RE-DUAL PCI

A TRIAL EVALUATING ANTITHROMBOTIC THERAPY POST-PCI IN PATIENTS WITH AF[1]

Dual therapy (D150 or D110 + P2Y12 inhibitor) — P2Y12i — VS — W + P2Y12i + ASA — Triple therapy (warfarin + ASA* + P2Y12 inhibitor)

MAIN ANALYSIS[1]

AF+ PCI

All patients

ACS SUBANALYSIS[2]

AF+ PCI + ACS — VS — AF+ PCI + NO ACS

Patients with ACS — or without ACS

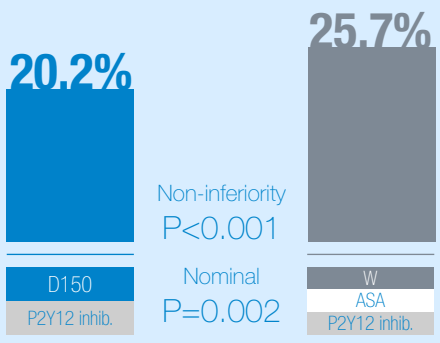
THE INDEX INDICATION FOR PCI WAS ACS IN APPROXIMATELY 50% OF PATIENTS[2]

Patient enrolment

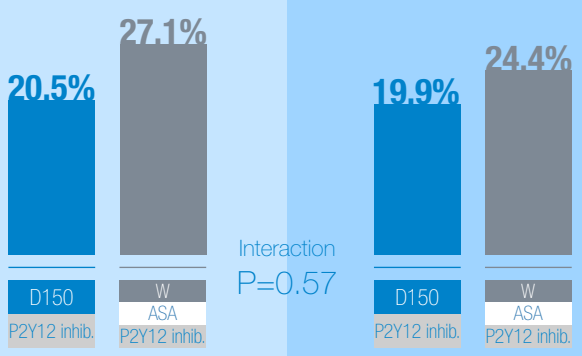
All patients	With ACS	Without ACS
N=2725	**n=1375†**	**n=1349†**

LOWER RATES OF ISTH MAJOR OR CRNM BLEEDING‡ WITH DABIGATRAN VS WARFARIN FOR PATIENTS WITH OR WITHOUT ACS

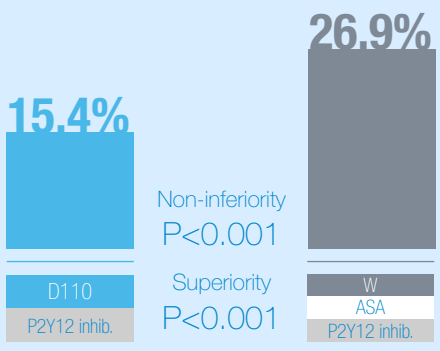
Primary safety endpoint: ISTH major or CRNM bleeding[1,2]

