1. TITLE PAGE

Clinical and Economic Assessment of Patients with Acute Coronary Syndrome Managed with Percutaneous Coronary Intervention and Treated with Prasugrel or Clopidogrel using Academic Center Databases (H7T-US-B020) – The PROMETHEUS Study

Retrospective Observational Registry

Final Report

Name of the sponsor: Eli Lilly and Company, Indianapolis, Indiana USA 46285
Daiichi-Sankyo, Inc., Parsippany, New Jersey (US Headquarters) 07054

Study initiation date: June 6, 2014

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The study was conducted in accordance with the design and specific provisions of this protocol, in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirements.

Date of the report: 20-APR-2015

Approval Date: **30-Jun-2015 EST**
Approver: **Xiang Zhang**
Approver: **Nayan Acharya**

2. SYNOPSIS

Title	**Clinical and Economic Assessment of Patients with Acute Coronary Syndrome Managed with Percutaneous Coronary Intervention and Treated with Prasugrel or Clopidogrel using Academic Center Databases**
Steering Committee	Roxana Mehran, MD (Chair) Usman Baber, MD, MS Timothy Henry, MD Sunil Rao, MD William Weintraub, MD
Rationale:	Dual antiplatelet therapy (DAPT) using aspirin and a $P2Y_{12}$ adenosine diphosphate (ADP) receptor inhibitor is standard therapy for prevention of thrombotic complications of percutaneous coronary intervention (PCI). The American College of Cardiology (ACC), American Heart Association (AHA), and European Society of Cardiology (ESC) practice guidelines recommend DAPT in patients with acute coronary syndromes (ACS), particularly among those undergoing PCI (Jneid et al. 2012; Hamm et al. 2012). Significant variability in the response to clopidogrel has been observed secondary to genetic polymorphisms and pharmacodynamic interactions, with some individuals having minimal inhibition of ADP-induced platelet aggregation leading to the concern that some patients may be at increased risk for thrombotic events (Mega et al. 2011; Mega et al. 2010; Mega et al. 2009). Results from the TRITON-TIMI 38 established the superior efficacy of prasugrel in combination with aspirin over clopidogrel plus aspirin in reducing ischemic events in ACS patients managed with PCI (Wiviott et al. 2007). Compared with clopidogrel, prasugrel caused higher rates of major bleeding, particularly in patients with advanced age, low body weight, previous stroke or transient ischemic attack. Since its United States (US) approval in 2009, there have been 2 reports directly comparing outcomes between prasugrel and clopidogrel for ischemic and bleeding events. The TRANSLATE-ACS registry was a prospective observational study of approximately 12,000 patients with myocardial infarction ([MI], ST-segment elevation myocardial infarction [STEMI] or non-ST-segment elevation myocardial infarction [NSTEMI]) managed with PCI (Chin et al. 2011). The study evaluated the effectiveness and safety of prasugrel compared with clopidogrel in the usual care environment. However, long-term follow-up was being prospectively collected, requiring patient informed consent. This limited the ability to collect data on all MI patients managed with PCI. Therefore, a large number of eligible patients would not have been included in the TRANSLATE-ACS database because they either did not give consent or were discharged prior to being identified and consent obtained. A prior comparative retrospective, observational analysis between clopidogrel and prasugrel using the Premier claims database assessed the impact of treatment group on readmission rates for MI or bleeding (Bae et al. 2014). Adjusted results showed that prasugrel was associated with significantly lower acute myocardial infarction (AMI)-related rehospitalizations compared with clopidogrel 30 and 90 days post-discharge. Additionally, adjusted results showed no significant difference in bleeding-related rehospitalization rates between prasugrel- and clopidogrel-treated patients (Bae et al. 2014). However, analyses conducted in payer databases are usually less robust than registries or prospective observational studies in capturing pre-existing conditions prior to the index admission, particularly if the patients were not in the plan for the particular payer at the time of the previous diagnosis. Therefore, the true baseline profile of the cohorts may be inadequately determined resulting in inadequate adjustment of the data for

	unmeasured differences in known confounders. Additionally, payer databases are dependent upon claims made on discharge form the hospital, and may not differentiate from the primary event or the secondary event, especially if secondary diagnoses are allowed in the definition of an outcome event. Hence, an observational retrospective database analysis using data collected from patients and/or their medical records at the time of index hospitalization with post-hospitalization follow-up will provide important information and may allow better adjustment for baseline differences and a more accurate representation of the results. Study B020 utilized pooled databases from academic institutions where data is routinely collected on all patients undergoing PCI both during and after the index hospitalization. With regard to clinical and economic outcomes, this approach provided appropriately controlled baseline characteristic collection to adjust for differences in treatment groups resulting in a robust comparison of prasugrel with clopidogrel in ACS patients treated with PCI. Additionally, this study included many of the patients who were not able to be enrolled in TRANSLATE-ACS as their data was already captured in these institutional databases. The databases from these institutions collect a large amount of data as either part of or consistent with the ACC NCDR CathPCI Registry, which includes not only clinical characteristics but also detailed procedural characteristics of patients. Additionally, as these data are entered from patient records based on the clinical evaluation, there is no prespecified time window for capturing prior events. The participating in this study followed these patients post-hospitalization as part of the ongoing evaluation of their results. The majority of the centers have published based on results of analyses from their individual, or in some cases combined, data (Bagai et al. 2012; Hess et al. 2012; Hess et al. 2014; Mathews et al. 2012; Wang et al. 2014).
Hypotheses	a. Prasugrel use will be associated with a significantly lower adjusted rate of MACE compared with clopidogrel at 90 days following index hospital PCI among patients with ACS who undergo PCI (the overall ACS/PCI population)
Population	4,058 patients who received prasugrel and 15,856 patients who received clopidogrel at time of PCI
Eligibility	Inclusion Criteria 1. At least 18 years of age 2. Diagnosed with ACS (STEMI, NSTEMI, UA) and managed by PCI with stent implantation during index hospitalization between 01 January 2010 and 30 June 2013 3. Initiated use of prasugrel or clopidogrel during index hospitalization either prior to, during or in the peri-procedural period of the index PCI.
Design	Multicenter, retrospective observational registry
Site Recruitment Modalities	There was no patient recruitment for this study. Each of the academic centers selected to participate in Study B020 provided information on the patterns of antiplatelet use for ACS patients undergoing PCI and specifically their volumes for the period from 01 January 2010 to 30 June 2013 through a site selection questionnaire. Each of the participating centers maintains high quality institutional databases of both in-hospital and post-discharge follow-up events. The data in these sets are derived primarily from the NCDR CathPCI database while the post-discharge follow-up data is simple physician-determined diagnoses at time of hospitalization. The index hospital data was collected at most sites according to the definitions used in CathPCI. No adjudication of the data was performed. These databases do not typically include prescriptions, adherence, or outpatient encounters. This project extracted data from the participating ARC data sets using standardized extraction sheets with standardized definitions. Extracted data was entered in a Core Study

	Dataset for data analyses.
Primary Objective	Compare major adverse cardiac event (MACE) outcomes (defined as the composite of all-cause death, MI, stroke, or unplanned coronary revascularization) within 90 days of index PCI in patients with ACS treated with prasugrel or clopidogrel.
Secondary Objective	1. Examine the following clinical outcomes for ACS patients managed with PCI initiating treatment with prasugrel versus those initiating treatment with clopidogrel: a. Describe differences in the demographic, clinical, and angiographic profiles. To compare the composite MACE endpoint within 30, 180, and 365 days following index PCI. b. Compare the individual components of the MACE endpoint (all-cause death, MI, stroke, and unplanned revascularization) within 30, 90, 180, and 365 days following index PCI. 2. Compare all in and out of hospital bleeding events, defined as clinically overt hemorrhage requiring hospitalization, within 30, 90, 180 and 365 days from index PCI. Compare bleeding-related rehospitalizations within 30, 90, 180, and 365 days from index hospital discharge with prasugrel versus clopidogrel 3. Compare post-procedural (in-hospital) MACE and bleeding events. 4. Compare Academic Research Consortium (ARC) defined definite/probable stent thrombosis at 30, 90, 180, and 365 days following index PCI with prasugrel versus clopidogrel. 5. Compare MACE and bleeding events at 30, 90, 180 and 365 days following index PCI in the following pre-specified subgroups: 1. ACS-PCI patients with no prior transient ischemic attack (TIA) or stroke 2. ACS-PCI patients with no prior TIA or stroke and are: a. <75 years of age, or b. If ≥75 years of age, have diabetes mellitus or a history of MI 3. Presence or absence of Diabetes mellitus 4. NSTEMI/unstable angina (UA) 5. STEMI 6. Gender 7. Presence or absence of multivessel disease 8. Presence or absence of chronic kidney disease, defined as an estimated glomerular filtration rate < 60 ml/min/1.73m^2
Enrollment Sites	8 US sites
Methodology	• Retrospective cohort study evaluating ACS patients undergoing PCI in academic centers in the US, and treated with Prasugrel or Clopidogrel • PCI databases at each center analyzed to identify patients receiving Prasugrel or Clopidogrel between 01 January 2010 and 30 June 2013
Sample size derivation	Using 8.0% as the control rate from previously reported data, it was expected that the relative reduction with Prasugrel would be 20% lower than with Clopidogrel (hazard ratio 0.80). To achieve 80% power with an alpha of 0.05 at least 4,303 patients were required in each treatment group, yielding a minimum enrollment of 8,606 patients.
Data extraction and analysis	• Pre-specified data extraction sheet with standardized data elements sent to all sites (112 variables) • Site Level Data Extraction and quality assurance conducted • Data exported to Data coordinating center (DCC) with further quality assurance conducted • DCC Data Harmonization • Data Analysis
Statistical Analysis	The primary analysis included the overall ACS/PCI population. Baseline clinical, demographic and procedural parameters were compared between treatment groups using the Student's t-test and chi-square test for continuous and categorical variables, respectively.

	The primary endpoint of interest was the first occurrence of MACE within 90 days from index PCI. For the primary outcome of interest, the crude unadjusted 90-day rates of MACE were calculated for each group using the Kaplan-Meier method, including index hospital events. Crude rates were compared between groups using the log rank test. Adjusted analyses were performed using propensity methods and conventional covariate adjustment. The following propensity methods were used: propensity stratification (primary); inverse probability weighting (IPW); propensity matching. The primary comparison was between patients treated with prasugrel versus clopidogrel in an intention-to-treat (ITT) fashion, after adjustment for demographic, clinical, and procedural differences. All analyses were repeated in all of the subgroups. Subgroups of interest: 1. ACS-PCI patients with no prior TIA or stroke 2. ACS-PCI patients with no prior history of TIA or stroke and are: a. <75 years of age, or b. If ≥75 years of age, have diabetes mellitus or a prior history of MI 3. Age ≥75 years 4. Diabetes mellitus 5. STEMI 6. NSTEMI/UA 7. Chronic kidney disease (estimated glomerular filtration rate <60 ml/min/1.73m^2) 8. Gender 9. Prior TIA or stroke 10. Low body weight (<60 kgs)
Timelines	Protocol Finalized: Q2 2014 First Site Contracted: Q3 2014 First Data Set Received: Q3 2014 Last Site Contracted: Q4 2014 Last Dataset Received: Q1 2015 CSR Delivered: Q2 2015

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4. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

4.1 List of Abbreviations

AE	Adverse Event
ACS	Acute Coronary Syndrome
CRF	Case Report Form
ARC	Academic Research Consortium
DRG	Diagnosis-related group
IMP	Investigational Medical Product
IRB	Institutional Review Board
MACE	Major Adverse Cardiac Outcomes (All cause death or hospitalization for myocardial infarction, stroke, or unplanned revascularization)
MI or AMI	Acute Myocardial Infarction
MSSM	Mount Sinai School of Medicine
NSTEMI	Non-ST elevation myocardial infarction
PCI	Percutaneous Coronary Intervention
SAP	Statistical Analysis Plan
SD	Standard Deviation
STEMI	ST elevation MI
TIA	Transient Ischemic Attack

4.2 Definitions of terms – Refer to Attachment 1 in Section 13.1

5. ETHICS

5.1 Independent Ethics Committee (IEC) or Institutional Review Board (IRB)

The Data Coordinating Center for this study was approved by the IRB at Icahn School of Medicine at Mount Sinai. Each enrolling site obtained IRB approval at their local IRB for the duration of the study.

5.2 Ethical Conduct of the Study

The study was conducted in accordance with the design and specific provisions of this protocol, in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with Good Clinical Practice (GCP) and the applicable regulatory requirements.

5.3 Patient Information and Consent

This is a retrospective review of de-identified data.

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

Participating Sites

Site	**Principal Investigator**
Aurora Medical Center	Anthony De Franco, MD,
Christiana Care Health Services	Sandra Weiss, MD
Cleveland Clinic	Samir Kapadia, MD
Duke University Medical Center	Sunil Rao, MD
Intermountain Heart Institute	Brent Muhlestein, MD
Minneapolis Heart Institute	Craig Strauss, MD, MPH
Mount Sinai Medical Center	Annapoorna Kini, MD
University of Pittsburgh	Catalin Toma, MD

Steering Committee

Roxana Mehran, MD (Chair)
Usman Baber, MD, MS
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William Weintraub, MD
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Data Coordinating Center

Site	**Key Personnel**
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Site	Key Personnel
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Eli Lilly	Douglas E. Faries, PhD
Eli Lilly	Stuart Keller, BS Pharm
Daiichi Sankyo	Elizabeth Marrett, MPH
Eli Lilly	Cliff Molife, PhD

7. INTRODUCTION

Dual antiplatelet therapy (DAPT) using aspirin and a P2Y12 adenosine diphosphate (ADP) receptor inhibitor is standard therapy for prevention of thrombotic complications of percutaneous coronary intervention (PCI). The American College of Cardiology (ACC), American Heart Association (AHA), and European Society of Cardiology (ESC) practice guidelines recommend DAPT in patients with acute coronary syndromes (ACS), particularly among those undergoing PCI (Jneid et al. 2012; Hamm et al. 2012). Significant variability in the response to clopidogrel has been observed secondary to genetic polymorphisms and pharmacodynamic interactions, with some individuals having minimal inhibition of ADP-induced platelet aggregation leading to the concern that some patients may be at increased risk for thrombotic events (Mega et al. 2011; Mega et al. 2010; Mega et al. 2009).

Results from the TRITON-TIMI 38 established the superior efficacy of prasugrel in combination with aspirin over clopidogrel plus aspirin in reducing ischemic events in ACS patients managed with PCI (Wiviott et al. 2007). Compared with clopidogrel, prasugrel caused higher rates of major bleeding, particularly in patients with advanced age, low body weight, previous stroke or transient ischemic attack. Since its United States (US) approval in 2009, there have been 2 reports directly comparing outcomes between prasugrel and clopidogrel for ischemic and bleeding events. The TRANSLATE-ACS registry was a prospective observational study of approximately 12,000 patients with myocardial infarction ([MI], ST-segment elevation myocardial infarction [STEMI] or non-ST-segment elevation myocardial infarction [NSTEMI]) managed with PCI (Chin et al. 2011). The study evaluated the effectiveness and safety of prasugrel compared with clopidogrel in the usual care environment. However, long-term follow-up was being prospectively collected, requiring patient informed consent. This limited the ability to collect data on all MI patients managed with PCI. Therefore, a large number of eligible patients would not have been included in the TRANSLATE-ACS database because they either did not give consent or were discharged prior to being identified and consent obtained.

A prior comparative retrospective, observational analysis between clopidogrel and prasugrel using the Premier claims database assessed the impact of treatment group on readmission rates for MI or bleeding (Bae et al. 2014). Adjusted results showed that prasugrel was associated with significantly lower acute myocardial infarction (AMI)-related rehospitalizations compared with clopidogrel 30 and 90 days post-discharge. Additionally, adjusted results showed no significant difference in bleeding-related rehospitalization rates between prasugrel- and clopidogrel-treated patients (Bae et al. 2014). However, analyses conducted in payer databases are usually less robust than registries or prospective observational studies in capturing pre-existing conditions prior to the index admission, particularly if the patients were not in the plan for the particular payer at the time of the previous diagnosis. Therefore, the true baseline profile of the cohorts may be inadequately determined resulting in inadequate adjustment of the data for unmeasured differences in known confounders. Additionally, payer databases are dependent upon claims made on discharge form the hospital, and may not differentiate from the primary event or the secondary event, especially if secondary diagnoses are allowed in the definition of an outcome event.

Hence, an observational retrospective database analysis using data collected from patients and/or their medical records at the time of index hospitalization with post-hospitalization follow-up will provide important information and may allow better adjustment for baseline differences and a more accurate representation of the results. Study B020 utilized pooled databases from academic institutions where data is routinely collected on all patients undergoing PCI both during and after the index hospitalization. With regard to clinical and economic outcomes, this approach provided appropriately controlled baseline characteristic collection to adjust for differences in treatment groups resulting in a robust comparison of prasugrel with clopidogrel in ACS patients treated with PCI. Additionally, this study included many of the patients who were not able to be enrolled in TRANSLATE-ACS as their data was already captured in these institutional databases. The databases from these institutions collect a large amount of data as either part of or consistent with the ACC NCDR CathPCI Registry, which includes not only clinical characteristics but also detailed procedural characteristics of patients. Additionally, as these data are entered from patient records based on the clinical evaluation, there is no prespecified time window for capturing prior events. The participating in this study followed these patients post-hospitalization as part of the ongoing evaluation of their results. The majority of the centers have published based on results of analyses from their individual, or in some cases combined, data (Bagai et al. 2012; Hess et al. 2012; Hess et al. 2014; Mathews et al. 2012; Wang et al. 2014).

8. STUDY OBJECTIVES

8.1 Primary Objective

To compare the composite major adverse cardiac event (MACE) outcomes (all-cause death, MI, stroke, or unplanned coronary revascularization) within 90 days of index hospital admission in patients with ACS managed with PCI (the overall ACS/PCI population) who initiated treatment in-hospital with prasugrel versus those treated with clopidogrel.

8.1.2 Secondary Objectives

1. Examine the following clinical outcomes for ACS patients managed with PCI initiating treatment with prasugrel versus those treated with clopidogrel:

    a. Describe differences in the clinical and angiographic profiles of ACS patients managed with PCI treated with prasugrel versus clopidogrel
    b. Compare the composite MACE endpoint at 30, 180, and 365 days following index hospital PCI
    c. Compare the individual components of the MACE endpoint (all-cause death, MI, stroke, and unplanned revascularization) at 30, 90, 180, and 365 days following index hospital PCI
    d. Compare prasugrel with clopidogrel with regard to the following non-fatal individual components of MACE at 90, 180, and 365 days following index hospital admission:
        1. New MI
        2. Unplanned revascularization
        3. Stroke
    e. Compare all bleeding events or transfusions during index hospital
    f. Compare bleeding-related rehospitalizations within 30, 90, 180, and 365 days from index hospital discharge with prasugrel compared with clopidogrel
    g. Compare Academic Research Consortium (ARC) defined definite/probable stent thrombosis at 30, 90, and 365 days following index hospital admission with prasugrel versus clopidogrel
    h. Compare composite MACE and bleeding events at 30, 90, 180, and 365 days following index hospital admission in the following pre-specified subgroups:

1. ACS-PCI patients with no prior transient ischemic attack (TIA) or stroke
2. ACS-PCI patients with no prior history of TIA or stroke and are:
a. <75 years of age, or
b. If ≥75 years of age, have diabetes mellitus or a history of MI
3. Age ≥75 years
4. Diabetes mellitus
5. STEMI
6. NSTEMI/unstable angina (UA)
7. Chronic kidney disease (creatinine clearance <60 ml/min/1.73m2
8. Gender
9. Prior stroke or TIA
10. Low body weight (<60 kgs)

8.1.3 Hypotheses

Prasugrel use will be associated with a significantly lower adjusted rate of MACE compared with clopidogrel at 90 days following index hospital PCI among patients with ACS who undergo PCI (the overall ACS/PCI population)

9. INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan: Description

Study B020 was designed as a retrospective cohort study evaluating data for patients presenting with ACS managed with a PCI from 8 academic centers in the US between 01 January 2010 to 30 June 2013, with any follow-up data available for analysis. The centers include: Mount Sinai Medical Center, Intermountain Heart Institute, Duke University, Cleveland Clinic Foundation, University of Pittsburgh, University of Minnesota, Christiana Health Care and Aurora Research Institute. This study evaluates the comparative effectiveness of a treatment strategy initiating prasugrel relative to clopidogrel in 4,058 patients who received prasugrel and 15,856 patients who received clopidogrel at time of PCI in a usual care environment from academic centers in the US. These academic centers maintain institutional databases related to baseline characteristics, procedural characteristics, and clinical and economic outcomes during and following index hospitalization of patients with ACS undergoing PCI.

The participating academic centers ran a query in their ACS-PCI database to identify all patients who received prasugrel or clopidogrel between 01 January 2010 and 30 June 2013. The study period was selected based on the approval and availability of prasugrel in the US market at the end of 2009 and by the need for a study with a minimum 90-day follow-up in this population. The primary endpoint of the study is 90 days from index PCI; at this point in therapy, the adherence rate was expected to continue to be high while the switching rate was expected to be low (≤10%). Figure 1 illustrates the study time periods.

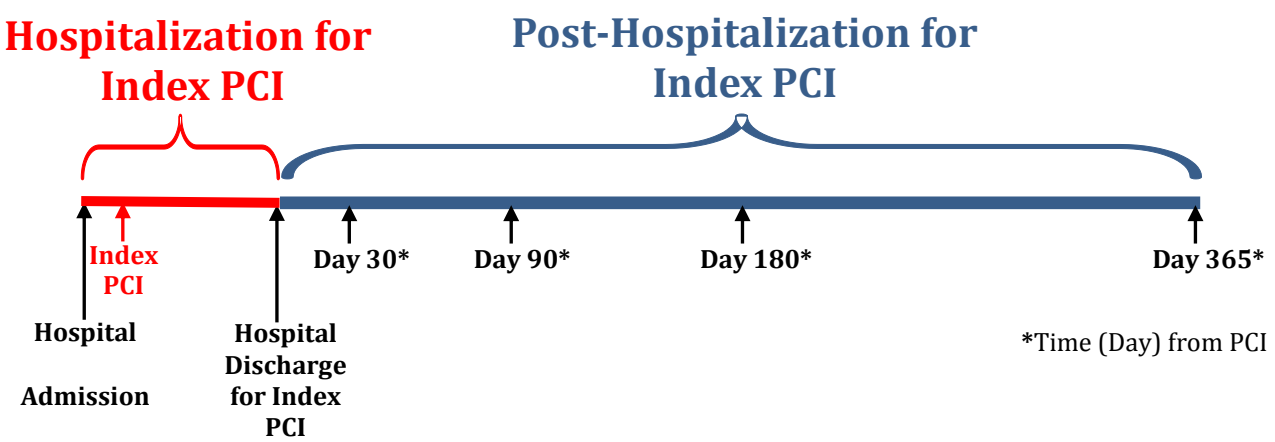


Figure 1 Study B020 design for patients with ACS managed with PCI and treated with prasugrel or clopidogrel between 01 January 2010 and 30 June 2013.

