MASTER-DAPT: Le design

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BACKGROUND

2020 Guidelines for the management of patients with ACS in patients without persistent ST-segment elevation

Collet J-P, Thiele H. | Eur Heart J 2020

Aspirin is recommended for all patients without contraindications at an initial oral LD of 150–300 mg (or 75–250 mg i.v.), and at a MD of 75–100 mg o.d. for long-term treatment.[179–181]	I	A
A $P2Y_{12}$ receptor inhibitor is recommended in addition to aspirin, and maintained over 12 months unless there are contraindications or an excessive risk of bleeding.[170,171,182]	I	A

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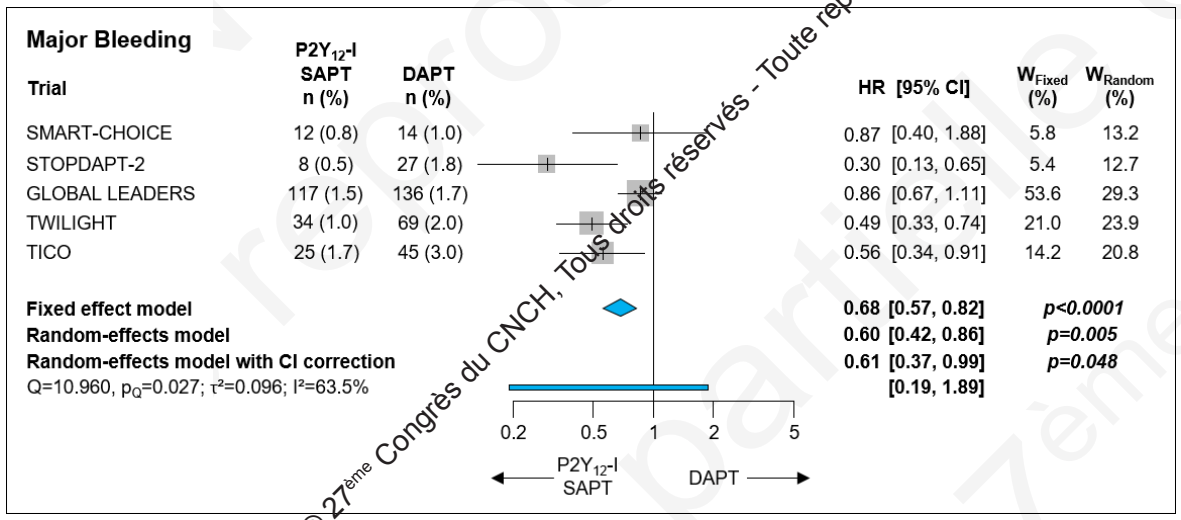
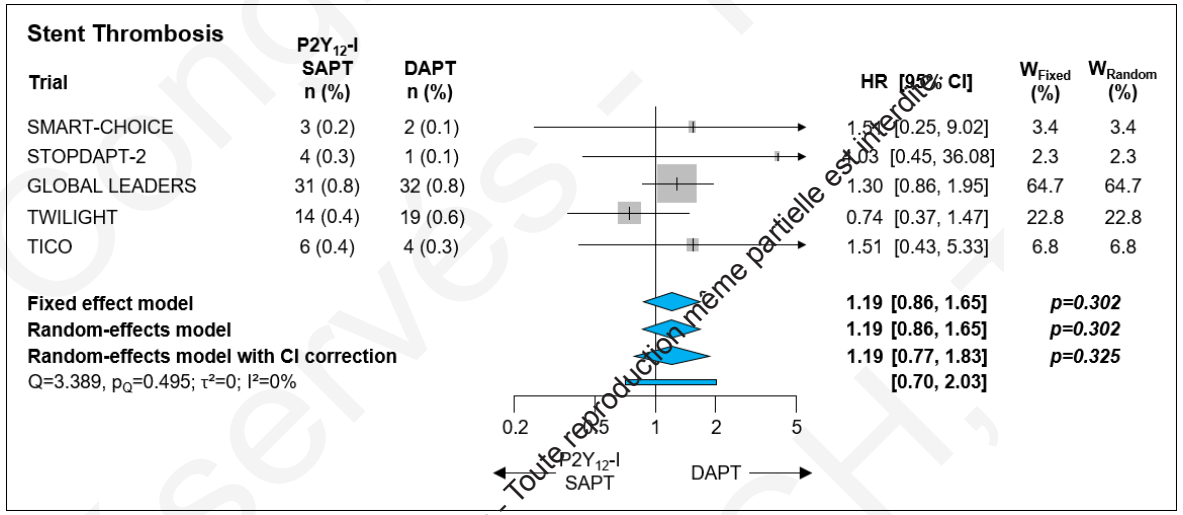
Short DAPT followed by P2Y12i monotherapy

After 1-3 months DAPT, randomization to P2Y12i-monotherapy or continued DAPT





CAVEATS: Different P2Y12 inhibitors were used, differing proportion of ACS patients, DAPT stopped at different time points, no short DAPT followed by ASA monotherapy comparator and no HBR

Giacoppo et al. | Eur Heart J. 2021

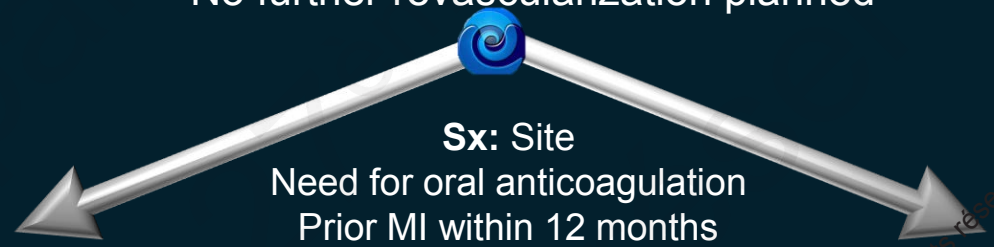
MASTER DAPT Trial

Screened Population: HBR pts, treated exclusively with Ultimaster stent, with no restriction based on clinical presentation or PCI complexity

