# Supplemental Online Content

Dawson LP, Chen D, Dagan M, et al. Assessment of pretreatment with oral P2Y12 inhibitors and cardiovascular and bleeding outcomes in patients with non-ST elevation acute coronary syndromes. *JAMA Netw Open.* 2021;4(11):e2134322. doi:10.1001/jamanetworkopen.2021.34322



This supplemental material has been provided by the authors to give readers additional information about their work.

**eTable 1. Details of Search Strategy**

| Database | Search Strategy | Results |
|---|---|---|
| MEDLINE | [pretreatment.mp OR upstream.mp OR up front.mp OR before PCI.mp OR early.mp OR loading.mp OR timing.mp OR pre-hospital.mp] AND [P2Y12 inhibitor.mp OR Purinergic P2Y Receptor Antagonist/ OR clopidogrel.mp OR Clopidogrel/ OR prasugrel.mp OR Prasugrel Hydrochloride/ OR ticagrelor.mp OR Ticagrelor/] AND [Percutaneous Coronary Intervention/ OR Acute Coronary Syndrome/ OR Non-ST Elevated Myocardial Infarction/ OR nsteacs.mp OR Coronary Angiography/ or Myocardial Infarction/ OR ischemic heart disease.mp OR Myocardial Ischemia/]; limited to humans, English, and year 2000 to current | 1336 |
| PubMed | (("P2Y12"[All Fields] AND ("antagonists and inhibitors"[MeSH Subheading] OR ("antagonists"[All Fields] AND "inhibitors"[All Fields]) OR "antagonists and inhibitors"[All Fields] OR "inhibitors"[All Fields] OR "inhibitor"[All Fields] OR "inhibitor s"[All Fields])) OR ("clopidogrel"[MeSH Terms] OR "clopidogrel"[All Fields] OR "clopidogrel s"[All Fields]) OR ("prasugrel hydrochloride"[MeSH Terms] OR ("prasugrel"[All Fields] AND "hydrochloride"[All Fields]) OR "prasugrel hydrochloride"[All Fields] OR "prasugrel"[All Fields] OR "prasugrel s"[All Fields]) OR ("ticagrelor"[MeSH Terms] OR "ticagrelor"[All Fields])) AND ("non st elevated myocardial infarction"[MeSH Terms] OR ("non-st"[All Fields] AND "elevated"[All Fields] AND "myocardial"[All Fields] AND "infarction"[All Fields]) OR "non st elevated myocardial infarction"[All Fields] OR ("non"[All Fields] AND "st"[All Fields] AND "elevation"[All Fields] AND "myocardial"[All Fields] AND "infarction"[All Fields]) OR "non st elevation myocardial infarction"[All Fields] OR ("non-st"[All Fields] AND ("elevate"[All Fields] OR "elevated"[All Fields] OR "elevates"[All Fields] OR "elevating"[All Fields] OR "elevation"[All Fields] OR "elevational"[All Fields] OR "elevations"[All Fields]) AND ("acute coronary syndrome"[MeSH Terms] OR ("acute"[All Fields] AND "coronary"[All Fields] AND "syndrome"[All Fields]) OR "acute coronary syndrome"[All Fields])) OR ("acute coronary syndrome"[MeSH Terms] OR ("acute"[All Fields] AND "coronary"[All Fields] AND "syndrome"[All Fields]) OR "acute coronary syndrome"[All Fields])) AND ("pretreat"[All Fields] OR "pretreated"[All Fields] OR "pretreating"[All Fields] OR "pretreatment"[All Fields] OR "pretreatments"[All Fields] OR ("upstream"[All Fields] OR "upstreams"[All Fields]) OR ("up"[All Fields] AND ("front"[All Fields] OR "front s"[All Fields] OR "fronts"[All Fields])) OR "early"[All Fields] OR ("loaded"[All Fields] OR "loading"[All Fields] OR "loadings"[All Fields] OR "loads"[All Fields]) OR ("timely"[All Fields] OR "timing"[All Fields] OR "timings"[All Fields]) OR "pre-hospital"[All Fields]) | 1064 |
| Embase | [pretreatment.mp OR upstream.mp OR up front.mp OR before PCI.mp OR early.mp OR loading.mp OR timing.mp OR pre-hospital.mp] AND [clopidogrel/ OR purinergic P2Y12 receptor/ OR prasugrel/ OR P2Y12 inhibitor.mp OR ticagrelor/] AND [acute coronary syndrome.mp OR acute coronary syndrome/ OR non-st elevation myocardial infarction.mp OR non ST segment elevation myocardial infarction/ or non st segment elevation acute coronary syndrome/ or nsteacs.mp]; limited to humans and English language and yr=”2000-Current” | 4166 |
| Scopus | (pretreatment OR upstream OR "up front" OR "before PCI" OR early OR loading OR timing OR pre-hospital) AND ("P2Y12 inhibitor" OR clopidogrel OR prasugrel OR ticagrelor) AND ("non-ST elevation myocardial infarction" OR "non-ST acute coronary syndrome") AND (LIMIT-TO (PUBYEAR, 2021) OR LIMIT-TO (PUBYEAR, 2020) OR LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018) OR LIMIT-TO (PUBYEAR, 2017) OR LIMIT-TO (PUBYEAR, 2016) OR LIMIT-TO (PUBYEAR, 2015) OR LIMIT-TO (PUBYEAR, 2014) OR LIMIT-TO (PUBYEAR, 2013) OR LIMIT-TO (PUBYEAR, 2012) OR LIMIT-TO (PUBYEAR, 2011) OR LIMIT-TO (PUBYEAR, 2010) OR LIMIT-TO (PUBYEAR, 2009) OR LIMIT-TO (PUBYEAR, 2008) OR LIMIT-TO (PUBYEAR, 2007) OR LIMIT-TO (PUBYEAR, 2006) OR LIMIT-TO (PUBYEAR, 2005) OR LIMIT-TO (PUBYEAR, 2004) OR LIMIT-TO (PUBYEAR, 2003) OR LIMIT-TO (PUBYEAR, 2002) OR LIMIT-TO (PUBYEAR, 2001) OR LIMIT-TO (PUBYEAR, 2000)) AND (LIMIT-TO (LANGUAGE, "English")) | 3532 |
| Web of Science | ALL=(pretreatment OR upstream OR “up front” OR “before PCI” OR early OR loading OR timing OR pre-hospital) AND ALL=(“P2Y12 inhibitor” OR clopidogrel OR ticagrelor OR prasugrel) AND ALL=(“acute coronary syndrome” OR “non-ST elevation myocardial infarction” OR “non-ST acute coronary syndrome”) AND LANGUAGE: (English) Indexes=SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH, BKCI-S, BKCI-SSH, ESCI, CCR-EXPANDED, IC Timespan=2000-2021 | 1225 |
| Science Direct | (pretreatment OR timing OR early OR upstream) AND (clopidogrel OR ticagrelor OR prasugrel) AND (“non-ST elevation myocardial infarction” OR “non-ST acute coronary syndrome”); Year(s) 2000-2021 | 1360 |
| clinicaltrials.gov | (pretreatment OR upstream OR up front OR before PCI OR early OR loading OR timing OR pre-hospital) AND (P2Y12 inhibitor OR clopidogrel OR ticagrelor OR prasugrel) AND (acute coronary syndrome OR non-ST elevation myocardial infarction) | 154 |
| Cochrane Central Register | [(coronary angiography) OR (myocardial infarction) OR (“ischaemic heart disease”) OR (ischemic heart disease) OR (“myocardial ischemia”) OR (percutaneous coronary intervention) OR (“percutaneous coronary revascularisation”) OR (acute coronary syndrome) OR (“NSTEMI”) | 1819 |

| | | |
|---|---|---|
| of Controlled Trials | OR (nsteacs)] AND [("loading dose") OR (loading) OR (timing) OR ("pre-hospital treatment") OR (pre-hospital) OR (pretreatment) OR (upstream) OR (up front) OR (before PCI) OR (early)] AND [(prasugrel) OR (clopidogrel) OR (ticagrelor) OR (P2Y12 inhibitor); with Publication Year from 2000 to 2021, in Trials (Word variations have been searched) | |

