

Efficacy and Safety of the first polymer free Rapamycin-eluting stent system in unselected patients: The results of the YUKON Choice DES registry.

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Background: First generation DES were characterized by the use of durable polymers to control drug release. However, the permanent presence of a polymer in the vessel wall could have negative effects on the long term safety of DES. Currently, only one **polymer-free** drug eluting coronary stent system could prove efficacy (YUKON Choice DES, Translumina GmbH, Hechingen, Germany). The aim of this registry was to determine the efficacy and safety as well as the reproducibility of this “In-cathlab-coated product” for all indications in clinical routine (on-label and off-label use) and compare it with available randomized trials.

Methods: Between 2006 and 2009 1.280 coronary stent systems (Yukon Choice DES) were coated with a validated coating process using a 2 % Ethanol-Rapamycin coating solution. After the coating process the stent systems were stored at 4 °C until implantation. So far, 861 unselected patients were treated with the polymer-free Rapamycin-eluting stent in 1041 lesions and monitored afterwards. Primary endpoint of this prospective registry study was the rate of clinically induced target lesion revascularisations (TLR) after 6 months. Additionally, the rate of major adverse cardiac events (MACE) and stent thromboses were evaluated.

Results: During the stent implantation, there were no abnormalities due to handling or angiographic characteristics (e.g. flow behaviour) compared to standard polymer-coated stents. The TLR rate 6 months after implantation of the Yukon Choice DES system was 3.6% accounting for all patients. Major adverse cardiac events (MACE) were recorded for 7.5% of all patients after 6 months. The rate of early stent thrombosis according to ARC-definition (up to 30 days) was 0.85%, late stent thromboses were observed for 0.3% of the patients (0.17% definitely, 0.13% possible stent thromboses according to ARC-Definition). There were no unusual clinical events during routine follow-up.

Characteristic	Begin
No. Of patients	861
Age (years)	65,7±10,0
Sex (f/m)	222/639
Diabetics (%)	38,6
Multi-Vessel-Disease (%)	73,3
Prior Myocardinfarct (%)	33,8
Prior PCI (%)	46,1
Prior CABG (%)	22,2

Tab. 1: Patient Characteristic

PCI Procedure	N = 861
No. of lesions	1041
No. of stents (Yukon DES)	1281
Complex lesions -B2, C (%)	73,2
Stented length (mm)	17,0±5,3
Direct stenting (%)	71,7
Pressure deployment (atm)	15,5±1,7
Inflation duration (sec)	30,9±9,3
Post-dilation (%)	9,9

Tab. 2: Details of PCI Procedure

MACE	6-Months
All Death (%)	0,47
Non Cardiac Death (%)	0,23
Cardiac Death (%)	0,23
Myocardinfarct (%)	0,93
TLR (%)	3,6
Early Stent Thrombosis (%)	0,85
Late Stent Thrombosis (%)	0,3
Total MACE (%)	7,54

Tab. 3: MACE-Rate

Conclusion: The largest registry of the YUKON Choice DES proved the safety and reproducibility of the in-house coating of a polymer-free Rapamycin-eluting stent directly in the catheterization laboratory. After 6 months the YUKON Choice DES stent system proved non-inferiority to common first generation DES (Taxus, Cypher) in the clinical routine regarding efficacy and safety.

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