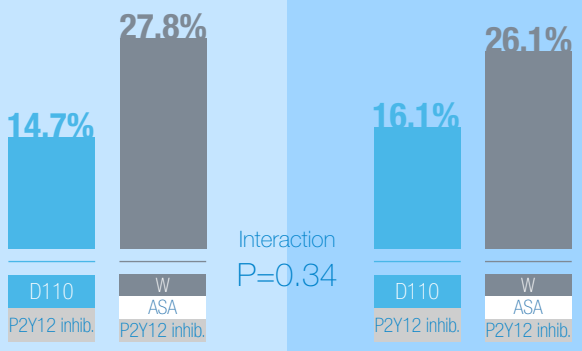


All patients



With ACS — Without ACS

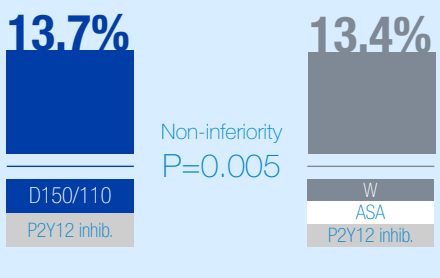


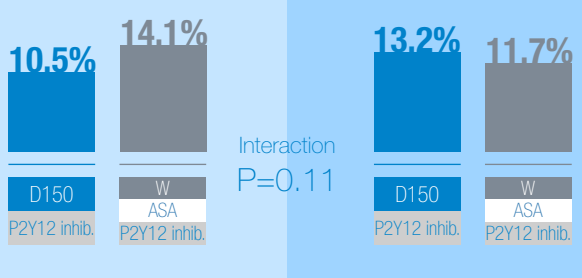


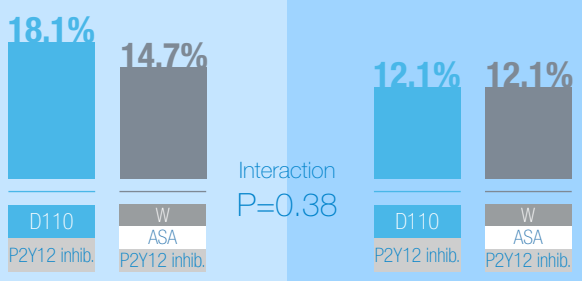
SIMILAR RATES OF THE COMPOSITE EFFICACY ENDPOINT WITH DABIGATRAN VS WARFARIN FOR PATIENTS WITH OR WITHOUT ACS

Efficacy endpoint: death, thromboembolic event, or unplanned revascularization[1,2]

All patients — With ACS — Without ACS







FINDINGS FOR PATIENTS WITH OR WITHOUT ACS WERE CONSISTENT WITH THE MAIN ANALYSIS

Dual therapy with either dose of dabigatran significantly reduced the risk of bleeding vs warfarin triple therapy in patients with or without ACS, with non-inferior efficacy for the combined dabigatran dose

*ASA was discontinued 1 month after bare-metal stent or 3 months after drug-eluting stent; †ACS information not available for one patient; ‡An ISTH major bleeding event is symptomatic bleeding in a critical area or organ, and/or bleeding associated with reduced haemoglobin ≥2 g/dL (1.24 mmol/L) or transfusion of ≥2 units of blood or packed cells and/or fatal bleed, while a CRNM bleeding event does not meet the criteria for a major bleed but prompts ≥1 of: hospital admission, physician-guided medical or surgical treatment, or physician-guided change, interruption, or discontinuation of study drug

ACS, acute coronary syndrome; AF, atrial fibrillation; ASA, acetylsalicylic acid; BID, twice daily; CRNM, clinically relevant non-major; D110, dabigatran 110 mg BID; D150, dabigatran 150 mg BID; dL, decilitre; ISTH, International Society on Thrombosis and Haemostasis; P2Y12i, P2Y12 inhibitor; P2Y12 inhib., P2Y12 inhibitor; PCI, percutaneous coronary intervention; W, warfarin

1. Cannon CP et al. N Engl J Med 2017;377:1513–24; 2. Oldgren J et al. Presented at AHA 2017

RE-DUAL PCI

A TRIAL EVALUATING ANTITHROMBOTIC THERAPY POST-PCI IN PATIENTS WITH AF[1]

Dual therapy (D150 or D110 + P2Y12 inhibitor) — P2Y12i — VS — W + P2Y12i + ASA — Triple therapy (warfarin + ASA* + P2Y12 inhibitor)

MAIN ANALYSIS[1]

AF+ PCI

All patients

P2Y12 INHIBITOR SUBANALYSIS[2]

AF+ PCI + CL — On clopidogrel

VS

AF+ PCI + T — or on ticagrelor

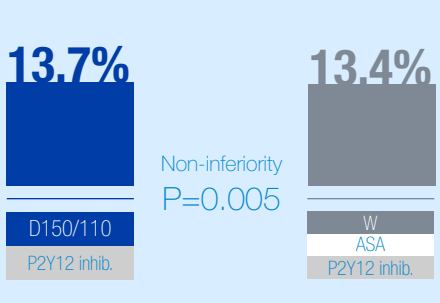
MOST PATIENTS (88%) RECEIVED CLOPIDOGREL; PATIENTS ON TICAGRELOR WERE MORE LIKELY TO HAVE ACS[2]