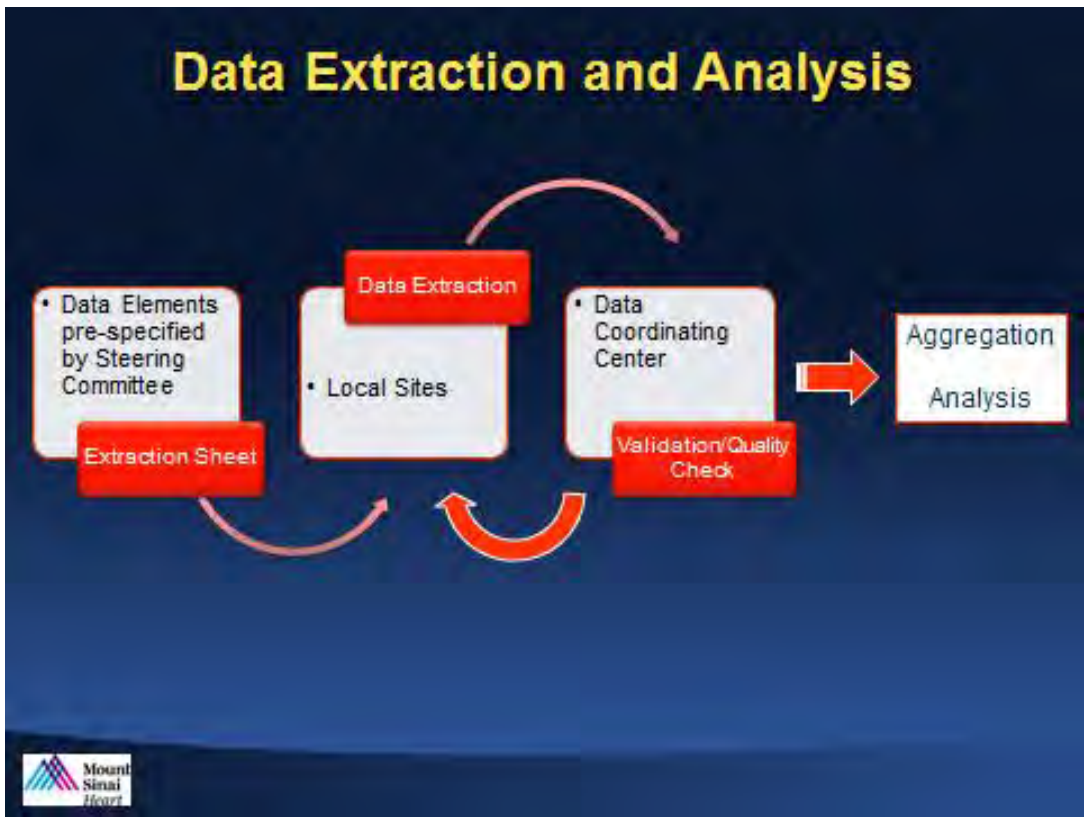
9.1.1 Data Sources

Each of the academic centers selected to participate in Study B020 provided information on the patterns of antiplatelet use for ACS patients undergoing PCI and specifically their volumes for the period from 01 January 2010 to 30 June 2013 through a site selection questionnaire. Each of the participating centers maintains high quality institutional databases of both in-hospital and post-discharge follow-up events. The data in these sets are derived primarily from the NCDR CathPCI database while the post-discharge follow-up data is physician-determined diagnoses at time of hospitalization. The index hospital data is collected at most sites according to the definitions used in CathPCI registry data collection form. No adjudication of the data will be performed. These databases do not typically include outpatient prescriptions, or outpatient encounters. This project extracted data from the participating centers using extraction sheets with standardized definitions. Extracted data was entered in a Core Study Dataset for data analyses.

9.1.2 Data Extraction

A total of 112 variables were extracted by each of the sites and the data forwarded to the Mount Sinai DCC where quality assurance check was performed. This was followed by query resolution and further data extraction. Over ten months, data were collected for the total of 19,914 patients.

Figure 2: Schema for data acquisition



9.2 Study Population

Data from eight academic medical centers located in the United States were collected for this retrospective database.

9.2.1 Inclusion Criteria

1. At least 18 years of age at time of index PCI.
2. Diagnosed with ACS (STEMI, NSTEMI, UA) and managed by PCI with stent implantation during the index hospitalization between 01 January 2010 and 30 June 2013
3. Treatment with prasugrel or clopidogrel during index hospitalization either prior to, or during the peri-procedural period.

9.2.2 Exclusion Criteria

Exclusion criteria were not used for this study as subjects were not consented to participate in the study. The participating sites maintained databases which were queried for subjects meeting the inclusion criteria listed above. Patients who were initiated on one agent at the time of PCI and then switched to the other agent in the periprocedural period were excluded forom analysis.

9.2.3 Populations of Interest

1. ACS-PCI patients with no prior TIA or stroke
2. ACS-PCI patients with no prior history of TIA or stroke and are:
    a. <75 years of age, or
    b. If ≥75 years of age, have diabetes mellitus or a prior history of MI
3. Age ≥75 years
4. Diabetes mellitus
5. STEMI
6. NSTEMI/UA
7. Chronic kidney disease (estimated glomerular filtration rate <60 ml/min/1.73m^2)
8. Gender
9. Prior TIA or stroke
10. Low body weight (< 60 kgs)

9.3 Efficacy and Safety Variables

The primary dependent variable was MACE (composite of all-cause death, non-fatal MI, stroke or unplanned coronary revascularization) through 90 days from index hospital PCI. Secondary dependent clinical variables included components of MACE, bleeding, and index hospital length of stay. Other clinical and economic variables of interest were defined in the Statistical Analysis Plan (SAP). The primary independent variable was treatment cohort (prasugrel versus clopidogrel) and other independent variables (covariates) included baseline demographic and clinical characteristics, and baseline treatment utilization.

The variables and their definitions collected for the analysis dataset are listed in Appendix 13.1.

9.4 Plan of Analysis

9.4.1 Methods

Primary Objective

The exposure groups for the primary analysis was defined as those patients receiving prasugrel or clopidogrel at the time of PCI (i.e. loaded peri-procedurally or currently taking in the absence of a load). All patients were assigned to one of these mutually exclusive groups irrespective of medication administered at discharge. Patients administered both medications at the time of PCI were excluded for any comparative analyses of treatments.

For descriptive purposes, baseline clinical (including laboratory evaluations) and demographic and procedural characteristics were compared between groups using student's t-test and chi-square test or Fisher's exact test for continuous and categorical variables, respectively.

In-hospital (that is, post-procedural) outcomes were assessed by comparing the proportion of post-procedural events between prasugrel and clopidogrel groups. These crude unadjusted binary proportions were performed using a Chi-square test between groups.

The primary endpoint of interest was the first occurrence of MACE within 90 days from date of index PCI. For purposes of this primary analysis, event-free patients were censored at 90 days or last contact, whichever came first. For the primary outcome of interest, the crude unadjusted 90-day rates of MACE were calculated for each group using the ***Kaplan-Meier method, including index hospital events***. Crude rates were compared between groups using the logrank test (Kalbfleisch et al. 1980; Prentice et al. 1978).

To evaluate the adjusted associations between treatment group (therapy initiation with prasugrel versus clopidogrel) and the primary MACE outcome, hazard ratios were calculated using Cox proportional hazards regression that were stratified by the propensity to receive prasugrel.

Propensity scores were calculated using a multivariable logistic regression model with the dependent outcome as treatment initiation with prasugrel (versus clopidogrel). In addition to age, and gender, this model included all baseline covariates demonstrating significant differences ($p<0.05$) between groups. Additional variables for which there is consensus that may be related to either the outcome or exposure were included as covariates, even in the absence of significant baseline differences between groups. The final model included the following main effects: center (categorical); CAD presentation; DM; age; age squared; bivalirudin; smoking; gender; African-American race; hypertension; family history of CAD; Prior PCI; Prior CABG; Prior PAD; Prior CHF; Prior cerebrovascular disease (CVD); stent length; stent diameter; GP 2b3a inhibitor use; hypercholesterolemia; prior MI; eGFR; stent type; BMI; hemoglobin and the following interaction terms: center*procedural 2b3a; bmi*hemoglobin; prior CVD*prior PCI; prior CVD*prior CABG.
From this logistic regression model, each observation was assigned a predicted probability for prasugrel treatment. Baseline characteristics including calculated propensity score were reviewed to better understand the data and specified analyses plan for the outcomes (stratification, matching, IPW, and etc.) were finalized and documented prior to any actual analyses on the outcomes. The distribution of propensity scores for the entire cohort and each treatment group were visually examined. Mutually exclusive strata were then generated based on the propensity scores for the entire cohort, a process which was blinded to any outcome data in order to avoid bias in selection. The number of strata and their respective cut-points were defined *a priori* but were based on fulfilling the following criteria:

1. Sufficient number of strata to ensure adequate bias adjustment (i.e. at least 5 strata) [Rosenbaum et al., 1984);
2. Sufficient proportion of prasugrel and clopidogrel patients (at least 3%) within each stratum to allow reliable risk estimation [D'Agostino et al., circulation 2007];
3. Adequate balance in baseline covariates assessed by calculating the standardized differences between exposure groups within strata for the following variables: age, gender, serum creatinine, serum hemoglobin and prevalence of DM. A standardized difference exceeding 10% was considered inadequate bias adjustment.

The adjusted associations between exposure groups and the primary MACE outcome were calculated using Cox proportional hazards regression. This model included the following two covariates: exposure group (prasugrel versus clopidogrel) and study center, with propensity group entered as a stratification variable. Additional covariates were included to account for residual imbalances between groups and/or adjust for important variables related to the outcome of interest. These additional covariates included age, stent type, stent length, CAD presentation, CKD, hemoglobin, center and previous MI. The final adjusted estimate was a “pooled” estimated across all strata.

The following sensitivity analyses for the primary MACE outcome were also be performed:

1. Covariate adjustment. Hazard ratios for the primary MACE outcome associated with prasugrel versus clopidogrel treatment were generated using a fully-fitted Cox proportional hazards regression model. In addition to age, gender and

study center, this model included all baseline covariates demonstrating significant differences ($p < 0.05$) between groups. Other baseline variables that were plausibly related to the primary outcome were also included: center, age, diabetes mellitus, hemoglobin, hypertension, prior MI, prior cerebrovascular disease, CKD, CAD presentation (unstable angina vs. nstemi vs. stemi), current smoking, procedural bivalirudin, stent type, stent length, and stent diameter (maximum) (Appendix 13.2).

1. Propensity matching: A 1:1 matched cohort was derived from the overall sample using the propensity scores as described above. Matches were generated using nearest neighbour matching without replacement (Austin 2011). (Appendix 13.23)
2. Equipoise Analysis: From the overall cohort, an 'equipoise' subgroup were derived that include all patients with preference scores ranging between 0.4 - 0.6. These patients are assumed to have a reasonable high probability of being assigned to either treatment (Walker et al., 2013). (Appendix 13.24)
3. Inverse Probability Weight Analysis: Inverse probability weights (IPW) were derived for all observations using the propensity scores. Weights exceeding the 99th percentile or below the 1st percentile for each treatment group were truncated (i.e. reset to these values) for purposes of this specific analysis as described by Cole et al., AJE 2008. (Appendix 13.2)
4. A sensitivity analysis for the primary MACE outcome was performed by defining exposure groups as those patients receiving the same medication at the time of PCI and at discharge. For purposes of this sensitivity analysis, dependent outcome was restricted to out-of hospital MACE and exclude those patients with in-hospital death. (Appendix 13.22)

Secondary Objectives

Analyses for the secondary clinical outcomes, including subgroups, were performed using propensity score with stratification as outlined above with covariate adjustment as a sensitivity analysis.

9.4.2 Bias Adjustment

Based on prior studies (Bae et al. 2012; Wang et al. 2013), significant differences in baseline and other characteristics between groups was expected. Therefore, 2 types of statistical procedures were performed to account for such bias; these include multivariate and inverse propensity weighting.

9.4.3 Subgroups

Associations for the primary MACE outcome were examined in the pre-defined clinical subgroups of interest as described in Section 9.2.3. Stratum-specific hazard ratios were calculated within each subgroup using Cox proportional hazards regression. Formal interaction testing was performed between the main effects of subgroup (yes/no) and treatment allocation (prasugrel versus clopidogrel) on the MACE endpoint. Interaction terms with p-value <0.05 are considered significant.

9.4.4 Multiplicity

The primary endpoint of interest in the present study is 90-day MACE, for which a Type I error rate of 0.05 was used. All other endpoints are secondary and therefore no multiplicity adjustments were performed.

9.4.5 Missing Data

The amount of missing data was minimal in the present study as sites were specifically asked to ensure that the data elements requested were available. In instances where baseline clinical or procedural data were missing, data were imputed with values using multiple imputations with the mi command in Stata. Missing outcome data were not imputed.

9.4.6 Robustness

The primary analysis involved multivariate Cox proportional hazards regression as described above. The analysis incorporated a step-wise selection procedure to generate a parsimonious model with selected covariates. Several sensitivity analyses were performed to ensure that the primary findings were robust. First, select covariates were selected using different approaches

(forward and backward selection) to assess whether or not the association for the primary variable of interest changes substantially. Second, all analyses were repeated in an IPW-adjusted cohort.

These additional analyses are meant to be confirmatory (that is, yield approximately the same answer) to the primary analysis.

9.4.7 Sample Size and Power Considerations

Study B020 was designed to assess the difference in MACE associated with prasugrel versus clopidogrel in patients presenting with ACS managed with a PCI from academic centers in the US from 01 January 2010 to 30 June 2013. Data from the Premier study and from TRANSLATE-ACS have suggested that the MACE rate at 90 days would be approximately 8.0%. Using 8.0% as the control rate, it was expected that the relative reduction with prasugrel would be 20% lower than with clopidogrel (hazard ratio 0.80). To achieve 80% power with an alpha of 0.05, and factoring in a 10% patient drop-out, at least 4,303 patients on prasugrel and clopidogrel needed to be enrolled, yielding a minimum enrollment of 8,606 patients.

9.5. Management and Reporting of Adverse Events

During the course of retrospective observational research, information pertaining to adverse reactions (ARs) was not discovered as the study does not involve identifiable patient data associated with a Lilly drug. The data in this study was only being analyzed in aggregate, study data sets do not include safety measures, and there was no medical chart review or review of free text data fields. Patient level data from the database was not transferred to Lilly and/or Daiichi Sankyo Incorporated (DSI).

10. STUDY RESULTS

The study included 19,914 patients undergoing PCI between 01 Jan 2010 to 30 June 2013.

10.1 Study Sites

This was a multicenter observational registry across 8 US sites shown in **Table 1**.

Table 1: Study sites and number of patients enrolled per site

Site	No. of patients	Prasugrel	Clopidogrel
Mount Sinai Medical Center	5344	888	4456
Cleveland Clinic	3146	142	3004
Christiana Care	2751	771	1980
Minneapolis Heart Institute	2464	885	1579
Intermountain Heart Institute	1893	715	1178
University of Pittsburgh Medical Center	1710	211	1499
Duke University	1651	84	1567
Aurora Healthcare	955	362	593

10.2 Timelines and Milestone achievement

The study protocol was finalized on 2June 2014. An approved extraction dataset was provided to the sites on 2 June 2014. A revision was made on 17 October 2014. The first dataset was received at the DCC on 29 September 2014, and the final dataset was received on 15 February 2015. Quality assurance and query resolution was conducted with receipt of each dataset and the database locked on 5 March 2015.

10.3 Prasugrel Use in the Overall Cohort

Of the total population, 20% (n = 4058) received prasugrel and 80% (15861) received clopidogrel. Prasugrel use varied across the 8 sites from a minimum of 5% to a maximum of 38%. Prasugrel was more likely to be used in patients with ST-elevation myocardial infarction (STEMI) or non-ST elevation myocardial infarction (NSTEMI) rather than unstable angina. The frequency of use in specific sub-groups is shown in **Table 2**.

Table 2: Prasugrel use in specific sub-groups

Subgroup	Frequency of Prasugrel Use
Age ≥ 75 years	188/4038 (4.7%)
Prior cerebrovascular disease	188/2385 (7.9%)
Weight < 60Kg	124/1269 (9.8%)
Any of the above comorbidities	441/6206 (7.1%)

10.4 Overall Cohort

10.4.1. Unadjusted Baseline characteristics

The mean age of the study population was 64.4 ± 12.3 years and 31.6% were women. The frequency of diabetes, prior MI, prior cerebrovascular disease, chronic kidney disease and anemia in the entire cohort was 38%, 30%, 12%, 28.3% and 14.5% respectively. The overall presentation of patients was unstable angina in 57%, NSTEMI in 27% and STEMI in 16% patients. Discharge prescription therapy was changed in 13.4% patients initiated on prasugrel compared 4.6% of patients initiated on clopidogrel for PCI.

The baseline differences between patients receiving prasugrel and clopidogrel are indicated in **Table 3.**

Table 3: Baseline characteristics

	Overall (n = 19914)	**Prasugrel (n = 4058)**	**Clopidogrel (n = 15856)**	**p**
Age, years	64.40± 12.27	58.7 ± 10.3	65.8 ± 12.3	<0.0001
Female sex	6304 (31.6%)	989 (24.4%)	5315 (33.5%)	<0.0001
African-American	2125 (10.7%)	253 (6.2%)	1,872 (11.8%)	<0.0001
BMI (kg/m^2)	29.9 ± 6.2	30.7 ± 6.2	29.7± 6.2	<0.0001
Weight < 60kg	1269 (6.4%)	124 (3.1%)	1145 (7.2%)	<0.0001
Diabetes	7580 (38.1%)	1382 (34.1%)	6198 (39.1%)	<0.0001
Diabetes on insulin	2534 (12.7%)	394 (9.7%)	2140 (13.5%)	<0.0001
Hypertension	16381 (82.3%)	2915 (71.8%)	13466 (84.9%)	<0.0001
Dyslipidemia	16689 (83.8%)	3220 (79.3%)	13469 (84.9%)	<0.0001
Smoking	5006 (25.1%)	1175 (29.0%)	3831 (24.2%)	<0.0001
Prior MI	5963 (30.0%)	833 (20.5%)	5130 (32.4%)	<0.0001
Prior PCI	5038 (25.3%)	788 (19.4%)	4250 (26.8%)	<0.0001
Prior CABG	3433 (17.2%)	359 (8.8%)	3074 (19.4%)	<0.0001
Prior cerebrovascular disease	2385 (12.0%)	188 (4.6%)	2197 (13.9%)	<0.0001
Prior CHF	4251 (21.3%)	567 (14.0%)	3684 (23.2%)	<0.0001
Prior PAD	2431 (12.2%)	291 (7.2%)	2140 (13.5%)	<0.0001
CKD	5613 (28.3%)	619 (15.3%)	4994 (31.5%)	<0.0001
Anemia	2892 (14.5%)	339 (8.4%)	2553 (16.1%)	<0.0001

CAD Presentation				
STEMI	3285 (16.0%)	773 (19.0%)	2512 (15.8%)	<0.0001
NSTEMI	5412 (27.0%)	1159 (28.6%)	4253 (26.8%)	<0.0001
Unstable Angina	11216 (57.0%)	2126 (52.4%)	9090 (57.3%)	<0.0001
Admission Medications				
Aspirin	9195 (46.2%)	1423 (35.1%)	7772 (49.0%)	<0.0001
Clopidogrel	3133 (15.7%)	265 (6.5%)	2868 (18.1%)	<0.0001
Prasugrel	326 (1.64%)	317 (7.8%)	9 (0.1%)	<0.0001
Ticagrelor	6 (0.03%)	3(0.1%)	3(0.02%)	0.15
Beta blocker	9655 (48.5%)	1913 (47.1%)	7742 (48.8%)	<0.0001
Calcium channel blocker	3211 (16.1%)	618 (15.2%)	2593 (16.4%)	<0.0001
Nitrate	2606 (13.1%)	508 (12.5%)	2098 (13.2%)	0.0002
Ranolazine	377 (1.9%)	67 (1.7%)	310 (2.0%)	0.04
Discharge Medications				
Aspirin	19533 (98.1%)	3999 (98.5%)	15534 (98.0%)	0.62
Clopidogrel	15440 (77.5%)	544 (13.4%)	14896 (93.9%)	<0.0001
Prasugrel	4225 (21.2%)	3498 (86.2%)	727 (4.6%)	<0.0001
Prasugrel 5mg (9258 missing data)	390 (2.0%)	327 (8.1%)	63 (0.4%)	<0.0001
Prasugrel 10mg (9258 missing data)	2083 (10.5%)	1798 (44.3%)	285 (1.8%)	<0.0001
Anticoagulant	3908 (19.6%)	1048 (25.8%)	2860 (18.0%)	0.76
Beta blocker	16856 (85.0%)	3403 (83.9%)	13453 (84.8%)	0.29
ACEI or ARB	11819 (59.4%)	2551 (62.9%)	9268 (58.5%)	0.51
Statin	18295 (91.9%)	3779 (93.1%)	14516 (91.5%)	0.09

10.4.2 Unadjusted Procedural Characteristics

Angiographically, patients receiving prasugrel had a lower prevalence of left main stem disease, fewer complex lesions (ACC/AHA type B2/C) and lesions with moderate/severe calcification. In contrast these patients received longer stent length and bigger stents. Additionally prasugrel patients received more 2nd generation DES whereas patients receiving clopidogrel were more likely to have received bare metal stents or first generation drug eluting stents (DES). Patients on prasugrel also received less bivalirudin but more glycoprotein IIb/IIIa inhibitors for procedural anticoagulation. **Table 4** highlights the procedural differences between the two groups.

