Cost-effectiveness of Transcatheter Aortic Valve Implantation (TAVI) in high-risk or inoperable patients with symptomatic aortic valve stenosis in Spain.

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Introduction

Aortic valve stenosis (AVS) is one of the most frequent structural pathologies of the heart, particularly in older patients [1]. The development of symptoms associated to the disease is an indicator of poor prognosis. It increases the two years mortality risk in more than half of the affected individuals [2]. Open-heart conventional surgery decreases symptoms and improves survival [3]. However, it cannot be performed in about a third of patients due to their poor medical condition [4]. Medical management alone is the only remaining option for this group of patients. Transcatheter Aortic Valve Implantation (TAVI) is a minimally-invasive technique that offers a therapeutic alternative superior to medical management (PARTNER study, US) in inoperable patients with severe AVS.

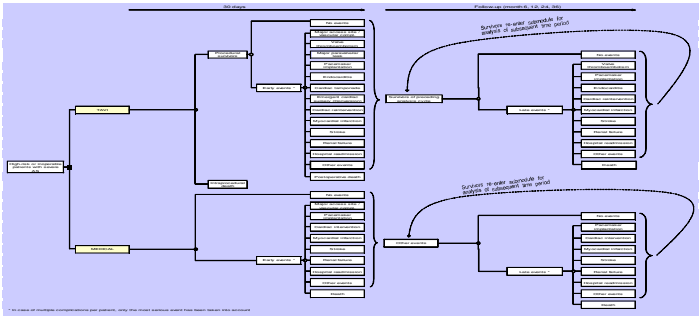
Objective

To estimate the cost-effectiveness of TAVI Edwards SAPIEN, delivered through the transapical (TA-TAVI) or transfemoral (TF-TAVI) approach compared to conservative medical management alone in high risk or inoperable patients with symptomatic AVS in Spain.

Methods

A deterministic longitudinal cohort economic model was developed (**Figure 1**) to predict the clinical and economic outcomes of symptomatic AVS patients treated with either transapical (TA) or transfemoral (TF) TAVI, or with medical management alone (MEDICAL) over three years. The perspective adopted was that of the National Health System in Spain. Only direct costs were taking into account. Benefits and costs were discounted with 3% per year.

Figure 1. Model framework.



Clinical input data for TAVI was derived from the real-world SOURCE (*SAPIEN Aortic Bioprosthesis European Outcomes)* registry [5], and for MEDICAL it was gathered from a registry of 60 Spanish AVS patients followed up during 336 days in a tertiary hospital (**Table 1**), and from the literature. They included early perioperative (30 days) and late complications (6, 12, 24, 36 months). In **Table 2**, the corresponding incidence figures for early complications for TAVI and for MEDICAL patients used for the base case scenario are summarized.

Estimates on the use of resources considered diagnostic and follow up visits, hospital admissions, length of hospital stay, domiciliary hospitalization and home care. Each different clinical outcome and resource used was assigned a specific cost value. **Table 3** shows the corresponding of cost value for the clinical event and the medical resource utilization incorporated into the model.

Health utility estimates were based on published data [6,7]. Missing information was substituted by expert estimates. According to expert consensus, health utilities, resource use and unit costs were representative for Spain.

Economic results were expressed as cost per patient, cost per Life Year Gained (LYG) and cost per Quality Adjusted Life Year (QALY). All costs were expressed in €, 2011.

Table 1. Sociodemographic and clinical characteristics of MEDICAL patients [8]

SOCIO-DEMOGRAPHIC CHARACTERISTICS	
Average Age (SD)	81 (7,2)
Sex [women; (%)]	27 (43,5)
Average Weight (SD)	70.8 (14,3)
Average Height (SD)	160.2 (9,3)
CLINICAL CHARACTERISTICS	
Cardiovascular risk factors	
Diabetes [n;(%)]	25 (40,3)
Hypertension [n;(%)]	51 (82,3)
Dyslipidemia [n;(%)]	34 (54,8)
Intermittent claudication [n;(%)]	3 (4,8)
Angina [n;(%)]	20 (32,3)
Syncope [n;(%)]	6 (9,7)
Comorbidities	
History of stroke [n;(%)]	15 (16,1)
Neurological Dysfunction [n;(%)]	5 (8,0)
Cirrhosis of the liver [n;(%)]	3 (5,8)
Pneumonia [n,(%)]	20 (32,3)
NYHA functional class	
0 [n;(%)]	3 (4,8)
I [n;(%)]	2 (3,2)
II [n;(%)]	10 (16,1)
III [n;(%)]	26 (41,9)
IV [n;(%)]	21 (33,9)
Echocardiographic Data	
Average gradient (SD)	53 (17,5)
Average Valve area (SD)	0.63 (0,22)
Average Logistic EuroSCORE (SD)	18.2 (13,2)

Table 2. Incidence of early clinical events

Early complications (< 30 days)	TA-TAVI (N = 1,387)	TF-TAVI (N = 920)	MEDICAL
Deaths	10.90%	7.50%	11.90%
Home venous access / complications vascular	2.00%	11.30%	-
Valve thromboembolism	0.70%	0.20%	-
Major paravalvular leak	4.30%	4.00%	-
Pacemaker	7.10%	6.70%	-
Endocarditis	0.20%	0.00%	-
Emergency cardiac surgery (Conversion)	0.60%	1.00%	-
Myocardial infarction	0.50%	0.90%	-
Ictus	2.50%	2.90%	-
Renal failure requiring dialysis	6.70%	1.80%	-
Hospital Readmissions (readmissions / patient)	-	-	1.17

