

APPENDIX 3: STUDY CHARACTERISTICS

RCT	Study design (no. randomized)	Population	Stent type	Treatments	Timing of randomization	Primary outcome	Country	Funding Source
Mauri 2014 (DAPT; NCT00977938)	Multi-centre, placebo-controlled, superiority RCT DAPT: 12 months (5786) vs. 30 months (5862)	≥ 18 yr, PCI with a DES or BMS.	SES, ZES, PES, BMS	ASA 75–162 mg/d+ clopidogrel (75 mg/d) or prasugrel (10 mg/d) for 12 months, followed by continuation on DAPT or discontinuation of P2Y12 inhibitor (ASA continued) for 18 mo	12 months post PCI for patients with no MACCE, repeat revascularization, or moderate or severe bleeding, and who had been adherent to thienopyridine	Co-primary outcomes: cumulative incidence of definite or probable ST and MACCE (composite of death, MI, or stroke)	Multi-national	Abbott, Boston Scientific, Cordis, and Medtronic, Bristol-Myers Squibb–Sanofi Pharmaceuticals Partnership, Eli Lilly, and Daiichi Sankyo, and the Department of Health and Human Services
Valgimigli 2012 (PRODIGY; NCT00611286)	Multi-centre, open-label, superiority RCT DAPT: 6 months (723) vs. 24 months (725)	≥ 18 yr; elective, urgent or emergent coronary angioplasty with intended stent implantation; chronic stable coronary artery disease or ACS, including non–STEMI and STEMI	ZES, EES, PES, BMS	ASA (160 to 325 mg orally or 500 mg IV as a loading dose, 80 to 160 mg daily) + clopidogrel (300 or 600 mg orally as a loading dose), then 75 mg/d for 6 or 24 months	30d +/- 5 days post PCI	Composite: death of any cause, MI, cerebrovascular accident	Italy	University of Ferrara
Collet 2014 (ARCTIC- Interruption; NCT00827411)	Multi-centre, open-label, superiority RCT DAPT: 12 months (641) vs. 18–30 months (645)	≥ 18 yr; DES implantation	SES, PES, ZES, EES	ASA (75-100 mg/d) alone or ASA (75-100 mg/d) + clopidogrel (75-150 mg/d) or prasugrel (10 mg/d)	12 mo post PCI for patients who did not have an ischaemic event of the primary endpoint or any event of the primary safety endpoint during	Composite: death, MI, ST, stroke, urgent revascularization	France	Allies in Cardiovascular Trials Initiatives and Organized Networks (ACTION Study Group), Fondation de France, Sanofi - Aventis, Cordis, Medtronic, Boston

Appendix 3, as supplied by the authors. Appendix to: Elliott J, Kelly SE, Bai Z, et al. Extended dual antiplatelet therapy following percutaneous coronary intervention in clinically important patient subgroups: a systematic review and meta-analysis. *CMAJ Open* 2023. doi:10.9778/cmajo.2021-0119. Copyright © 2023 The Author(s) or their employer(s). To receive this resource in an accessible format, please contact us at cmajgroup@cmaj.ca.

					the first 12 months			Scientific, Fondation SGAM.
Lee 2014 (DES-LATE; NCT01186146)	Multi-centre, open-label RCT DAPT: 12 months (2514) vs. 24 months (2531)	≥ 18 yr; DES implanted ≥ 12 months before enrollment	SES, PES, ZES, EES and “other DES”	ASA (100 to 200 mg/d) alone or ASA (100 to 200 mg/d) + clopidogrel (75 mg/d)	12-18 mo post PCI for patients with no MACCE or major bleeding since DES implantation, and were receiving dual antiplatelet therapy at the time of enrollment	Composite: death resulting from cardiac causes, MI, or stroke	Korea	CardioVascular Research Foundation, Seoul, Korea, and the Health 21 R&D Project, Ministry of Health & Welfare, Korea
Gilard 2015 (ITALIC; NCT01476020)	Multi-centre, open-label, non-inferiority RCT DAPT: 6 months (926) vs. 24 months (924)	≥ 18 yr; PCI with a DES for any indication, with the exception of acute MI and treatment of the left main artery, with confirmed non-resistance to ASA	EES	ASA 75 to 325 mg/d + clopidogrel 75 mg/d, prasugrel 60 mg/d, or ticagrelor 90 mg twice daily	During PCI hospitalization; Patients were withdrawn if an endpoint occurred during the first 6 months of DAPT	Composite: death, MI, urgent target vessel revascularization, stroke, and major bleeding	Multi-national	Abbott Vascular Devices
Helft 2016 (OPTIDUAL; NCT00822536)	Multi-centre, open-label, superiority RCT DAPT: 12 months (697) vs. 18–48 months (701)	≥ 18 yr with symptoms of stable angina, silent ischemia, or ACS (unstable angina, non-STEMI, or STEMI),	SES, PES, ZES, EES, BES	ASA (75–160 mg/d) alone or ASA (75–160 mg/d) + clopidogrel (75 mg/d)	12 +/- 3 months post PCI for patients who had not experienced MACCE or major bleeding event in the first 12 months post PCI	Composite: death, MI, stroke, major bleeding	France	Assistance Publique-Hôpitaux de Paris (Département de la Recherche Clinique et du Développement), Programme Hospitalier de Recherche Publique-PHRC 2008, and unrestricted research grants from Federation française de Cardiologie, Cordis, Boston,