Table 4: Procedural characteristics

	Overall (n = 19914)	Prasugrel (n = 4058)	Clopidogrel (n = 15861)	p
Multivessel disease	8396 (42.2%)	1672 (41.2%)	6724 (42.4%)	0.17
PCI vessel				
Left Main	667 (3.3%)	84 (2.1%)	583 (3.7%)	<0.0001
LAD	8895 (44.7%)	1972 (48.6%)	6923 (43.7%)	<0.0001
Circumflex	5894 (29.6%)	1100 (27.1%)	4794 (30.2%)	<0.0001
RCA	6797 (34.1%)	1430 (35.2%)	5367 (33.9%)	0.097
At least one B2/C type lesion	13606 (68.3%)	2848 (70.2%)	10758 (67.8%)	<0.0001
At least one lesion with moderate/severe calcification	2771 (13.9%)	422 (10.4%)	2349 (14.8%)	<0.0001
At least one bifurcation lesion	2122 (10.7%)	446 (11.0%)	1676 (10.6%)	0.38

Total stent length, mm	30.7 ± 21.0	31.4 ± 20.2	30.50 ± 20.9	0.016
Minimum stent diameter, mm	2.97 ± 0.5	3.01 ± 0.49	2.96 ± 0.50	<0.0001
At least one 1st gen DES	2792 (14.0%)	297 (7.3%)	2495 (15.7%)	<0.0001
At least one 2nd gen DES	13561 (68.1%)	3283 (80.9%)	10278 (64.8%)	<0.0001
At least one BMS	4495 (22.6%)	569 (14.0%)	3926 (24.8%)	<0.0001
Procedural anticoagulation				
Bivalirudin	14469 (72.7%)	2743 (67.6%)	11726 (74.0%)	<0.0001
GPIIb/IIIa inhibitor	4566 (22.9%)	1178 (29.0%)	3388 (21.4%)	<0.0001
LMWH	207 (1.03%)	38 (0.9%)	169 (1.1%)	0.77

10.4.3 Outcomes

10.4.3.1 Unadjusted Outcomes

The primary endpoint of MACE at 90 days occurred in 8.2% of the overall population. The incidence per site varied from 4.9%-14.4% (**Table 4**). The results for unadjusted primary and secondary endpoints are shown in Appendix 13.2. At 90 days, MACE occurred in 5.7% patients of prasugrel patients compared with 9.6% patients of clopidogrel patients (unadjusted HR 0.58, 95% CI 0.50-0.67, p < 0.0001). The unadjusted MACE rates were significantly lower at all other time points – 30 days, 180 days and 365 days in patients receiving prasugrel compared with clopidogrel (p < 0.0001). Similarly, the incidence of all cause death was significantly lower at all-time points in prasugrel treated patients. At 90 days the incidence of death was 0.6% in prasugrel patients and 2.8% in clopidogrel patients, with an unadjusted HR of 0.21, 95% CI 0.14-0.33, p <0.0001.

The incidence of non-fatal myocardial infarction was significantly lower in prasugrel treated patients at all time-points. At 90 days the incidence of non- fatal MI was 1.9% in prasugrel patients and 3.8% in clopidogrel patients, the unadjusted was HR 0.51, 95% CI 0.40-0.64, p <0.0001. While there was no difference in the incidence of unplanned revascularization at 30 or 90 days, the rate of revascularization was lower with prasugrel at 180 days (HR 0.76, 95% CI 0.66-0.89, p 0.0005) and 1 year (HR 0.74, 95% CI 0.65-0.83, p < 0.0001). Unadjusted rates of stroke and bleeding were lower at all time-points with prasugrel. The incidence of stroke at 90 days was 0.3% with prasugrel and 0.7% with clopidogrel (HR 0.46, 95% CI 0.26,0.82 , p = 0.008). The incidence of bleeding at 90 days was 2.0% vs 2.9% in prasugrel and clopidogrel treated patients, HR 0.65, 95% CI 0.51-0.83, p = 0.0007. There was no statistical difference in the incidence of stent thrombosis at any time point.

Table 4: Primary endpoint - 90 day MACE by Site

Site	90 day MACE
1	14.4%
2	14.4%
3	10.0%
4	5.4%
5	4.9%
6	5.9%
7	7.0%
8	6.5%

10.4.3.2 Subgroup Analyses

10.4.3.2.1 STEMI

A total of 3285 patients with STEMI were included in the overall cohort, of which 773 (23.5%) received prasugrel and 2512 (76.5%) received clopidogrel.

Unadjusted, the incidence of MACE, death, non-fatal MI, unplanned revascularization, and bleeding was significantly lower with prasugrel compared to clopidogrel across all time points. After adjusting using propensity stratification, prasugrel was associated with a 29% reduction in MACE at 90 days (p=0.06). Adjusted hazard ratios for all-cause mortality were large and favored prasugrel yet were non-significant at all time-points (**Appendix 13.3**).

10.4.3.2.2 Subgroup analysis in patients with NSTEMI/UA

A total of 16628 patients with NSTEMI/UA were included in the overall cohort, of which 3285 (19.8%) received prasugrel and 13343 (80.2%) received clopidogrel.

Unadjusted, the incidence of MACE, death, MI and stroke at all time-points, and bleeding and revascularization at 1 year was significantly lower in patients treated with prasugrel. After propensity and multivariable adjustment, one-year rates of MACE and death were significantly lower with prasugrel compared to clopidogrel. While adjusted bleed risk was higher with prasugrel at 30 and 90 days, associations were attenuated at later time points (**Appendix 13.4**).

10.4.3.2.3 Diabetes Mellitus

A total of 7580 patients with diabetes mellitus were included in the overall cohort, of which 1382 (18.2%) received prasugrel and 6198 (81.8%) received clopidogrel. Unadjusted and adjusted outcomes are shown in (**Appendix 13.5**).

10.4.3.2.4 Patients without Diabetes Mellitus

A total of 12329 patients without diabetes mellitus were included in the overall cohort, of which 2675 (21.7%) received prasugrel and 9654 (78.3 %) received clopidogrel. Unadjusted and adjusted outcomes are shown in **Appendix 13.6**.

10.4.3.2.5 Patients with CKD

A total of 5613 patients with CKD were included in the overall cohort, of which 619 (11.0%) received prasugrel and 4994 (89.0%) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in **Appendix 13.7**.

10.4.3.2.6 Patients without CKD

A total of 14219 patients without CKD were included in the overall cohort, of which 3425 (24.1%) received prasugrel and 10794 (75.9%) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in **Appendix 13.8**.

10.4.3.2.7 Subgroup analysis in Women

A total of 6304 women were included in the overall cohort, of which 989 (15.7%) received prasugrel and 5315 (84.3 %) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in **Appendix 13.9**.

10.4.3.2.8 Subgroup analysis in Men

A total of 13610 men were included in the overall cohort, of which 3069 (22.5%) received prasugrel and 10541 (77.5 %) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in **Appendix 13.10.**

10.4.3.2.9 Subgroup analysis in patients with Multivessel disease

A total of 8396 patients with Multivessel disease were included in the overall cohort, of which 1672 (19.9%) received prasugrel and 6724 (80.1%) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in **Appendix 13.11**.

10.4.3.2.10 Subgroup analysis in patients without Multivessel disease

A total of 11518 patients without multivessel disease were included in the overall cohort, of which 2386 (20.1%) received prasugrel and 9132 (79.9%) received clopidogrel. Unadjusted and adjusted outcomes are shown in **Appendix 13.12**.

10.4.3.2.11 Subgroup analysis in patients without previous TIA or stroke

A total of 17529 patients without previous TIA or stroke were included in the overall cohort, of which 3870 (22.1%) received prasugrel and 13659 (77.9%) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in **Appendix 13.13**.

10.4.3.2.12 Subgroup analysis in patients without previous stroke and patients < 75y or >/=75 years with DM or prior PCI

A total of 15891 patients without previous stroke and patients < 75y or >/=75 years with DM or prior PCI were included in the overall cohort, of which 3765 (23.7%) received prasugrel and 12126 (76.3%) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in Appendix 13.14.

10.4.3.2.13 Subgroup analysis in patients with low body weight

A total of 6304 patients with low body weight (<60 kg) were included in the overall cohort, of which 989 (15.7%) received prasugrel and 5315 (84.3%) received clopidogrel. Unadjusted and Adjusted Outcomes are shown in Appendix 13.15.

11. DISCUSSION AND OVERALL CONCLUSION

11.1 Interpretation

The present study represents a collaborative effort involving 8 academic medical centers across the United States providing patient-level data on both baseline and longitudinal outcomes in over 19,000 patients presenting with ACS undergoing PCI with stent implantation. Salient findings from this report include: (i) use of prasugrel is relatively uncommon in an ACS setting as only 20% of the overall cohort received this agent - although use was higher among those with troponin (+) syndromes; (ii) patients receiving prasugrel were highly selected with fewer comorbidities compared to their counterparts receiving clopidogrel and the decision to use prasugrel appears to be strongly influenced by the warnings in the USPI; (iii) unadjusted risks for both ischemic and bleeding complications were substantially lower among those receiving prasugrel compared to clopidogrel; (iv) differences in adverse events were attenuated and no longer significant at 90 days after adjusting for baseline imbalances between groups. In aggregate, the current findings represent the first cohort study using real-world data from academic medical centers across the US to study the use, efficacy and safety of prasugrel as compared to clopidogrel in patients undergoing PCI and presenting across the entire clinical spectrum of ACS.

In the TRITON-TIMI 38 randomized trial, prasugrel was associated with a significant 19% reduction in thrombotic events, albeit at an excess cost of bleeding, among high-risk ACS patients undergoing PCI with stent implantation. Consistent with these earlier randomized data, our results show lower 90 day and one year MACE rates with prasugrel before and after adjustment, although adjusted differences at 90 days were modest and not statistically significant. The magnitude and direction of benefit was largely consistent across the different analytic approaches and after excluding patients lost to follow-up. There are several possibilities that might reconcile the divergent results between earlier randomized trial data and our observational findings. First, the proportion of patients who might be expected to derive the largest benefit from potent platelet inhibition (i.e. STEMI) comprised only 17% of the PROMETHEUS cohort whereas 26% of patients enrolled in TRITON-TIMI 28 presented with STEMI. An accentuated benefit in higher risk STEMI patients is supported by our subgroup analyses showing an approximate 30% relative risk reduction (not statistically significant) at 90 days with prasugrel use compared to no apparent benefit in patients with UA or NSTEMI with evidence of statistical interaction (p = 0.01). Second, it is possible that patients selected to receive

prasugrel in the real-world are less likely to need the same level of therapeutic protection compared to those enrolled in randomized trials (i.e. risk/treatment paradox). Indeed, the frequency of many clinical risk factors that are associated with greater thrombotic risk, including diabetes mellitus, prior MI and prior PAD were substantially lower among those treated with prasugrel compared to clopidogrel. Such selected use of prasugrel is consistent with the results of the prospective TRANSLATE-ACS registry, which also showed a similar imbalance in underlying risk factors among MI patients treated with prasugrel compared to clopidogrel. Clearly, further study is needed to further explore the determinants of clinical decision-making at the time of PCI as our results, combined with those of TRANSLATE-ACS, suggest that a more potent treatment is being used in patients with a lower likelihood to derive meaningful benefit. Whether or not recalibrating the intensity of antiplatelet pharmacotherapy to more closely approximate a patient's inherent thrombotic risk is a hypothesis that warrants further study.

We also observed a reduction in all-cause mortality associated with prasugrel use in both unadjusted and adjusted analyses. Although this effect is directionally consistent with prior observations in both TRANSLATE-ACS and TRITON-TIMI 38, the magnitude of benefit was much larger in our retrospective analysis. This finding may be attributable to both selection bias, coupled with a modest reduction in ischemic events without concordant excess bleeding risk. With respect to the former, it is possible that residual or unmeasured confounding may strongly influence the mortality point estimates. In support of the latter, it is plausible that a modest reduction in MACE risk in the absence of bleeding harm may confer a mortality advantage. This hypothesis remains speculative, however, as the reductions in MI and MACE were numerically lower without statistical significance.

Unadjusted bleeding rates were also significantly lower among prasugrel versus clopidogrel-treated patients in our study, findings that are consistent with TRANSLATE-ACS and are most likely attributable to the lower risk profile of patients selected to receive prasugrel. After adjustment, however, hazard ratios for bleeding were not significantly different between groups whereas there was an increase in adjusted bleeding risk with prasugrel in TRANSLATE-ACS. Differences in patient populations, bleeding ascertainment, and/or selection bias may account for the variable results between studies. First, we relied on bleeding-related hospitalizations as our safety endpoint whereas bleeding was prospectively ascertained and adjudicated in TRANSLATE-ACS. Under reporting of this event, therefore, may have biased our results to the null. Second, it is also possible that the degree of patient selection in our cohort may have simultaneously mitigated the potential for thrombotic benefit yet also minimized the possibility of harm in terms of bleeding. In other words, real-world selection for prasugrel use may be largely driven by factors that correlate with bleeding propensity rather than ischemic risk, resulting in the treatment of patients who are unlikely to derive substantial benefit and also unlikely to experience harm. Indeed, at one year the absolute differences in bleeding rates in favor of prasugrel in our study and TRANSLATE-ACS were 1.7% and 1.0%, respectively. This suggests that prasugrel-treated patients in PROMETHEUS were somewhat healthier and at lower risk for bleeding compared to their counterparts in the TRANSLATE-ACS study, further supporting the inclusion of a more selected cohort unlikely to manifest overt bleeding risk in the present study.

Among the important limitations of our study is its' observational retrospective design, thereby precluding causal inferences. Although we used a multitude of statistical methods to account for the substantial imbalances between treatment groups, we cannot exclude the possibility of residual or unmeasured confounders influencing our point estimates. However, our findings were consistent in both direction and magnitude across the different adjustment techniques. In the absence of standard prospective data collection that was uniform across study centers we may have underestimated the rate of adverse events. Data on medication adherence was not collected, an important determinant of risk after PCI. Although we used an early time point of 90 days for our primary analysis, we were unable to account for therapeutic cross-over and/or treatment non-adherence.

In conclusion, results of the PROMETHEUS study demonstrate that prasugrel is used relatively uncommonly and preferentially in low risk patients presenting with ACS undergoing PCI. Compared to clopidogrel, prasugrel is associated with a large unadjusted benefit that is no longer apparent after accounting for baseline differences between groups. Paradoxically, adjusted bleeding risk with prasugrel is also not increased when used in this context, which may be attributable to selection of patients unlikely to experience bleeding complications, even when treated with a potent antiplatelet agent.

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13 APPENDICES: TABLES, FIGURES AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

13.1 Data Fields and Descriptions/Definitions

Data Field Term	VALUE	Description/Definition
Patient ID	########	Patient ID for terms of this dataset (assigned after data consolidation, deidentified)
Date of Index PCI	DDMMYYYY	Actual date of procedure
Date of admission	DDMMYYYY	Actual date of admission associated with index event
Date of discharge	DDMMYYYY	Actual date of discharge associated with index event
Date of birth	DDMMYYYY	Date patient was born
Weight (Kg)	## in kilograms	Indicate the patient's weight in kilograms
Gender	0=male, 1=female	Indicate patient's gender
Height (cm)	### in cms	Indicate patient's height in cm
Hispanic	0=no, 1=yes	Hispanic or Latino Ethnicity: A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

Black/African American	0=no, 1=yes	Black/African American (Race): Having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
White	0=no, 1=yes	White (Race): Having origins in any of the original peoples of Europe, the Middle East, or North Africa
Diabetes at baseline	0=no, 1=yes	Indicate if the patient has a history of diabetes mellitus regardless of duration of disease or need for antidiabetic agents. Supporting Definitions: Diabetes Mellitus: Diabetes mellitus is diagnosed by a physician or can be defined as a fasting blood sugar greater than 7 mmol/l or 126 mg/dL. It does not include gestational diabetes.

Data Field Term	VALUE	Description/Definition
Insulin-requiring diabetes at baseline	0=no, 1=yes	Indicate if patient currently using insulin (Y/N) Target Value: The value on arrival at this facility Selections: Supporting Definitions: (none) Note(s): Patients placed on a pre-procedure diabetic pathway of insulin drip after arrival but were not on insulin therapy (treated by diet or oral method) are not coded as insulin treatment. If a patient had a pancreatic transplant, code "other", since the insulin from the new pancreas is not exogenous insulin.
Hypertension	0=no, 1=yes	Hypertension is defined by any one of the following: b. History of hypertension diagnosed and treated with medication, diet and/or exercise c. Prior documentation of blood pressure greater than 140 mm Hg systolic and/or 90 mm Hg diastolic for patients without diabetes or chronic kidney disease, or prior documentation of blood pressure greater than130 mm Hg systolic and/or 80 mm Hg diastolic on at least two occasions for patients with diabetes or chronic kidney disease d. Currently on pharmacologic therapy for treatment of hypertension.
Hypercholesterolemia	0=no, 1=yes	Indicate if the patient has a history of dyslipidemia diagnosed and/or treated by a physician. Target Value: Any occurrence between birth and arrival at this facility Dyslipidemia: National Cholesterol Education Program criteria include documentation of the following: A. Total cholesterol greater than 200 mg/dL (5.18 mmol/l); or B. Low-density lipoprotein (LDL) greater than or equal to 130 mg/dL (3.37 mmol/l); or, C. High-density lipoprotein (HDL) less than 40 mg/dL (1.04 mmol/l). For patients with known coronary artery disease, treatment is initiated if LDL is greater than 100 mg/dL (2.59mmol/l), and this would qualify as hypercholesterolemia
Serum creatinine	in mg/dl	Pre-procedure value

Data Field Term	VALUE	Description/Definition
Serum hemoglobin	in g/dl	Pre-procedure value
Troponin		Pre-procedure value

CK-MB baseline	ng/ml	Pre-procedure value
Peak serum creatinine	in mg/dl	highest value; leave missing if not drawn
Nadir hemoglobin	in g/dl	lowest within 72 hours;. leave missing if not drawn
Peak CK-MB	ng/ml	highest 6-24 hours; leave missing if not drawn
Peak Troponin		highest 6-24 hours; leave missing if not drawn
Smoking	0=no, 1=yes	Indicate if the patient has smoked cigarettes anytime during the year prior to arrival Coding Instructions: at your facility. Target Value: Any occurrence between 1 year prior to arrival at this facility and arrival at this facility
Family history of CAD	0=no, 1=yes	Family Hx Premature CAD Direct Relatives: Family history includes any direct blood relatives (parents, siblings, children) who have had any of the following diagnosed at age less than 55 years for male relatives or less than 65 years for female relatives: A. Angina B. Acute myocardial infarction C. Sudden cardiac death without obvious cause D. Coronary artery bypass graft surgery E. Percutaneous coronary intervention
Previous MI	0=no, 1=yes	Indicate if the patient has had at least one documented previous myocardial Coding Instructions: infarction. Target Value: Any occurrence between birth and arrival at this facility. Note(s): Code 'No' if the patient's only MI occurred at the transferring facility. Admit Source (3010) must be "Transfer in from another acute care facility." MI: A myocardial infarction is evidenced by any of the following: A. A rise and fall of cardiac biomarkers (preferably troponin) with at least one of the values in the abnormal range for that laboratory [typically above the 99th percentile of the upper reference limit (URL) for normal subjects] together with at least one of the following manifestations of myocardial ischemia: a. Ischemic symptoms b. b. ECG changes indicative of new ischemia (new ST-T changes, new left bundle branch block, or loss of R wave voltage). c. Development of pathological Q waves in 2 or more contiguous leads in the ECG (or equivalent findings for true posterior MI). d. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. e. Documentation in the medical record of the diagnosis of acute myocardial infarction based on the cardiac biomarker pattern in the absence of any items enumerated in a-d due to conditions that may mask their appearance (for example, peri-operative infarct when the patient cannot report ischemic symptoms; baseline left bundle branch block or ventricular pacing). B. ECG changes associated with prior myocardial infarction can include the following (with or without prior symptoms): a. b. c. Any Q-wave in leads V2-V3 >=0.02 seconds or QS complex in leads V2 and V3 Q-wave >=0.03 seconds and >=0.1 mV deep or QS complex in leads I, II,

		aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V6; V4- V6; II, III, and aVF). R-wave >=0.04 seconds in V1-V2 and R/S >=1 with a concordant positive T-wave in the absence of a conduction defect. C. Imaging evidence of a region with new loss of viable myocardium at rest in the absence of a non-ischemic cause. This can be manifest as: a. Echocardiographic, CT, MR,

Data Field Term	VALUE	Description/Definition
		ventriculographic or nuclear imaging evidence of left ventricular thinning or scarring and failure to contract appropriately (i.e., hypokinesis, akinesis, or dyskinesis). b. Fixed (non-reversible) perfusion defects on nuclear radioisotope imaging (for example, MIBI, thallium). D. Medical records documentation of prior myocardial infarction.
Previous PCI	0=no, 1=yes	Indicate if the patient had a previous percutaneous coronary intervention. Target Value: Any occurrence between birth and arrival at this facility Note(s): Timeframe does NOT include PCIs performed after arrival. PCI: Percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (for example, stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.
Previous CABG	0=no, 1=yes	Indicate if the patient had a previous coronary artery bypass graft (CABG) surgery. Target Value: Any occurrence between birth and arrival at this facility Note(s): Timeframe does NOT include CABG performed after arrival.
Prior CHF	0=no, 1=yes	Indicate if there is a previous history of heart failure. Target Value: Any occurrence between birth and arrival at this facility. Note(s): A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history. Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distension, pulmonary edema on physical exam, or pulmonary edema on chest x-ray. A low ejection fraction alone, without clinical evidence of heart failure does not qualify as heart

Data Field Term	VALUE	Description/Definition
		failure.
Prior PAD	0=no, 1=yes	Indicate if the patient has a history of peripheral arterial disease (PAD) (includes upper and lower extremity, renal, mesenteric, and abdominal aortic systems). Supporting Definitions: PAD: Peripheral arterial disease can include: A. Claudication, either with exertion or at rest. B. Amputation for arterial vascular insufficiency. C. Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping). D. Documented aortic aneurysm with or without repair. E. Positive non-invasive test (for example, ankle brachial index <=0.9);

		ultrasound, magnetic resonance, computed tomography, or angiographic imaging of > 50% diameter stenosis in any peripheral artery (for example, renal, subclavian, femoral, iliac). For purposes of the Registry, peripheral arterial disease excludes disease in the carotid and cerebrovascular arteries.

