Clinical Summary

Dual antiplatelet therapy after PCI in patients at high bleeding risk

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MASTER DAPT (MAnagement of high bleeding risk patients post bioresorbable polymer coated STEnt implantation with an abbReviated versus prolonged DAPT regimen) was a multicentre, investigator-initiated, open-label, randomised trial comparing clinical outcomes according to duration of dual antiplatelet therapy (DAPT) among patients who received an Ultimaster™/ Ultimaster™ Tansei™ drug-eluting stent (DES) and had high bleeding risk. Individuals eligible for inclusion were randomly assigned (1:1) 1 month (30–44 days) after implantation of an Ultimaster™ family DES to receive either abbreviated DAPT (immediate discontinuation of DAPT) or standard-therapy DAPT (continuation of DAPT for ≥5 additional months, or ≥2 additional months for individuals receiving clinically indicated oral anticoagulation). In both groups, patients continued with single antiplatelet therapy (investigator's choice of $P2Y_{12}$ inhibitor or acetylsalicylic acid).

Previous trials evaluating clinical outcomes after the implantation of a DES were not designed to assess the appropriate duration of DAPT in patients at high bleeding risk. The MASTER DAPT trial recruited patients at high bleeding risk regardless of clinical presentation, and is valuable to inform treatment decisions surrounding DAPT duration.

What was the aim of the trial?

This trial aimed to evaluate how the duration of DAPT following implantation of an Ultimaster™ family DES influences clinical outcomes in patients at high bleeding risk. Three prespecified primary outcomes were investigated:

- Net adverse clinical events (a composite of death from any cause, myocardial infarction [MI], stroke, or major bleeding) (per-protocol population)
- Major adverse cardiac or cerebral events (a composite of death from any cause, MI, or stroke) (per-protocol population)
- Major bleeding (Bleeding Academic Research Consortium [BARC] type 3 or 5) or clinically relevant nonmajor bleeding (BARC type 2, 3, or 5) occurring up to 335 days post-randomisation (intention-to-treat [ITT] population).

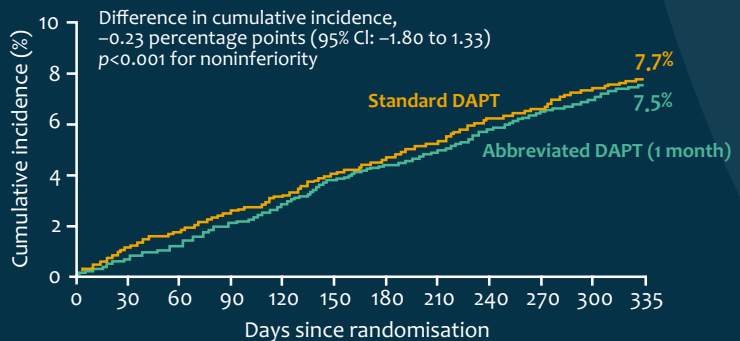
What were the key findings?

A total of 4579 patients underwent randomisation, of whom 2295 received abbreviated DAPT (1-month DAPT) and 2284 received standard-therapy DAPT (ITT population). The per-protocol population comprised 4434 patients (abbreviated DAPT: 2204; standard-therapy DAPT: 2230) who met the selection criteria and initiated protocol-mandated therapy within 14 days of randomisation. Median duration of DAPT following implantation of an Ultimaster™ family DES was 34 days in the abbreviated DAPT group and 193 days in the standard-therapy group.

Baseline patient characteristics and clinical presentation were well balanced between the two therapy groups. Overall, mean age was 76 years, and the majority of patients were male (69.3%). Comorbidities were common: 33.6% of patients had diabetes; 19.1% had chronic kidney disease; and 18.9% had heart failure. Over one-third (36.4%) of patients were receiving concomitant oral anticoagulation.

Abbreviated DAPT was noninferior to standard-therapy DAPT for net adverse clinical events, occurring in 165 patients (7.5%) and 172 patients (7.7%), respectively (difference: −0.23 percentage points; 95% confidence interval [CI]: −1.80 to 1.33, $p<0.001$ for noninferiority; Figure 1).

1 Net adverse clinical events* (per-protocol population, n=4434)



No. at risk												
Standard DAPT	2230	2203	2188	2169	2155	2137	2118	2102	2081	2068	2052	2041
Abbreviated DAPT (1 month)	2204	2184	2173	2153	2138	2144	2101	2091	2070	2056	2044	2027

*Composite of death from any cause, MI, stroke, or major bleeding.