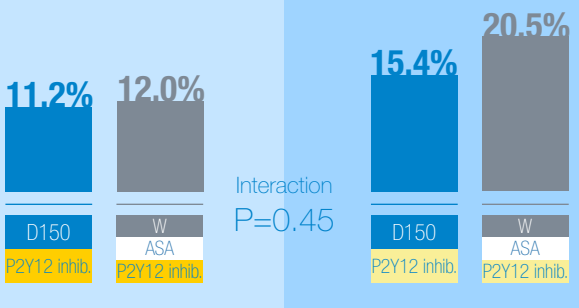
Patient enrolment

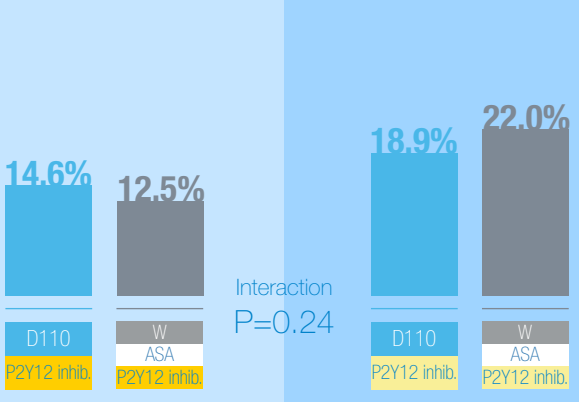
All patients	On clopidogrel	or on ticagrelor
N=2725	**n=2398†**	**n=327†**

LOWER RATES OF ISTH MAJOR OR CRNM BLEEDING‡ WITH DABIGATRAN VS WARFARIN FOR PATIENTS ON EITHER P2Y12 INHIBITOR

Primary safety endpoint: ISTH major or CRNM bleeding[1,2]

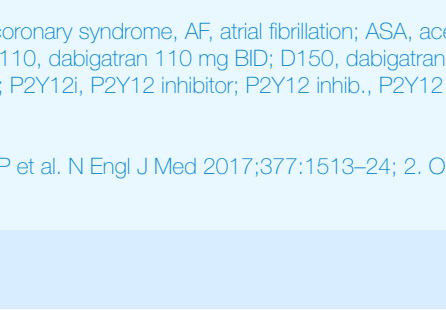


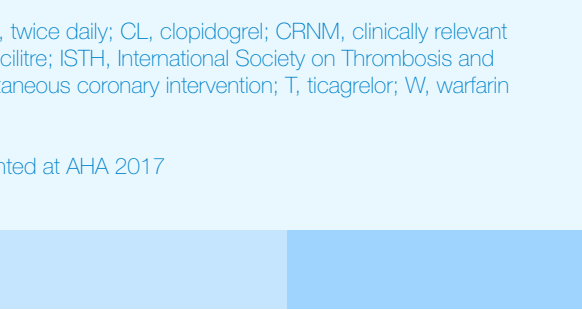




SIMILAR RATES OF THE COMPOSITE EFFICACY ENDPOINT WITH DABIGATRAN VS WARFARIN FOR PATIENTS ON EITHER P2Y12 INHIBITOR

Efficacy endpoint: death, thromboembolic event, or unplanned revascularization[1,2]





FINDINGS FOR PATIENTS ON EITHER P2Y12 INHIBITOR WERE CONSISTENT WITH THE MAIN ANALYSIS

Dual therapy with either dose of dabigatran significantly reduced the risk of bleeding vs warfarin triple therapy in patients regardless of P2Y12 inhibitor, with non-inferior efficacy for the combined dabigatran dose

*ASA was discontinued 1 month after bare-metal stent or 3 months after drug-eluting stent; †58 patients who received clopidogrel and ticagrelor were included in the ticagrelor subgroup, 93 patients who received neither clopidogrel nor ticagrelor were included in the clopidogrel subgroup; ‡An ISTH major bleeding event is symptomatic bleeding in a critical area or organ, and/or bleeding associated with reduced haemoglobin ≥2 g/dL (1.24 mmol/L) or transfusion of ≥2 units of blood or packed cells and/or fatal bleed, while a CRNM bleeding event does not meet the criteria for a major bleed but prompts ≥1 of: hospital admission, physician-guided medical or surgical treatment, or physician-guided change, interruption, or discontinuation of study drug