Data Field Term	VALUE	Description/Definition
Prior Cerebrovascular Disease	0=no, 1=yes	Indicate if the patient has a history of cerebrovascular disease. Coding Instructions: Target Value: Any occurrence between birth and arrival at this facility Cerebrovascular Disease documented by any one of the following: A. Cerebrovascular Accident (CVA): Patient has a history of stroke, i.e., loss of neurological function with residual symptoms at least 24 hrs after onset, presumed to be from vascular etiology. B. Transient Ischemic Attack (TIA): Patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hrs, presumed to be due to vascular etiology C. Non-invasive/invasive carotid test with > 79% occlusion. D. Previous carotid artery surgery/intervention for carotid artery stenosis. This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy.
Left ventricular ejection fraction (%)	## %	If only a range is reported, report the median of the range (i.e.50-55%, is reported as 53%). If only a descriptive value is reported (i.e.normal), enter the corresponding percentage value from the list below: Normal = 60% Good function = 50% Mildly reduced = 45% Fair function = 40% Moderately reduced = 30% Poor function = 25% Severely reduced = 20% The Left Ventricular Ejection Fraction can be assessed via invasive (i.e. LV gram) or non-invasive (i.e. Echo, MR, CT or Nuclear) testing. If an ejection fraction is not measured during this admission and prior to the PCI, and their clinical status has not changed, it is acceptable to code an ejection fraction that was obtained prior to arrival. LVEF: The left ventricular ejection fraction is the percentage of the blood emptied from the left ventricle at the end of the contraction.
CAD Presentation	1=No sxs/no angina; 2=unlikely ischemic; 3=stable angina; 4=Unstable Angina; 5=Non- ST-elevation myocardial infarction, 6=ST- elevation myocardial infarction	patients with non-cardiac pain (for example, pulmonary embolism, musculoskeletal, or esophageal discomfort), or cardiac pain not caused by myocardial ischemia (for example, acute pericarditis). 3. Stable angina: Angina without a change in frequency or pattern for the 6 weeks prior to this cath lab visit. Angina is controlled by rest and/or oral or transcutaneous medications 4. Unstable angina: There are three principal presentations of unstable angina: a. Rest angina (occurring at rest and prolonged, usually >20 minutes) b. New onset angina (within the past 2 months, of at least Canadian Cardiovascular Society Class III severity); or c. Increasing angina (previously diagnosed angina that has become distinctly more frequent, longer in duration, or increased by 1 or more Canadian Cardiovascular Society class to at least CCS III severity). 5. Non-STEMI: The patient was hospitalized for a non-ST elevation myocardial infarction (STEMI) as documented in the medical record. Non-STEMIs are characterized by the presence of both criteria: a. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I) exceed the upper limit of normal according to the

		individual hospital's laboratory parameters with a clinical presentation which is consistent or suggestive of ischemia. ECG changes and/or ischemic symptoms may or may not be present. b. Absence of ECG changes diagnostic of a STEMI (see STEMI) STEMI: The patient presented with a ST elevation myocardial infarction (STEMI) or its equivalent as documented in the medical record. STEMIs are characterized by the presence of both criteria: a) ECG evidence of STEMI: New or presumed new ST-segment elevation or new left bundle branch block not documented to be resolved within 20 minutes. ST-segment elevation is defined by new or presumed new sustained ST-segment elevation at the J-point in two contiguous electrocardiogram (ECG) leads with the cut-off points: >=0.2 mV in men or >= 0.15mV in women in leads V2-V3 and/or >= 0.1 mV in other leads and lasting greater than or equal to 20 minutes. If no exact ST- elevation measurement is recorded in the medical chart, physician's written documentation of ST- elevation or Q-waves is acceptable. a. If only one ECG is performed, then the assumption that the ST elevation persisted at least the required 20 minutes is acceptable. Left bundle branch block (LBBB) refers to new or presumed new LBBB on the initial ECG. b. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I)exceed the upper limit of normal according to the individual hospital's laboratory parameters a clinical presentation which is consistent or suggestive of ischemia. Note: For purposes of the Registry, ST elevation in the posterior chest leads (V7 through V9), or ST depression that is maximal in V1-3, without ST- segment elevation in other leads, demonstrating posterobasal myocardial infarction, is considered a STEMI equivalent and qualifies the patient for reperfusion therapy.

Data Field Term	VALUE	Description/Definition
PCI Status	1=elective; 2=urgent; 3=emergency; 4=salvage	1. Elective: The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective. 2. Urgent: The procedure should be performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation. 3. Emergency: The procedure should be performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on-call team were this to occur during off-hours. Salvage: The procedure is a last resort. The patient is in cardiogenic shock when the PCI begins (i.e. at the time of introduction into a coronary artery or bypass graft of the first guidewire or intracoronary device for the purpose of mechanical revascularization). Within the last ten minutes prior to the start of the case or during the diagnostic portion of the case, the patient has also received chest compressions for a total of at least sixty seconds or has been on unanticipated extracorporeal circulatory support (for example, extracorporeal mechanical oxygenation, or cardiopulmonary support). Code the best estimate of current left ventricular ejection fraction. Target Value:

		The last value between 6 months prior to current procedure and prior to the intervention
PCI Indication	1=Immediate PCI for STEMI; 2= PCI for STEMI, unstable > 12 hours; 3=PCI for STEMI, stable > 12 hours; 4=PCI for STEMI stable after successful lytics; 5=Rescue PCI for STEMI after failed lytics; 6=PCI for high risk NSTEMI or unstable angina; 7= Staged PCI; 8=Other	Selection Text Definition 1. Immediate PCI for STEMI: Immediate PCI for patient with STEMI (or STEMI equivalent). 2. PCI for STEMI (Unstable, >12hrs from Sx onset): PCI for STEMI (or STEMI equivalent) more than 12 hours from symptom onset with recurrent or persistent symptoms, symptoms of heart failure or ventricular arrhythmia. 3. PCI for STEMI (Stable, >12 hrs from Sx onset): Patient with STEMI (or STEMI equivalent) who is stable, and is more than 12 hours from symptom onset. The patient does not have any symptoms of recurrent or persistent ischemia, symptoms of heart failure, or electrical instability. 4. PCI for STEMI (Stable after successful full- dose Thrombolysis): PCI for STEMI (or STEMI equivalent) who is stable after receiving full dose thrombolysis. Rescue PCI for STEMI (after failed full-dose lytics): Rescue PCI for STEMI (or STEMI equivalent) after failed full-dose lytics. 6. PCI for high risk Non-STEMI or unstable angina: Incudes patients with unstable angina or Non-STEMI who have high risk features for short-term risk of death or nonfatal MI. High risk features includes at least one of the following: a. History - accelerating tempo of ischemic symptoms in preceding 48 hours. b. Character of pain - prolonged ongoing (greater than 20 minutes) rest pain. c. Clinical findings: i. Pulmonary edema, most likely due to ischemia ii. New or worsening mitral regurgitation murmur iii. S3 or new worsening rales d) Hypotension, bradycardia, tachycardia iv. Age greater than 75 years v. ECG vi. a) Angina at rest with transient ST-segment changes greater than 0.5 mm vii. Bundle-branch block, new or presumed new viii. Sustained ventricular tachycardia ix. Cardiac markers - NSTEMI patients with elevated cardiac TnT, TnI, or CK-MB. x. Staged PCI The second PCI of a planned, staged procedure (the first PCI could have been during a prior admission, or during this admission). 4. Other: Includes patients that don't fit into any of the above categories. This can include patients with elective or urgent status, status/post cardiac arrest or cardiogenic shock but without ECG or biomarker evidence of acute infarction.

Data Field Term	VALUE	Description/Definition
Stress or Imaging pre procedure	0=no, 1=yes	For any subsequent procedures during this episode of care, only code new imaging or stress test results that were performed after the previous procedure until the current procedure.
Beta Blocker on admit	0=no, 1=yes	Indicate if the patient has taken or has been prescribed a beta blocker to treat anginal symptoms. Target Value: Any occurrence between 2 weeks prior to current procedure and current procedure Note(s): Code 'no' if a patient was given a sublingual, IV, or short acting formula of one of these medications. Code 'yes' if the patient was started on an oral form of a beta-blocker after admission but prior to this cath lab visit. If this medication was prescribed for this patient, but you are unsure if it has been prescribed specifically to treat anginal symptoms, code 'yes'.
Ca channel blocker on admit	0=no, 1=yes	Indicate if the patient has taken or has been prescribed a calcium channel blocker to treat anginal symptoms. Target Value: Any occurrence between 2 weeks prior to current procedure and current procedure Note(s): Code 'no' if a patient was given a sublingual, IV, or short acting formula of one of these medications. Code 'yes' if the patient was started on an oral form of a calcium channel blocker after admission but prior to this cath lab visit. If this medication was prescribed for this patient, but you are unsure if it has been prescribed specifically to treat anginal symptoms, code 'yes'.
ASA on admission	0=no, 1=yes	Indicate if the patient is currently taking aspirin at the time of admission.
Clopidogrel on admission	0=no, 1=yes	Indicate if the patient is currently taking clopidogrel at the time of admission.
Prasugrel on admission	0=no, 1=yes	Indicate if the patient is currently taking prasugrel at the time of admission.
Ticagrelor on admission	0=no, 1=yes	Indicate if the patient is currently taking ticagrelor at the time of admission.
Nitrate on admit	0=no, 1=yes	Indicate if the patient is currently taking nitrates at the time of admission.
Ranexa on admit	0=no, 1=yes	Indicate if the patient has taken or has been prescribed Ranolazine to treat anginal symptoms. Target Value: Any occurrence between 2 weeks prior to current procedure and current procedure Note(s): Code 'no' if a patient was given a sublingual, IV, or short acting formula of one of these medications. Code 'yes' if the patient was started on an oral form of Ranolzine after admission but prior to this cath lab visit. If this medication was prescribed for this patient, but you are unsure if it has been prescribed specifically to treat anginal symptoms, code 'yes'.

Procedural ASA	0=no, 1=yes	Indicate if the patient was administered aspirin at any time during index procedure
Procedural Fondaparinux	0=no, 1=yes	Indicate if the patient was administered fondaparinux at any time during index procedure
Procedural LMWH	0=no, 1=yes	Indicate if the patient was administered a low- molecular heparin at any time during index procedure
Procedural UFH	0=no, 1=yes	Indicate if the patient was administered fondaparinux at any time during index procedure
Procedural Bival	0=no, 1=yes	Indicate if the patient was administered bivalirudin at any time during index procedure
Procedural IIb/IIIa	0=no, 1=yes	Indicate if the patient was administered IIb/IIIa inhibitor at any time during index procedure
Clopidogrel loading	0=no, 1=yes	Indicate if the patient was administered a loading dose of clopidogrel

Prasugrel loading	0=no, 1=yes	Indicate if the patient was administered a loading dose of prasugrel
Ticagrelor loading	0=no, 1=yes	Indicate if the patient was administered a loading dose of ticagrelor
Discharge ACE-I or ARB	0=no, 1=yes	At the time of discharge, was the patient prescribed an ACE-Inhibitor (or ARB)
Discharge ASA	0=no, 1=yes	At the time of discharge, was the patient prescribed aspirin
Discharge bbl	0=no, 1=yes	At the time of discharge, was the patient prescribed a beta blocker
Discharge Statin	0=no, 1=yes	At the time of discharge, was the patient prescribed a statin
Discharge Clopidogrel	0=no, 1=yes	At the time of discharge, was the patient prescribed clopidogrel
Discharge Clopidogrel 75 mg	0=no, 1=yes	At the time of discharge, was the patient prescribed clopidogrel 75mg
Discharge Clopidogrel 150 mg	0=no, 1=yes	At the time of discharge, was the patient prescribed clopidogrel 150mg
Discharge Prasugrel	0=no, 1=yes	At the time of discharge, was the patient prescribed prasugrel
Discharge Prasugrel 5mg	0=no, 1=yes	At the time of discharge, was the patient prescribed prasugrel 5mg
Discharge Prasugrel 10mg	0=no, 1=yes	At the time of discharge, was the patient prescribed prasugrel 10mg
Discharge Ticagrelor	0=no, 1=yes	At the time of discharge, was the patient prescribed ticagrelor
Discharge Anticoagulant	0=no, 1=yes	At the time of discharge, was the patient prescribed an anticoagulant (warfarin; LMWH; rivoraxaban)
Multivessel disease	0=no, 1=yes	Value is 1 if number of diseased vessels > 1
Number of lesions treated	##	Total number of lesions treated during the index PCI

Number of stents implanted	##	Total number of stents implanted during index PCI
mean stent diameter	#.## mm	Mean diameter of all stents implanted during index PCI
Total stent length	## mm	Total length of all stents implanted during index PCI
At least 1 type B2/C lesion	0=no, 1=yes	Does patient have at least 1 type B2/C Lesion
At least 1 lesion with moderate/severe calcifications	0=no, 1=yes	Does patient have 1 lesion with moderate/severe calcifications
At least 1 bifurcation lesion	0=no, 1=yes	Does patient have at least 1 bifurcation lesion
At least one bare metal stent	0=no, 1=yes	yes if any BMS used to treat any lesion during index PCI
At least one drug eluting stent (1st gen)	0=no, 1=yes	yes if any 1st generation DES used to treat any lesion during index PCI
At least one drug eluting stent (2nd gen)	0=no, 1=yes	yes if any 2nd generation DES used to treat any lesion during index PCI
PCI vessel LM	0=no, 1=yes	PCI was performed of LM
PCI vessel LAD	0=no, 1=yes	PCI was performed of LAD
PCI vessel LCx	0=no, 1=yes	PCI was performed of LCx

PCI vessel RCA	0=no, 1=yes	PCI was performed of RCA
Post procedure MI	0=no, 1=yes	Indicate the NEW occurrence of a biomarker positive myocardial infarction after PCI. At least one determination of biomarkers obtained no sooner than 6 hours after PCI, and preferably within the interval of 6-24 hours post-PCI, should be used to make this diagnosis. Target Value: Any occurrence between start of procedure and until the next procedure or until discharge. Note(s): Q waves with absent, incomplete or inconclusive biomarkers should be considered evidence of MI and should be coded as yes. In rare situations, biomarkers may not be obtained in the setting of a post-PCI acute MI (for example, sudden unexpected cardiac death without symptoms or ECG changes suggestive of ischemia, patient is transferred, or biomarkers were just not ordered). In these situations, the site may choose to report a clinically-diagnosed post-PCI myocardial infarction even in the absence of the usually required biomarker elevations. For patients with extended hospital stays, restrict coding of post- procedure events to 30 days after the last procedure.
Post Procedure Cardiogenic Shock	0=no, 1=yes	Indicate if the patient had a new onset or acute recurrence of Coding Instructions: cardiogenic shock. Target Value: Any occurrence between start of procedure and until next procedure or discharge. Note(s): Transient episodes of hypotension reversed with IV fluid or atropine do not constitute cardiogenic shock. The hemodynamic compromise (with or without extraordinary supportive therapy) must persist for at least 30 minutes. For patients with extended hospital stays, restrict coding of post- procedure events to 30 days after the last procedure. Cardiogenic shock is defined as a sustained (>30 minutes) episode of systolic blood pressure <90 mm Hg, and/or cardiac index <2.2 L/min/m2 determined to be secondary to cardiac dysfunction, and/or the requirement for parenteral inotropic or vasopressor agents or mechanical support (for example, IABP, extracorporeal circulation, ventricular assist devices) to maintain blood pressure and cardiac index above those specified levels.
Post Procedure Heart Failure	0=no, 1=yes	Indicate if the patient had new onset or acute recurrence of heart failure which necessitated new or increased pharmacologic therapy. Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Heart Failure: A previous hospital admission with a principal diagnosis of heart failure is considered evidence of heart failure history. Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure: unusual dyspnea on light exertion; recurrent dyspnea occurring in the supine position; fluid retention; the description of rales, jugular venous distension, pulmonary edema on physical exam; or pulmonary edema on chest x-ray. A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history. A low ejection fraction without clinical evidence of heart failure does not qualify as heart failure.
Post Procedure CVA/Stroke	0=no, 1=yes	Indicate if the patient had a cerebrovascular Coding Instructions: accident (CVA). Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): A stroke or CVA is documented by a loss of neurological function caused by an ischemic or hemorrhagic event with residual symptoms lasting at least 24 hours after onset or leading to death. For patients with extended hospital stays, restrict coding of post- procedure events to 30 days after the last procedure.
Post Procedure Tamponade	0=no, 1=yes	Indicate if the patient experienced fluid in the pericardial space compromising cardiac filling and requiring intervention. Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Tamponade should be documented by either: A. Echocardiogram showing pericardial fluid and signs of tamponade such as right heart compromise, or B. Systemic Hypotension due to pericardial fluid compromising cardiac function.
Post Procedure Dialysis	0=no, 1=yes	Indicate if the patient experienced acute or worsening renal failure necessitating Coding Instructions: renal dialysis. Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): If a patient is on receiving continuous veno-venous hemofiltration (CVVH) as a result of renal failure (and not as treatment to remove fluid for heart failure), code yes. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure.

Post Procedure Vascular Complication	0=no, 1=yes	Indicate if the patient experienced any other vascular complications (excluding external bleeding or hematomas) at the percutaneous entry site that required treatment or intervention. Note: Code 'yes' for patients treated with IV therapy for loss of distal pulse. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Target Value: Any occurrence between start of procedure and until next procedure or discharge. Vascular complications can include, but are not limited to, access site occlusions, peripheral embolizations, dissections, pseudoaneurysms and/or AV fistulas. Any noted vascular complication must have had an intervention such as a fibrin injection, angioplasty, or surgical repair to qualify. Prolonged pressure does not qualify as an intervention, but ultrasonic guided compression after making a diagnosis of pseudoaneurysm does qualify. A retroperitoneal bleed or hematoma requiring transfusion is not a vascular complication under this data element. To qualify, this adverse outcome should be attributable to this procedure and not related to a previous or subsequent procedure.
Post Procedure Blood Transfusion	0=no, 1=yes	Indicate if there was a transfusion(s) of either whole blood or packed red blood cells. For patients with extended hospital stays, restrict coding of post- procedure events to 30 days after the last procedure. Target Value: Any occurrence between start of procedure and until next procedure or discharge.
Units of Blood Transfused	##	Number of prbc transfused. Leave as missing if pp_trans = 0.
Post Procedure Bleeding event (72 hours)	0=no, 1=yes	Note(s): A patient who was actively bleeding with coffee ground emesis pre-procedure should not qualify as bleeding. However, a patient with peptic ulcer disease with no noted or active bleeding prior to procedure who starts bleeding after the procedure would qualify as a "yes".
Death (all)	0=no, 1=yes	Report of patient death
Death (all) date	DDMMYYYY	Date of death
Type of Death	1=cardiac, 2=noncardiac, 3= unknown	Enter type of death
Myocardial infarction	0=no, 1=yes	hospitalization for acute (spontaneous) MI after index PCI
Myocardial infarction date	DDMMYYYY	date of event
Number of acute MI hospitalization until 12/31/2012		Total number of acute MI hospitalization from 1/1/2010 - 12/31/2012
Unplanned revascularization	0=no, 1=yes	Hospitalization for unplanned revascularization with CABG or PCI after index PCI
Unplanned revascularization date	DDMMYYYY	date of event
Number of unplanned revasc hospitalization until 12/31/2012		Total number of unplanned revasc hospitalization from 1/1/2010 - 12/31/2012
Bleeding	0=no, 1=yes	Hospitalization for bleeding after index PCI
Bleeding date	DDMMYYYY	date of event
Number of bleeding hospitalization until 12/31/2012		Total number of bleeding hospitalizations from 1/1/2010 - 12/31/2012
Type of Bleeding	1=access site; 2=GI; 3=GU; 4=CNS; 5= other; 6=unknown	1)access site 2) GI 3) GU 4) CNS 5) Other 6) Unknown
Stroke		

	0=no, 1=yes	Was the patient diagnosed as having a stroke
Stroke date	DDMMYYYY	Date of event
Stroke type	1=ischemic; 2=hemorrhagic; 3= unknown	1) Ischemic 2) hemorrhagic
Number of stroke hospitalizations until 12/31/2012		Total number of stroke hospitalizations from 1/1/2010 - 12/31/2012
Definite/Prob ST	0=no, 1=yes	Hospitalizations for Definite/Probable Stent Thrombosis
Definite/Prob ST date	DDMMYYYY	Date of Event
last follow up date	DDMMYYYY	Last date of encounter with patient

13.2 Outcomes in Overall ACS/PCI Cohort

Outcomes in Overall ACS/PCI Cohort												
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]		IPW	
		Overall (N = 19914)	Prasugrel (N= 4058)	Clopidogrel (N=15856)	HR [CI%]	P-value	HR [CI%]	P-value	HR [CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	5.62% [5.30%,5.96%]	3.48% [2.95%,4.11%]	6.17% [5.80%,6.56%]	0.56 [0.47,0.67]	<.0001	0.84 [0.68,1.03]	0.0874	0.90 [0.74,1.10]	0.2928	0.85 [0.65,1.12]	0.2531
	90 Day	8.80% [8.40%,9.21%]	5.70% [5.00%,6.49%]	9.59% [9.13%,10.08%]	0.58 [0.50,0.67]	<.0001	0.89 [0.76,1.05]	0.1685	0.94 [0.80,1.09]	0.4109	0.94 [0.76,1.16]	0.5544
	180 Day	13.06% [12.57%,13.56%]	8.27% [7.42%,9.21%]	14.30% [13.73%,14.88%]	0.56 [0.50,0.63]	<.0001	0.90 [0.78,1.03]	0.1152	0.89 [0.78,1.02]	0.0842	0.96 [0.81,1.15]	0.6618
	1 Year	18.89% [18.31%,19.48%]	12.06% [11.03%,13.17%]	20.65% [19.98%,21.34%]	0.56 [0.50,0.62]	<.0001	0.86 [0.77,0.96]	0.0084	0.85 [0.76,0.95]	0.0042	0.91 [0.79,1.06]	0.2330
Death	30 Day	1.30% [1.14%,1.47%]	0.24% [0.12%,0.45%]	1.57% [1.38%,1.78%]	0.15 [0.08,0.29]	<.0001	0.47 [0.23,0.95]	0.0366	0.57 [0.29,1.13]	0.1057	0.29 [0.12,0.67]	0.0037
	90 Day	2.38% [2.17%,2.61%]	0.62% [0.41%,0.94%]	2.83% [2.57%,3.12%]	0.21 [0.14,0.33]	<.0001	0.62 [0.40,0.99]	0.0445	0.68 [0.44,1.05]	0.0805	0.52 [0.28,0.94]	0.0304
	180 Day	3.71% [3.44%,4.00%]	1.14% [0.84%,1.55%]	4.38% [4.06%,4.74%]	0.25 [0.18,0.35]	<.0001	0.69 [0.49,0.98]	0.0363	0.71 [0.51,0.98]	0.0401	0.68 [0.43,1.06]	0.0869
	1 Year	5.64% [5.30%,5.99%]	1.77% [1.38%,2.27%]	6.64% [6.24%,7.08%]	0.26 [0.20,0.33]	<.0001	0.69 [0.52,0.91]	0.0087	0.67 [0.51,0.87]	0.0034	0.63 [0.43,0.91]	0.0134
Myocardial infarction	30 Day	2.73% [2.50%,2.97%]	1.59% [1.25%,2.03%]	3.02% [2.76%,3.30%]	0.53 [0.41,0.69]	<.0001	0.81 [0.60,1.09]	0.1645	0.82 [0.62,1.09]	0.1776	1.02 [0.69,1.49]	0.9335
	90 Day	3.38% [3.13%,3.64%]	1.89% [1.51%,2.37%]	3.76% [3.47%,4.08%]	0.51 [0.40,0.64]	<.0001	0.84 [0.64,1.11]	0.2185	0.84 [0.65,1.10]	0.2047	1.09 [0.76,1.55]	0.6385
	180 Day	4.33% [4.05%,4.64%]	2.39% [1.95%,2.92%]	4.84% [4.50%,5.21%]	0.49 [0.40,0.61]	<.0001	0.85 [0.66,1.08]	0.1823	0.80 [0.63,1.01]	0.0623	1.10 [0.80,1.51]	0.5566
	1 Year	5.52% [5.19%,5.87%]	3.34% [2.80%,3.97%]	6.10% [5.71%,6.51%]	0.54 [0.44,0.65]	<.0001	0.90 [0.72,1.11]	0.3295	0.86 [0.70,1.06]	0.1647	1.13 [0.86,1.49]	0.3823
Unplanned Revascularization	30 Day	2.05% [1.85%,2.26%]	1.82% [1.44%,2.30%]	2.11% [1.89%,2.35%]	0.86 [0.66,1.12]	0.2643	0.99 [0.74,1.34]	0.9728	0.99 [0.74,1.31]	0.9217	1.20 [0.81,1.76]	0.3627
	90 Day	4.04% [3.76%,4.34%]	3.72% [3.16%,4.38%]	4.12% [3.80%,4.46%]	0.90 [0.75,1.08]	0.2583	1.06 [0.86,1.31]	0.5884	1.05 [0.86,1.29]	0.6298	1.21 [0.92,1.58]	0.1670
	180 Day	6.89% [6.52%,7.28%]	5.53% [4.84%,6.33%]	7.25% [6.82%,7.70%]	0.76 [0.66,0.89]	0.0005	0.98 [0.82,1.16]	0.7926	0.93 [0.78,1.09]	0.3664	1.07 [0.86,1.33]	0.5435
	1 Year	10.86% [10.39%,11.34%]	8.52% [7.64%,9.50%]	11.49% [10.95%,12.05%]	0.74 [0.65,0.84]	<.0001	0.92 [0.80,1.06]	0.2417	0.89 [0.78,1.02]	0.0845	1.00 [0.84,1.20]	0.9662
Bleeding	30 Day	2.01% [1.82%,2.22%]	1.34% [1.03%,1.75%]	2.18% [1.96%,2.43%]	0.61 [0.46,0.81]	0.0008	0.98 [0.70,1.35]	0.8829	0.99 [0.72,1.36]	0.9604	1.02 [0.65,1.60]	0.9431

