

RANDOMIZED TRIAL OF A TITANIUM-NO* COATED STENTS VS BARE METAL STENTS IN ACUTE CORONARY SYNDROMES: EARLY AND LATE THROMBOSIS AND RESTENOSIS

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BACKGROUND

The purpose of this randomized study was to evaluate the efficacy of a Titanium-NO coated stent versus bare metal stents (BMS) on early and late thrombosis as well as on angiographic restenosis in a group of patients with either unstable angina or acute myocardial infarction (AMI) undergoing percutaneous Coronary Intervention.

METHODS AND RESULTS

- Seventy-one patients with acute ischaemic symptoms (44 UA pts and 27 AMI pts, 19 primary and 8 rescue PCI) were randomized to treatment with Titanium-NO stents (n=32, age 59 ± 14 , 20 men) or BMS (n=39, age 62 ± 11 , 26 men).
- Angiograms were analyzed by quantitative coronary angiography pre and post procedure and at 6-month follow-up.
- Patients were followed for adverse cardiac events at 30 days and at 6 months.
- Baseline characteristics were similar in both groups. Stent diameter ranged from 2.25 to 4 mm.
- At 30 days no stent thrombosis or other adverse events were observed in either group.
- At 6 months, late thrombosis was absent in Titanium-NO group, while one stent was found occluded in BMS group.
- TVR was needed in 9.4% in Titanium-NO group and in 18% in BMS group (p=NS).
- QCA at 6 months showed a late loss of 0.68 ± 0.32 for Titanium-NO group (ref D 2.94 ± 0.27 mm) and of 1.04 ± 0.58 for BMS group (ref D 2.44 ± 0.41 mm) (p< 0.05). Binary Restenosis was 9.4% for Titanium-NO group and 33.3% for BMS group (p< 0.05).

STUDY POPULATION

	TITAN (N=32)	BMS (N=39)	P
Age	59.1 ± 14	62.1 ± 11	Ns
Sex (males)	63%	67%	Ns
Family history	34%	26%	Ns
Hypertention	38%	56%	Ns
DM type I	0	0	Ns
DM type II	3%	10%	Ns

CLINICAL PRESENTATION

	TITAN	BMS	p
Stable angina	0	21%	0.006 5
Unstable angina	65%	38%	0.027
AMI	22%	30%	Ns
AMI < 3 days	13%	10%	Ns

TECHNICAL DATA OF IMPLANTATION

	TITAN	BMS	p
Direct stenting	50%	15%	0.0017
Stent diameter (min. 2.25, max 4.0 mm)	3.07 ± 0.45	2.87 ± 0.36	Ns
Stent length	13.25 ± 2.93	13.36 ± 3.55	Ns
Atmospheres	13.45 ± 2.05	13.49 ± 2.39	Ns

ANATOMY

	TITAN	BMS
LM	0	0
Proximal LAD	19%	10%
LAD	31%	36%
CX	6%	31%
RCA	44%	23%
Grafts	3%	0

METHODS AND RESULTS

**MORPHOLOGY OF THE TREATED VESSEL 1
(pre-procedure)**

	TITAN	BMS	P
MLD	0.98 ± 0.47	1.03 ± 0.39	Ns
REF DIAM	2.88 ± 0.52	2.7 ± 0.47	Ns
% STENOSIS	71.9 ± 15.5	61.3 ± 15.3	Ns
TIMI 3	84%	82%	Ns

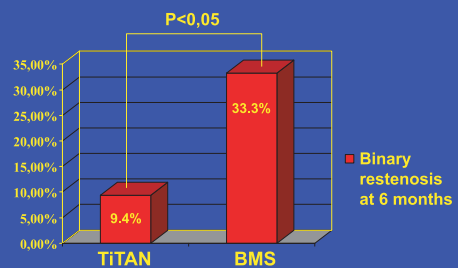
**MORPHOLOGY OF THE TREATED VESSEL 2
(post-procedure)**

	TITAN	BMS	P
MLD	2.84 ± 0.46	2.56 ± 0.44	Ns
REF DIAM	3.16 ± 0.44	2.84 ± 0.46	Ns
% STENOSIS	7.04 ± 6.89	10.35 ± 7.2	0.024
TIMI 3	100%	100%	Ns

**MORPHOLOGY OF THE TREATED VESSEL 3
6-month follow-up**

	TITAN	BMS	P
MLD	2.16 ± 0.91	1.52 ± 0.61	0.0023
REF DIAM	2.94 ± 0.27	2.44 ± 0.41	Ns
% STENOSIS	28 ± 20	37.6 ± 21	0.046
LATE LOSS	0.68	1.04	<0.05

BINARY RESTENOSIS



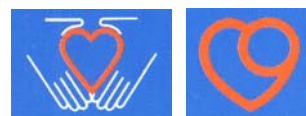
CONCLUSION

- This angiographic study, employing the TITAN stent, shows that this stent is correlated with a lower binary restenosis incidence and a lower late loss comparing with bare metal stents.
- Our study shows also that this somehow encouraging restenosis rate can be obtained in a very unstable population as well as in elective patients.

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