ACS; acute coronary syndrome, AF, atrial fibrillation; ASA, acetylsalicylic acid; BID, twice daily; CL, clopidogrel; CRNM, clinically relevant non-major; D110, dabigatran 110 mg BID; D150, dabigatran 150 mg BID; dL, decilitre; ISTH, International Society on Thrombosis and Haemostasis; P2Y12i, P2Y12 inhibitor; P2Y12 inhib., P2Y12 inhibitor; PCI, percutaneous coronary intervention; T, ticagrelor; W, warfarin

1. Cannon CP et al. N Engl J Med 2017;377:1513–24; 2. Oldgren J et al. Presented at AHA 2017

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Dual therapy (D150 or D110 + P2Y12 inhibitor) — P2Y12i — VS — W + P2Y12i + ASA — Triple therapy (warfarin + ASA* + P2Y12 inhibitor)

MAIN ANALYSIS[1]

AF+ PCI

All patients

STENT TYPE SUBANALYSIS[2]

AF+ PCI DES VS AF+ PCI BMS

Patients with a DES or with a BMS

MOST PATIENTS (~85%) HAD A DES PLACED DURING THEIR PROCEDURE[2]

Patient enrolment

AF+ PCI — All patients — **N=2725**

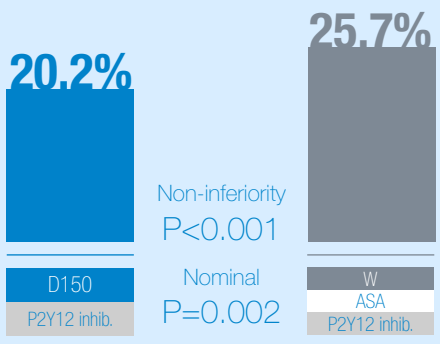
AF+ PCI DES — Receiving DES — **n=2251†**

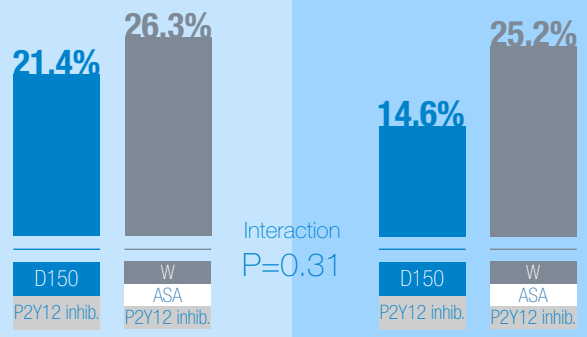
VS

AF+ PCI BMS — Receiving BMS — **n=404†**

LOWER RATES OF ISTH MAJOR OR CRNM BLEEDING‡ WITH DABIGATRAN VS WARFARIN REGARDLESS OF STENT TYPE

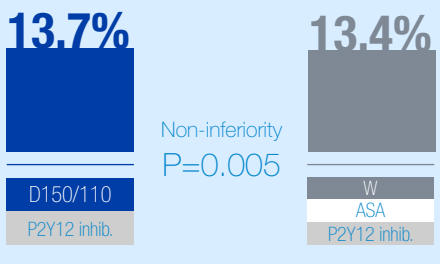
Primary safety endpoint: ISTH major or CRNM bleeding[1,2]

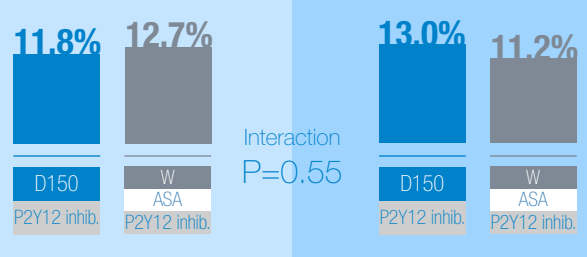


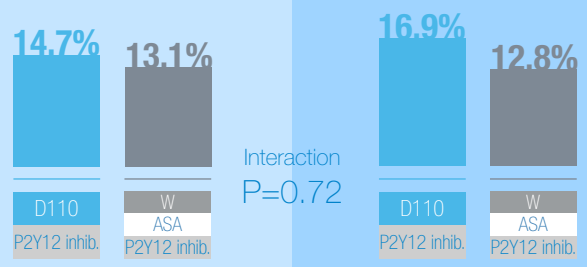


SIMILAR RATES OF THE COMPOSITE EFFICACY ENDPOINT WITH DABIGATRAN VS WARFARIN REGARDLESS OF STENT TYPE

Efficacy endpoint: death, thromboembolic event, or unplanned revascularization[1,2]