**eTable 2. End Point Definitions by Study**

| Study | Time point | Primary endpoint (MACE) | | Major Bleeding |
|---|---|---|---|---|
| CURE PCI[1] | 30d | CV death, MI, urgent target vessel revascularisation | | Major (fatal, Hb drop ≥50g/L, caused hypotension requiring inotropes or surgery, intracranial haemorrhage, ≥4 units transfusion) or minor (interruption of study medication) |
| CREDO[2] | 28d | Death, MI, urgent target vessel revascularisation | | TIMI major or minor |
| ARMYDA-5[3] | 30d | CV death, MI, target vessel revascularisation | | TIMI major or minor |
| ACCOAST[4, 5] | 30d | CV death, MI, urgent revascularisation | | TIMI major or minor |
| Bonello et al[6] | 30d | CV death, MI, urgent revascularisation, stroke | | BARC score 3,4,5 |
| ISAR-REACT 5[7] | 30d | Death, MI, stroke | | BARC score 3,4,5 |
| DUBIUS[8] | 30d | CV death, MI, non-fatal stroke, major or fatal bleeding (BARC>2) | | BARC score 3,4,5 |

TIMI major: intracranial haemorrhage, ≥5g/dl decrease in Hb, or ≥15% decrease in Hct
TIMI minor: 3-5g/dl decrease in Hb with clinically overt bleeding
BARC 3: overt bleeding plus Hb drop of ≥3/dL, any transfusion, intracranial haemorrhage, tamponade, bleeding requiring surgical intervention
BARC 4: CABG related bleeding, perioperative intracranial bleeding within 48h, reoperation after closure of sternotomy to control bleeding, transfusion ≥5 units within 48h period, chest tube output ≥2L within 24 hours
BARC 5: fatal bleeding
Mehran 2011

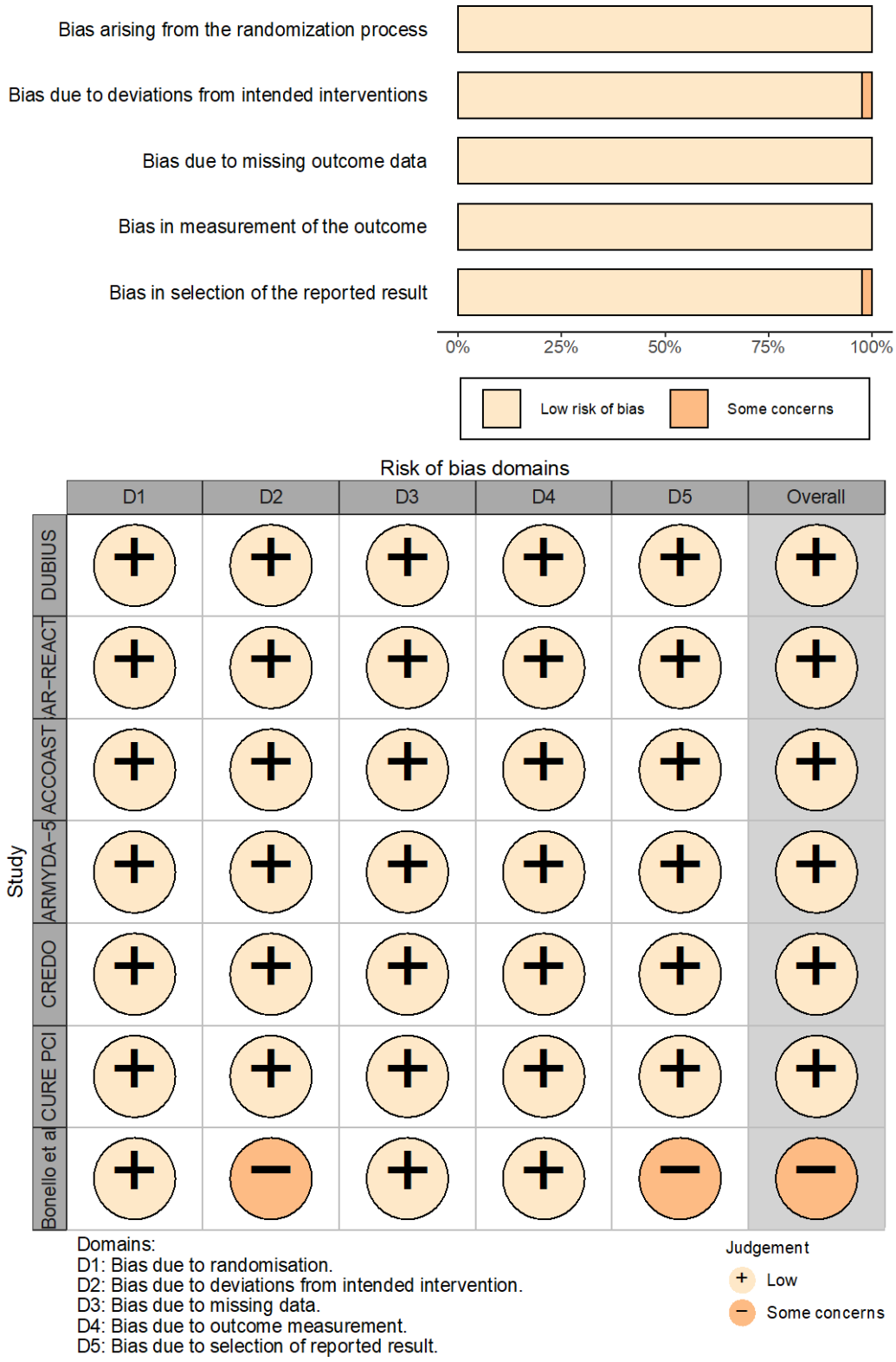
**eTable 3. Risk of Bias (RoB 2) Output**

| Question | DUBIUS | ISAR-REACT5 | ACCOAST | ARMYDA-5 | CREDO | Bonello et al | CURE PCI |
|---|---|---|---|---|---|---|---|
| 1.1 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 1.2 | Yes | Yes | Yes | Probably yes | Yes | Probably yes | Yes |
| 1.3 | No | No | No | No | No | No | No |
| **1 Overall** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** |
| 2.1 | Yes | Yes | No | Yes | No | Yes | No |
| 2.2 | Yes | Yes | No | Yes | No | Yes | No |
| 2.3 | No | No | n/a | No | n/a | No | n/a |
| 2.4 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| 2.5 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| 2.6 | Yes | Yes | Yes | Yes | Yes | No information | Yes |
| 2.7 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| **2 Overall** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Some concerns** | **Low risk** |
| 3.1 | Yes | Yes | Yes | Probably yes | Yes | Yes | Yes |
| 3.2 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| 3.3 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| 3.4 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| **3 Overall** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** |
| 4.1 | No | No | No | No | No | No | No |
| 4.2 | No | No | No | No | No | No | No |
| 4.3 | n/a | n/a | n/a | Yes | n/a | n/a | n/a |
| 4.4 | n/a | n/a | n/a | No | n/a | n/a | n/a |
| 4.5 | n/a | n/a | n/a | n/a | n/a | n/a | n/a |
| **4 Overall** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** |
| 5.1 | Yes | Yes | Yes | Yes | Yes | No information | Yes |
| 5.2 | No | No | No | No | No | Probably no | No |
| 5.3 | No | No | No | No | No | Probably no | No |
| **5 Overall** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Some concerns** | **Low risk** |
| **Overall RoB** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Low risk** | **Some concerns** | **Low risk** |