Outcomes in Overall ACS/PCI Cohort												
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]		IPW	
		Overall (N = 19914)	Prasugrel (N= 4058)	Clopidogrel (N=15856)	HR [CI%]	P-value	HR [CI%]	P-value	HR [CI%]	P-value	HR [CI%]	P-value
	90 Day	2.73% [2.51%,2.98%]	1.95% [1.55%,2.43%]	2.94% [2.68%,3.22%]	0.65 [0.51,0.83]	0.0006	1.03 [0.78,1.36]	0.8110	1.03 [0.79,1.35]	0.8272	1.01 [0.69,1.48]	0.9557
	180 Day	3.25% [3.01%,3.52%]	2.18% [1.76%,2.69%]	3.53% [3.24%,3.85%]	0.61 [0.49,0.77]	<.0001	0.97 [0.75,1.26]	0.8075	0.95 [0.74,1.22]	0.6945	0.92 [0.64,1.32]	0.6524
	1 Year	4.38% [4.09%,4.70%]	3.06% [2.55%,3.68%]	4.73% [4.39%,5.10%]	0.64 [0.52,0.78]	<.0001	0.97 [0.78,1.22]	0.8041	0.96 [0.77,1.19]	0.7114	0.86 [0.63,1.18]	0.3467
Stroke	30 Day	0.39% [0.31%,0.49%]	0.17% [0.08%,0.37%]	0.45% [0.35%,0.57%]	0.40 [0.18,0.87]	0.0207	0.55 [0.22,1.37]	0.1969	0.78 [0.34,1.81]	0.5672	0.21 [0.09,0.53]	0.0009
	90 Day	0.65% [0.55%,0.78%]	0.34% [0.20%,0.58%]	0.74% [0.61%,0.89%]	0.46 [0.26,0.82]	0.0084	0.85 [0.44,1.66]	0.6357	1.04 [0.55,1.94]	0.9061	1.41 [0.58,3.42]	0.4492
	180 Day	0.91% [0.78%,1.06%]	0.48% [0.30%,0.77%]	1.02% [0.87%,1.21%]	0.47 [0.29,0.77]	0.0026	0.95 [0.54,1.67]	0.8648	1.04 [0.61,1.77]	0.8907	1.42 [0.67,3.01]	0.3637
	1 Year	1.44% [1.27%,1.63%]	0.78% [0.54%,1.14%]	1.62% [1.41%,1.85%]	0.49 [0.33,0.72]	0.0003	1.04 [0.66,1.62]	0.8763	1.07 [0.70,1.65]	0.7555	1.22 [0.65,2.26]	0.5375
Def/Prob Stent Thrombosis	30 Day	0.24% [0.18%,0.32%]	0.34% [0.20%,0.59%]	0.21% [0.15%,0.30%]	1.62 [0.85,3.10]	0.1436	1.06 [0.52,2.16]	0.8823	1.05 [0.53,2.11]	0.8808	1.28 [0.52,3.15]	0.5924
	90 Day	0.33% [0.26%,0.42%]	0.39% [0.24%,0.65%]	0.31% [0.23%,0.42%]	1.28 [0.71,2.30]	0.4047	0.92 [0.48,1.75]	0.7990	0.87 [0.47,1.63]	0.6742	1.10 [0.50,2.45]	0.8124
	180 Day	0.41% [0.33%,0.52%]	0.45% [0.28%,0.73%]	0.41% [0.31%,0.53%]	1.14 [0.66,1.96]	0.6380	0.82 [0.46,1.49]	0.5196	0.78 [0.44,1.38]	0.3912	1.02 [0.49,2.11]	0.9649
	1 Year	0.51% [0.41%,0.63%]	0.64% [0.42%,0.96%]	0.47% [0.37%,0.61%]	1.34 [0.84,2.16]	0.2229	0.96 [0.57,1.61]	0.8770	0.88 [0.53,1.47]	0.6280	1.09 [0.58,2.04]	0.7964

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.3 Outcomes in STEMI

Subgroup: Patients Outcomes in STEMI										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 3285)	Prasugrel (N= 773)	Clopidogrel (N= 2512)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	9.32% [8.34%,10.42%]	4.55% [3.22%,6.42%]	10.71% [9.53%,12.03%]	0.41 [0.28,0.59]	<.0001	0.76 [0.50,1.14]	0.1867	0.87 [0.58,1.29]	0.4837
	90 Day	12.64% [11.50%,13.88%]	5.96% [4.40%,8.04%]	14.57% [13.20%,16.08%]	0.39 [0.28,0.54]	<.0001	0.71 [0.49,1.02]	0.0613	0.75 [0.53,1.06]	0.1039
	180 Day	16.49% [15.19%,17.89%]	8.71% [6.78%,11.15%]	18.74% [17.20%,20.41%]	0.43 [0.33,0.57]	<.0001	0.84 [0.62,1.14]	0.2718	0.84 [0.62,1.13]	0.2405
	1 Year	20.74% [19.30%,22.28%]	13.82% [11.34%,16.78%]	22.75% [21.06%,24.55%]	0.55 [0.44,0.69]	<.0001	0.95 [0.74,1.23]	0.7201	0.99 [0.77,1.27]	0.9343
Death	30 Day	3.07% [2.51%,3.75%]	0.60% [0.22%,1.58%]	3.80% [3.09%,4.66%]	0.15 [0.06,0.42]	0.0002	0.41 [0.14,1.20]	0.1031	0.55 [0.20,1.55]	0.2597
	90 Day	4.20% [3.54%,4.99%]	1.07% [0.51%,2.23%]	5.12% [4.29%,6.11%]	0.20 [0.09,0.43]	<.0001	0.51 [0.22,1.21]	0.1282	0.63 [0.28,1.39]	0.2497
	180 Day	5.59% [4.81%,6.50%]	1.55% [0.84%,2.87%]	6.77% [5.81%,7.90%]	0.22 [0.12,0.42]	<.0001	0.64 [0.32,1.30]	0.2179	0.68 [0.35,1.31]	0.2480
	1 Year	6.82% [5.95%,7.81%]	2.39% [1.45%,3.94%]	8.10% [7.04%,9.32%]	0.28 [0.16,0.47]	<.0001	0.81 [0.45,1.43]	0.4617	0.83 [0.47,1.44]	0.5009
Myocardial infarction	30 Day	3.72% [3.09%,4.46%]	1.91% [1.11%,3.27%]	4.25% [3.50%,5.16%]	0.44 [0.25,0.79]	0.0056	0.88 [0.46,1.69]	0.6933	1.03 [0.55,1.91]	0.9333
	90 Day	4.88% [4.15%,5.72%]	2.38% [1.46%,3.86%]	5.62% [4.74%,6.65%]	0.42 [0.25,0.70]	0.0010	0.84 [0.47,1.51]	0.5604	0.91 [0.52,1.59]	0.7387
	180 Day	5.86% [5.06%,6.79%]	2.87% [1.84%,4.47%]	6.75% [5.78%,7.88%]	0.42 [0.26,0.67]	0.0003	0.85 [0.50,1.45]	0.5520	0.85 [0.51,1.41]	0.5305
	1 Year	7.50% [6.58%,8.54%]	4.84% [3.40%,6.86%]	8.30% [7.21%,9.54%]	0.55 [0.37,0.81]	0.0022	1.00 [0.64,1.55]	0.9885	1.04 [0.68,1.58]	0.8611
Unplanned Revascularization	30 Day	3.60% [2.99%,4.34%]	2.71% [1.71%,4.27%]	3.87% [3.15%,4.75%]	0.69 [0.41,1.14]	0.1484	0.94 [0.54,1.66]	0.8444	1.00 [0.57,1.75]	0.9988
	90 Day	5.39% [4.62%,6.28%]	3.49% [2.34%,5.21%]	5.95% [5.04%,7.02%]	0.58 [0.37,0.91]	0.0164	0.75 [0.46,1.22]	0.2457	0.75 [0.46,1.21]	0.2405
	180 Day	7.86% [6.92%,8.92%]	4.97% [3.54%,6.97%]	8.72% [7.60%,9.99%]	0.56 [0.39,0.82]	0.0026	0.79 [0.52,1.19]	0.2555	0.78 [0.52,1.16]	0.2200
	1 Year	10.80% [9.69%,12.04%]	8.63% [6.66%,11.16%]	11.45% [10.15%,12.90%]	0.72 [0.54,0.97]	0.0332	0.88 [0.63,1.23]	0.4492	0.91 [0.66,1.26]	0.5579
Bleeding	30 Day	4.84% [4.15%,5.64%]	2.03% [1.23%,3.34%]	5.70% [4.85%,6.69%]	0.35 [0.20,0.59]	<.0001	0.55 [0.31,0.99]	0.0475	0.59 [0.34,1.04]	0.0687
	90 Day	5.35% [4.61%,6.19%]	2.50% [1.58%,3.94%]	6.22% [5.33%,7.25%]	0.38 [0.24,0.63]	0.0001	0.60 [0.35,1.04]	0.0680	0.63 [0.38,1.06]	0.0848
	180 Day	5.77% [5.00%,6.64%]	2.83% [1.83%,4.36%]	6.67% [5.74%,7.74%]	0.40 [0.25,0.64]	0.0001	0.63 [0.38,1.05]	0.0755	0.64 [0.39,1.05]	0.0778
	1 Year	6.72% [5.88%,7.68%]	3.88% [2.65%,5.67%]	7.59% [6.59%,8.75%]	0.47 [0.31,0.71]	0.0003	0.70 [0.45,1.11]	0.1320	0.71 [0.46,1.11]	0.1300

Subgroup: Patients Outcomes in STEMI										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 3285)	Prasugrel (N= 773)	Clopidogrel (N= 2512)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
Stroke	30 Day	0.51% [0.31%,0.83%]	0.26% [0.06%,1.03%]	0.58% [0.35%,0.98%]	0.47 [0.11,2.06]	0.3157	0.69 [0.14,3.53]	0.6565	0.79 [0.16,3.91]	0.7680
	90 Day	0.95% [0.65%,1.37%]	0.73% [0.30%,1.75%]	1.01% [0.67%,1.52%]	0.72 [0.27,1.88]	0.4990	1.21 [0.41,3.55]	0.7309	1.32 [0.45,3.85]	0.6154
	180 Day	1.18% [0.84%,1.64%]	1.22% [0.61%,2.44%]	1.16% [0.79%,1.71%]	1.01 [0.46,2.24]	0.9724	2.05 [0.84,5.02]	0.1171	2.07 [0.85,5.09]	0.1112
	1 Year	1.66% [1.24%,2.21%]	1.57% [0.85%,2.91%]	1.69% [1.22%,2.33%]	0.92 [0.46,1.85]	0.8088	1.98 [0.90,4.36]	0.0891	1.94 [0.89,4.25]	0.0978
Def/Prob Stent Thrombosis	30 Day	0.51% [0.31%,0.84%]	0.88% [0.40%,1.95%]	0.39% [0.20%,0.76%]	2.24 [0.80,6.31]	0.1250	1.45 [0.45,4.65]	0.5341	1.45 [0.47,4.49]	0.5221
	90 Day	0.62% [0.39%,0.97%]	0.88% [0.40%,1.95%]	0.54% [0.30%,0.94%]	1.68 [0.63,4.48]	0.2993	0.96 [0.32,2.85]	0.9380	0.95 [0.33,2.71]	0.9244
	180 Day	0.65% [0.42%,1.02%]	0.88% [0.40%,1.95%]	0.59% [0.34%,1.01%]	1.55 [0.59,4.08]	0.3744	0.93 [0.32,2.76]	0.9025	0.92 [0.33,2.59]	0.8744
	1 Year	0.74% [0.48%,1.13%]	1.07% [0.51%,2.25%]	0.64% [0.38%,1.08%]	1.68 [0.68,4.16]	0.2628	0.96 [0.35,2.64]	0.9418	0.97 [0.37,2.55]	0.9522

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.4 Outcomes in NSTEMI/UA

Subgroup: Patients NSTEMI/unstable angina										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 16628)	Prasugrel (N= 3285)	Clopidogrel (N=13343)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	4.91% [4.59%,5.26%]	3.26% [2.70%,3.94%]	5.32% [4.95%,5.73%]	0.61 [0.50,0.75]	<.0001	0.83 [0.65,1.05]	0.1279	0.89 [0.71,1.12]	0.3266
	90 Day	8.06% [7.64%,8.50%]	5.66% [4.90%,6.53%]	8.66% [8.18%,9.17%]	0.64 [0.55,0.75]	<.0001	0.93 [0.77,1.11]	0.4063	0.98 [0.82,1.16]	0.7826
	180 Day	12.39% [11.88%,12.93%]	8.19% [7.26%,9.22%]	13.46% [12.86%,14.09%]	0.59 [0.52,0.68]	<.0001	0.89 [0.77,1.04]	0.1493	0.90 [0.77,1.04]	0.1407
	1 Year	18.53% [17.91%,19.18%]	11.69% [10.58%,12.91%]	20.27% [19.54%,21.02%]	0.56 [0.50,0.62]	<.0001	0.83 [0.73,0.94]	0.0039	0.82 [0.72,0.92]	0.0012
Death	30 Day	0.96% [0.81%,1.12%]	0.16% [0.07%,0.38%]	1.16% [0.98%,1.36%]	0.14 [0.06,0.34]	<.0001	0.45 [0.17,1.17]	0.1006	0.58 [0.23,1.46]	0.2493
	90 Day	2.03% [1.82%,2.27%]	0.53% [0.32%,0.86%]	2.41% [2.15%,2.70%]	0.21 [0.13,0.35]	<.0001	0.64 [0.37,1.11]	0.1149	0.69 [0.41,1.17]	0.1678
	180 Day	3.35% [3.07%,3.66%]	1.05% [0.74%,1.49%]	3.94% [3.60%,4.31%]	0.26 [0.18,0.37]	<.0001	0.69 [0.46,1.03]	0.0678	0.70 [0.48,1.03]	0.0696
	1 Year	5.41% [5.05%,5.80%]	1.64% [1.23%,2.18%]	6.38% [5.94%,6.84%]	0.25 [0.18,0.33]	<.0001	0.65 [0.47,0.89]	0.0079	0.61 [0.45,0.84]	0.0020
Myocardial infarction	30 Day	2.55% [2.31%,2.80%]	1.54% [1.17%,2.03%]	2.80% [2.53%,3.10%]	0.55 [0.41,0.74]	<.0001	0.76 [0.54,1.06]	0.1092	0.77 [0.56,1.06]	0.1099
	90 Day	3.10% [2.84%,3.38%]	1.81% [1.40%,2.33%]	3.43% [3.12%,3.76%]	0.53 [0.40,0.70]	<.0001	0.81 [0.59,1.10]	0.1736	0.82 [0.60,1.10]	0.1803
	180 Day	4.05% [3.75%,4.38%]	2.30% [1.83%,2.89%]	4.50% [4.15%,4.88%]	0.51 [0.40,0.65]	<.0001	0.81 [0.61,1.07]	0.1433	0.78 [0.60,1.02]	0.0698
	1 Year	5.16% [4.81%,5.53%]	3.04% [2.48%,3.71%]	5.70% [5.29%,6.14%]	0.53 [0.42,0.66]	<.0001	0.85 [0.67,1.09]	0.2098	0.82 [0.64,1.04]	0.0984
Unplanned Revascularization	30 Day	1.75% [1.56%,1.97%]	1.63% [1.24%,2.15%]	1.78% [1.57%,2.03%]	0.91 [0.67,1.24]	0.5665	1.04 [0.73,1.49]	0.8146	1.01 [0.72,1.42]	0.9574
	90 Day	3.78% [3.49%,4.10%]	3.77% [3.15%,4.51%]	3.78% [3.46%,4.14%]	0.99 [0.81,1.22]	0.9362	1.17 [0.92,1.48]	0.2025	1.15 [0.92,1.44]	0.2321
	180 Day	6.70% [6.30%,7.12%]	5.65% [4.88%,6.54%]	6.97% [6.52%,7.45%]	0.81 [0.69,0.96]	0.0150	1.03 [0.85,1.24]	0.7796	0.98 [0.81,1.17]	0.7920
	1 Year	10.86% [10.36%,11.40%]	8.50% [7.54%,9.58%]	11.49% [10.90%,12.10%]	0.74 [0.65,0.85]	<.0001	0.93 [0.80,1.09]	0.3772	0.89 [0.77,1.03]	0.1284
Bleeding	30 Day	1.45% [1.28%,1.65%]	1.18% [0.86%,1.62%]	1.52% [1.32%,1.75%]	0.77 [0.55,1.10]	0.1492	1.47 [0.98,2.22]	0.0638	1.41 [0.95,2.08]	0.0878
	90 Day	2.22% [2.00%,2.46%]	1.81% [1.40%,2.35%]	2.32% [2.07%,2.60%]	0.78 [0.59,1.04]	0.0853	1.39 [1.00,1.94]	0.0498	1.33 [0.97,1.82]	0.0798
	180 Day	2.75% [2.51%,3.03%]	2.03% [1.59%,2.59%]	2.94% [2.66%,3.26%]	0.69 [0.53,0.90]	0.0070	1.20 [0.88,1.64]	0.2402	1.14 [0.85,1.54]	0.3729
	1 Year	3.92% [3.62%,4.25%]	2.88% [2.33%,3.54%]	4.19% [3.84%,4.57%]	0.69 [0.55,0.86]	0.0013	1.11 [0.86,1.45]	0.4153	1.09 [0.85,1.40]	0.5118
Stroke	30 Day	0.37% [0.29%,0.47%]	0.15% [0.06%,0.37%]	0.42% [0.32%,0.55%]	0.37 [0.15,0.93]	0.0339	0.49 [0.16,1.50]	0.2125	0.77 [0.29,2.07]	0.6026
	90 Day	0.60% [0.49%,0.73%]	0.25% [0.13%,0.51%]	0.69% [0.56%,0.85%]	0.37 [0.18,0.77]	0.0075	0.69 [0.29,1.64]	0.4036	0.91 [0.41,1.99]	0.8114
	180 Day	0.86% [0.73%,1.02%]	0.32% [0.17%,0.60%]	1.00% [0.84%,1.20%]	0.33 [0.17,0.63]	0.0007	0.64 [0.30,1.35]	0.2391	0.75 [0.37,1.49]	0.4068
	1 Year	1.40% [1.22%,1.61%]	0.62% [0.39%,0.98%]	1.60% [1.39%,1.85%]	0.38 [0.24,0.62]	0.0001	0.82 [0.47,1.42]	0.4713	0.86 [0.51,1.46]	0.5765
Def/Prob Stent Thrombosis	30 Day	0.19% [0.13%,0.27%]	0.22% [0.11%,0.47%]	0.18% [0.12%,0.27%]	1.26 [0.54,2.95]	0.5916	1.00 [0.40,2.54]	0.9948	0.96 [0.39,2.40]	0.9326
	90 Day	0.27% [0.20%,0.37%]	0.29% [0.15%,0.55%]	0.27% [0.19%,0.38%]	1.08 [0.51,2.25]	0.8474	0.96 [0.43,2.15]	0.9235	0.87 [0.39,1.91]	0.7252

Subgroup: Patients NSTEMI/unstable angina										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 16628)	Prasugrel (N= 3285)	Clopidogrel (N=13343)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
	180 Day	0.37% [0.28%,0.48%]	0.36% [0.20%,0.65%]	0.37% [0.28%,0.50%]	0.98 [0.50,1.89]	0.9435	0.79 [0.39,1.61]	0.5127	0.72 [0.36,1.46]	0.3613
	1 Year	0.46% [0.37%,0.59%]	0.54% [0.33%,0.88%]	0.44% [0.34%,0.58%]	1.22 [0.69,2.13]	0.4938	0.96 [0.52,1.76]	0.8858	0.85 [0.46,1.55]	0.5950

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.
[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi
[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.5 Outcomes in in Patients with Diabetes Mellitus