FINDINGS FOR PATIENTS RECEIVING A DES OR BMS WERE CONSISTENT WITH THE MAIN ANALYSIS

Dual therapy with either dose of dabigatran significantly reduced the risk of bleeding vs warfarin triple therapy in patients regardless of stent type, with non-inferior efficacy for the combined dabigatran dose

*ASA was discontinued 1 month after bare-metal stent or 3 months after drug-eluting stent; †Information on stent type not available for eight patients and excluded for 62 patients with both DES and BMS, or another type of stent; ‡An ISTH major bleeding event is symptomatic bleeding in a critical area or organ, and/or bleeding associated with reduced haemoglobin ≥2 g/dL (1.24 mmol/L) or transfusion of ≥2 units of blood or packed cells and/or fatal bleed, while a CRNM bleeding event does not meet the criteria for a major bleed but prompts ≥1 of: hospital admission, physician-guided medical or surgical treatment, or physician-guided change, interruption, or discontinuation of study drug

AF, atrial fibrillation; ASA, acetylsalicylic acid; BID, twice daily; BMS, bare-metal stent; CRNM, clinically relevant non-major; D110, dabigatran 110 mg BID; D150, dabigatran 150 mg BID; DES, drug-eluting stent; dL, decilitre; ISTH, International Society on Thrombosis and Haemostasis; P2Y12i, P2Y12 inhibitor; P2Y12 inhib., P2Y12 inhibitor; PCI, percutaneous coronary intervention; W, warfarin

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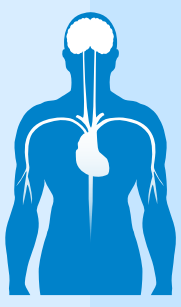
Dual therapy (D150 or D110 + P2Y12 inhibitor) — P2Y12i — VS — W + P2Y12i + ASA — Triple therapy (warfarin + ASA* + P2Y12 inhibitor)

MAIN ANALYSIS[1]

AF+ PCI

All patients

RENAL FUNCTION SUBANALYSIS[2,3]



AF+ PCI CrCl

- ≥80 mL/min
- 50–<80 mL/min
- 30–<50 mL/min
- <30 mL/min

MOST PATIENTS (78%) HAD A NORMAL OR MILDLY IMPAIRED RENAL FUNCTION AT BASELINE[3]

Patient enrolment

AF+ PCI

All patients

N=2725

AF+ PCI CrCl

- ≥80 mL/min — **n=1013†**
- 50–<80 mL/min — **n=1114†**
- 30–<50 mL/min — **n=347†**
- <30 mL/min — **n=19†**