**eTable 4. Summary of Observational Studies Available Assessing P2Y12 Inhibitor Timing in NSTEACS**

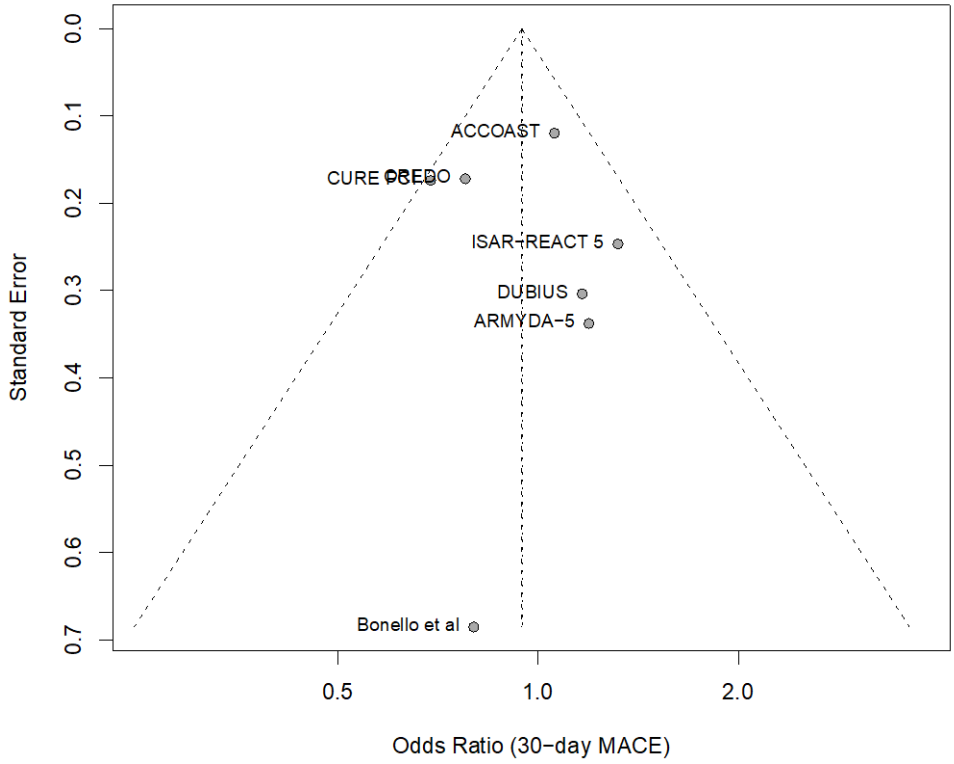
| Study | Year | N | Population | Pre-treatment | Impact on MACE | Impact on bleeding | Results |
|---|---|---|---|---|---|---|---|
| Dworeck et al[9] | 2020 | 64,857 | NSTEACS | Any | - | ↑ | Pre-treatment not associated with improved clinical outcomes but was associated with increased risk of bleeding. |
| Verdoia et al[10] | 2018 | 168 | SIHD/ NSTEACS | Any | - | n/a | No difference in MI or periprocedural myonecrosis. |
| Sukul et al[11] | 2017 | 24,733 | Mixed | Any | - | - | No differences in outcomes between pre-treatment and no pre-treatment. |
| Yudi et al[12] | 2015 | 6,817 | NSTEACS | Any | - | - | No difference in 30-day mortality, MACE or bleeding complications. |
| Ikegami et al[13] | 2015 | 6,528 | ACS | Any | ↓ | - | Pre-treatment associated with reduced MACE and no difference in bleeding endpoints. |
| Almendro-delia et al[14] | 2015 | 9,621 | NSTEACS | Clopidogrel | - | ↑ | No difference in reinfarction, stent thrombosis, or mortality among NSTEACS subgroup. |
| Wang et al[15] | 2011 | 9,166 | NSTEACS | Clopidogrel | - | ↑ | No interaction between upstream clopidogrel administration with randomized eptifibatide for MACE, but increased risk of bleeding with both (EARLY ACS substudy). |
| Feldman et al[16] | 2010 | 1,041 | NSTEACS | Clopidogrel | - | - | No difference in MACE or bleeding complications. |
| Lincoff et al[17] | 2008 | 13,819 | NSTEACS | Clopidogrel | ↓ | - | Post-hoc analysis of the ACUITY trial, increase in ischemic events for patients not pre-treated if randomized to bivalirudin |
| Szuk et al[18] | 2007 | 4,160 | Mixed | Clopidogrel | ↓ | ↑ | Pre-treatment associated with increased MACE and higher major bleeding. |
| Dery et al[19] | 2007 | 2,040 | Mixed | Clopidogrel | ↓ | - | Pre-treatment associated with reduced MACE and no impact on bleeding (ESPRIT substudy.). |
| Chan et al[20] | 2003 | 4,809 | Mixed | Clopidogrel | ↓ | - | Clopidogrel pre-treatment associated with reduced death and MI irrespective of GP IIb/IIIa inhibitor used (TARGET substudy). |
| Assali et al[21] | 2001 | 299 | Mixed | Clopidogrel | ↓ | - | Reduced MACE and no difference on bleeding endpoints |

**eFigure 1. Risk of Bias (RoB 2) Summary**
Upper panel shows weighted summary for all studies, while lower panel shows risk of bias by domain for each individual study.