Randomization and Regimens

30 (+14) Days after PCI

Free from cardiac and cerebral ischemic events
and active bleeding
No further revascularization planned



Sx: Site
Need for oral anticoagulation
Prior MI within 12 months

Abbreviated DAPT
Immediate DAPT discontinuation

followed by SAPT for 11 months
or 5 months if OAC is indicated

Standard DAPT
DAPT for ≥ 2 or 5 months in pts with or without OAC indication, respectively

followed by SAPT up to 11 months

HBR: high bleeding risk; DAPT: dual antiplatelet therapy; SAPT: single antiplatelet therapy; MI myocardial infarction: OAC: oral anticoagulation

Study Endpoints

The study has 3 primary endpoints to be tested in an hierarchical order:

Net adverse clinical events (NACE): the composite of all-cause death, MI, stroke, and major bleeding defined as BARC type 3 or 5

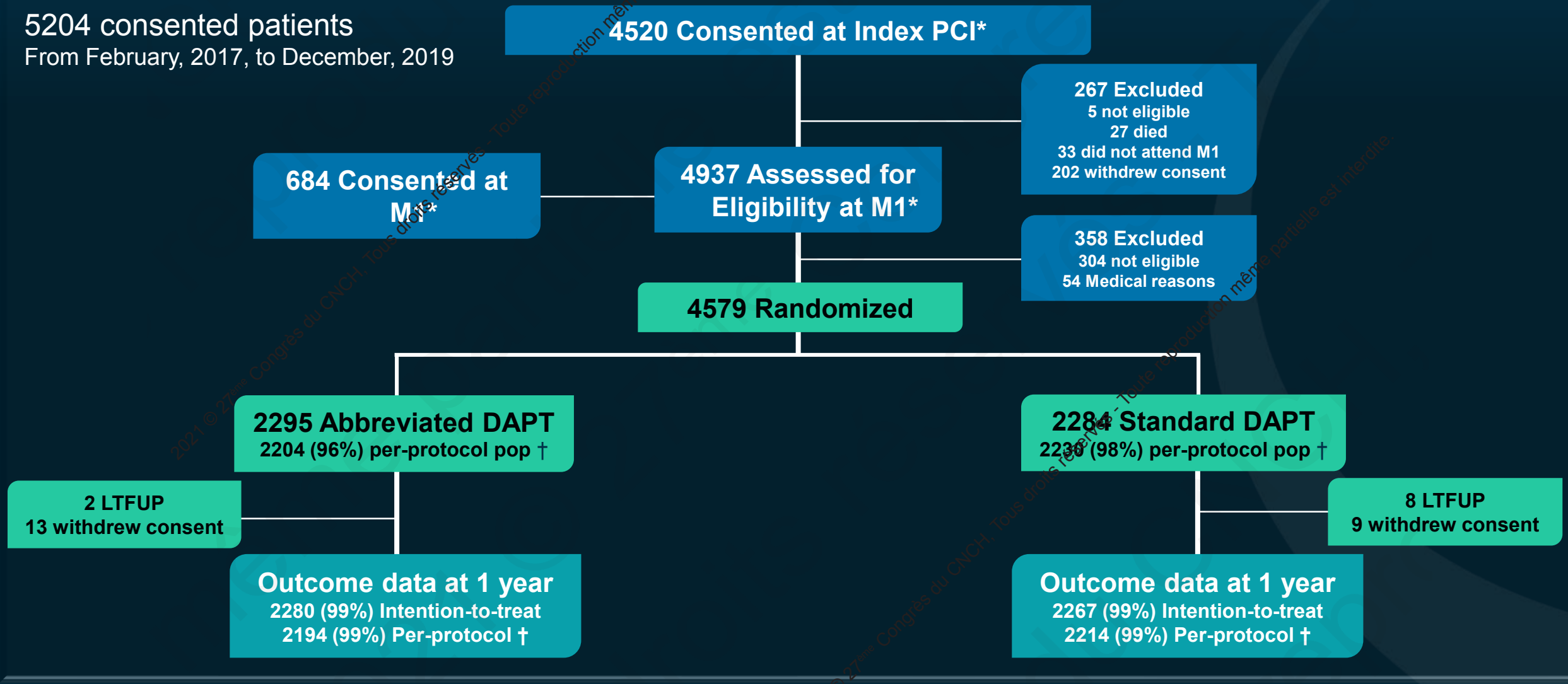
Major adverse cardiac and cerebral events (MACCE): the composite of all-cause death, MI, and stroke

Major or clinically relevant non-major bleeding (MCB): the composite of BARC type 2, 3 and 5 bleeding

The first two primary endpoints were to be tested on a non-inferiority basis in the per protocol population. If non-inferiority was met for both, the third primary endpoint was to be tested on superiority basis in the Intention to treat population. The main analyses evaluate the occurrence of the primary endpoints between randomization and 335 after index PCI

Patient Disposition

5204 consented patients
From February, 2017, to December, 2019



*: From February 28, 2017 through December 5, 2019 † : Per-protocol population: met eligibility criteria and implemented study Tx within 14 days after Rx