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								Medtronic, Terumo, and Biotronik
Nakamura 2017 (NIPPON; NCT01514227)	Multi-centre, non-inferiority, open-label RCT DAPT: 6 mo (1654) vs. 18 mo (1653)	21–79 yr, with coronary artery disease, including acute MI	DES	ASA (81-162 mg/d) + clopidogrel (75 mg/d) or ticlopidine (200 mg/d) [†]	During hospitalization for PCI	Composite: all-cause mortality, MI, stroke, major bleeding	Japan	Association for Establishment of Evidence in Interventions
<p>Note: ACS = acute coronary syndrome, ASA = acetylsalicylic acid, BES = biolimus-eluting stent, BMS = bare-metal stent, DAPT = dual anti-platelet therapy, DES = drug-eluting stent, EES = everolimus-eluting stent, MACCE = major adverse cardiac and cerebrovascular events, MI = myocardial infarction, PCI = percutaneous coronary intervention, PES = paclitaxel-eluting stent, RCT = randomized controlled trial, SES = sirolimus-eluting stent, STEMI = ST-elevation myocardial infarction, ZES = zotarolimus-eluting stent.</p> <p>*Biodegradable polymer-coated DES.</p> <p>[†]Less than 3% of patients received ticlopidine.</p> <p>‡Open-label inferred from description of methods; not explicitly stated.</p>								

P2Y12 INHIBITORS USED AS PART OF DAPT REGIMENS

Author, year	Eligible P2Y12 inhibitors	Group	No. (%) of participants			
			Clopidogrel	Prasugrel	Ticagrelor	Other P2Y12 inhibitor
Nakamura 2017 (NIPPON) ¹	Clopidogrel, ticlopidine	6 mo 18 mo	1619 (97.9) 1605 (97.1)	1 (0.1) 3 (0.2)	NA	32 (1.9) 44 (2.7)
Helft 2016 (OPTIDUAL) ²	Clopidogrel	12 mo 48 mo	100	NR	NR	NR
Gilard 2015 (ITALIC) ³	Clopidogrel, prasugrel, ticagrelor	6 mo 24 mo	902 (98.9) 895 (98.4)	15 (1.6) 16 (1.8)	1 (0.1) 0 (0)	NA
Mauri 2014 (DAPT) ^{*4}	Clopidogrel, prasugrel	12 mo 30 mo	3230 (65.4) 3275 (65.2)	1711 (34.6) 1745 (34.8)	NA	NA
Lee 2014 (DES-LATE) ⁵	Clopidogrel	12 mo 24 mo	2502 (99.5) 2521 (99.6)	NR	NR	NR
Collet 2014 (ARCTIC-INT) ⁶	Clopidogrel, prasugrel	12 mo 18–30 mo	562 (90.1) 569 (89.6)	53 (8.5) 54 (8.5)	NR	NR
Valgimigli 2012 (PRODIGY) ⁷	Clopidogrel	6 mo 24 mo	983 (100) [†] 987 (100) [†]	NA	NA	NA
<p>Note: DAPT = dual anti-platelet therapy, mo = months, NA = not applicable, NR = not reported.</p> <p>*P2Y12 inhibitor use among randomized participants with an implanted DES.</p> <p>[†]At randomization (30 days post PCI). At 6-months post PCI, 83.6% of participants in the 6-month DAPT group were receiving clopidogrel (98.3% among participants with a DES; 39.2% among participants with a BMS), and 99.4% of participants in the 24-month DAPT group.</p>						

DEFINITION OF DIABETES AMONG THE INCLUDED TRIALS

Author, year	Definition of diabetes*
Nakamura 2017 (NIPPON) ¹	"Diabetes mellitus"
Helft 2016 (OPTIDUAL) ²	"Diabetes mellitus"
Gilard 2015 (ITALIC) ³	"Type 2 diabetes"
Mauri 2014 (DAPT) ⁴	"Diabetes mellitus" (DM); "DM was defined as diet, oral medication, or insulin treated."
Lee 2014 (DES-LATE) ⁵	"Diabetes mellitus"
Collet 2014 (ARCTIC-INT) ⁶	"Diabetes"
Valgimigli 2012 (PRODIGY) ⁷	"Diabetes mellitus"
*With the exception of the DAPT trial, no definition of diabetes was provided. Terminology used to describe "diabetes" has been captured from the primary publication or publication in which subgroup data for patients with diabetes were reported.	