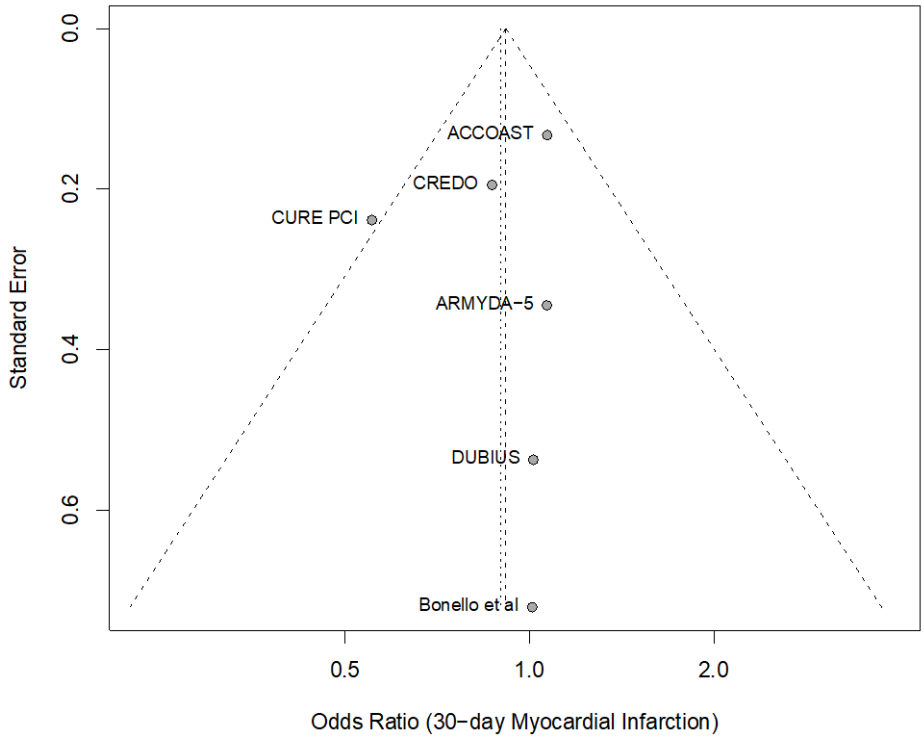


## **eFigure 2.** Funnel Plots

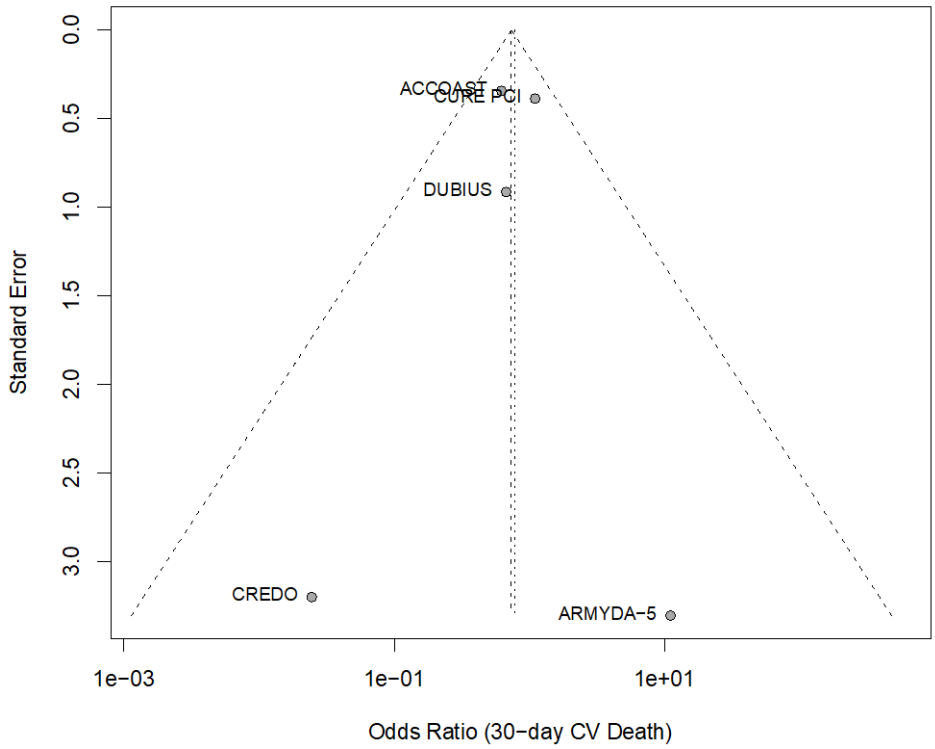
**eFigure 2a.** Funnel plot for 30-day major adverse cardiac events (Egger's test, p=0.78)