RESULTS FOR THE PRIMARY SAFETY ENDPOINT IN PATIENTS WITH DIFFERING RENAL FUNCTION WERE CONSISTENT WITH THE MAIN ANALYSIS

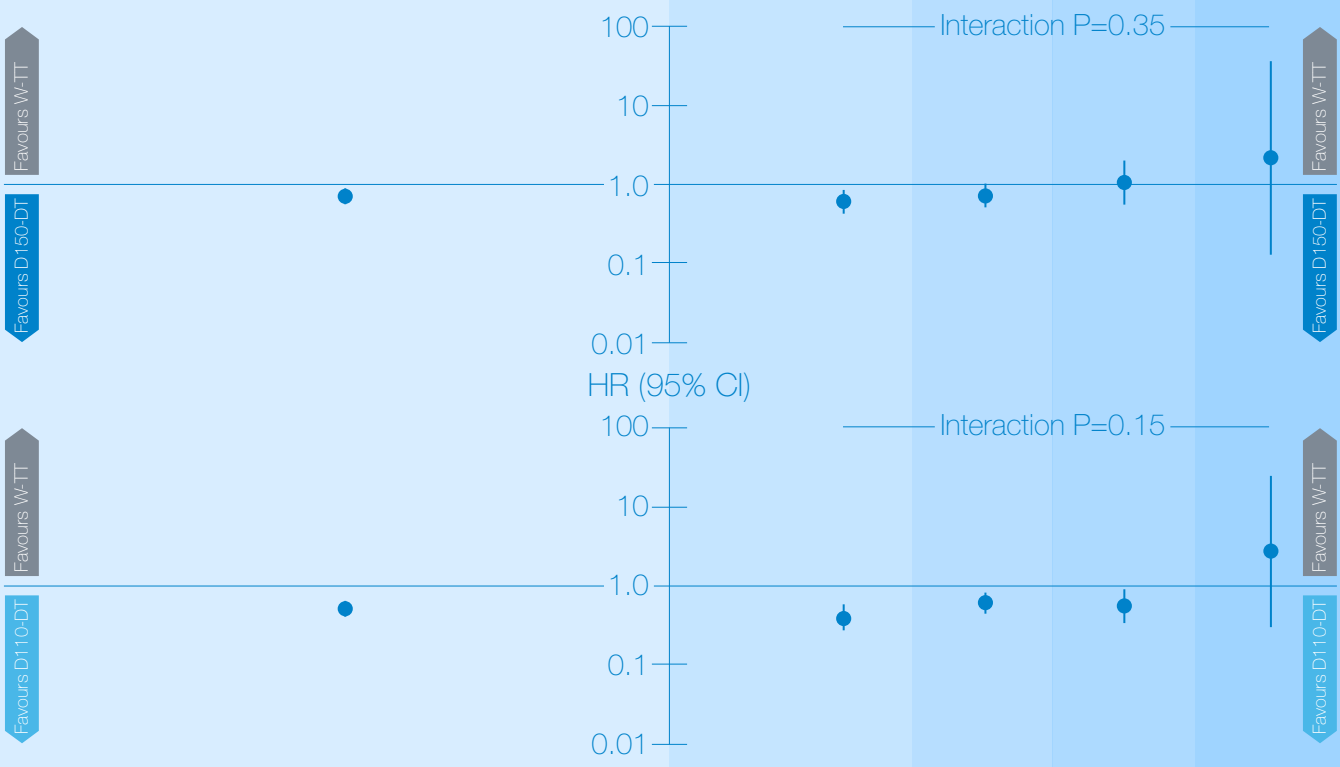
Primary safety endpoint: ISTH major or CRNM bleeding[1–3‡]