Table 3. Economic data imputed

COSTS	TA-AVI	TF-AVI	MEDICAL	REFERENCE
Cost of procedures	€24,909	€24.405		[6]
Length of stay (days)				
ICU (days)	1.5	1.5	0.7	[9]
Ward (days)	9.7	7	5.9	[6]
Cost of hospital admission (per day)				
UCI	€1,442			[6]
Ward	€502			[6]
Cost of clinical events				
Valve thromboembolism	€34,170			DRG
Paravalvular leak	€31,194			Assumptions
Pacemaker implantation	€4,900			DRG
Endocarditis	€11,830			DRG
Myocardial infarction	€4,115			DRG
Ictus	€3,460			DRG
Renal failure requiring dialysis	€3,240			DRG
Hospital readmissions	€3,970		€3,970	[8]
Annual cost of routine outpatient care (doctor visits and diagnostic)	€1.150	€1.150	€1.840	Assumptions
Annual cost of drug treatment	€220	€220	€220	Assumptions
Annual cost of home care	€700	€700	€700	Assumptions

Results

Over the 3 year period of analysis, 2.12 life years per patient were achieved with TA TAVI, 2.31 with TF TAVI and 1.51 with MEDICAL management, representing 1.24, 1.38 and 0.74 QALYs, respectively (**Table 4**).

Table 4. Survival Outcomes vs Therapies at 36 months

Clinical and Economics Outcomes	Therapies		
	TA-TAVI	**TF-TAVI**	**MEDICAL**
LIFE YEARS GAINED	2.12	2.31	1.51
QUALITY ADJUSTED LIFE YEARS (QALYs)	1.24	1.38	0.74

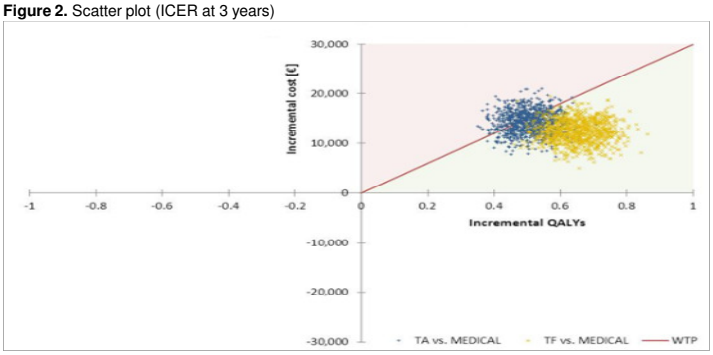
Cumulative direct costs were predicted to amount to **€37,311 and €35,689 with TA and TF TAVI,** respectively, and to sum up **€23,103 with MEDICAL** management.

While the estimated cost per patient treated with TAVI remained very much the same over the three years of analysis, the cost per patient managed with MEDICAL treatment tended to increase over time, indicating that TAVI might become a more cost-effective alternative over the years.

The **cost/QALY** gained was **€28,003 for TA TAVI** and **€19,499 for TF TAVI**, both ratios remaining well below the accepted threshold for Spain [8].

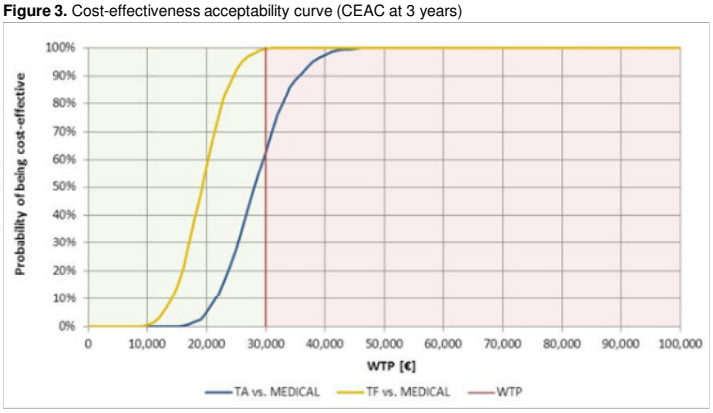
The scatter plot diagram (**Figure 2**) shows that TAVI provides better clinical results, but at a higher cost than MEDICAL management only.

Figure 2. Scatter plot (ICER at 3 years)



Considering a maximum acceptable ceiling ratio of € 30,000, TF TAVI had a 100% probability of being cost -effective while the chances for TF TAVI for being cost -effective, was of 60%. management alone (**Figure 3**).

Figure 3. Cost-effectiveness acceptability curve (CEAC at 3 years)



Conclusions

►For high-risk inoperable patients with symptomatic AVS, TAVI resulted to be cost-effective compared to MEDICAL treatment alone in Spain.

►Patients survival was longer, and more years of life with better quality were gained with TAVI than with medical treatment alone.

►The initial high acquisition costs of the device was offset over time by the cumulative savings derived from preventing hospital readmissions for cardiac reasons.

►These findings, however, have to be interpreted in the context of the model limitations inherent to its nature and to the diversity of the sources of information used. These limitations are similar to the identified by other authors [6].

References

[1] Circulation 2005; 111: 3316-3326. [2] N Engl J Med. 2002; 346:677-682. [3] Eur J Cardiothorac Surg. 2006;30:722-727. [4] Catheter Cardiovasc Interv. 2010;75:1121-1126. [5] Circulation 2010. Doi: 10.1161/CIRCULATIONAHA.109.907402. [6] Madrid: Plan de Calidad para el SNS del MSC. Unidad de Evaluacion de Tecnologias Sanitarias, Agencia Laín Entralgo; 2010: Informes de Evaluación de Tecnologías Sanitarias: UETS 09/03. [7] Qual Life Res 2008; 17: 1229-1238. [8] Unpublished data. Vall d'Hebron Hospital registry. Barcelona. Spain. [8] Gac Sanit 2002;16: 334-343. [9] Experts' opinion. Vall d'Hebron Hospital registry. Barcelona. Spain.