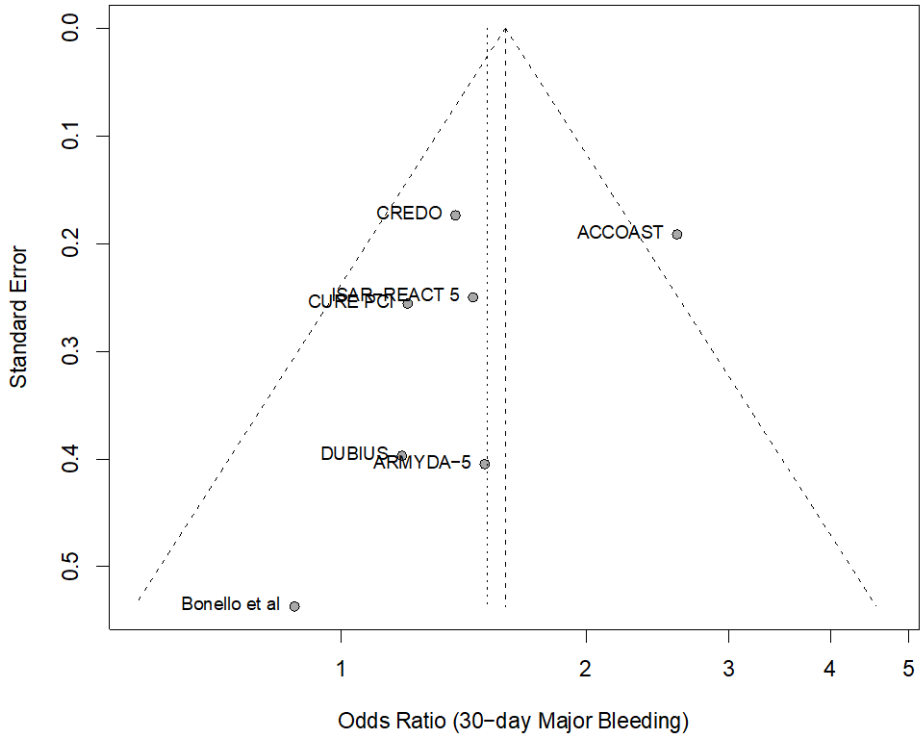

**eFigure 2b.** Funnel plot for 30-day myocardial infarction (Egger's test, p=0.73)



**eFigure 2c.** Funnel plot for 30-day cardiovascular death (Egger's test, p=0.87)

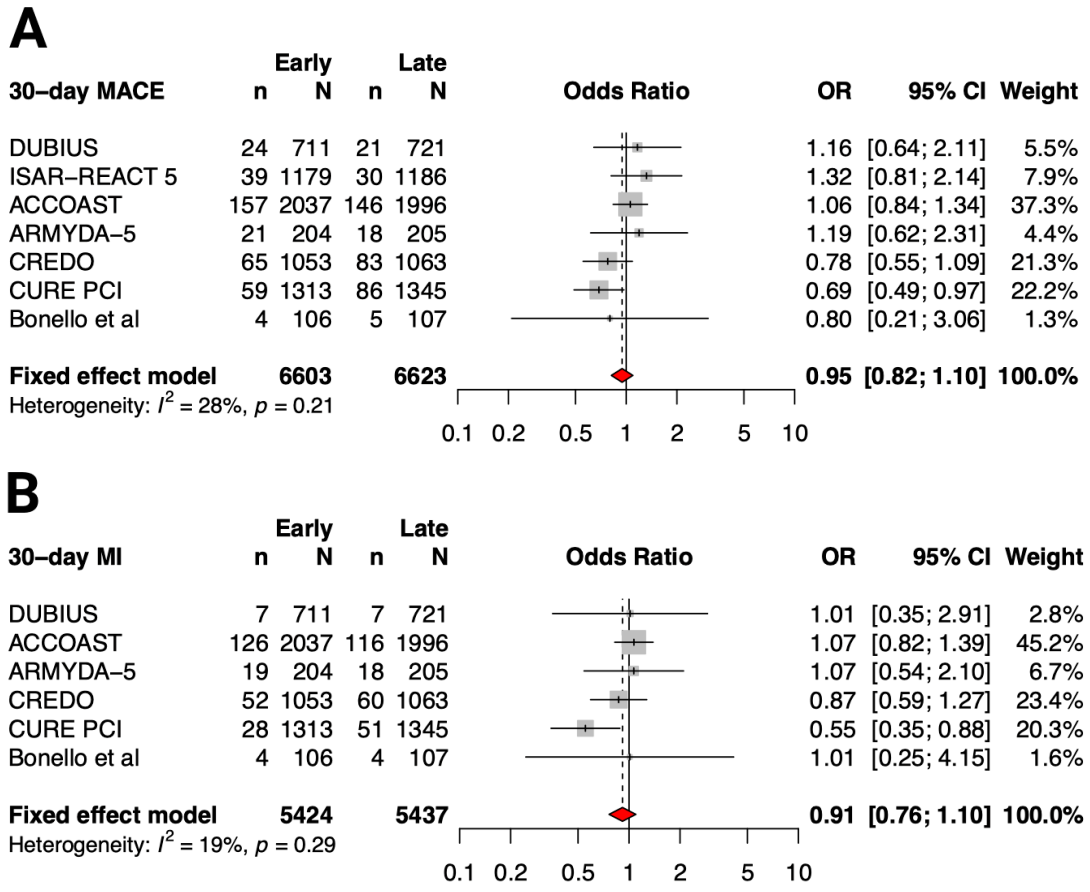



**eFigure 2d.** Funnel plot for 30-day major bleeding (Egger's test, p=0.29)

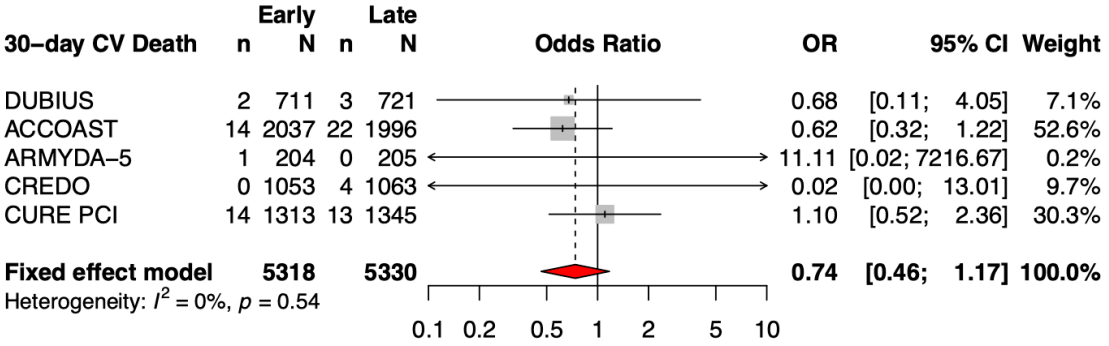


**eFigure 3. Sensitivity Analysis Using a Fixed-Effects Model**

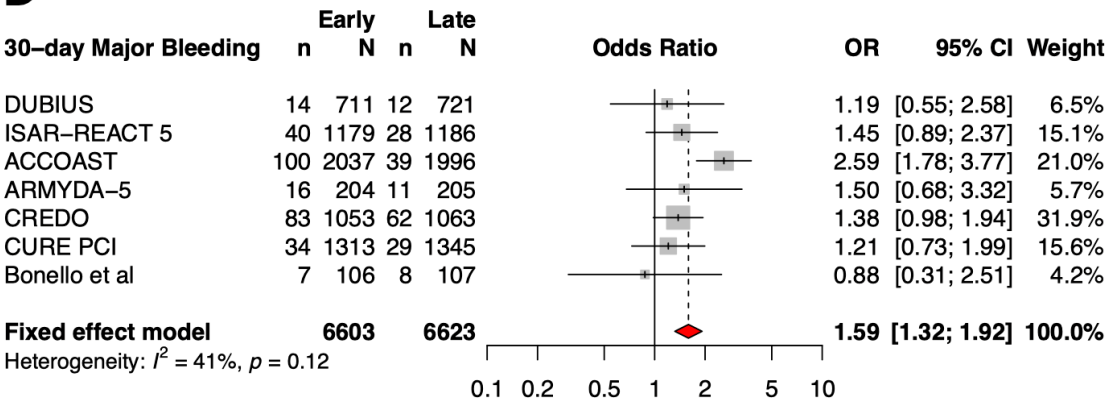
**(A) 30-day MACE, (B) 30-day myocardial infarction, (C) 30-day cardiovascular death, and (D) 30-day major bleeding.**



