COST-EFFECTIVENESS OF TITANIUM NITRIDE-COATED BIOACTIVE CORONARY STENTS COMPARED TO BMS AND DES

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Background:
The Commission of Medical Devices (CMD) of United Hospitals of Ancona (UHA), established from the year 2005, was asked to authorize a coronary stent in steel, coated with bioactive titanium nitride (TITAN 2).This stent is biocompatible: does not release nickel chromium and molybdenum ions; its outer layer made of protective nitride-oxide shows bioactive properties, inhibits thrombosis, reduces platelet aggregation, induces relaxation of smooth muscle cells, is vasodilator and reduces neointimal proliferation. TITAN 2 is indicated in patients who can not guarantee the compliance to the antiplatelet therapy, in acute myocardial infarction and in allergic to nickel chromium and molybdenum patients.

Methods:
The commission conducted a cost-effectiveness confrontation of the required stent with BMS and Paclitaxel, Everolimus and Sirolimus eluting stents.
The direct healthcare costs were considered as overlapping, assuming that the only difference was the cost of the devices. Efficacy data were retrieved through a systematic review of the literature that would provide conclusions with respect to relevant outcomes such as Composite Myocardial Infarction, target lesion revascularization (TLR) and Major Adverse Cardiovascular Events (MACE)

Objective:
The Commission, responsible for approving the acquisition of medical devices out of the yearly approved repertoire, has considered whether Titan 2 is cost-effective compared to Bar Metal Stents (BMS) and Drug Eluting Stents (DES): Paclitaxel, Everolimus and Sirolimus in patients requiring Percutaneous Transluminal Coronary Angioplasty (PTCA)

Tab. 1: Cost-effectiveness of BMS and DES

TREATMENT	SOURCE	OUTCOME	SETTING	COMPLICATIONS	EFFECTIVENESS %	COST (€)	C/E
Stainless steel stent	Windecker S. et al (2005)	Major adverse cardiac events at 6 months (MACE)	47 patients with de novo lesions	27,0%	73,0%	€ 650	€ 890
Titanium-nitride-oxide coated stent			45 patients with de novo lesions	7,0%	93,0%	€ 850	€ 914
						DISCOUNT	€ 24
						%DISCOUNT	2,58
Everolimus eluiting stent (Xience)	on press	Major adverse cardiac events at 12 months (MACE)	410 patients with acute coronary syndrome	9,0%	91,0%	€ 1.200	€ 1.319
Titanium-nitride-oxide coated stent			417 patients with acute coronary syndrome	9,6%	90,4%	€ 850	€ 940
						DISCOUNT	-€ 378
Paclitaxel eluiting stent (Taxus)	Karjalainen PP et al (2009)	Composite myocardial infarction, TLR e death for cardiac events (=MACE)after a follow-up of 2 years	425 patients with acute myocardial infarction	21,8%	78,2%	€ 1.050	€ 1.343
Titanium-nitride-oxide coated stent				11.2%	88,80%	€ 850	€ 957
						DISCOUNT	-€ 386
Sirolimus eluiting stent (Cypher)	Limacher A. et al (2011)	Major adverse cardiac events at 3 years (MACE)	319 patients treated vith Titan or **Cypher**	19%	81,00%	€ 1.050	€ 1.296
Titanium-nitride-oxide coated stent			337 patients treated with **Titan** or Taxus	20%	80,00%	€ 850	€ 1.062,50
						DISCOUNT	-€ 233,80

Results:
The studies procured in the literature has shown that MACE at six months was less frequent in patients treated with Titan 2 compared to controls treated with BMS of identical design (7% vs 27%) in 92 patients with de novo lesions randomly assigned to treatment with titanium-nitride-oxide-coated stents or stainless steel stents (Table 1)
Based on the initial processed data, Titan 2 was not showing a favorable cost-effectiveness ratio (C/E): 914 Euro compared to a BMS C/E of 890 Euro.
The commission contacted the medical device distributor and obtained a discount on the price of 2.58% .
Titan 2 has proven cost-effective with respect to Everolimus eluiting stents because the MACE at 12 months is a primary non-inferiority endpoint in a sample of 427 patients treated with Titan 2 and in one of 410 patients treated with Everolimus eluiting stents (9.6% vs 9.0%)
A favorable C/E for Titan 2 was obtained comparing this stent to Paclitaxel eluting stent for MACE after 2 years of follow-up in 425patients (11.2% versus 21.8%).
Another study compared clinical outcome MACE among 319 patients treated with TITAN 2 or sirolimus eluiting stents and 337 patients treated with TITAN 2 or placlitaxel eluting stent. At 3 years of follow-up, MACE occurred in 20% patients treated with TITAN 2, in 19% of patients with sirolimus eluting stents and in 23% of patients with paclitaxel eluting stent. TITAN 2 is cost-effective respect to Sirolimus eluiting stent but not superior to sirolimus and paclitaxel-eluting stent. In view of the one month of dual antiplatelet therapy used with TITAN 2, it may be an alternative to drug eluting stents in patients unsuitable for long-term dual antiplatelet therapy.

Conclusion:
With the cost-effectiveness analysis conducted on the basis of EBM methodology, has been possible introduce in UHA Titan 2 with a discount of 24 Euro compared to the steel stents for patients with allergies to metals and their alloys or that require only a month of dual antiplatelet therapy