Subgroup: Patients with diabetes mellitus										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 7580)	Prasugrel (N= 1382)	Clopidogrel (N= 6198)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	6.07% [5.54%,6.64%]	4.05% [3.12%,5.26%]	6.52% [5.92%,7.18%]	0.62 [0.46,0.82]	0.0009	0.87 [0.62,1.21]	0.3980	0.96 [0.70,1.31]	0.7995
	90 Day	9.96% [9.28%,10.68%]	7.48% [6.17%,9.05%]	10.52% [9.75%,11.34%]	0.70 [0.56,0.86]	0.0009	1.04 [0.82,1.33]	0.7388	1.09 [0.86,1.38]	0.4690
	180 Day	15.34% [14.51%,16.22%]	11.54% [9.89%,13.44%]	16.21% [15.26%,17.20%]	0.69 [0.58,0.82]	<.0001	1.09 [0.89,1.33]	0.3958	1.06 [0.88,1.29]	0.5432
	1 Year	22.78% [21.78%,23.82%]	16.85% [14.85%,19.09%]	24.12% [22.99%,25.29%]	0.67 [0.58,0.78]	<.0001	1.01 [0.86,1.20]	0.8762	1.01 [0.86,1.19]	0.8706
Death	30 Day	1.59% [1.33%,1.91%]	0.22% [0.07%,0.69%]	1.90% [1.58%,2.29%]	0.12 [0.04,0.38]	0.0003	0.28 [0.08,0.93]	0.0378	0.38 [0.12,1.23]	0.1072
	90 Day	3.02% [2.64%,3.45%]	0.63% [0.31%,1.25%]	3.57% [3.11%,4.08%]	0.17 [0.08,0.35]	<.0001	0.38 [0.17,0.84]	0.0173	0.49 [0.24,1.02]	0.0560
	180 Day	4.81% [4.32%,5.35%]	1.65% [1.07%,2.55%]	5.53% [4.95%,6.17%]	0.28 [0.18,0.45]	<.0001	0.67 [0.41,1.11]	0.1212	0.73 [0.45,1.17]	0.1918
	1 Year	7.46% [6.84%,8.13%]	2.54% [1.78%,3.61%]	8.58% [7.86%,9.38%]	0.28 [0.19,0.41]	<.0001	0.69 [0.46,1.03]	0.0678	0.69 [0.47,1.02]	0.0630
Myocardial infarction	30 Day	2.80% [2.44%,3.20%]	1.69% [1.13%,2.54%]	3.04% [2.64%,3.51%]	0.56 [0.36,0.87]	0.0091	0.86 [0.52,1.40]	0.5402	0.91 [0.57,1.45]	0.6808
	90 Day	3.64% [3.23%,4.11%]	2.34% [1.65%,3.31%]	3.94% [3.47%,4.48%]	0.59 [0.41,0.86]	0.0062	1.02 [0.66,1.56]	0.9344	1.03 [0.69,1.55]	0.8828
	180 Day	5.00% [4.51%,5.54%]	3.20% [2.36%,4.32%]	5.41% [4.85%,6.04%]	0.59 [0.42,0.81]	0.0014	1.01 [0.69,1.46]	0.9771	0.95 [0.66,1.36]	0.7860
	1 Year	6.79% [6.20%,7.43%]	4.76% [3.69%,6.12%]	7.26% [6.59%,7.99%]	0.64 [0.49,0.84]	0.0015	1.01 [0.74,1.39]	0.9394	1.01 [0.74,1.37]	0.9562
Unplanned Revascularization	30 Day	2.11% [1.80%,2.48%]	2.14% [1.48%,3.09%]	2.11% [1.77%,2.51%]	1.01 [0.67,1.53]	0.9458	1.17 [0.72,1.89]	0.5300	1.11 [0.70,1.76]	0.6466
	90 Day	4.54% [4.07%,5.06%]	5.35% [4.24%,6.73%]	4.35% [3.85%,4.92%]	1.22 [0.94,1.60]	0.1405	1.43 [1.04,1.95]	0.0260	1.35 [1.00,1.83]	0.0496
	180 Day	8.03% [7.39%,8.72%]	7.99% [6.61%,9.65%]	8.04% [7.34%,8.81%]	1.00 [0.81,1.25]	0.9662	1.29 [1.00,1.65]	0.0459	1.17 [0.92,1.49]	0.2037
	1 Year	13.06% [12.24%,13.93%]	12.23% [10.49%,14.23%]	13.26% [12.35%,14.23%]	0.93 [0.78,1.12]	0.4498	1.14 [0.93,1.40]	0.2006	1.11 [0.91,1.35]	0.3115
Bleeding	30 Day	1.88% [1.59%,2.21%]	1.70% [1.13%,2.55%]	1.91% [1.60%,2.29%]	0.88 [0.56,1.38]	0.5837	1.49 [0.87,2.54]	0.1432	1.52 [0.92,2.53]	0.1023
	90 Day	2.75% [2.40%,3.16%]	2.18% [1.52%,3.12%]	2.88% [2.48%,3.35%]	0.76 [0.51,1.13]	0.1707	1.23 [0.78,1.94]	0.3649	1.24 [0.80,1.91]	0.3322
	180 Day	3.44% [3.03%,3.89%]	2.44% [1.73%,3.44%]	3.67% [3.21%,4.19%]	0.67 [0.46,0.98]	0.0381	1.15 [0.75,1.76]	0.5180	1.10 [0.73,1.66]	0.6377
	1 Year	4.92% [4.42%,5.48%]	3.17% [2.33%,4.30%]	5.34% [4.76%,5.98%]	0.61 [0.43,0.84]	0.0030	0.98 [0.68,1.42]	0.9315	0.94 [0.66,1.34]	0.7162
Stroke	30 Day	0.50% [0.36%,0.69%]	0.22% [0.07%,0.69%]	0.56% [0.40%,0.78%]	0.40 [0.12,1.31]	0.1306	0.51 [0.11,2.32]	0.3819	0.79 [0.22,2.86]	0.7237
	90 Day	0.77% [0.59%,1.00%]	0.46% [0.21%,1.02%]	0.84% [0.63%,1.11%]	0.55 [0.23,1.28]	0.1619	1.14 [0.41,3.11]	0.8054	1.31 [0.51,3.38]	0.5717
	180 Day	1.13% [0.90%,1.41%]	0.72% [0.37%,1.38%]	1.22% [0.96%,1.55%]	0.58 [0.29,1.16]	0.1248	1.24 [0.56,2.77]	0.5967	1.30 [0.60,2.82]	0.5140
	1 Year	1.89% [1.58%,2.26%]	1.26% [0.76%,2.08%]	2.03% [1.68%,2.46%]	0.61 [0.36,1.06]	0.0781	1.44 [0.77,2.67]	0.2515	1.42 [0.77,2.60]	0.2615
Def/Prob Stent Thrombosis	30 Day	0.21% [0.13%,0.35%]	0.46% [0.21%,1.01%]	0.16% [0.08%,0.30%]	2.93 [1.04,8.23]	0.0415	2.47 [0.77,7.91]	0.1269	2.17 [0.68,6.92]	0.1890
	90 Day	0.39% [0.27%,0.57%]	0.53% [0.26%,1.12%]	0.36% [0.23%,0.56%]	1.52 [0.64,3.60]	0.3384	1.37 [0.53,3.51]	0.5160	1.17 [0.46,2.97]	0.7443
	180 Day	0.47% [0.33%,0.67%]	0.62% [0.31%,1.23%]	0.44% [0.29%,0.66%]	1.44 [0.65,3.21]	0.3683	1.31 [0.54,3.16]	0.5459	1.08 [0.46,2.58]	0.8545
	1 Year	0.64% [0.47%,0.86%]	0.90% [0.50%,1.62%]	0.58% [0.40%,0.82%]	1.58 [0.79,3.15]	0.1956	1.27 [0.60,2.71]	0.5347	1.08 [0.51,2.28]	0.8421

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.
[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi
[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.6 Outcomes in Patients without Diabetes Mellitus

Subgroup: Patients without diabetes mellitus										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 12329)	Prasugrel (N= 2675)	Clopidogrel (N= 9654)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	5.34% [4.95%,5.77%]	3.18% [2.57%,3.94%]	5.94% [5.48%,6.45%]	0.53 [0.42,0.67]	<.0001	0.83 [0.64,1.09]	0.1769	0.88 [0.68,1.13]	0.3230
	90 Day	8.08% [7.60%,8.59%]	4.77% [4.00%,5.68%]	9.00% [8.42%,9.61%]	0.52 [0.43,0.63]	<.0001	0.81 [0.65,1.00]	0.0524	0.85 [0.69,1.05]	0.1231
	180 Day	11.66% [11.08%,12.27%]	6.58% [5.66%,7.64%]	13.08% [12.39%,13.81%]	0.49 [0.41,0.58]	<.0001	0.78 [0.65,0.94]	0.0087	0.78 [0.66,0.94]	0.0073
	1 Year	16.51% [15.83%,17.23%]	9.59% [8.47%,10.85%]	18.45% [17.64%,19.30%]	0.50 [0.43,0.57]	<.0001	0.76 [0.65,0.89]	0.0006	0.75 [0.65,0.87]	0.0002
Death	30 Day	1.11% [0.94%,1.32%]	0.24% [0.11%,0.54%]	1.36% [1.14%,1.62%]	0.18 [0.08,0.40]	<.0001	0.76 [0.32,1.79]	0.5237	0.79 [0.34,1.84]	0.5790
	90 Day	1.98% [1.74%,2.26%]	0.62% [0.38%,1.03%]	2.36% [2.06%,2.70%]	0.26 [0.15,0.43]	<.0001	0.91 [0.52,1.61]	0.7516	0.87 [0.50,1.50]	0.6076
	180 Day	3.05% [2.74%,3.39%]	0.88% [0.58%,1.35%]	3.65% [3.28%,4.07%]	0.24 [0.15,0.37]	<.0001	0.73 [0.45,1.18]	0.2016	0.70 [0.44,1.12]	0.1357
	1 Year	4.53% [4.15%,4.94%]	1.38% [0.98%,1.95%]	5.41% [4.94%,5.92%]	0.25 [0.17,0.35]	<.0001	0.72 [0.48,1.06]	0.0927	0.66 [0.45,0.96]	0.0293
Myocardial infarction	30 Day	2.68% [2.41%,2.99%]	1.54% [1.13%,2.09%]	3.00% [2.67%,3.37%]	0.51 [0.37,0.72]	<.0001	0.80 [0.55,1.16]	0.2386	0.79 [0.55,1.13]	0.1963
	90 Day	3.21% [2.91%,3.55%]	1.66% [1.24%,2.24%]	3.64% [3.28%,4.05%]	0.46 [0.33,0.63]	<.0001	0.76 [0.53,1.09]	0.1311	0.75 [0.53,1.06]	0.1072
	180 Day	3.93% [3.59%,4.31%]	1.97% [1.50%,2.59%]	4.49% [4.07%,4.94%]	0.44 [0.33,0.59]	<.0001	0.77 [0.55,1.06]	0.1116	0.71 [0.52,0.98]	0.0384
	1 Year	4.77% [4.38%,5.18%]	2.61% [2.05%,3.32%]	5.37% [4.92%,5.87%]	0.48 [0.37,0.62]	<.0001	0.83 [0.62,1.11]	0.2074	0.78 [0.58,1.03]	0.0800
Unplanned Revascularization	30 Day	2.01% [1.77%,2.28%]	1.65% [1.22%,2.24%]	2.11% [1.83%,2.43%]	0.78 [0.56,1.10]	0.1527	0.92 [0.63,1.35]	0.6638	0.92 [0.64,1.34]	0.6772
	90 Day	3.73% [3.39%,4.10%]	2.87% [2.28%,3.62%]	3.97% [3.58%,4.41%]	0.72 [0.56,0.93]	0.0119	0.85 [0.63,1.13]	0.2556	0.86 [0.65,1.14]	0.3027
	180 Day	6.20% [5.76%,6.67%]	4.26% [3.52%,5.15%]	6.75% [6.24%,7.31%]	0.63 [0.51,0.78]	<.0001	0.79 [0.62,1.00]	0.0462	0.77 [0.61,0.96]	0.0231
	1 Year	9.55% [8.99%,10.13%]	6.62% [5.68%,7.71%]	10.39% [9.74%,11.08%]	0.63 [0.53,0.75]	<.0001	0.78 [0.64,0.94]	0.0096	0.75 [0.62,0.90]	0.0023
Bleeding	30 Day	2.10% [1.85%,2.37%]	1.16% [0.81%,1.65%]	2.36% [2.07%,2.68%]	0.48 [0.33,0.71]	0.0002	0.77 [0.50,1.18]	0.2254	0.77 [0.51,1.16]	0.2174
	90 Day	2.72% [2.44%,3.04%]	1.83% [1.37%,2.43%]	2.97% [2.64%,3.34%]	0.60 [0.44,0.82]	0.0013	0.95 [0.67,1.35]	0.7617	0.92 [0.66,1.29]	0.6357
	180 Day	3.14% [2.84%,3.48%]	2.04% [1.56%,2.68%]	3.45% [3.09%,3.85%]	0.58 [0.43,0.78]	0.0003	0.89 [0.64,1.24]	0.5024	0.87 [0.63,1.21]	0.4104
	1 Year	4.06% [3.71%,4.45%]	3.01% [2.40%,3.78%]	4.36% [3.95%,4.81%]	0.67 [0.52,0.86]	0.0016	0.98 [0.74,1.30]	0.8834	0.97 [0.74,1.28]	0.8384
Stroke	30 Day	0.33% [0.24%,0.45%]	0.15% [0.06%,0.40%]	0.38% [0.27%,0.52%]	0.41 [0.15,1.16]	0.0916	0.59 [0.19,1.87]	0.3727	0.80 [0.26,2.43]	0.6960
	90 Day	0.58% [0.46%,0.74%]	0.27% [0.13%,0.58%]	0.67% [0.52%,0.86%]	0.42 [0.19,0.91]	0.0277	0.73 [0.30,1.77]	0.4901	0.91 [0.39,2.11]	0.8250
	180 Day	0.78% [0.63%,0.96%]	0.36% [0.19%,0.69%]	0.90% [0.72%,1.12%]	0.41 [0.20,0.81]	0.0106	0.81 [0.37,1.75]	0.5890	0.90 [0.43,1.89]	0.7793
	1 Year	1.17% [0.99%,1.40%]	0.54% [0.32%,0.94%]	1.36% [1.13%,1.63%]	0.40 [0.23,0.72]	0.0020	0.81 [0.43,1.53]	0.5162	0.84 [0.45,1.56]	0.5792
Def/Prob Stent Thrombosis	30 Day	0.25% [0.18%,0.36%]	0.28% [0.13%,0.59%]	0.25% [0.16%,0.37%]	1.14 [0.49,2.67]	0.7598	0.70 [0.27,1.76]	0.4444	0.75 [0.30,1.85]	0.5327
	90 Day	0.29% [0.21%,0.41%]	0.32% [0.16%,0.64%]	0.28% [0.19%,0.42%]	1.15 [0.52,2.54]	0.7381	0.73 [0.31,1.75]	0.4842	0.75 [0.32,1.76]	0.5100
	180 Day	0.38% [0.28%,0.51%]	0.36% [0.19%,0.70%]	0.38% [0.27%,0.54%]	0.97 [0.46,2.02]	0.9319	0.63 [0.28,1.40]	0.2571	0.64 [0.30,1.40]	0.2692
	1 Year	0.43% [0.32%,0.57%]	0.50% [0.28%,0.88%]	0.41% [0.30%,0.57%]	1.21 [0.63,2.33]	0.5657	0.80 [0.39,1.63]	0.5381	0.79 [0.39,1.59]	0.5064

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.
[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi
[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.7 Outcomes in Patients with CKD

Subgroup: Patients with CKD										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 5613)	Prasugrel (N= 619)	Clopidogrel (N= 4994)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	7.45% [6.78%,8.18%]	4.01% [2.71%,5.93%]	7.87% [7.14%,8.67%]	0.50 [0.33,0.76]	0.0011	0.84 [0.53,1.32]	0.4415	0.90 [0.59,1.39]	0.6384
	90 Day	11.97% [11.12%,12.87%]	8.14% [6.18%,10.69%]	12.44% [11.53%,13.42%]	0.63 [0.47,0.84]	0.0021	1.06 [0.76,1.47]	0.7404	1.09 [0.80,1.49]	0.5917
	180 Day	18.19% [17.16%,19.28%]	12.45% [9.97%,15.48%]	18.90% [17.79%,20.07%]	0.62 [0.49,0.80]	0.0002	1.02 [0.78,1.33]	0.8754	1.01 [0.78,1.31]	0.9444
	1 Year	25.59% [24.40%,26.83%]	18.27% [15.26%,21.79%]	26.50% [25.22%,27.83%]	0.64 [0.53,0.79]	<.0001	0.99 [0.79,1.23]	0.9036	0.98 [0.79,1.22]	0.8583
Death	30 Day	2.78% [2.37%,3.26%]	0.51% [0.17%,1.59%]	3.06% [2.60%,3.59%]	0.17 [0.05,0.52]	0.0020	0.47 [0.15,1.52]	0.2079	0.52 [0.16,1.66]	0.2687
	90 Day	4.85% [4.30%,5.47%]	1.95% [1.09%,3.50%]	5.21% [4.60%,5.89%]	0.36 [0.20,0.66]	0.0009	0.93 [0.49,1.75]	0.8199	0.93 [0.50,1.73]	0.8168
	180 Day	7.73% [7.02%,8.50%]	3.47% [2.22%,5.39%]	8.26% [7.49%,9.10%]	0.40 [0.25,0.63]	<.0001	0.92 [0.57,1.50]	0.7462	0.89 [0.55,1.44]	0.6407
	1 Year	11.37% [10.52%,12.30%]	5.25% [3.65%,7.51%]	12.14% [11.20%,13.14%]	0.41 [0.28,0.59]	<.0001	0.86 [0.57,1.28]	0.4500	0.85 [0.57,1.26]	0.4189

Subgroup: Patients with CKD										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 5613)	Prasugrel (N= 619)	Clopidogrel (N= 4994)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
Myocardial infarction	30 Day	3.32% [2.87%,3.83%]	2.31% [1.37%,3.87%]	3.44% [2.97%,4.00%]	0.67 [0.39,1.16]	0.1550	1.11 [0.61,2.03]	0.7231	1.09 [0.61,1.96]	0.7645
	90 Day	4.46% [3.93%,5.05%]	2.84% [1.78%,4.54%]	4.66% [4.09%,5.31%]	0.61 [0.37,1.01]	0.0528	1.11 [0.64,1.90]	0.7171	1.09 [0.65,1.85]	0.7382
	180 Day	6.14% [5.51%,6.84%]	4.19% [2.82%,6.19%]	6.39% [5.71%,7.14%]	0.65 [0.43,0.98]	0.0419	1.05 [0.66,1.67]	0.8295	1.01 [0.65,1.59]	0.9507
	1 Year	7.86% [7.14%,8.66%]	6.22% [4.48%,8.62%]	8.07% [7.29%,8.92%]	0.75 [0.52,1.06]	0.1025	1.20 [0.81,1.77]	0.3685	1.16 [0.79,1.69]	0.4587
Unplanned Revascularization	30 Day	1.84% [1.51%,2.24%]	1.03% [0.46%,2.28%]	1.94% [1.58%,2.38%]	0.53 [0.23,1.21]	0.1295	0.71 [0.29,1.71]	0.4424	0.56 [0.24,1.32]	0.1862
	90 Day	4.19% [3.67%,4.79%]	3.95% [2.62%,5.94%]	4.22% [3.67%,4.85%]	0.91 [0.58,1.41]	0.6734	1.16 [0.72,1.88]	0.5462	1.02 [0.64,1.64]	0.9203
	180 Day	7.55% [6.84%,8.34%]	6.45% [4.67%,8.88%]	7.69% [6.93%,8.54%]	0.82 [0.58,1.17]	0.2728	1.05 [0.71,1.53]	0.8183	0.93 [0.64,1.36]	0.7244
	1 Year	11.66% [10.76%,12.62%]	10.49% [8.15%,13.45%]	11.81% [10.85%,12.84%]	0.87 [0.66,1.15]	0.3246	1.04 [0.76,1.41]	0.8050	0.97 [0.72,1.31]	0.8650
Bleeding	30 Day	3.33% [2.89%,3.84%]	2.49% [1.51%,4.09%]	3.44% [2.96%,3.99%]	0.72 [0.42,1.21]	0.2133	1.04 [0.58,1.88]	0.8852	1.09 [0.62,1.91]	0.7739
	90 Day	4.53% [4.00%,5.13%]	3.55% [2.33%,5.40%]	4.65% [4.09%,5.29%]	0.76 [0.48,1.18]	0.2184	1.03 [0.63,1.69]	0.8957	1.06 [0.66,1.70]	0.8235
	180 Day	5.39% [4.80%,6.04%]	3.75% [2.48%,5.64%]	5.59% [4.97%,6.30%]	0.67 [0.43,1.04]	0.0722	0.94 [0.58,1.51]	0.7974	0.92 [0.58,1.47]	0.7388
	1 Year	7.22% [6.53%,7.98%]	5.97% [4.27%,8.31%]	7.38% [6.64%,8.20%]	0.79 [0.55,1.13]	0.1974	1.03 [0.70,1.53]	0.8789	1.05 [0.72,1.53]	0.8071
Stroke	30 Day	0.68% [0.49%,0.94%]	0.33% [0.08%,1.33%]	0.72% [0.52%,1.01%]	0.46 [0.11,1.90]	0.2811	0.28 [0.03,2.43]	0.2492	0.88 [0.20,3.91]	0.8623
	90 Day	1.05% [0.80%,1.36%]	0.69% [0.26%,1.84%]	1.09% [0.83%,1.43%]	0.62 [0.22,1.72]	0.3590	0.89 [0.24,3.37]	0.8653	1.48 [0.50,4.39]	0.4826
	180 Day	1.44% [1.15%,1.81%]	1.27% [0.61%,2.66%]	1.46% [1.15%,1.86%]	0.83 [0.38,1.82]	0.6483	1.52 [0.59,3.97]	0.3878	2.00 [0.86,4.69]	0.1094
	1 Year	2.16% [1.78%,2.62%]	1.87% [1.01%,3.46%]	2.20% [1.79%,2.69%]	0.84 [0.44,1.61]	0.5952	1.67 [0.78,3.58]	0.1901	1.87 [0.92,3.81]	0.0829
Def/Prob Stent Thrombosis	30 Day	0.12% [0.05%,0.26%]	0.17% [0.02%,1.22%]	0.11% [0.04%,0.26%]	1.58 [0.19,13.56]	0.6744	5.75 [0.34,96.13]	0.2234	5.52 [0.34,88.41]	0.2273
	90 Day	0.30% [0.18%,0.49%]	0.17% [0.02%,1.22%]	0.31% [0.18%,0.53%]	0.56 [0.07,4.26]	0.5763	0.65 [0.08,5.52]	0.6897	0.67 [0.08,5.61]	0.7111
	180 Day	0.38% [0.25%,0.60%]	0.17% [0.02%,1.22%]	0.41% [0.26%,0.65%]	0.43 [0.06,3.25]	0.4167	0.58 [0.07,4.77]	0.6098	0.53 [0.07,4.33]	0.5570
	1 Year	0.51% [0.34%,0.76%]	0.37% [0.09%,1.49%]	0.52% [0.34%,0.79%]	0.71 [0.17,3.00]	0.6376	0.60 [0.13,2.78]	0.5156	0.61 [0.13,2.80]	0.5267

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.8 Outcomes in Patients without CKD