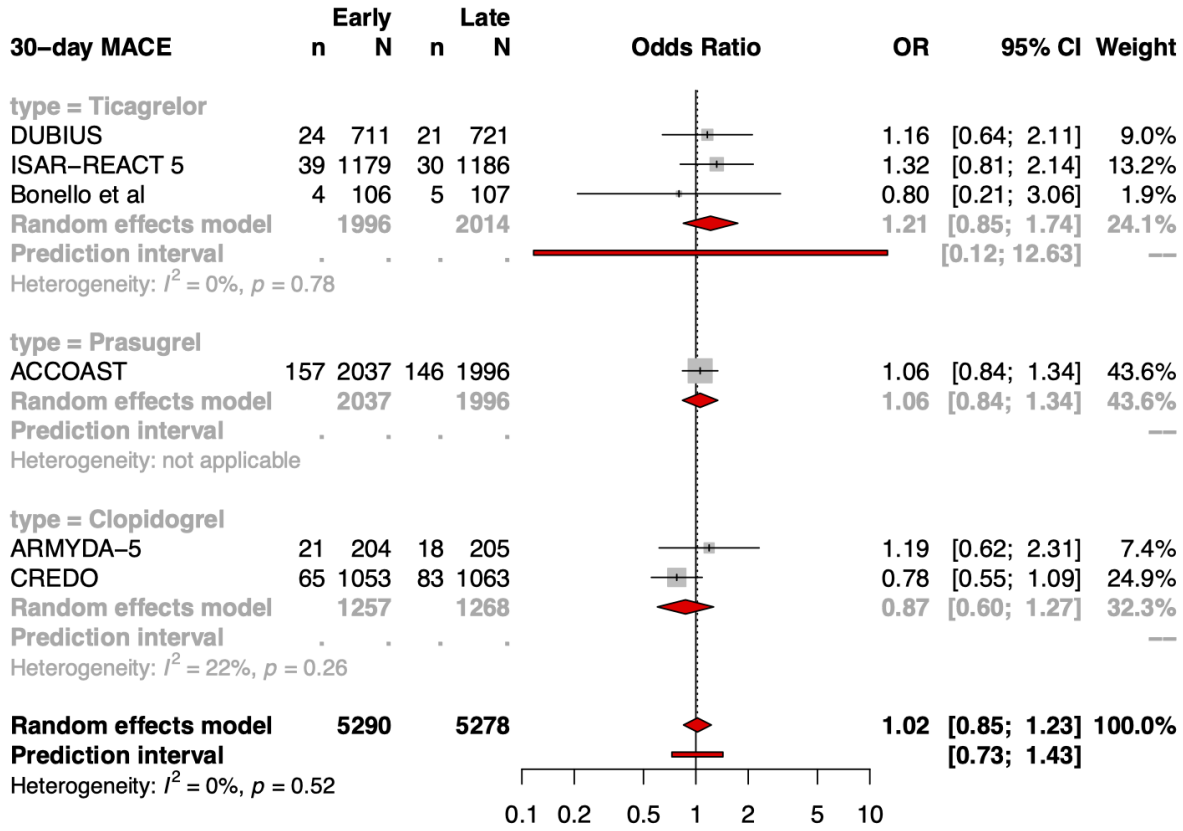
**C**



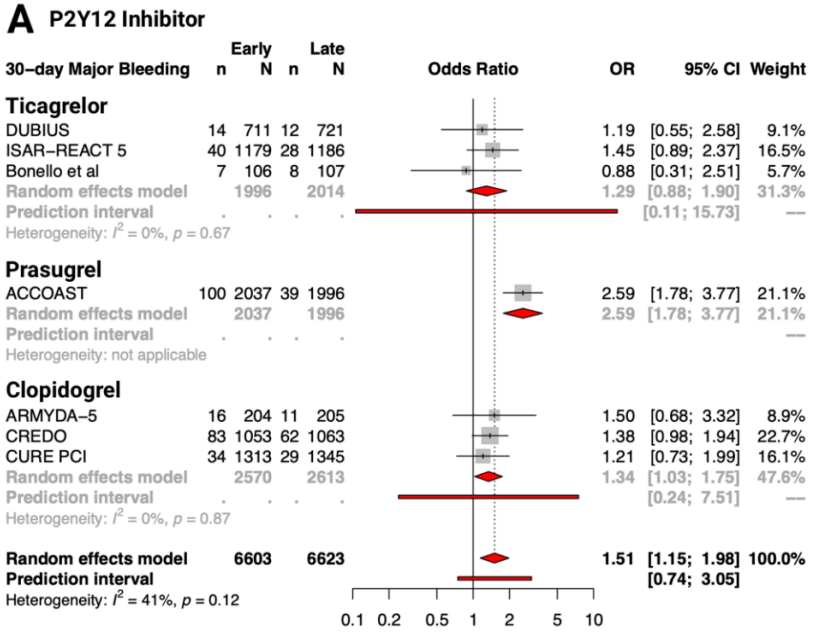

**D**

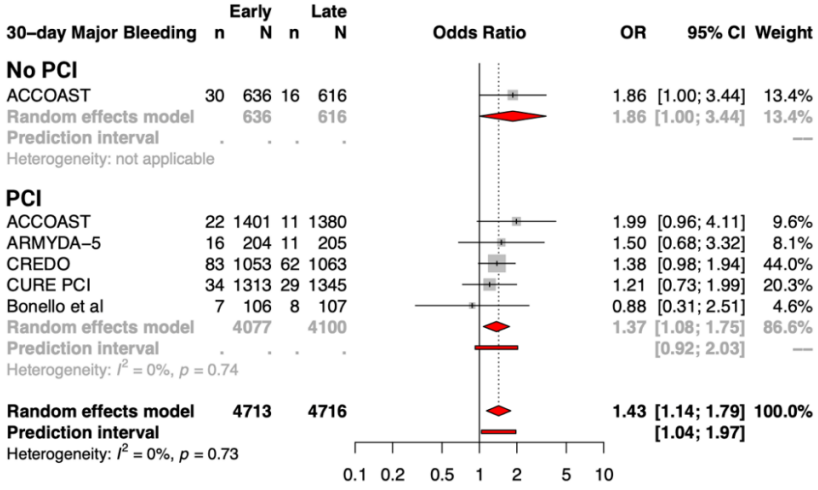


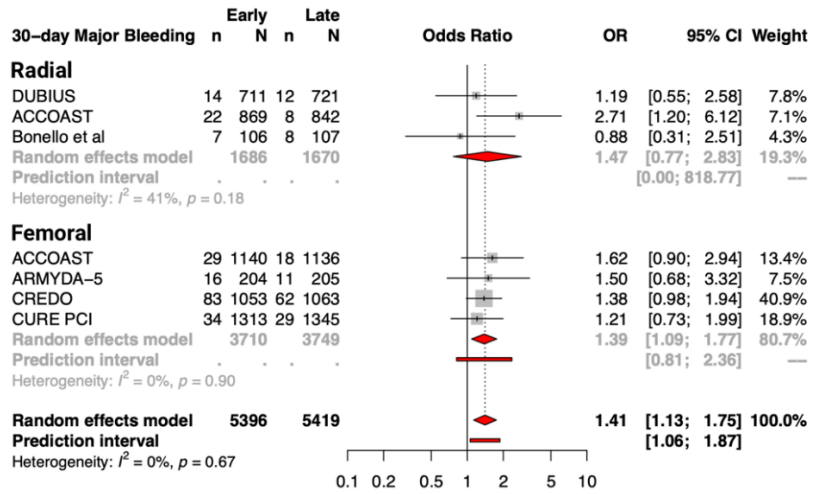
**eFigure 4. Sensitivity Analysis Excluding PCI CURE From P2Y12 Inhibitor Subgroup Analysis**



**eFigure 5. Subgroup Analyses for the Primary Safety End Point (Bleeding)**
**Stratified by (A) P2Y12 inhibitor used for pre-treatment, (B) revascularisation strategy, (C) arterial access site.**

