Impact of diabetes mellitus on 2-year outcomes of Absorb BVS compared to Xience EES: a pooled analysis of the COMPARE-ABSORB and AIDA trial

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Background and purpose: Diabetes mellitus (DM) is associated with increased risk of cardiovascular events after percutaneous coronary intervention (PCI). To evaluate the impact of Absorb bioresorbable vascular scaffold (BVS) in patients with DM, we aimed to compare the 2-year outcomes of Absorb BVS versus 2nd generation drug eluting stents Xience (EES) by pooling diabetic patients treated with BVS or EES from two large, randomized controlled trial.

Methods: Patients with medically-treated DM and treated by Absorb BVS in the COMPARE-ABSORB and AIDA trial were pooled for analysis. The primary efficacy outcomes measure was target lesion failure (cardiac death, target-vessel myocardial infarction or target lesion revascularization), and the primary safety outcome measure was device thrombosis at 2-year follow-up.

Results: Out of a total 3515 enrolled subjects in the two trials, 913 were diabetics. Compared with the non-diabetic patients, those with DM were older, more often to have a history of hypercholesterolemia, chronic renal failure, stroke, hypertension, heart failure, peripheral vascular disease and previous PCI. At 2-years, target lesion failure occurred in 10.8% of BVS DM patients and 7.6% of EES DM patients (adjusted HR 1.43, 95% CI: 0.87–2.34, P=0.115). The 2-year rates of cardiac death (2.4% vs 1.6%, P=0.385), TV-MI (5% vs 1.6%, P=0.123) and TLR (7.8% vs 5.8%, P=0.416) showed not significant difference. The 2-year incidence of definite device thrombosis was 3.2% in Absorb BVS versus 0.7% in Xience EES (adjusted HR 4.77, 95% CI: 1.01–22.43, P=0.048).

Conclusion: This pooling of the diabetic patients from two large scale RCTs compared BVS versus 2nd generation DES, showed an increased rate of device thrombosis in BVS-treated patients at 2 years.

Table 1. Clinical outcomes of the adjusted Cox regression comparing BVS and EES in DM and non-DM patients

	Non-DM					DM				p inter
	BVS n=1308	EES n=1294	HR (95% CI)	p value		BVS n=464	EES n=494	HR (95% CI)	p value	
Target lesion failure	100 (7.6%)	89 (6.9%)	1.13 (0.84–1.53)	0.421	Target lesion failure	50 (10.8%)	34 (7.6%)	1.43 (0.87–2.34)	0.155	0.149
Cardiac death	16 (1.2%)	17 (1.3%)	0.64 (0.3–1.37)	0.252	Cardiac death	11 (2.4%)	7 (1.6%)	1.61 (0.55–4.74)	0.385	0.984
Target vessel-MI	49 (3.7%)	34 (2.6%)	1.38 (0.87–2.17)	0.167	Target vessel-MI	23 (5%)	7 (1.6%)	2.06 (0.82–5.16)	0.123	0.193
MI	63 (4.8%)	45 (3.5%)	1.33 (0.89–1.98)	0.159	MI	27 (5.8%)	12 (2.7%)	1.37 (0.64–2.9)	0.417	0.101
Target lesion Revascularization	72 (5.5%)	58 (4.5%)	1.35 (0.93–1.95)	0.114	Target lesion Revascularization	36 (7.8%)	26 (5.8%)	1.27 (0.71–2.29)	0.416	0.195
Definite/probable ST	33 (2.5%)	11 (0.9%)	2.86 (1.43–5.69)	0.003	Definite/probable ST	17 (3.7%)	3 (0.7%)	5.45 (1.2–24.84)	0.028	0.358
Definite ST	30 (2.3%)	8 (0.6%)	3.5 (1.59–7.69)	0.002	Definite ST	15 (3.2%)	3 (0.7%)	4.77 (1.01–22.43)	0.048	0.739