

The Spanish Multicenter Registry

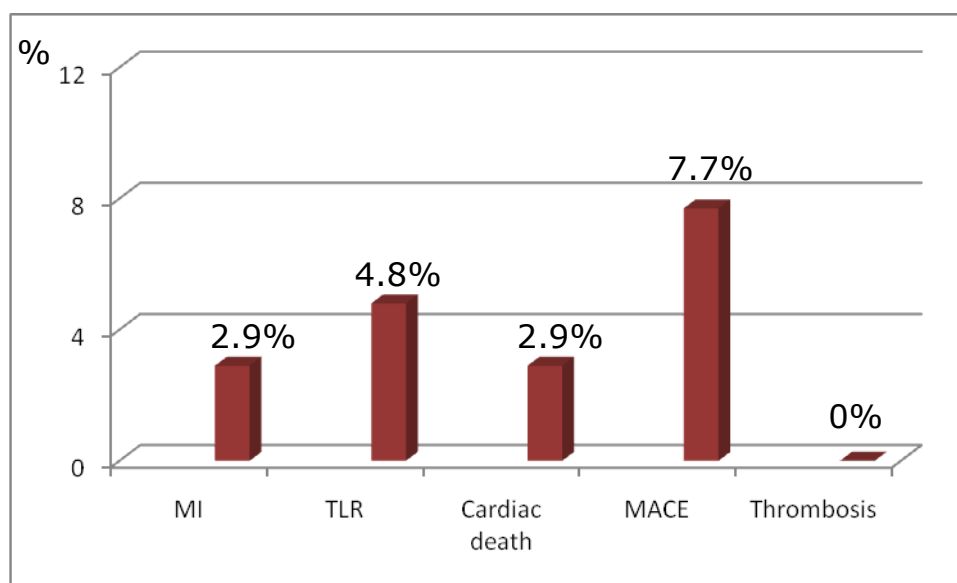
DIOR[®] in ISR and Small Vessel Disease

Excellent Intermediate Results presented on AHA congress 2009

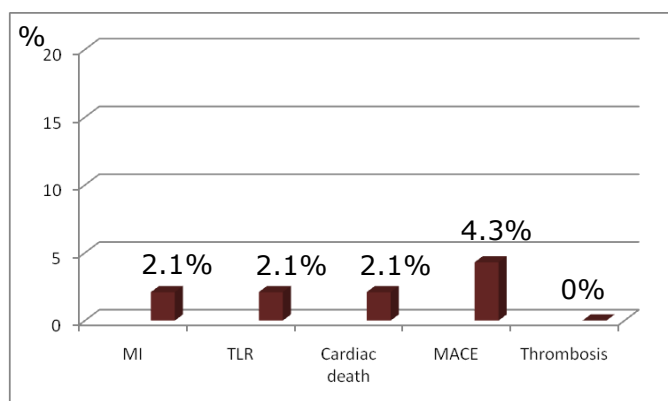
- ✓ *Study Title:*
Efficacy and safety of PCI with the new Paclitaxel-Eluting Balloon: The DIOR[®] Multicenter Registry
- ✓ *Principal Investigator:*
Dr. Serra, Dr. Vaquerizo, Dr. Miranda (Hospital Del Mar, Barcelona)
- ✓ *Aim of the Study:*
Assessment of efficacy and safety of the Paclitaxel-eluting balloon DIOR[®] in patients with ISR or *de novo* lesions in small vessels (<2.5 mm)
- ✓ *Study Design:*
Prospective, multicenter registry (9 Spanish centers)
- ✓ *Follow-up:*
Clinical follow-up at 1, 6 and 12 months
Angiographic follow-up at 6-8 months in 40% of patients
- ✓ *Included Patients:*
191 patients and 199 lesions
- ✓ *Demography and Clinical Characteristics of Patients:*
Age (65.6 ± 10.4 years)
Male Gender (80%)
History of PCI (66.8%)
Diabetes (31.6%)
Current Smoker (31.1%)
Clinical presentation with ACS (54.2%)
- ✓ *Baseline Lesion Characteristics:*
Indication for use of DIOR[®]
 - In-stent restenosis (56%)
 - De novo lesion small vessel <2.5 mm (38.2%)
- ✓ *Baseline Procedural Characteristics:*
Pre-dilatation with plain balloon (100%)
DIOR[®] balloon mean diameter (2.7 ± 0.5 mm)
DIOR[®] balloon mean length (19.2 ± 5.1 mm)
DIOR[®] balloon mean inflation time (94.9 ± 37.8 sec)



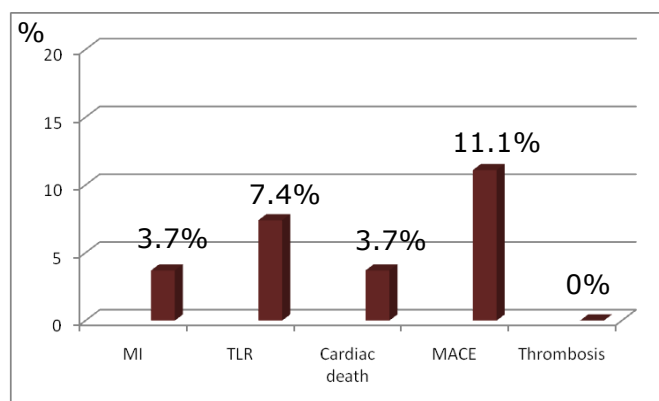
Cumulative Results at 6 months (completed in 104 patients)



Small vessel subgroup at 6 months (completed in 47 patients)



ISR subgroup at 6 months (completed in 54 patients)



Conclusion:

- Use of the Paclitaxel-eluting balloon DIOR[®] provides an excellent mid-term outcome with 5% TLR at 6 months
- Use of DIOR in ISR is a promising treatment to avoid stent-in-stent implantation
- Use of DIOR in Small Vessel Disease provides remarkable results which have not been described before

Vaquerizo et al., AHA congress 2009