

THE TIBET STUDY: MULTICENTER TITAN* REGISTRY IN THE TREATMENT OF CORONARY LESIONS IN DIABETIC PATIENTS

BACKGROUND

Stents coated with Rapamycine and Paclitaxel have shown efficacy in reducing restenosis and cardiac events. Diabetics have one of the highest restenosis rate after PTCA. Despite results obtained with stents coated with Rapamycine and Paclitaxel in diabetic patients, results with other sort of coated stents are not well known.

METHODS

TIBET is a multicentric study to document diabetic patients with De Novo lesions treated by PTCA with a Titan coronary stent (Titanox Coating**). The study enrolled 156 diabetics patients with 197 stents implanted in 9 hospitals in Spain. Hereafter are the clinical results from the TIBET study: death, reMI and target lesion revascularization at six months.

RESULTS-I *n=156 (all patients)*

- Mean age was 66.67 ± 9.61 years and 68.35% were men.
- The clinical status was unstable angina: 63.91%.
- Lesions were type A: 13.19%, type B: 74.16%, type C: 12.65%.
- 2.52% were diabetics type I and of the 97.47% diabetics type II, 23.4% were ID.
- 34.17% were treated with Reopro during the procedure.
- Direct stenting: 45.17%.
- Reference diameter was 3.07 ± 0.59 mm, mean lesion length was 17.24 ± 8.60 mm, and % of stenosis was 83.03 ± 11.61 %.
- Average inflation was 13.86 ± 4.23 , and visual residual stenosis was 4.69 ± 8.92 .
- Stent delivery with clinical success was present in 99.2% of patients.
- During hospital stay, two patients had enzyme elevation compatible with non Q-wave MI.

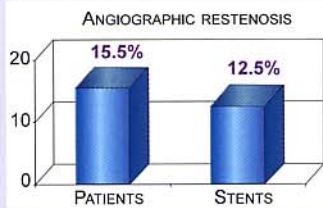
* TITAN and TITAN2 are registered trademarks of Hexacath.

** Titanox is a registered trademark of Hexacath for its proprietary Titanium-Nitride-Oxide Coating.

RESULTS-II n=45 (subgroup)

9 months angiographic follow-up

LATE LOSS	MM	0.56
LATE LOSS INDEX		0.32

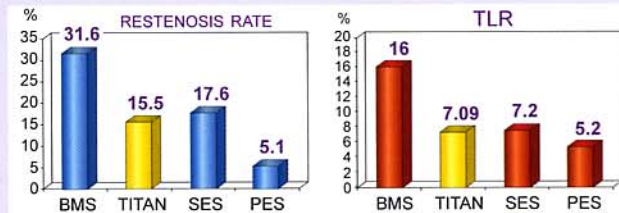


All restenosis in-stent and focal.
No diffuse or proliferative patterns.

9 months IVUS study follow-up Preliminary results

	DIAMETER	AREA
LUMEN PROX REF	3.47	9.65
VESSEL PROX REF	4.29	14.9
LUMEN DISTAL REF	3	6.2
VESSEL DISTAL REF	3.3	8.4
STENT POST-IMPL	3.22	8.3
STENT FOLLOW-UP	2.72	5.87
LATE LOSS	0.50	2.43

Angiographic restenosis and TLR in diabetics in BMS, TiTAN, SES and PES*



* BMS: Bare Metal Stent - SES: Sirolimus Eluting Stent - PES: Paclitaxel Eluting Stent

CONCLUSIONS

- In diabetics treated with TiTAN stent, MACE at 6 months were 10.3%.
- At 6 months cardiac death 1.95%, QwMI 1.29% and TLR 7.09%.
- Angiographic restenosis was 15.5%.
- Late loss 0.56mm by QCA and 0.50 by IVUS.
- So far those are the best results that a non-DES ever had, and are close to some DES. Other studies would be very important to elucidate the true possibility of the TiTAN stent.

PARTICIPATING CENTERS (Spain)

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