Subgroup: Patients without CKD										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 14219)	Prasugrel (N= 3425)	Clopidogrel (N=10794)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	4.87% [4.52%,5.25%]	3.36% [2.80%,4.04%]	5.35% [4.93%,5.80%]	0.63 [0.51,0.77]	<.0001	0.84 [0.66,1.06]	0.1332	0.88 [0.70,1.10]	0.2655
	90 Day	7.52% [7.08%,7.98%]	5.25% [4.53%,6.08%]	8.24% [7.72%,8.80%]	0.63 [0.53,0.74]	<.0001	0.85 [0.71,1.02]	0.0878	0.88 [0.73,1.05]	0.1630
	180 Day	10.99% [10.46%,11.54%]	7.51% [6.64%,8.49%]	12.11% [11.47%,12.78%]	0.61 [0.53,0.70]	<.0001	0.86 [0.74,1.01]	0.0627	0.85 [0.73,0.99]	0.0404
	1 Year	16.14% [15.50%,16.80%]	10.87% [9.81%,12.04%]	17.84% [17.08%,18.64%]	0.59 [0.53,0.67]	<.0001	0.82 [0.72,0.94]	0.0035	0.81 [0.71,0.92]	0.0010
Death	30 Day	0.69% [0.56%,0.85%]	0.19% [0.08%,0.42%]	0.86% [0.69%,1.06%]	0.22 [0.10,0.50]	0.0003	0.47 [0.19,1.15]	0.0978	0.55 [0.23,1.31]	0.1761
	90 Day	1.37% [1.19%,1.59%]	0.35% [0.19%,0.63%]	1.70% [1.46%,1.98%]	0.20 [0.11,0.38]	<.0001	0.46 [0.24,0.88]	0.0197	0.49 [0.26,0.92]	0.0263
	180 Day	2.09% [1.85%,2.35%]	0.69% [0.45%,1.06%]	2.54% [2.24%,2.88%]	0.27 [0.17,0.42]	<.0001	0.56 [0.35,0.91]	0.0184	0.57 [0.36,0.91]	0.0191
	1 Year	3.31% [3.00%,3.64%]	1.11% [0.79%,1.56%]	4.02% [3.64%,4.45%]	0.27 [0.19,0.39]	<.0001	0.59 [0.40,0.86]	0.0068	0.56 [0.38,0.81]	0.0023
Myocardial infarction	30 Day	2.48% [2.24%,2.76%]	1.44% [1.08%,1.90%]	2.82% [2.52%,3.16%]	0.51 [0.38,0.70]	<.0001	0.74 [0.53,1.04]	0.0869	0.76 [0.54,1.05]	0.0982
	90 Day	2.94% [2.67%,3.24%]	1.70% [1.31%,2.20%]	3.34% [3.01%,3.71%]	0.51 [0.38,0.68]	<.0001	0.78 [0.57,1.07]	0.1202	0.78 [0.57,1.06]	0.1094
	180 Day	3.61% [3.30%,3.94%]	2.04% [1.60%,2.59%]	4.11% [3.74%,4.53%]	0.50 [0.38,0.64]	<.0001	0.78 [0.59,1.04]	0.0950	0.75 [0.57,1.00]	0.0471
	1 Year	4.59% [4.24%,4.97%]	2.76% [2.24%,3.40%]	5.18% [4.75%,5.65%]	0.53 [0.42,0.66]	<.0001	0.81 [0.63,1.04]	0.0982	0.78 [0.61,1.00]	0.0522
Unplanned Revascularization	30 Day	2.13% [1.90%,2.39%]	1.97% [1.55%,2.52%]	2.18% [1.91%,2.48%]	0.90 [0.68,1.20]	0.4790	1.06 [0.77,1.46]	0.7348	1.10 [0.81,1.51]	0.5389
	90 Day	3.98% [3.66%,4.34%]	3.70% [3.09%,4.42%]	4.08% [3.70%,4.49%]	0.91 [0.74,1.11]	0.3453	1.04 [0.83,1.32]	0.7243	1.07 [0.85,1.34]	0.5825

Subgroup: Patients without CKD										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 14219)	Prasugrel (N= 3425)	Clopidogrel (N=10794)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
	180 Day	6.63% [6.21%,7.09%]	5.40% [4.65%,6.26%]	7.04% [6.54%,7.58%]	0.77 [0.65,0.91]	0.0024	0.96 [0.80,1.17]	0.7016	0.94 [0.78,1.13]	0.4984
	1 Year	10.51% [9.98%,11.08%]	8.14% [7.21%,9.18%]	11.30% [10.66%,11.98%]	0.72 [0.63,0.83]	<.0001	0.89 [0.76,1.04]	0.1516	0.87 [0.75,1.01]	0.0718
Bleeding	30 Day	1.46% [1.28%,1.68%]	1.11% [0.81%,1.53%]	1.58% [1.36%,1.83%]	0.70 [0.49,1.00]	0.0484	0.95 [0.64,1.41]	0.8045	0.97 [0.66,1.43]	0.8675
	90 Day	2.00% [1.78%,2.25%]	1.63% [1.25%,2.13%]	2.12% [1.86%,2.42%]	0.76 [0.56,1.03]	0.0722	1.04 [0.74,1.45]	0.8318	1.04 [0.75,1.45]	0.8003
	180 Day	2.39% [2.14%,2.66%]	1.87% [1.46%,2.40%]	2.55% [2.26%,2.88%]	0.73 [0.55,0.96]	0.0264	0.98 [0.72,1.34]	0.9080	0.98 [0.72,1.33]	0.8808
	1 Year	3.24% [2.95%,3.57%]	2.52% [2.03%,3.14%]	3.48% [3.13%,3.87%]	0.72 [0.56,0.92]	0.0088	0.95 [0.72,1.24]	0.6882	0.94 [0.72,1.23]	0.6470
Stroke	30 Day	0.28% [0.20%,0.38%]	0.15% [0.06%,0.35%]	0.32% [0.23%,0.45%]	0.47 [0.18,1.21]	0.1195	0.67 [0.24,1.85]	0.4387	0.76 [0.28,2.10]	0.5990
	90 Day	0.50% [0.40%,0.64%]	0.28% [0.14%,0.53%]	0.58% [0.44%,0.75%]	0.49 [0.24,0.99]	0.0454	0.84 [0.39,1.82]	0.6612	0.93 [0.43,2.00]	0.8595
	180 Day	0.71% [0.58%,0.87%]	0.34% [0.19%,0.62%]	0.83% [0.66%,1.03%]	0.43 [0.23,0.80]	0.0080	0.77 [0.39,1.52]	0.4473	0.78 [0.39,1.54]	0.4765
	1 Year	1.15% [0.97%,1.36%]	0.59% [0.37%,0.94%]	1.34% [1.12%,1.59%]	0.45 [0.27,0.74]	0.0016	0.84 [0.49,1.45]	0.5341	0.85 [0.50,1.46]	0.5642
Def/Prob Stent Thrombosis	30 Day	0.29% [0.21%,0.40%]	0.37% [0.21%,0.66%]	0.26% [0.18%,0.38%]	1.44 [0.73,2.85]	0.2969	0.99 [0.47,2.08]	0.9845	0.98 [0.47,2.01]	0.9457
	90 Day	0.34% [0.26%,0.46%]	0.44% [0.26%,0.74%]	0.31% [0.22%,0.45%]	1.40 [0.75,2.64]	0.2924	0.99 [0.50,1.95]	0.9715	0.93 [0.48,1.81]	0.8247
	180 Day	0.43% [0.33%,0.56%]	0.50% [0.31%,0.82%]	0.41% [0.30%,0.55%]	1.27 [0.71,2.27]	0.4264	0.87 [0.47,1.61]	0.6515	0.82 [0.44,1.50]	0.5130
	1 Year	0.51% [0.40%,0.66%]	0.69% [0.45%,1.05%]	0.46% [0.34%,0.62%]	1.50 [0.89,2.53]	0.1265	1.04 [0.60,1.82]	0.8810	0.94 [0.55,1.63]	0.8391

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.9 Outcomes in Women

Subgroup: Female Patients										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 6304)	Prasugrel (N= 989)	Clopidogrel (N= 5315)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	6.50% [5.91%,7.15%]	4.29% [3.17%,5.78%]	6.92% [6.25%,7.65%]	0.61 [0.44,0.85]	0.0029	0.96 [0.67,1.38]	0.8274	0.99 [0.70,1.41]	0.9720
	90 Day	10.01% [9.27%,10.81%]	6.61% [5.19%,8.40%]	10.66% [9.83%,11.55%]	0.61 [0.47,0.79]	0.0002	0.95 [0.71,1.28]	0.7414	0.99 [0.74,1.31]	0.9174
	180 Day	14.91% [14.01%,15.86%]	9.98% [8.20%,12.12%]	15.84% [14.84%,16.91%]	0.61 [0.49,0.76]	<.0001	0.97 [0.77,1.24]	0.8343	0.96 [0.76,1.21]	0.7154
	1 Year	21.07% [20.02%,22.18%]	13.49% [11.40%,15.92%]	22.51% [21.34%,23.75%]	0.57 [0.47,0.69]	<.0001	0.90 [0.73,1.11]	0.3116	0.87 [0.71,1.06]	0.1702
Death	30 Day	1.72% [1.42%,2.09%]	0.42% [0.16%,1.12%]	1.97% [1.62%,2.39%]	0.21 [0.08,0.58]	0.0025	0.50 [0.18,1.43]	0.1970	0.58 [0.21,1.60]	0.2905
	90 Day	3.02% [2.61%,3.49%]	0.76% [0.36%,1.58%]	3.45% [2.97%,4.00%]	0.22 [0.10,0.46]	<.0001	0.45 [0.19,1.04]	0.0603	0.57 [0.26,1.23]	0.1499
	180 Day	4.82% [4.29%,5.41%]	1.46% [0.85%,2.50%]	5.46% [4.84%,6.14%]	0.26 [0.15,0.45]	<.0001	0.57 [0.31,1.05]	0.0730	0.64 [0.36,1.15]	0.1348
	1 Year	6.97% [6.33%,7.68%]	1.94% [1.21%,3.11%]	7.93% [7.18%,8.76%]	0.24 [0.15,0.39]	<.0001	0.53 [0.32,0.90]	0.0177	0.54 [0.33,0.90]	0.0171
Myocardial infarction	30 Day	2.97% [2.57%,3.43%]	1.45% [0.86%,2.44%]	3.26% [2.80%,3.78%]	0.44 [0.26,0.76]	0.0034	0.74 [0.40,1.38]	0.3417	0.71 [0.40,1.27]	0.2477
	90 Day	3.86% [3.40%,4.38%]	1.78% [1.11%,2.85%]	4.25% [3.73%,4.85%]	0.42 [0.25,0.68]	0.0005	0.79 [0.45,1.38]	0.4014	0.74 [0.44,1.24]	0.2532
	180 Day	5.04% [4.50%,5.64%]	2.48% [1.66%,3.72%]	5.53% [4.92%,6.21%]	0.44 [0.29,0.68]	0.0002	0.85 [0.53,1.36]	0.4879	0.73 [0.46,1.14]	0.1668

Subgroup: Female Patients										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 6304)	Prasugrel (N= 989)	Clopidogrel (N= 5315)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
	1 Year	6.52% [5.90%,7.20%]	3.84% [2.76%,5.34%]	7.03% [6.33%,7.81%]	0.53 [0.37,0.75]	0.0004	1.01 [0.68,1.49]	0.9789	0.88 [0.60,1.28]	0.4901
Unplanned Revascularization	30 Day	2.06% [1.72%,2.45%]	2.34% [1.54%,3.53%]	2.00% [1.65%,2.43%]	1.17 [0.74,1.86]	0.5072	1.44 [0.85,2.47]	0.1782	1.34 [0.80,2.24]	0.2727
	90 Day	4.09% [3.61%,4.64%]	4.34% [3.20%,5.87%]	4.04% [3.52%,4.64%]	1.08 [0.77,1.52]	0.6624	1.36 [0.92,2.01]	0.1196	1.29 [0.89,1.89]	0.1793
	180 Day	7.12% [6.46%,7.83%]	6.81% [5.34%,8.67%]	7.18% [6.47%,7.97%]	0.96 [0.73,1.26]	0.7521	1.25 [0.92,1.69]	0.1558	1.14 [0.85,1.54]	0.3785
	1 Year	11.16% [10.33%,12.04%]	9.64% [7.85%,11.81%]	11.46% [10.55%,12.45%]	0.85 [0.67,1.07]	0.1636	1.09 [0.84,1.41]	0.5247	1.01 [0.79,1.30]	0.9329
Bleeding	30 Day	2.81% [2.43%,3.25%]	2.05% [1.32%,3.15%]	2.95% [2.53%,3.45%]	0.69 [0.44,1.10]	0.1231	1.11 [0.65,1.88]	0.7080	1.07 [0.65,1.77]	0.7962
	90 Day	3.66% [3.21%,4.16%]	2.93% [2.03%,4.22%]	3.79% [3.30%,4.36%]	0.77 [0.52,1.14]	0.1885	1.21 [0.77,1.89]	0.4092	1.14 [0.74,1.75]	0.5623
	180 Day	4.38% [3.88%,4.93%]	3.17% [2.23%,4.51%]	4.61% [4.06%,5.23%]	0.69 [0.47,1.01]	0.0557	1.05 [0.68,1.60]	0.8357	0.98 [0.65,1.47]	0.9183
	1 Year	5.72% [5.14%,6.36%]	3.92% [2.84%,5.39%]	6.07% [5.42%,6.79%]	0.65 [0.46,0.92]	0.0142	0.90 [0.61,1.32]	0.5860	0.89 [0.61,1.29]	0.5314
Stroke	30 Day	0.64% [0.47%,0.88%]	0.40% [0.15%,1.07%]	0.69% [0.49%,0.96%]	0.61 [0.22,1.71]	0.3427	0.99 [0.31,3.19]	0.9865	1.18 [0.39,3.61]	0.7705
	90 Day	0.95% [0.73%,1.23%]	0.52% [0.22%,1.24%]	1.03% [0.78%,1.36%]	0.51 [0.21,1.29]	0.1556	0.76 [0.28,2.09]	0.5977	0.90 [0.34,2.41]	0.8390
	180 Day	1.34% [1.07%,1.67%]	0.75% [0.36%,1.57%]	1.45% [1.15%,1.84%]	0.53 [0.24,1.14]	0.1048	0.85 [0.36,2.00]	0.7094	0.96 [0.42,2.20]	0.9200
	1 Year	2.12% [1.77%,2.55%]	0.99% [0.52%,1.91%]	2.34% [1.94%,2.83%]	0.44 [0.22,0.86]	0.0171	0.79 [0.38,1.65]	0.5333	0.81 [0.39,1.67]	0.5697
Def/Prob Stent Thrombosis	30 Day	0.22% [0.13%,0.38%]	0.21% [0.05%,0.85%]	0.22% [0.12%,0.40%]	0.95 [0.21,4.29]	0.9481	0.82 [0.14,4.66]	0.8223	0.97 [0.19,4.90]	0.9708
	90 Day	0.35% [0.22%,0.54%]	0.32% [0.10%,1.00%]	0.35% [0.22%,0.56%]	0.92 [0.27,3.13]	0.8912	0.89 [0.22,3.56]	0.8701	1.00 [0.27,3.73]	0.9985
	180 Day	0.44% [0.30%,0.66%]	0.32% [0.10%,1.00%]	0.47% [0.31%,0.71%]	0.70 [0.21,2.35]	0.5698	0.66 [0.18,2.42]	0.5316	0.64 [0.18,2.28]	0.4945
	1 Year	0.53% [0.37%,0.76%]	0.57% [0.24%,1.37%]	0.52% [0.35%,0.78%]	1.07 [0.41,2.81]	0.8884	0.91 [0.32,2.59]	0.8560	0.93 [0.33,2.58]	0.8830

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.
[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi
[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.10 Outcomes in Men

Subgroup: Male Patients										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 13610)	Prasugrel (N= 3069)	Clopidogrel (N=10541)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	5.21% [4.84%,5.61%]	3.21% [2.63%,3.92%]	5.79% [5.35%,6.27%]	0.55 [0.44,0.69]	<.0001	0.78 [0.61,1.01]	0.0553	0.86 [0.68,1.09]	0.2136
	90 Day	8.23% [7.76%,8.72%]	5.40% [4.63%,6.29%]	9.05% [8.50%,9.64%]	0.58 [0.49,0.69]	<.0001	0.87 [0.72,1.06]	0.1604	0.91 [0.76,1.10]	0.3519
	180 Day	12.19% [11.63%,12.79%]	7.71% [6.77%,8.76%]	13.51% [12.84%,14.22%]	0.55 [0.48,0.64]	<.0001	0.87 [0.74,1.02]	0.0856	0.87 [0.74,1.02]	0.0828
	1 Year	17.86% [17.18%,18.57%]	11.59% [10.43%,12.86%]	19.71% [18.90%,20.54%]	0.56 [0.50,0.63]	<.0001	0.85 [0.74,0.97]	0.0160	0.85 [0.74,0.97]	0.0134
Death	30 Day	1.10% [0.93%,1.30%]	0.18% [0.07%,0.42%]	1.37% [1.15%,1.62%]	0.13 [0.05,0.31]	<.0001	0.45 [0.17,1.18]	0.1043	0.54 [0.21,1.37]	0.1963
	90 Day	2.08% [1.84%,2.35%]	0.58% [0.36%,0.95%]	2.52% [2.22%,2.86%]	0.22 [0.13,0.37]	<.0001	0.74 [0.43,1.30]	0.2954	0.72 [0.42,1.24]	0.2357
	180 Day	3.20% [2.90%,3.53%]	1.04% [0.72%,1.50%]	3.84% [3.47%,4.25%]	0.26 [0.18,0.38]	<.0001	0.77 [0.50,1.17]	0.2190	0.74 [0.49,1.12]	0.1579
	1 Year	5.01% [4.63%,5.42%]	1.72% [1.28%,2.29%]	5.99% [5.51%,6.50%]	0.28 [0.20,0.37]	<.0001	0.78 [0.56,1.10]	0.1573	0.74 [0.53,1.02]	0.0657

Subgroup: Male Patients										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 13610)	Prasugrel (N= 3069)	Clopidogrel (N=10541)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
Myocardial infarction	30 Day	2.61% [2.35%,2.90%]	1.64% [1.24%,2.16%]	2.90% [2.59%,3.24%]	0.57 [0.42,0.77]	0.0003	0.84 [0.60,1.19]	0.3261	0.88 [0.63,1.23]	0.4512
	90 Day	3.15% [2.86%,3.47%]	1.93% [1.49%,2.49%]	3.51% [3.16%,3.89%]	0.55 [0.42,0.73]	<.0001	0.87 [0.64,1.20]	0.3972	0.90 [0.66,1.22]	0.5032
	180 Day	4.01% [3.68%,4.37%]	2.35% [1.86%,2.98%]	4.50% [4.10%,4.93%]	0.53 [0.41,0.68]	<.0001	0.86 [0.64,1.15]	0.3017	0.85 [0.64,1.13]	0.2617
	1 Year	5.06% [4.69%,5.47%]	3.17% [2.58%,3.90%]	5.63% [5.18%,6.12%]	0.56 [0.44,0.70]	<.0001	0.87 [0.68,1.13]	0.3038	0.87 [0.68,1.12]	0.2907
Unplanned Revascularization	30 Day	2.05% [1.81%,2.31%]	1.65% [1.24%,2.19%]	2.16% [1.89%,2.47%]	0.76 [0.55,1.04]	0.0903	0.86 [0.60,1.23]	0.4119	0.89 [0.63,1.27]	0.5292
	90 Day	4.01% [3.68%,4.38%]	3.52% [2.89%,4.27%]	4.16% [3.77%,4.58%]	0.84 [0.67,1.05]	0.1176	0.97 [0.76,1.25]	0.8388	0.99 [0.77,1.26]	0.9197
	180 Day	6.78% [6.34%,7.25%]	5.12% [4.35%,6.01%]	7.28% [6.77%,7.84%]	0.70 [0.58,0.84]	0.0001	0.89 [0.73,1.09]	0.2729	0.87 [0.71,1.06]	0.1597
	1 Year	10.72% [10.17%,11.31%]	8.16% [7.17%,9.27%]	11.50% [10.85%,12.19%]	0.70 [0.61,0.81]	<.0001	0.87 [0.74,1.02]	0.0933	0.85 [0.73,1.00]	0.0520
Bleeding	30 Day	1.64% [1.44%,1.87%]	1.12% [0.79%,1.57%]	1.79% [1.55%,2.07%]	0.61 [0.42,0.89]	0.0094	0.92 [0.61,1.41]	0.7115	0.97 [0.64,1.45]	0.8737
	90 Day	2.30% [2.06%,2.58%]	1.63% [1.22%,2.16%]	2.50% [2.21%,2.83%]	0.64 [0.47,0.87]	0.0049	0.96 [0.68,1.37]	0.8268	0.99 [0.70,1.39]	0.9376
	180 Day	2.73% [2.46%,3.03%]	1.86% [1.42%,2.42%]	2.99% [2.67%,3.35%]	0.61 [0.46,0.82]	0.0011	0.94 [0.67,1.30]	0.6967	0.95 [0.69,1.31]	0.7739
	1 Year	3.77% [3.44%,4.12%]	2.79% [2.23%,3.48%]	4.06% [3.67%,4.48%]	0.67 [0.53,0.86]	0.0016	1.03 [0.78,1.36]	0.8584	1.02 [0.78,1.33]	0.8990
Stroke	30 Day	0.27% [0.20%,0.38%]	0.10% [0.03%,0.31%]	0.33% [0.23%,0.46%]	0.31 [0.10,1.01]	0.0525	0.27 [0.06,1.21]	0.0871	0.53 [0.15,1.87]	0.3206
	90 Day	0.52% [0.41%,0.66%]	0.28% [0.14%,0.56%]	0.59% [0.45%,0.76%]	0.47 [0.23,0.99]	0.0477	0.93 [0.38,2.28]	0.8730	1.21 [0.53,2.77]	0.6561
	180 Day	0.71% [0.58%,0.88%]	0.40% [0.22%,0.72%]	0.81% [0.65%,1.01%]	0.48 [0.26,0.91]	0.0245	1.03 [0.49,2.18]	0.9294	1.14 [0.56,2.30]	0.7246
	1 Year	1.13% [0.95%,1.34%]	0.72% [0.46%,1.12%]	1.25% [1.04%,1.50%]	0.57 [0.35,0.92]	0.0220	1.28 [0.72,2.27]	0.4066	1.33 [0.77,2.32]	0.3040
Def/Prob Stent Thrombosis	30 Day	0.25% [0.17%,0.35%]	0.38% [0.21%,0.69%]	0.21% [0.13%,0.32%]	1.88 [0.90,3.92]	0.0932	1.14 [0.51,2.52]	0.7496	1.06 [0.49,2.32]	0.8789
	90 Day	0.32% [0.23%,0.44%]	0.42% [0.24%,0.74%]	0.29% [0.20%,0.42%]	1.46 [0.74,2.86]	0.2757	0.92 [0.45,1.92]	0.8334	0.83 [0.40,1.69]	0.5996
	180 Day	0.40% [0.30%,0.53%]	0.49% [0.29%,0.83%]	0.37% [0.27%,0.52%]	1.35 [0.73,2.51]	0.3425	0.89 [0.45,1.74]	0.7293	0.81 [0.42,1.55]	0.5165
	1 Year	0.50% [0.39%,0.64%]	0.66% [0.41%,1.04%]	0.45% [0.33%,0.61%]	1.47 [0.85,2.57]	0.1702	0.98 [0.54,1.78]	0.9411	0.85 [0.47,1.53]	0.5934

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.11 Outcomes in Patients with Multivessel Disease

