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Transcatheter Aortic Valve Implantation versus Surgical Aortic Valve Replacement for severe aortic stenosis Results from an intermediate risk propensity-matched population of the Italian **OBSERVANT** Study

Fulvia SECCARECCIA

National Centre for Epidemiology, Surveillance and Health Promotion
Istituto Superiore di Sanità, Rome, ITALY





Potential conflicts of interest

Speaker's name: Fulvia Seccareccia

I have the following potential conflicts of interest to report:

- Research contracts
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest



➤ **OBSERVANT** is an OOS

Observational outcome studies are increasingly used to address comparative effectiveness evaluations

- when experimental studies are difficult to set up
- when new treatments or health technologies are included and supplied by the National Health System, but no valid efficacy/effectiveness proofs exist

➤ **OBSERVANT** started in December 2010 in Italy with the aim of addressing comparative effectiveness of TAVI and SAVR procedures for the treatment of SSAS in a real population

➤ **OBSERVANT** is based on the development of a unique database for contemporary data collection on both procedures



AIMS

- 1. To evaluate and compare short-, medium-, and long-term outcomes in SSAS patients undergoing SAVR or TAVI, but potentially eligible to both procedures**
 - ✓ survival
 - ✓ major adverse cardiac and cerebrovascular events (MACCE), after adjusting for pre-treatment patient characteristics
- 2. To build a new pre-procedure risk score, specific for the elderly population**
- 3. To define specific “indication criteria” to guarantee appropriate patient selection for SAVR or TAVI**



METHODOLOGY

STUDY DESIGN Observational prospective multicenter cohort study

STUDY POPULATION All adult patients admitted to hospitals with a diagnosis of SSAS and requiring an interventional treatment (TAVI or SAVR)

DATA COLLECTION (18 months) includes information on:

- demographic characteristics
- health status prior to intervention
- therapeutic approach

END POINTS AND FOLLOW-UP

- Procedural outcomes (i.e.: PAV block, stroke, vascular damage,...)
- Mortality within 30 days and 6 months from intervention
- Mortality and incidence of in-hospital major adverse cardiac and cerebrovascular events (MACCE) within 12 and 24 months



DATA COLLECTION (March 2013)

	Cardiac Surgery	Hemodynamic Cardiology
Enlisted Centres	95	61
Participating Centers	60	41

TOTAL	SAVR	TAVI
7518	5595	1923



INTERMEDIATE RESULTS

Enrolled patients' characteristics

Characteristics	SAVR N=4169	TAVI N=1591	p_value
Age (years)*	73±9	82±6	0,000
Gender (male)	46,3%	58,4%	0,000
Diabetes	23,8%	25,7%	0,001
Creatinine (mg/dL)*	1.1±0.8	1.3±0.8	0,000
Chronic dialytic treatment	1,3%	2,1%	0,088
Albumin (mg/dL)*	3.6±1.0	3.5±0.9	0,000
Hemoglobin (mg/dL)*	12.7±1.6	11.6±2.7	0,000
Active endocarditis	0,9%	0,1%	0,000
Previous AMI	3,6%	3,6%	0,953
Unstable angina	4,9%	2,8%	0,000
COPD	9,7%	28,4%	0,000
Oxygen dependency	1,4%	6,5%	0,000



INTERMEDIATE RESULTS

Enrolled patients' characteristics

Characteristics	SAVR N=4169	TAVI N=1591	p_value
Neurologic dysfunction	2,5%	6,9%	0,000
Chronic liver disease	1,8%	3,5%	0,000
Active neoplastic disease	1,0%	3,6%	0,000
Peripheral arteriopathy	13,7%	26,2%	0,000
Previous cardiac surgery	4,7%	16,3%	0,000
Previous vascular surgery	2,2%	4,8%	0,000
Porcelain aorta	1,3%	7,9%	0,000
Difficult thoracic approach	0,9%	2,9%	0,000
Frailty score (severe)	6,6%	22,2%	0,000
Previous PCI	7,4%	26,1%	0,000
Previous aortic balloon plas	1,1%	14,6%	0,000
Critical preoperative state	2,1%	4,7%	0,000
NHYA class (III+IV)	36,9%	63,2%	0,000
EuroSCORE* (%)	6.8±8.0	14.5±12.3	0,000