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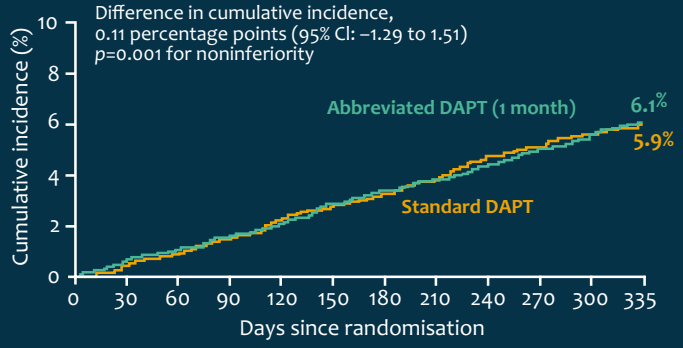
Abbreviated DAPT was also noninferior to standard-therapy DAPT with respect to the incidence of major adverse cardiac and cerebral events (6.1% vs 5.9%, respectively; difference: 0.11 percentage points; 95% CI: −1.29 to 1.51, *p*=0.001 for noninferiority; Figure 2). In addition, the incidence of major or clinically relevant nonmajor bleeding was significantly lower in the abbreviated DAPT group (6.5%) as compared with the standard-therapy group (9.4%) (difference: −2.82 percentage points; 95% CI: −4.40 to −1.24, *p*<0.001 for superiority; Figure 3). Secondary outcomes of death from any cause, MI, and definite or probable stent thrombosis were similar in the two therapy groups.

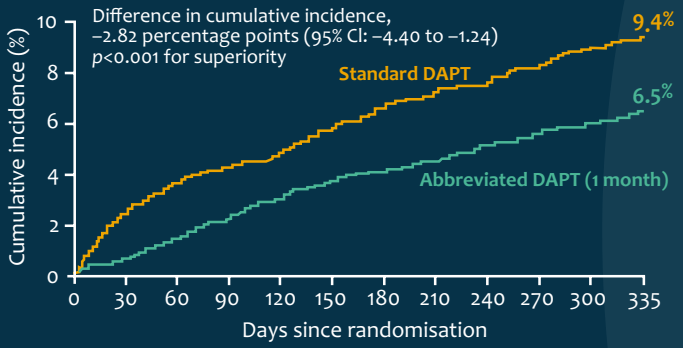
2 Major adverse cardiac or cerebral events* (per-protocol population, n=4434)



No. at risk												
Standard DAPT	2230	2218	2207	2192	2176	2165	2149	2134	2113	2102	2090	2081
Abbreviated DAPT (1 month)	2204	2186	2177	2164	2153	2135	2123	2114	2099	2086	2076	2058

*Composite of death from any cause, MI, or stroke.

3 Major or clinically relevant nonmajor bleeding* (ITT population, n=4579)



No. at risk												
Standard DAPT	2284	2220	2186	2166	2147	2122	2094	2077	2060	2035	2015	1999
Abbreviated DAPT (1 month)	2295	2269	2249	2223	2202	2173	2161	2150	2130	2117	2102	2078

*Major bleeding: BARC type 3 or 5; clinically relevant nonmajor bleeding: BARC type 2, 3, or 5.

What did the authors conclude?

Discontinuation of DAPT 1 month after the implantation of an Ultimaster™ family DES was noninferior to the continuation of DAPT for ≥2 additional months with regard to net adverse clinical events and major adverse cardiac or cerebral events. Furthermore, abbreviated DAPT was superior to standard-therapy DAPT with regards to major or clinically relevant nonmajor bleeding.

What was the impact of the data?

These data inform clinical decision making with regards to antiplatelet therapy, and demonstrate that early conversion (after 1 month) to single antiplatelet therapy post-coronary intervention with the Ultimaster™ DES family for patients at high bleeding risk is a viable treatment option and may reduce the risk of major or clinically relevant nonmajor bleeding, compared with standard therapy.

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MASTER DAPT

MAnagement of high bleeding risk patients post bioresorbable polymer coated **STE**nt implantation with an abb**R**eviated versus prolonged **DAPT** regimen

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ECRI European Cardiovascular Research Institute

TERUMO INTERVENTIONAL SYSTEMS