MASTER DAPT: Dual Antiplatelet Therapy after PCI in Patients at High Bleeding Risk

Purpose: After Ultimaster stent implementation, assess whether one month of dual antiplatelet therapy (DAPT) preserves the net and major adverse cardiovascular events. And if so, whether it mitigates major or nonmajor clinically relevant bleeding occurrences, compared with longer treatment durations.

Trial Design: Multicentre, randomised trial

Arm 1: Abbreviated antiplatelet regimen (APT - aspirin and P2Y12 inhibitor); Dual APT is discontinued immediately after randomization, and a single AP agent is continued until at least 11 months post randomization. In patients on oral anticoagulants, dual APT is discontinued immediately after randomization, and either Aspirin or Clopidogrel is continued until 5 months post randomization. Oral anticoagulation is continued until at least 11 months post randomization

Arm 2: Prolonged antiplatelet regimen (APT - aspirin and P2Y12 inhibitor). Aspirin is continued for at least 11 months post randomization, the P2Y12 inhibitor being taken at the time of randomization is continued for at least 5 months and up to 11 months post randomization. In patients on oral anticoagulants, aspirin and Clopidogrel are continued for at least 2 months post randomization and up to 11 months post randomization. Either aspirin or Clopidogrel is continued up to 11 months post randomization

Primary Endpoints: 1.Net adverse clinical endpoints (NACE) defined as a composite of all-cause death, myocardial infarction, stroke and bleeding events defined as BARC 3 or 5 [Time Frame: 11 months]

2.Major adverse cardiac and cerebral events (MACCE) defined as a composite of all-cause death, myocardial infarction and stroke [Time Frame: 11 months]

3.Major or clinically relevant non-major bleeding (MCB) defined as a composite of type 2, 3 and 5 BARC bleeding events [Time Frame: 11 months]

	Abbreviated APT	Prolonged APT	P value
Primary endpoints – Events (N = 4434)			
Net adverse clinical endpoints (NACE)	N = 165 (7.5%)	N = 172 (7.7%)	≤ 0.001 for inferiority
Major adverse cardiac and cerebral events (MACCE)	N = 133 (6.1%)	N = 132 (5.9%)	
Primary endpoint: Bleeding (N = 4579)			
Major or clinically relevant non-major bleeding	N = 148 (6.5%)	N = 211 (9.4%)	−2.82% difference for superiority; P < 0.001

Results: At least 2 additional months of therapy did not result in a significant increased occurrence of NACE or MACCE; Incidence of bleeding was significantly lower in patients receiving abbreviated therapy.

Results reflect the data available at the time of presentation.

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