INTERMEDIATE RESULTS

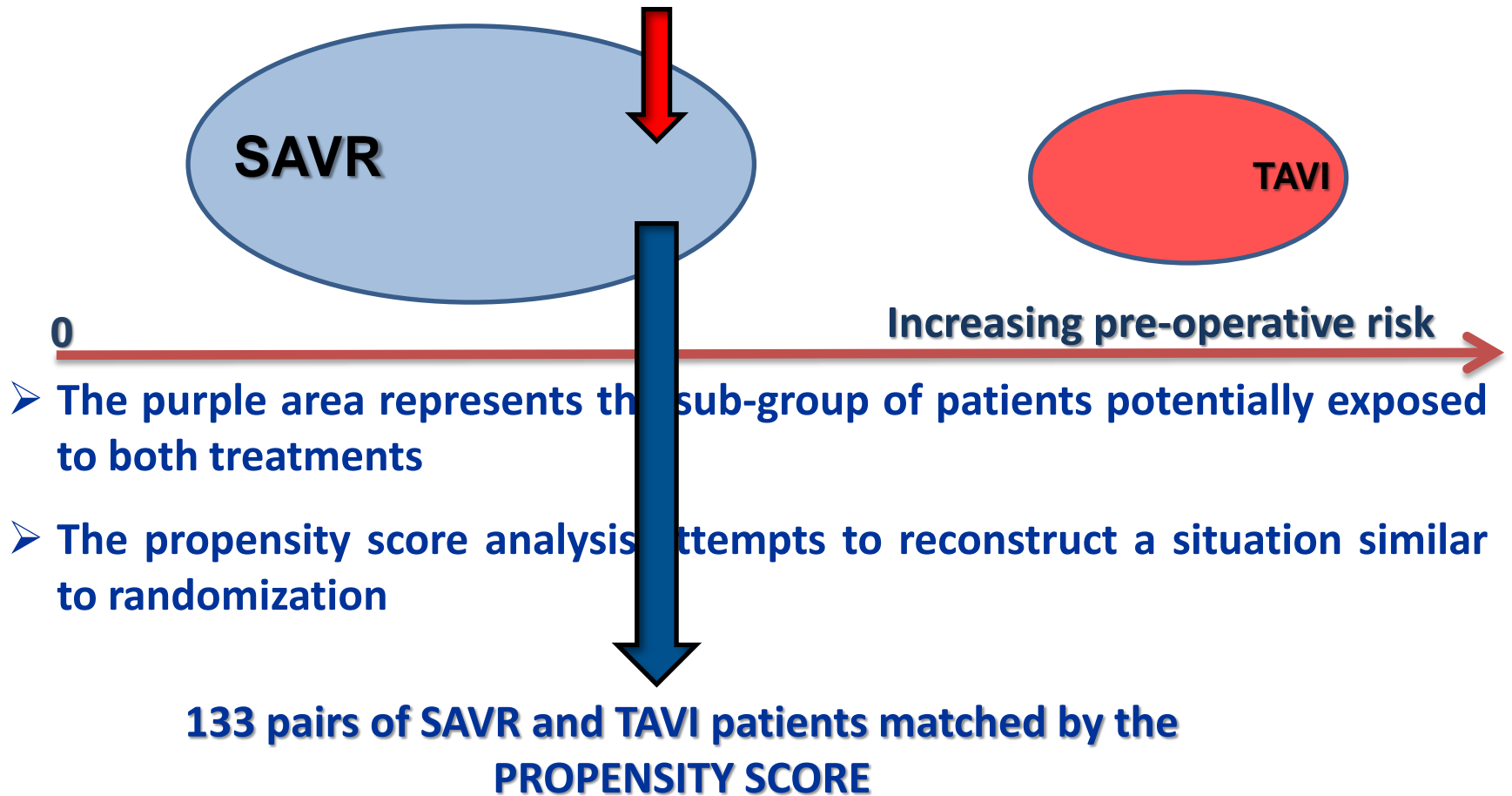
Enrolled patients' characteristics

Angiographic and ecocardiographic findings	SAVR N=4169	TAVI N=1591	p_value
Coronary artery disease (1-3 vessels)	31,4%	30,4%	0,791
Mitral valve regurgitation <i>Mild</i>	40,0%	51,9%	0,000
<i>Moderate</i>	10,4%	25,6%	
<i>Severe</i>	1,6%	3,0%	
Left ventricular ejection fraction<30	4,4%	5,1%	0,572
Aortic valve pattern			
<i>Valve area (cm²)</i>	0.7±0.2	0.6±0.3	0,000
<i>Peak gradient (mmHg)</i>	82.1±23.2	80.6±22.9	0,037
<i>Mean gradient (mmHg)</i>	50.7±15.4	49.7±15.1	0,028
<i>Annulus diameter (cms)</i>	21.6±2.4	22.0±2.2	0,000
Procedural Characteristics			
Emergency status	0,2%	0,6%	0,008
General Anesthesia	98,7%	34,7%	0,000
Associated coronary procedure	24,7%	3,7%	0,000



PROPENSITY APPROACH

- SAVR and TAVI were originally addressed to different population; an overlapping area is expected





PRELIMINARY RESULTS

Procedural outcomes (matched patients: N=266)

Outcomes	SAVR (N=133)	TAVI (N=133)	p_value
Valve migration	0.0%	0.0%	-
Residual aortic regurgitation	12 (9.0)	44 (33.1)	0.000
<i>Mild</i>	1 (0.8)	7 (5.3)	
<i>Moderate</i>	2 (1.5)	1 (0.8)	
<i>Severe</i>			
Cardiac tamponade	2 (1.5)	3 (2.3)	0.632
Permanent A-V Block	1 (0.8)	16 (12.0)	0.000
AMI	1 (0.8)	1 (0.8)	1.000
Major vascular damage	0 (0.0)	7 (5.3)	0.007
Stroke	2 (1.5)	0 (0.0)	0.156
Infection			
<i>Wound</i>	0.0%	3.3%	0.238
<i>Lung or other organs</i>	3.3%	3.3%	
