ISAR-TEST 1 trial: YUKON^{DES} vs. TAXUS

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Original Title:
Randomised Trial of a Nonpolymer-Based Rapamycin-Eluting Stent Versus a Polymer-Based Paclitaxel-Eluting Stent for the Reduction of Late Lumen Loss (ISAR-TEST 1 study)
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STUDY DESIGN:

A randomised, double blind study designed to test the noninferiority of the polymer-free Yukon DES coated on-site with 2% rapamycin solution (rapamycin stent) compared with the polymer-based paclitaxel-eluting Taxus stent (paclitaxel stent). 450 patients with the novo lesions in native coronary vessels, excluding the left main trunk, were randomly assigned to receive either the polymer-free rapamycin stent (n=255) or polymer-based paclitaxel stent (n=225).

Baseline demographic and clinical characteristics of the study patients

Characteristic	Polymer-Free Rapamycin Stent (Yukon, n=225)	Polymer-Based Paclitaxel Stent (Taxus, n=225)	P
Age (yrs)	66,8±10,5	66,6±10,2	0,88
Women, n (%)	56 (25)	48 (21)	0,37
Diabetes mellitus, n (%)	73 (32)	58 (26)	0,12
Current smoker, n (%)	43 (19)	39 (17)	0,63
Arterial hypertension, n (%)	142 (63)	155 (69)	0,2
Hypercholesterolemia, n (%)	165 (73)	170 (76)	0,59
Unstable angina, n (%)	94 (42)	99 (44)	0,63
Prior MI, n (%)	72 (32)	71 (32)	0,92
Prior CABG, n (%)	25 (11)	25 (11)	1
Left ventricular ejection fraction, %	54,0±4,1	55,3±13,5	0,33
No of lesions treated	1,2±0,44	1,1±0,36	0,13

Baseline angiographic characteristics of the study patients

Characteristic	Polymer-Free Rapamycin Stent (Yukon, n=225)	Polymer-Based Paclitaxel Stent (Taxus, n=225)	P
Vessel size, mm	2,72±0,46	2,73±0,49	0,94
Lesion length, mm	12,6±5,9	12,9±7,0	0,59
Minimal lumen diameter before procedure, mm	1,14±0,40	1,14±0,42	1
Diameter stenosis before procedure, %	58,3±12,4	58,1±12,7	0,87

STUDY ENDPOINTS:

The primary endpoint of the study was the assessment of in-stent lumen loss at 6 months follow-up angiography. Secondary endpoints were the assessment of angiographic restenosis at follow-up angiography and clinically driven TLR during the 9-month follow-up.

RESULTS:

Angiographic outcomes:
Follow-up angiography was performed in 183 patients (81,3%) in the rapamycin-stent group and in 181 patients (80,4%) in the paclitaxel-stent group. With respect to primary end point analysis, the mean difference in in-stent late lumen loss between the rapamycin stent group and the paclitaxel-stent group was 0,002mm and the upper limit of the 1-sided 95% confidence interval was 0,10mm.

Quantitative findings at follow-up angiography

Characteristic	Polymer-Free Rapamycin Stent (Yukon) (n=183)	Polymer-Based Paclitaxel Stent (Taxus) (n=181)	P
Late lumen loss			
In-stent, mm	0,48±0,61	0,48±0,58	0,98
In-segment, mm	0,34±0,59	0,24±0,57	0,09
Minimal lumen diameter			
In-stent	2,10±0,68	2,11±0,70	0,96
In-segment	1,93±0,65	1,93±0,68	0,98
Diameter stenosis			
In-stent, %	25,04±20,79	25,66±19,28	0,77
In-segment, %	31,64±18,48	31,97±18,72	0,87
Angiographic restenosis			
In-stent, n (%)	23 (12,6)	21 (11,6)	0,78
In-segment, n (%)	26 (14,2)	28 (15,5)	0,73

Clinical outcomes:
30 days after randomisation

Result	Polymer-Free Rapamycin Stent (Yukon) (n=225)	Polymer-Based Paclitaxel Stent (Taxus) (n=225)	P
Thrombotic stent occlusion, n (%)	1 (0,4)	1 (0,4)	NS
Death or myocardial infarction, n (%)	9 (4)	7 (3,1)	NS

9 months after randomisation

Result	Polymer-Free Rapamycin Stent (Yukon) (n=225)	Polymer-Based Paclitaxel Stent (Taxus) (n=225)	P
Death + myocardial infarction, %	4,4	4	0,81
Target lesion revascularization, %	9,3	9,3	1

CONCLUSION:

The polymer-free rapamycin eluting Translumina YUKON^{DES} stent was not inferior to the polymer based, paclitaxel-eluting TAXUS stent in reducing neointimal proliferation. The incidence of angiographic and clinical restenosis was virtually the same in both study groups. These findings may be very clinically relevant, with respect to elimination of the potential long-term negative effects of polymers.

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