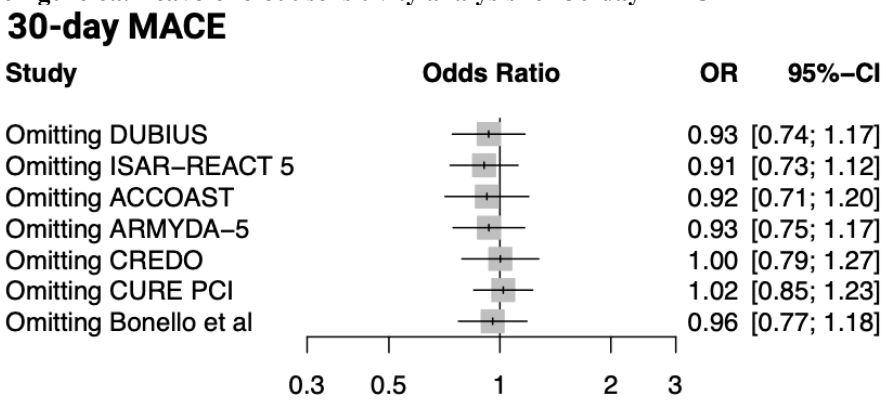


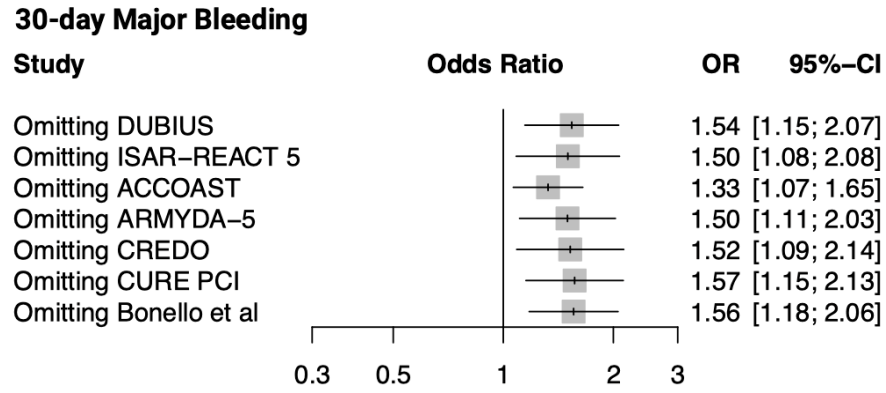



**eFigure 6.** Leave-One-Out Sensitivity Analyses

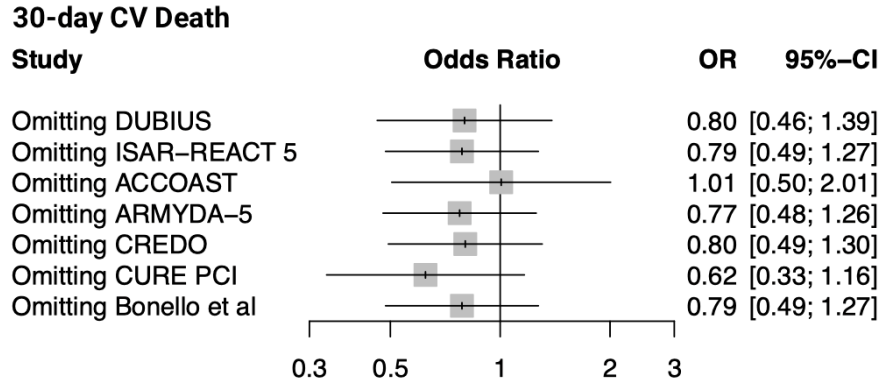
**eFigure 6a. Leave-one-out sensitivity analysis for 30-day MACE**



