

# RANDOMIZED STUDY COMPARING STAINLESS STEEL WITH TITANIUM-NITRIDE-OXIDE COATED STENTS FOR CORONARY ARTERY LESIONS

## BACKGROUND

Titanium-Nitride-Oxide coated stents have shown efficacy to reduce neointimal hyperplasia in comparison to conventional stents both in animals and human beings.

## PURPOSE

The aim of this prospective and randomized study is to assess the safety and efficacy of the TiTAN2 stent versus BMS and to compare the rate of Major Adverse Cardiac Events (MACE) and the percentage of patients free from angina at 6 months in both groups. MACE are defined as: death, AMI, and new revascularization.

## METHODS

- Period: July to December 2005 (6 months).
- Inclusion criteria: all patients candidate for stent implantation.
- Patients were randomized in two groups:
  - Group BMS: 63 patients (72 lesions)
  - Group TiTAN2: 53 patients (61 lesions)
- Patients were treated after stent implantation with ASA and TICLOPIDIN during **30 DAYS** and with other medications at the operator discretion.
- Follow up at 6 months was clinical either by clinic appointment or telephone call.
- Cohorts were compared with Fisher's test for categorical variables and test of Student for numerical variables.
- Event-free survival curves (MACE and angina) were calculated with Kaplan-Meier methods.

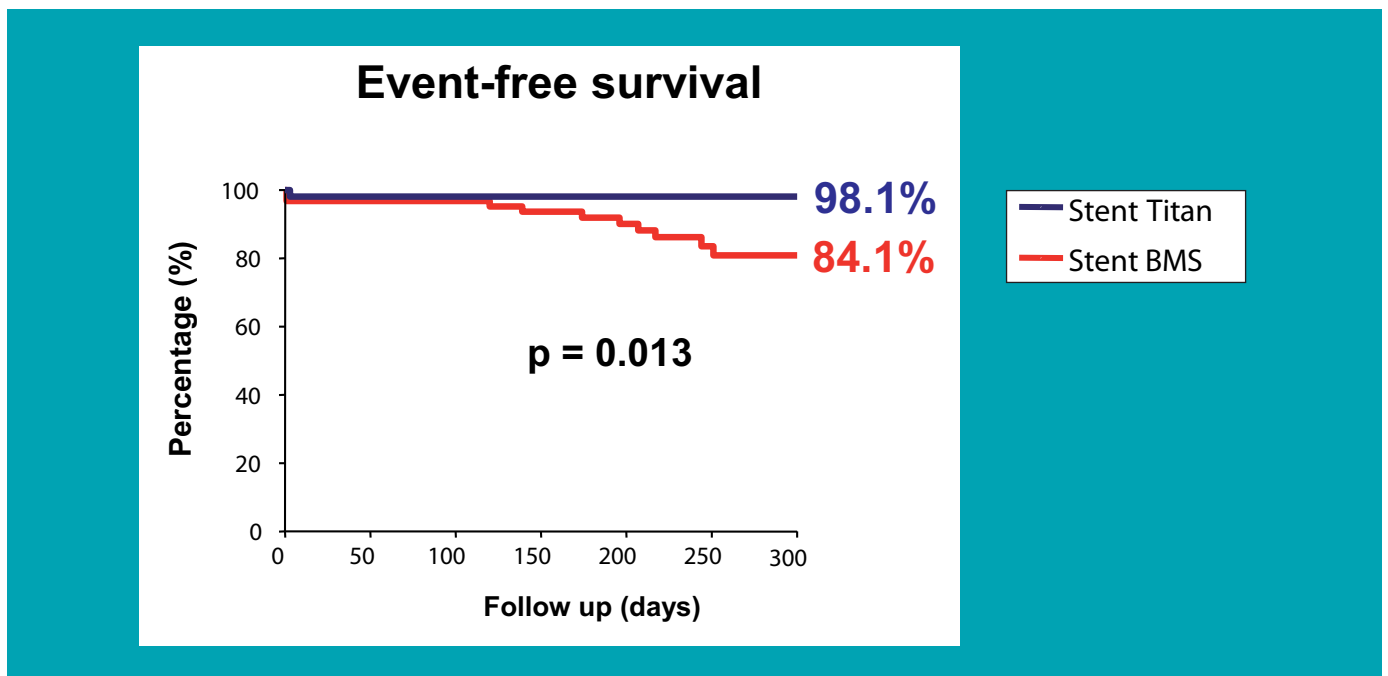
## RESULTS

CLINICAL DATA	PATIENTS (n=116)	GROUPS		P
		BMS (n=63)	TITAN2 (n=53)	
Age	61.2 ± 10.5	59.9 ± 10.2	62.7 ± 10.8	0.15
Female, %	32.8	28.6	37.7	0.33
Symptoms, n(%)				0.11
Stable angina	70 (60.3)	39 (61.9)	31 (58.5)	0.85
Silent ischemia	26 (22.4)	17 (27)	9 (17)	0.26
Unstable angina	20 (17.3)	7 (11.1)	13 (24.5)	0.08
Risks factors, n(%)				
Hypertension	90 (77.6)	53 (84.1)	37 (69.8)	0.08
Dislipidemia	63 (54.3)	32 (50.8)	31 (58.5)	0.46
HF de DAC	43 (37.1)	22 (34.9)	21 (39.6)	0.70
Smoker	25 (21.6)	17 (27)	8 (15.1)	0.17
Diabetes	28 (24.1)	15 (23.8)	13 (24.5)	0.93
Previous AMI, n(%)	54 (46.6)	30 (47.6)	24 (45.3)	0.85
Previous PCI, n(%)	10 (8.6)	3 (4.7)	7 (13.2)	0.18
Previous CABG, n(%)	0	0	0	
Ejection fraction (EF), %	60 ± 14	62 ± 13	59 ± 15	0.26
Multi-vessels, n(%)	79 (68.1)	41 (65.1)	38 (71.7)	0.55

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## RESULTS

RESULTS AT 6 MONTHS	PATIENTS (n=116)	GROUPS		P
		BMS (n=63)	TITAN2 (n=53)	
Death, n(%)	1 (0.8)	1 (1.6)	0	0.36
AMI, n(%)	6 (5.2)	5 (7.9)	1 (1.9) <sup>2</sup>	0.16
TLR, n(%)	5 (4.3)	5 (7.9)	1 (1.9)	0.16
<b>MACE, n(%)</b>	<b>11 (9.5)</b>	<b>10 (15.9)</b>	<b>1 (1.9)</b>	<b>0.013</b>
Angina, n(%)	10 (8.6)	8 (12.7)	2 (3.8)	0.09



## CONCLUSIONS

- This prospective and randomized study comparing Titanium-Nitride-Oxide Bio Active coated stent (TiTAN2) with conventional BMS for the treatment of coronary artery lesions, has demonstrated a lower incidence of MACE in the TiTAN2 group, as well as a lower trends of angina.
- Rates of sub acute thrombosis and AMI were low and similar in both groups treated only with Ticlopidin during 30 days after stent implantation.

## PARTICIPATING CENTER

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18-21 July 2006 - Porto Alegre  
 Revista Brasileira de Cardiologia Invasiva  
 N°2 - Vol14 - Abril/Mayo/Juno 2006

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