AF+ PCI

All patients

AF+ PCI CrCl

- ≥80 mL/min
- 50–<80 mL/min
- 30–<50 mL/min
- <30 mL/min



SIMILAR RATES OF THE COMPOSITE EFFICACY ENDPOINT WITH D110 VS WARFARIN REGARDLESS OF RENAL FUNCTION

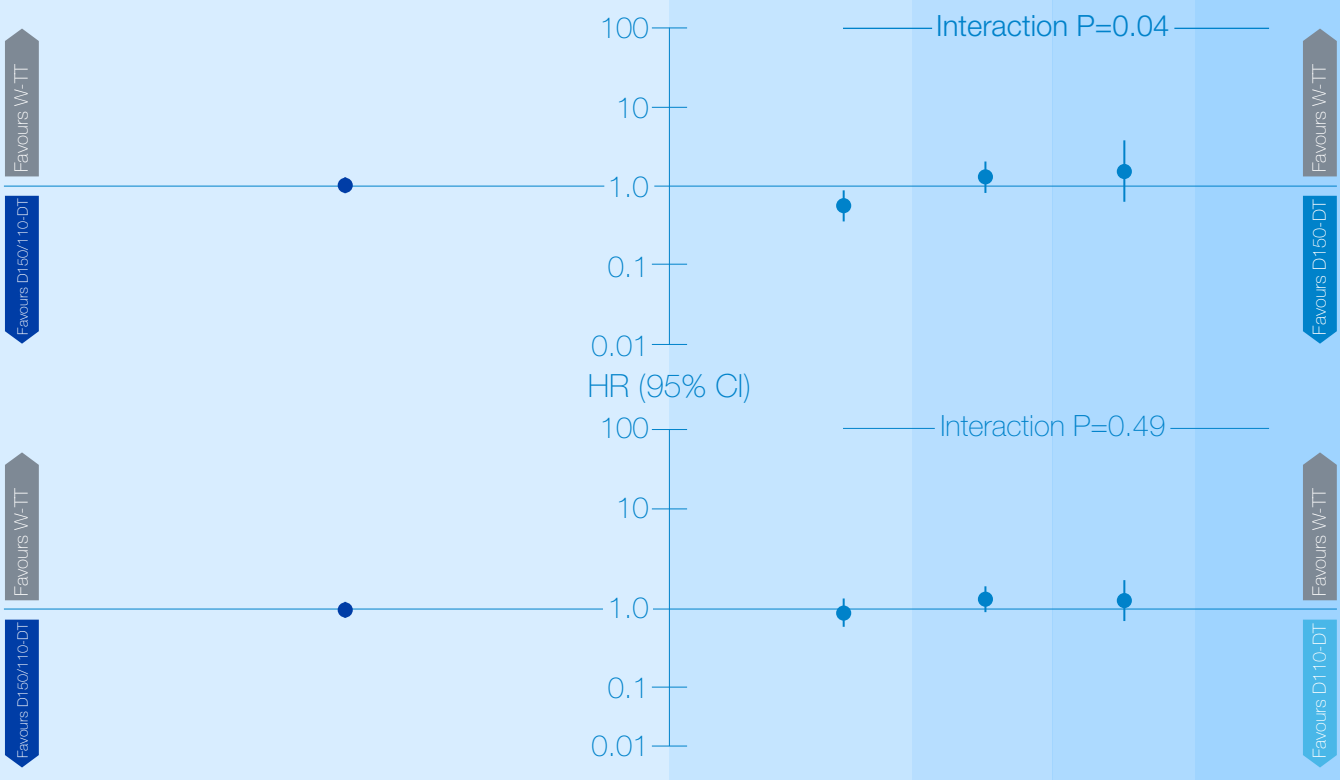
Efficacy endpoint: death, thromboembolic event, or unplanned revascularization[1–3]

AF+ PCI

All patients

AF+ PCI CrCl

- ≥80 mL/min
- 50–<80 mL/min
- 30–<50 mL/min
- <30 mL/min



THERE WAS AN INTERACTION BETWEEN CrCl AND D150-DT, BUT EFFICACY EVENT RATES FOR DABIGATRAN WERE COMPARABLE TO THOSE FOR WARFARIN

Dual therapy with either dose of dabigatran significantly reduced the risk of bleeding vs warfarin triple therapy in patients with differing renal function, with non-inferior efficacy for the combined dabigatran dose

*ASA was discontinued 1 month after bare-metal stent or 3 months after drug-eluting stent; †Baseline renal function information was not available for 232 patients, patients with baseline CrCl <30 mL/min should have been excluded from the trial according to the protocol, enrolled patients were still included in the analysis; ‡An ISTH major bleeding event is symptomatic bleeding in a critical area or organ, and/or bleeding associated with reduced haemoglobin ≥2 g/dL (1.24 mmol/L) or transfusion of ≥2 units of blood or packed cells and/or fatal bleed, while a CRNM bleeding event does not meet the criteria for a major bleed but prompts ≥1 of: hospital admission, physician-guided medical or surgical treatment, or physician-guided change, interruption, or discontinuation of study drug

AF, atrial fibrillation; ASA, acetylsalicylic acid; BID, twice daily; CI, confidence interval; CrCl, creatinine clearance; CRNM, clinically relevant non-major; D110, dabigatran 110 mg BID; D150, dabigatran 150 mg BID; dL, decilitre; DT, dual therapy; HR, hazard ratio; ISTH, International Society on Thrombosis and Haemostasis; P2Y12i, P2Y12 inhibitor; PCI, percutaneous coronary intervention; TT, triple therapy; W, warfarin

1. Cannon CP et al. N Engl J Med 2017;377:1513–24; 2. Hohnloser SH et al. JACC 2018;71:314;
3. Hohnloser SH et al. Presented at ACC 2018