

Coated Stents: Current Results (Oral Contributions)
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SCORE Trial Interim Safety Results: Despite Efficacy, Late Stent Thrombosis With the QuaDDS-QP2 Stent

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Background: The purpose of the SCORES trial was to compare safety and efficacy of the QuaDDS-QP2 stent with control, bare stents (QueST or any bare metal stent) for treatment of *de novo* lesions. The QuaDDS-QP2 stent has 5 polymer sleeves that contain 4000 µg of QP2, a taxane derivative intended to inhibit restenosis. QCA analysis (reported separately) showed improvements in restenosis despite including cases of stent thrombosis. The purpose of this abstract is analysis of long term clinical results reflecting high dose taxane delivery using the sleeve technology.

Methods: Of 400 planned patients at 15 sites, 266 patients were randomized and treated with either the QuaDDS-QP2 stent (N=128) or the QueST (112) or any bare metal stent (26)(Total control N=138). Enrollment was stopped due to increased early MACE events. Currently, 248 patients (120 QuaDDS; 128 QST) have completed the 6 month visit, including 18 patients that were lost to follow-up, dropped out or died. All MACE were adjudicated by a centralized Safety Adjudication Committee.

Results: The QuaDDS group had 12 stent thromboses (four at least 6 months after stent placement; ten associated with MI) and 5 deaths (three associated with stent thrombosis, one with multi-organ failure post CABG, one with cardiogenic shock).

Parameter	QuaDDS-QP2 (N=128)	QueST (N=138)	P value
Stent Thrombosis	12 (9%)	0	<0.01
Peri-procedural	1		
Discharge-Day 30	3		
Day 30-180	4		
After Day 180	4		
Death (cardiac-related)	5 (4%)	0	0.02

Conclusions: Early and late stent thromboses limit the utility of QuaDDS-QP2 stent despite its beneficial effect on restenosis. Likely explanations include high drug dose, sleeve capacity or sleeve properties.