<i>Sepsis</i>	2.2%	0.0%	
Transfusions: Number of units	4.0±4.5	2.4±1.6	0.024
Mean gradient after procedure (mmHg)	13.6±8.6	10.8±6.4	0.008
Peak postoperative creatinine value	1.3±0.6	1.4±0.9	0.284
ICU stay (days)	3.3±5.8	2.4±2.6	0.100
Hospital stay (days)	8.8±5.5	8.1±5.1	0.271
Logistic EuroSCORE (%)	9.4±7.8	8.7±6.1	0.553
Postprocedural Mortality (30 days)	5 (3.8)	5 (3.8)	1.000



Preliminary findings from OBSERVANT

In the real-world setting:

- **SSAS patients undergoing TAVI or SAVR are extremely different**
- **TAVI population agrees with a low risk profile (Log ES < 15)**
- **EuroSCORE is not tailored to properly identify TAVI/SAVR patients**

- **The matched population has a low risk profile (Log ES \approx 8)**
 - 30 days mortality low and no difference between groups
 - no differences in important outcomes (stroke and MI)
- **One of the first attempt in Europe for a new risk score**
- **“TAVI indication criteria” is one of the important expected output**
 - supporting professionals choices
 - controlling costs
 - enhancing patients quality of life and life expectancy



Fulvia SECCARECCIA

**National Centre for Epidemiology,
Surveillance and Health Promotion
Istituto Superiore di Sanità**

**Via Giano della Bella, 34
00162 Rome, Italy
Tel : +39 06 4990 4234
Fax : +39 06 4990 4230**

e-mail : fulvia.seccareccia@iss.it

Thank you!





Thanks' for your kind attention!!!!!!





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