,001
MR (%)	9,6	9,2	0,07
<i>POST-MATCHING COMMON SUPPORT (N=633) OHS: n=143; TA-TAVR: n=490</i>			
Male Sex (%)	49,7	40,8	0,07
NYHA (%)	54,5	81,2	<0,001
PVD (%)	37,1	48,8	0,17
COPD (%)	25,9	33,9	0,08
MR (%)	24,5	68,2	<0,001
<i>POST-CALIPER MATCHING (n=286) OHS: n=143; TA-TAVR:n= 143</i>			
Male Sex (%)	49,7	37,1	0,03
NYHA (%)	54,5	65	0,08
PVD (%)	37,1	42,7	0,43
COPD (%)	25,9	32,2	0,25
MR (%)	24,5	32,9	0,06

Post-match

Results – 1:1 matching

Outcome	TA-TAVR (n=143)	SU-AVR (n=31)	SAVR (n=112)	p-value TA-TAVR vs. SU-AVR	p.value TA-TAVR vs. SAVR
Death, n (%)	<u>10 (7)</u>	0	<u>1 (1,8)</u>	0,21	0,026
Stroke, n (%)	4 (2,8)	0	0	1	0,13
PPM, n (%)	7 (4,9)	1 (3,2)	1 (0,9)	1	0,082
RRT, n (%)	<u>7 (4,9)</u>	1 (3,2)	<u>0</u>	1	0,019
AMI, n (%)	5 (3,5)	0	1 (0,9)	0,59	0,23
Postoperative AR (≥1+/3+)	<u>41 (28,7)</u>	6 (19,4)	<u>2 (1,8)</u>	0,37	<0,001
Mean Gradient (mmHg)	<u>10,7±4,4</u>	11,1±3,3	<u>16,5±5,8</u>	0,69	<0,001

Results – Multivariate analysis

Outcome	SU-AVR vs. TA-	p-value *	SAVR vs. TA-	p-value *
	TAVR		TAVR	
Death (OR)	1,00	-	0,23	0,17
Postoperative AR ($\geq 1+/3+$) (OR)	0,55	0,23	0,04	<0,001
Stroke (OR)	1,00	-	1,00	-
PM implantation (OR)	0,51	0,53	0,97	0,14
RRT (OR)	0,61	0,68	1,00	-
AMI (OR)	1,00	-	0,38	0,47
Mean gradient at discharge (OR)	1,02	0,56	1,19	<0,001



Conclusions

- There are no main differences in outcomes among SAVR, TA-TAVR and SU-AVR
- SAVR was associated with a significant reduction of postoperative aortic regurgitation when compared to TA-TAVR
- TA-TAVR showed lower trans-aortic gradients than SAVR
- SU-AVR, when compared to TA-TAVR, did not show significant differences even if a trend towards less aortic regurgitation was evident

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