Clinical outcome up to 2 years after percutaneous coronary intervention in all-comers with concomitant symptomatic peripheral arterial disease: a pooled analysis in 9,204 randomized trial participants

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Background: An increasing number of patients with coronary artery disease, who undergo percutaneous coronary intervention, also have symptomatic peripheral arterial disease. These patients have a worse long-term prognosis, but it is unclear whether the inferior outcome can be seen as early as during the first 2 years from coronary stenting.

Purpose: The aim of this study in all-comers was to evaluate the impact of symptomatic peripheral arterial disease on 1- and 2-year clinical outcome after coronary stenting.

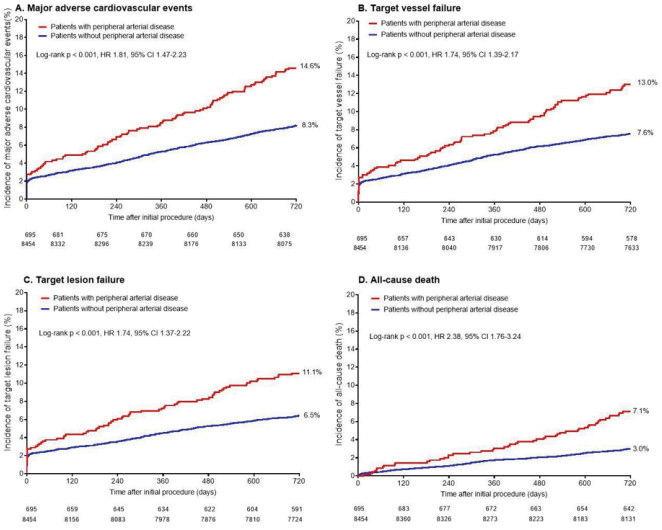
Methods: Patient-level data from four large-scale randomised coronary drug-eluting stent trials in all-comers (TWENTE (clinicaltrials.gov: NCT01066650), DUTCH PEERS (NCT01331707), BIO-RESORT (NCT01674803), and BIONYX (NCT02508714)) were pooled to evaluate the impact of symptomatic peripheral arterial disease on clinical outcome after coronary stenting. Peripheral arterial disease was defined as a history (by anamnesis or medical record) of an obstructive arterial lesion, resulting from atherosclerosis in peripheral locations including the lower and upper extremities, carotid or vertebral arteries, and mesenteric or renal arteries. Main clinical endpoint was target vessel failure, a composite of cardiac death, target vessel related myocardial infarction, or clinically indicated target vessel revascularisation.

Results: Of all 9,204 trial participants, 695 (7.6%) had symptomatic peripheral arterial disease. These patients were older and had a higher cardiovascular risk profile, including a higher prevalence of diabetes, renal failure, hypertension, hypercholesterolemia, and prior stroke. At 1-year follow-up, patients with peripheral arterial disease showed significantly higher event rates of some endpoints. At 2-year follow-up, patients with peripheral arterial disease showed significantly higher rates of various clinical endpoints, including mortality (7.1% vs. 3.0%, p<0.001), myocardial infarction (4.8% vs. 3.4%, p0.04), repeated revascularisation (6.7% vs 4.5%, p<0.04), and major adverse cardiac events (14.6% vs. 8.3%, p<0.001, Figure 1). After multivariate adjustment for confounders, symptomatic peripheral arterial disease was found to be independently associated with the 2-year risks of target vessel and lesion failure, major adverse cardiac events, and all-cause death (p<0.02, for all, Table 1).

Conclusion: Obstructive coronary artery disease with concomitant symptomatic peripheral arterial disease resulted in higher cardiovascular risk profiles and higher rates of all-cause mortality and various composite clinical endpoints during the first two years of follow-up after coronary stenting. Knowledge of these findings allows to identify patients with an increased short- and medium-term adverse event risk after percutaneous coronary intervention, which is useful for both Heart Team and informed consent discussions.

Table 1: Clinical outcome at 1- and 2-year follow-up

Variable	Peripheral arterial disease		HR (95%-CI)	P log-rank	Adjusted HR* (95-CI)	p-value
1-year	Yes (n=695)	No (n=8,454)				
Target vessel failure	54 (7.8)	445 (5.3)	1.50 [1.13-1.98]	*0.005*	1.18 (0.88-1.57)	0.27
All-cause death	21 (3.0)	146 (1.7)	1.76 [1.11-2.78]	*0.014*	1.11 (0.70-1.77)	0.66
Cardiac death	11 (1.6)	81 (1.0)	1.66 [0.88-3.12]	0.11	0.97 (0.51-1.85)	0.94
Any myocardial infarction	25 (3.6)	196 (2.3)	1.56 [1.03-2.36]	*0.035*	1.26 (0.82-1.92)	0.29
Target vessel related myocardial infarction	24 (3.5)	189 (2.2)	1.55 [1.01-2.37]	*0.041*	1.24 (0.81-1.91)	0.33
Target vessel revascularization	24 (3.5)	222 (2.7)	1.33 [0.87-2.02]	0.19	1.14 (0.74-1.75)	0.55
Target lesion revascularization	20 (2.9)	154 (1.8)	1.60 [1.00- 2.54]	*0.047*	1.28 (0.79-2.05)	0.31
Target lesion failure	50 (7.2)	382 (4.5)	1.61 [1.20-2.17]	*0.001*	1.22 (0.91-1.65)	0.19
Probable-or-definite stent thrombosis	7 (1.0)	82 (1.0)	1.04 [0.48-2.25]	0.92	0.64 (0.29-1.40)	0.27
Definite stent thrombosis	1 (0.1)	31 (0.4)	0.39 [0.05-2.88]	0.34	0.27 (0.04-2.04)	0.21
Major adverse cardiac events	63 (8.5)	465 (5.3)	1.67 [1.29-2.17]	*<0.001*	1.26 (0.96-1.65)	0.09
2-year						
Target vessel failure	89 (13.0)	640 (7.6)	1.74 [1.39-2.17]	*<0.001*	1.38 [1.10-1.73]	*0.006*
All-cause death	49 (7.1)	254 (3.0)	2.38 [1.76-3.24]	*<0.001*	1.57 [1.15-2.14]	*0.005*
Cardiac death	24 (3.5)	125 (1.5)	2.37 [1.53-3.66]	*<0.001*	1.46 (0.93-2.28)	0.10
Any myocardial infarction	33 (4.8)	280 (3.4)	1.45 [1.01-2.09]	*0.040*	1.23 (0.85-1.77)	0.28
Target vessel related myocardial infarction	30 (4.4)	242 (2.9)	1.53 [1.04-2.23]	*0.028*	1.27 (0.87-1.87)	0.22
Target vessel revascularization	45 (6.7)	373 (4.5)	1.50 [1.10-2.04]	*0.010*	1.31 (0.96-1.80)	0.09
Target lesion revascularization	31 (4.6)	260 (3.1)	1.48 [1.02-2.15]	*0.038*	1.26 (0.86-1.84)	0.23
Target lesion failure	76 (11.1)	543 (6.5)	1.74 [1.37-2.22]	*<0.001*	1.35 [1.06-1.73]	*0.015*
Probable-or-definite stent thrombosis	17 (2.5)	139 (1.7)	1.51 [0.91-2.49]	0.11	1.02 (0.61-1.69)	0.96
Definite stent thrombosis	2 (0.3)	54 (0.6)	0.45 [0.11-1.86]	0.26	0.39 (0.09-1.61)	0.19
Major adverse cardiac events	101 (14.6)	698 (8.3)	1.81 [1.47-2.23]	*<0.001*	1.38 [1.11-1.70]	*0.003*



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