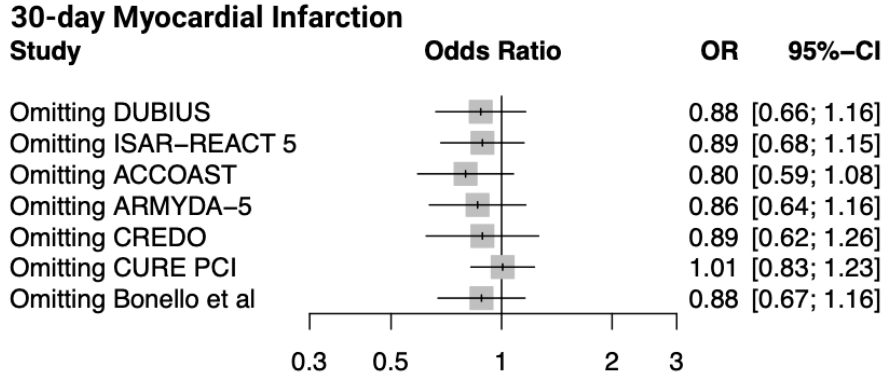

**eFigure 6b. Leave-one-out sensitivity analysis for 30-day Major Bleeding**




**eFigure 6c. Leave-one-out sensitivity analysis for 30-day Cardiovascular Mortality**

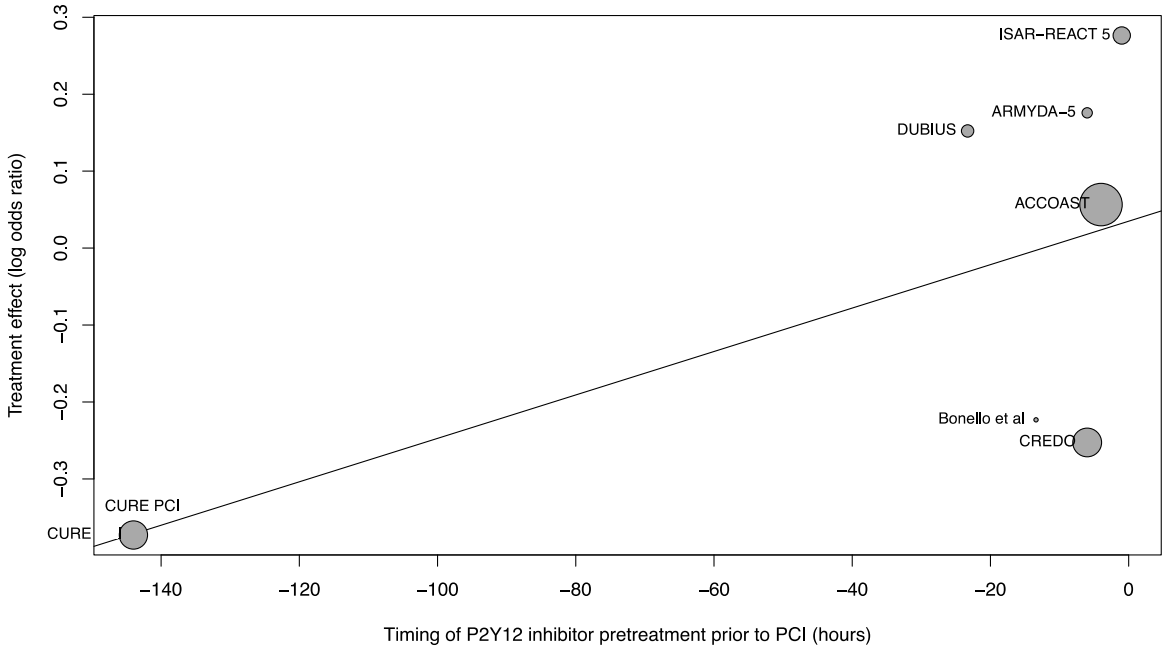



**eFigure 6d. Leave-one-out sensitivity analysis for 30-day Myocardial Infarction**

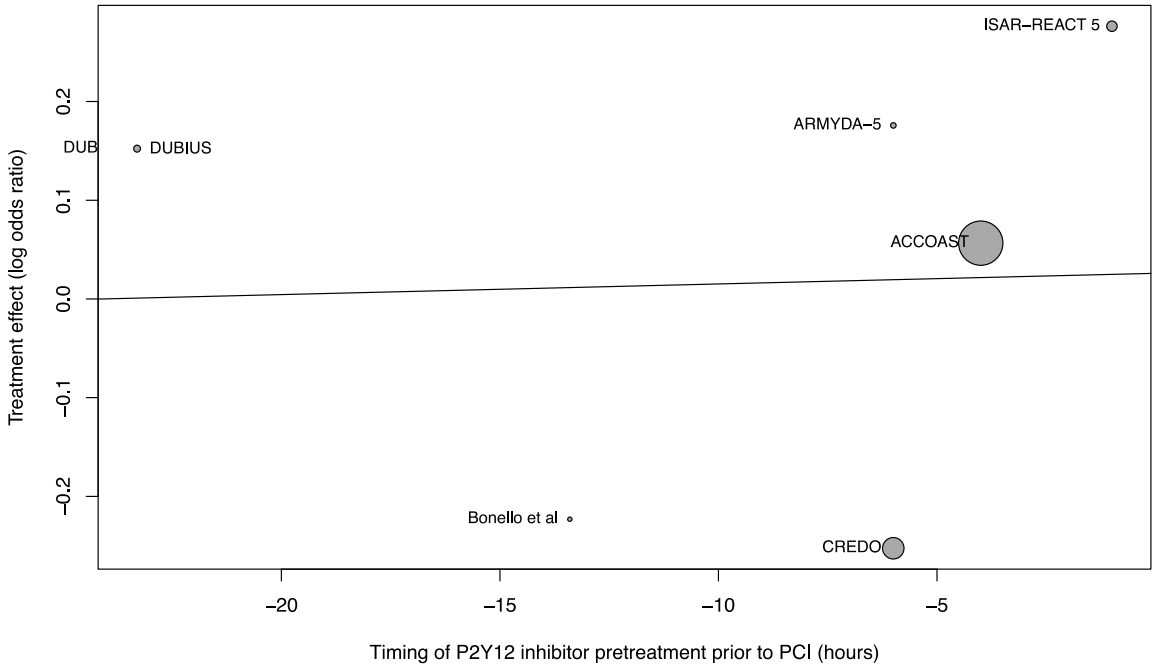


**eFigure 7.** Metaregression Assessing Timing of Pretreatment Loading Dose

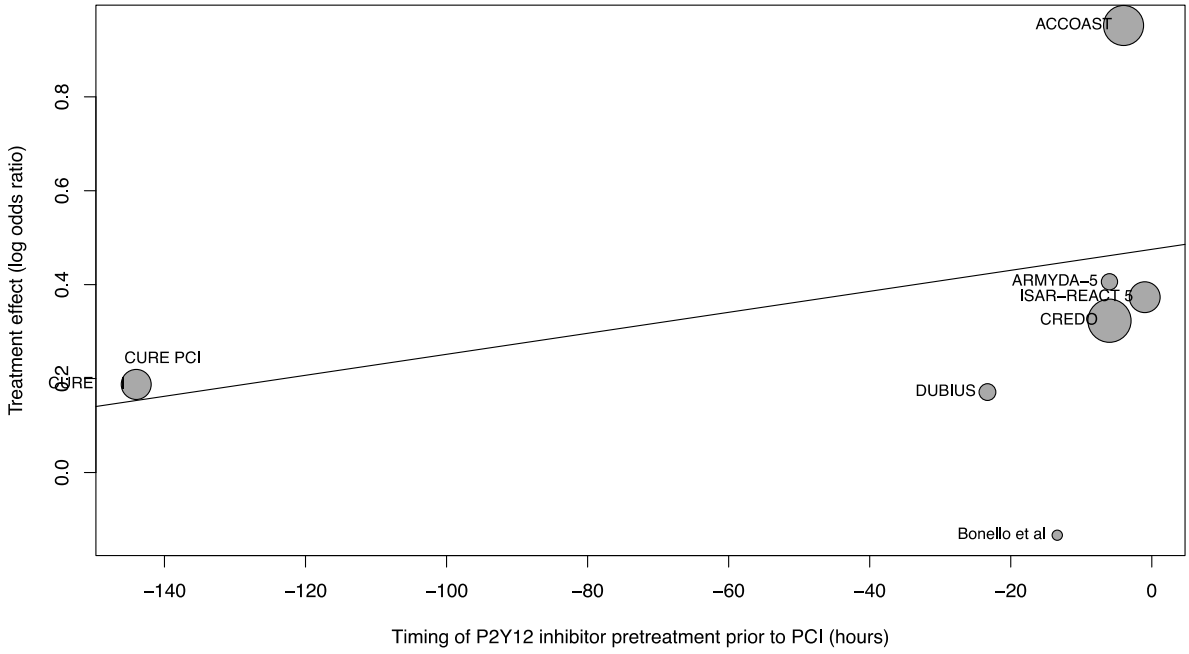
**eFigure 7a. Meta-regression assessing impact of P2Y12 inhibitor administration timing on 30-day MACE in all studies (meta-regression coefficient 0.0028, p=0.0629)**



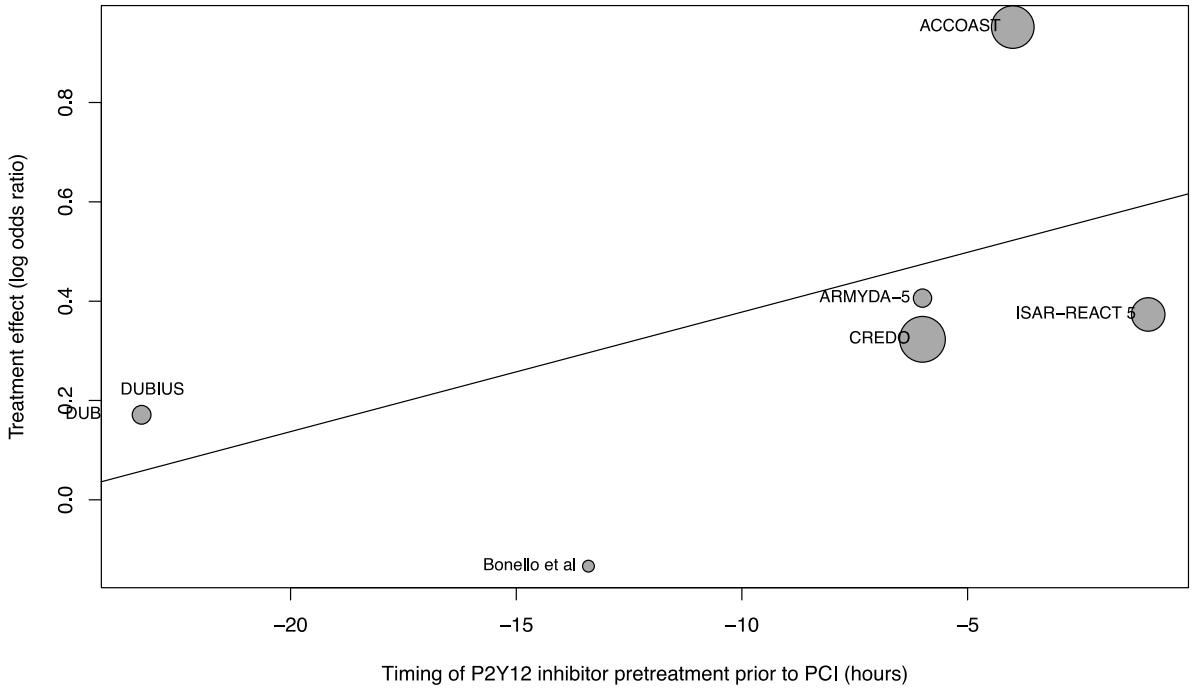

**eFigure 7b. Meta-regression assessing impact of P2Y12 inhibitor administration timing on 30-day MACE with CURE PCI trial excluded to more reflect a contemporary early invasive strategy (meta-regression coefficient 0.0006, p=0.0362)**



**eFigure 7c. Meta-regression assessing impact of P2Y12 inhibitor administration timing on 30-day major bleeding in all studies (meta-regression coefficient 0.0022, p=0.43)**




**eFigure 7d. Meta-regression assessing impact of P2Y12 inhibitor administration timing on 30-day major bleeding with CURE PCI trial excluded to more reflect a contemporary early invasive strategy (meta-regression coefficient 0.0240, p=0.3159)**



**eReferences**.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