Subgroup: Patients with Multivessel Disease										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 8396)	Prasugrel (N= 1672)	Clopidogrel (N= 6724)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	6.29% [5.79%,6.84%]	4.28% [3.40%,5.38%]	6.80% [6.21%,7.44%]	0.63 [0.49,0.81]	0.0003	0.82 [0.62,1.10]	0.1812	0.87 [0.66,1.15]	0.3310
	90 Day	9.93% [9.29%,10.61%]	7.70% [6.49%,9.12%]	10.49% [9.76%,11.27%]	0.72 [0.59,0.87]	0.0008	0.98 [0.78,1.22]	0.8384	1.03 [0.83,1.27]	0.8052
	180 Day	15.22% [14.43%,16.04%]	10.68% [9.24%,12.32%]	16.37% [15.46%,17.32%]	0.64 [0.54,0.75]	<.0001	0.91 [0.75,1.09]	0.2987	0.90 [0.76,1.08]	0.2691
	1 Year	21.72% [20.79%,22.67%]	14.70% [13.01%,16.59%]	23.49% [22.43%,24.59%]	0.60 [0.52,0.69]	<.0001	0.84 [0.72,0.98]	0.0314	0.83 [0.71,0.97]	0.0157
Death	30 Day	1.33% [1.10%,1.61%]	0.18% [0.06%,0.57%]	1.62% [1.34%,1.96%]	0.11 [0.04,0.36]	0.0002	0.38 [0.11,1.28]	0.1197	0.40 [0.12,1.31]	0.1286
	90 Day	2.68% [2.34%,3.06%]	0.77% [0.44%,1.35%]	3.15% [2.75%,3.62%]	0.24 [0.13,0.43]	<.0001	0.69 [0.37,1.31]	0.2577	0.70 [0.38,1.29]	0.2522
	180 Day	4.51% [4.06%,5.00%]	1.45% [0.96%,2.19%]	5.28% [4.75%,5.87%]	0.27 [0.17,0.41]	<.0001	0.71 [0.44,1.13]	0.1450	0.68 [0.43,1.08]	0.1047
	1 Year	6.94% [6.38%,7.54%]	2.16% [1.53%,3.04%]	8.15% [7.48%,8.88%]	0.26 [0.18,0.37]	<.0001	0.68 [0.46,1.00]	0.0484	0.63 [0.43,0.92]	0.0160
Myocardial infarction	30 Day	3.09% [2.74%,3.49%]	2.11% [1.52%,2.93%]	3.34% [2.93%,3.80%]	0.64 [0.45,0.91]	0.0132	0.85 [0.57,1.26]	0.4143	0.87 [0.59,1.28]	0.4885

Subgroup: Patients with Multivessel Disease										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 8396)	Prasugrel (N= 1672)	Clopidogrel (N= 6724)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
	90 Day	3.86% [3.46%,4.30%]	2.37% [1.74%,3.23%]	4.24% [3.77%,4.76%]	0.56 [0.40,0.79]	0.0009	0.81 [0.56,1.19]	0.2842	0.85 [0.59,1.22]	0.3705
	180 Day	5.07% [4.60%,5.58%]	2.99% [2.26%,3.95%]	5.60% [5.05%,6.20%]	0.54 [0.40,0.73]	<.0001	0.80 [0.57,1.12]	0.1965	0.78 [0.56,1.08]	0.1324
	1 Year	6.17% [5.65%,6.74%]	4.08% [3.20%,5.20%]	6.70% [6.10%,7.37%]	0.60 [0.46,0.78]	0.0001	0.90 [0.67,1.22]	0.4968	0.87 [0.65,1.16]	0.3505
Unplanned Revascularization	30 Day	2.19% [1.89%,2.54%]	1.93% [1.36%,2.73%]	2.26% [1.92%,2.66%]	0.85 [0.58,1.26]	0.4183	0.82 [0.53,1.27]	0.3786	0.83 [0.54,1.27]	0.3880
	90 Day	4.46% [4.03%,4.95%]	4.97% [4.00%,6.17%]	4.33% [3.85%,4.87%]	1.14 [0.89,1.47]	0.3057	1.16 [0.87,1.55]	0.3232	1.18 [0.89,1.56]	0.2515
	180 Day	8.10% [7.50%,8.74%]	7.03% [5.85%,8.43%]	8.38% [7.70%,9.12%]	0.85 [0.69,1.04]	0.1142	0.96 [0.76,1.21]	0.7373	0.93 [0.74,1.16]	0.5085
	1 Year	12.42% [11.67%,13.21%]	10.32% [8.88%,11.99%]	12.97% [12.12%,13.88%]	0.80 [0.67,0.95]	0.0114	0.88 [0.72,1.07]	0.1922	0.84 [0.70,1.02]	0.0757
Bleeding	30 Day	2.02% [1.73%,2.34%]	1.57% [1.07%,2.29%]	2.13% [1.81%,2.51%]	0.74 [0.49,1.13]	0.1614	1.13 [0.70,1.83]	0.6245	1.20 [0.75,1.92]	0.4377
	90 Day	2.90% [2.55%,3.29%]	2.09% [1.49%,2.91%]	3.10% [2.71%,3.56%]	0.68 [0.47,0.97]	0.0349	1.00 [0.66,1.51]	0.9906	1.04 [0.70,1.55]	0.8400
	180 Day	3.41% [3.03%,3.83%]	2.22% [1.61%,3.07%]	3.71% [3.27%,4.21%]	0.61 [0.43,0.86]	0.0053	0.91 [0.61,1.34]	0.6218	0.92 [0.63,1.35]	0.6780
	1 Year	4.58% [4.13%,5.08%]	3.10% [2.34%,4.09%]	4.96% [4.44%,5.55%]	0.62 [0.46,0.85]	0.0024	0.89 [0.64,1.25]	0.5126	0.89 [0.64,1.24]	0.5063
Stroke	30 Day	0.41% [0.30%,0.58%]	0.24% [0.09%,0.64%]	0.46% [0.32%,0.65%]	0.53 [0.19,1.51]	0.2364	0.53 [0.14,2.00]	0.3459	0.93 [0.30,2.89]	0.9011
	90 Day	0.70% [0.54%,0.91%]	0.44% [0.21%,0.91%]	0.77% [0.58%,1.02%]	0.56 [0.26,1.25]	0.1566	0.83 [0.31,2.22]	0.7038	1.09 [0.46,2.61]	0.8383
	180 Day	0.94% [0.75%,1.19%]	0.57% [0.30%,1.10%]	1.04% [0.81%,1.33%]	0.55 [0.27,1.11]	0.0931	0.94 [0.40,2.19]	0.8878	1.05 [0.49,2.25]	0.9089
	1 Year	1.43% [1.18%,1.73%]	0.94% [0.55%,1.58%]	1.56% [1.27%,1.91%]	0.59 [0.34,1.04]	0.0689	1.04 [0.53,2.04]	0.9058	1.11 [0.59,2.07]	0.7487
Def/Prob Stent Thrombosis	30 Day	0.20% [0.12%,0.33%]	0.19% [0.06%,0.57%]	0.20% [0.12%,0.35%]	0.92 [0.26,3.21]	0.8912	0.68 [0.18,2.62]	0.5751	0.73 [0.19,2.76]	0.6380
	90 Day	0.32% [0.21%,0.47%]	0.25% [0.09%,0.66%]	0.33% [0.22%,0.51%]	0.75 [0.26,2.19]	0.6009	0.65 [0.21,2.05]	0.4629	0.66 [0.21,2.04]	0.4648
	180 Day	0.44% [0.32%,0.62%]	0.38% [0.17%,0.85%]	0.46% [0.32%,0.67%]	0.84 [0.35,2.02]	0.6926	0.63 [0.24,1.63]	0.3425	0.61 [0.24,1.55]	0.3000
	1 Year	0.54% [0.39%,0.73%]	0.60% [0.31%,1.15%]	0.52% [0.37%,0.74%]	1.13 [0.54,2.37]	0.7502	0.85 [0.38,1.90]	0.6880	0.81 [0.36,1.78]	0.5943

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.12 Outcomes in Patients without Multivessel Disease

Subgroup: Patients without Multivessel Disease										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 11518)	Prasugrel (N= 2386)	Clopidogrel (N= 9132)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	5.12% [4.72%,5.56%]	2.91% [2.29%,3.70%]	5.70% [5.23%,6.21%]	0.50 [0.39,0.65]	<.0001	0.84 [0.62,1.12]	0.2342	0.91 [0.69,1.21]	0.5275
	90 Day	7.95% [7.45%,8.48%]	4.25% [3.48%,5.18%]	8.92% [8.33%,9.55%]	0.47 [0.38,0.58]	<.0001	0.80 [0.63,1.01]	0.0646	0.83 [0.66,1.05]	0.1123
	180 Day	11.43% [10.83%,12.07%]	6.52% [5.55%,7.65%]	12.73% [12.02%,13.47%]	0.49 [0.41,0.59]	<.0001	0.88 [0.72,1.07]	0.1975	0.87 [0.72,1.05]	0.1535
	1 Year	16.75% [16.03%,17.51%]	10.13% [8.90%,11.52%]	18.50% [17.65%,19.38%]	0.52 [0.45,0.60]	<.0001	0.87 [0.74,1.02]	0.0943	0.88 [0.75,1.03]	0.1014

Subgroup: Patients without Multivessel Disease										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 11518)	Prasugrel (N= 2386)	Clopidogrel (N= 9132)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
Death	30 Day	1.27% [1.07%,1.50%]	0.28% [0.12%,0.62%]	1.53% [1.29%,1.82%]	0.18 [0.08,0.40]	<.0001	0.51 [0.21,1.23]	0.1346	0.74 [0.32,1.71]	0.4760
	90 Day	2.15% [1.89%,2.45%]	0.52% [0.29%,0.93%]	2.58% [2.26%,2.95%]	0.20 [0.11,0.36]	<.0001	0.56 [0.29,1.09]	0.0854	0.66 [0.35,1.24]	0.1984
	180 Day	3.11% [2.79%,3.47%]	0.92% [0.59%,1.43%]	3.69% [3.30%,4.13%]	0.24 [0.15,0.38]	<.0001	0.67 [0.41,1.12]	0.1291	0.74 [0.45,1.20]	0.2167
	1 Year	4.64% [4.24%,5.08%]	1.49% [1.04%,2.13%]	5.48% [4.99%,6.01%]	0.26 [0.18,0.38]	<.0001	0.71 [0.47,1.06]	0.0909	0.72 [0.49,1.07]	0.1019
Myocardial infarction	30 Day	2.46% [2.19%,2.77%]	1.23% [0.85%,1.77%]	2.78% [2.46%,3.15%]	0.44 [0.30,0.65]	<.0001	0.76 [0.49,1.19]	0.2275	0.77 [0.50,1.17]	0.2199
	90 Day	3.02% [2.71%,3.36%]	1.56% [1.12%,2.17%]	3.40% [3.04%,3.81%]	0.46 [0.32,0.65]	<.0001	0.87 [0.58,1.29]	0.4860	0.84 [0.58,1.23]	0.3771
	180 Day	3.79% [3.44%,4.17%]	1.96% [1.46%,2.64%]	4.28% [3.86%,4.74%]	0.45 [0.33,0.62]	<.0001	0.89 [0.62,1.28]	0.5343	0.83 [0.59,1.18]	0.2977
	1 Year	5.04% [4.63%,5.49%]	2.81% [2.18%,3.61%]	5.64% [5.15%,6.18%]	0.49 [0.37,0.64]	<.0001	0.89 [0.65,1.21]	0.4506	0.86 [0.64,1.16]	0.3247
Unplanned Revascularization	30 Day	1.94% [1.69%,2.22%]	1.74% [1.27%,2.39%]	1.99% [1.71%,2.32%]	0.87 [0.61,1.24]	0.4477	1.15 [0.76,1.74]	0.5043	1.11 [0.75,1.64]	0.6144
	90 Day	3.71% [3.36%,4.10%]	2.80% [2.18%,3.59%]	3.96% [3.55%,4.41%]	0.71 [0.54,0.93]	0.0133	0.94 [0.69,1.29]	0.7154	0.91 [0.67,1.23]	0.5275
	180 Day	5.98% [5.53%,6.46%]	4.44% [3.63%,5.41%]	6.39% [5.87%,6.96%]	0.69 [0.55,0.86]	0.0011	0.98 [0.77,1.26]	0.9023	0.92 [0.72,1.18]	0.5082
	1 Year	9.69% [9.11%,10.31%]	7.20% [6.16%,8.42%]	10.37% [9.69%,11.08%]	0.69 [0.58,0.82]	<.0001	0.95 [0.78,1.16]	0.6327	0.94 [0.77,1.14]	0.5136
Bleeding	30 Day	2.00% [1.76%,2.28%]	1.19% [0.82%,1.73%]	2.21% [1.93%,2.54%]	0.52 [0.35,0.78]	0.0014	0.88 [0.56,1.38]	0.5720	0.88 [0.57,1.36]	0.5726
	90 Day	2.60% [2.32%,2.92%]	1.86% [1.37%,2.52%]	2.80% [2.47%,3.17%]	0.64 [0.46,0.89]	0.0076	1.08 [0.74,1.57]	0.6844	1.04 [0.73,1.50]	0.8246
	180 Day	3.13% [2.81%,3.48%]	2.16% [1.63%,2.86%]	3.38% [3.02%,3.79%]	0.62 [0.45,0.84]	0.0021	1.03 [0.73,1.46]	0.8615	0.99 [0.70,1.38]	0.9359
	1 Year	4.23% [3.85%,4.64%]	3.06% [2.40%,3.89%]	4.54% [4.10%,5.02%]	0.65 [0.50,0.85]	0.0014	1.03 [0.77,1.40]	0.8291	1.01 [0.76,1.35]	0.9421
Stroke	30 Day	0.38% [0.28%,0.51%]	0.13% [0.04%,0.39%]	0.44% [0.32%,0.61%]	0.30 [0.09,0.97]	0.0444	0.56 [0.16,1.96]	0.3628	0.65 [0.19,2.26]	0.4961
	90 Day	0.62% [0.49%,0.79%]	0.27% [0.12%,0.60%]	0.71% [0.55%,0.92%]	0.38 [0.16,0.88]	0.0246	0.87 [0.35,2.16]	0.7631	0.97 [0.39,2.42]	0.9514
	180 Day	0.89% [0.72%,1.09%]	0.42% [0.22%,0.80%]	1.02% [0.82%,1.26%]	0.41 [0.21,0.82]	0.0118	0.95 [0.45,2.01]	0.8893	1.02 [0.48,2.17]	0.9538
	1 Year	1.45% [1.23%,1.71%]	0.67% [0.40%,1.14%]	1.66% [1.39%,1.98%]	0.41 [0.24,0.71]	0.0016	1.02 [0.56,1.87]	0.9372	1.02 [0.56,1.86]	0.9523
Def/Prob Stent Thrombosis	30 Day	0.27% [0.18%,0.39%]	0.46% [0.25%,0.84%]	0.22% [0.14%,0.34%]	2.11 [0.97,4.56]	0.0591	1.27 [0.54,2.99]	0.5897	1.31 [0.57,3.02]	0.5229
	90 Day	0.34% [0.24%,0.47%]	0.50% [0.28%,0.91%]	0.29% [0.20%,0.44%]	1.73 [0.85,3.53]	0.1327	1.08 [0.49,2.38]	0.8472	1.07 [0.50,2.29]	0.8703
	180 Day	0.39% [0.29%,0.53%]	0.50% [0.28%,0.91%]	0.36% [0.25%,0.52%]	1.42 [0.71,2.85]	0.3176	0.95 [0.44,2.04]	0.8868	0.92 [0.44,1.94]	0.8333
	1 Year	0.48% [0.37%,0.64%]	0.66% [0.39%,1.12%]	0.44% [0.31%,0.61%]	1.54 [0.83,2.87]	0.1751	1.03 [0.52,2.04]	0.9378	0.97 [0.50,1.89]	0.9308

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.13 Outcomes in Patients with no previous TIA or Stroke

Subgroup: ACS-PCI patients with no prior transient ischemic attack (TIA) or stroke										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 17529)	Prasugrel (N= 3870)	Clopidogrel (N=13659)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	5.27% [4.94%,5.62%]	3.46% [2.92%,4.10%]	5.78% [5.39%,6.20%]	0.59 [0.49,0.72]	<.0001	0.85 [0.69,1.05]	0.1325	0.90 [0.74,1.11]	0.3327
	90 Day	8.23% [7.82%,8.66%]	5.53% [4.83%,6.33%]	9.00% [8.51%,9.51%]	0.60 [0.52,0.70]	<.0001	0.88 [0.74,1.04]	0.1416	0.92 [0.78,1.08]	0.3068
	180 Day	11.96% [11.47%,12.48%]	7.93% [7.09%,8.88%]	13.12% [12.53%,13.73%]	0.59 [0.52,0.67]	<.0001	0.90 [0.78,1.04]	0.1445	0.89 [0.77,1.02]	0.0954
	1 Year	17.32% [16.73%,17.94%]	11.51% [10.48%,12.63%]	18.99% [18.29%,19.71%]	0.58 [0.52,0.65]	<.0001	0.85 [0.76,0.96]	0.0100	0.85 [0.75,0.95]	0.0050
Death	30 Day	1.10% [0.95%,1.27%]	0.25% [0.13%,0.48%]	1.34% [1.16%,1.56%]	0.18 [0.09,0.36]	<.0001	0.55 [0.27,1.12]	0.0987	0.63 [0.31,1.26]	0.1910
	90 Day	2.06% [1.85%,2.29%]	0.63% [0.41%,0.95%]	2.47% [2.21%,2.76%]	0.25 [0.16,0.38]	<.0001	0.69 [0.43,1.11]	0.1302	0.72 [0.46,1.13]	0.1523
	180 Day	3.15% [2.88%,3.43%]	1.05% [0.76%,1.45%]	3.75% [3.43%,4.11%]	0.27 [0.19,0.38]	<.0001	0.74 [0.51,1.08]	0.1149	0.74 [0.52,1.06]	0.0955
	1 Year	4.74% [4.41%,5.09%]	1.59% [1.21%,2.07%]	5.65% [5.24%,6.08%]	0.27 [0.21,0.36]	<.0001	0.72 [0.53,0.98]	0.0341	0.69 [0.52,0.93]	0.0153
Myocardial infarction	30 Day	2.58% [2.35%,2.83%]	1.62% [1.26%,2.07%]	2.85% [2.58%,3.15%]	0.57 [0.44,0.75]	<.0001	0.83 [0.61,1.13]	0.2453	0.84 [0.63,1.13]	0.2469
	90 Day	3.18% [2.93%,3.46%]	1.88% [1.49%,2.37%]	3.56% [3.25%,3.89%]	0.53 [0.41,0.68]	<.0001	0.84 [0.64,1.12]	0.2405	0.86 [0.65,1.12]	0.2648
	180 Day	4.01% [3.71%,4.32%]	2.30% [1.86%,2.84%]	4.50% [4.15%,4.88%]	0.51 [0.41,0.65]	<.0001	0.85 [0.65,1.10]	0.2114	0.82 [0.64,1.05]	0.1120
	1 Year	5.05% [4.71%,5.40%]	3.20% [2.67%,3.85%]	5.58% [5.18%,6.01%]	0.56 [0.46,0.69]	<.0001	0.90 [0.72,1.13]	0.3481	0.88 [0.71,1.09]	0.2460
Unplanned Revascularization	30 Day	2.00% [1.80%,2.23%]	1.75% [1.37%,2.23%]	2.08% [1.84%,2.34%]	0.84 [0.64,1.10]	0.2110	0.96 [0.70,1.31]	0.7854	0.97 [0.72,1.31]	0.8404
	90 Day	3.98% [3.69%,4.30%]	3.54% [2.98%,4.21%]	4.11% [3.77%,4.48%]	0.86 [0.70,1.04]	0.1233	1.00 [0.80,1.25]	0.9986	1.02 [0.82,1.26]	0.8720
	180 Day	6.64% [6.26%,7.05%]	5.33% [4.63%,6.13%]	7.03% [6.58%,7.50%]	0.76 [0.65,0.89]	0.0006	0.95 [0.80,1.14]	0.6103	0.91 [0.77,1.09]	0.3089
	1 Year	10.45% [9.96%,10.96%]	8.25% [7.36%,9.23%]	11.10% [10.53%,11.69%]	0.74 [0.65,0.84]	<.0001	0.91 [0.78,1.05]	0.1789	0.88 [0.76,1.01]	0.0739
Bleeding	30 Day	1.95% [1.76%,2.17%]	1.20% [0.89%,1.60%]	2.17% [1.94%,2.43%]	0.55 [0.40,0.75]	0.0002	0.85 [0.60,1.22]	0.3760	0.87 [0.62,1.22]	0.4088
	90 Day	2.67% [2.44%,2.93%]	1.80% [1.42%,2.29%]	2.92% [2.64%,3.22%]	0.61 [0.47,0.79]	0.0002	0.95 [0.71,1.28]	0.7448	0.95 [0.72,1.27]	0.7381
	180 Day	3.16% [2.90%,3.44%]	2.05% [1.63%,2.56%]	3.48% [3.18%,3.82%]	0.58 [0.45,0.74]	<.0001	0.91 [0.69,1.20]	0.4977	0.90 [0.69,1.18]	0.4641
	1 Year	4.21% [3.91%,4.54%]	2.92% [2.40%,3.53%]	4.59% [4.23%,4.98%]	0.62 [0.50,0.77]	<.0001	0.93 [0.73,1.18]	0.5473	0.93 [0.74,1.17]	0.5498
Stroke	30 Day	0.32% [0.24%,0.41%]	0.18% [0.09%,0.38%]	0.36% [0.27%,0.47%]	0.52 [0.24,1.16]	0.1092	0.62 [0.24,1.58]	0.3168	0.86 [0.36,2.03]	0.7310
	90 Day	0.46% [0.36%,0.57%]	0.27% [0.15%,0.50%]	0.51% [0.40%,0.65%]	0.54 [0.28,1.04]	0.0658	0.69 [0.32,1.48]	0.3424	0.85 [0.41,1.73]	0.6488
	180 Day	0.57% [0.46%,0.70%]	0.39% [0.23%,0.66%]	0.62% [0.49%,0.77%]	0.63 [0.36,1.11]	0.1101	0.87 [0.45,1.67]	0.6727	0.98 [0.53,1.82]	0.9517
	1 Year	0.88% [0.74%,1.04%]	0.64% [0.42%,0.98%]	0.94% [0.78%,1.14%]	0.68 [0.43,1.07]	0.0955	1.02 [0.60,1.72]	0.9391	1.04 [0.63,1.71]	0.8797
Def/Prob Stent Thrombosis	30 Day	0.25% [0.19%,0.34%]	0.36% [0.21%,0.62%]	0.22% [0.15%,0.32%]	1.62 [0.84,3.13]	0.1486	1.12 [0.54,2.31]	0.7688	1.11 [0.55,2.25]	0.7668
	90 Day	0.34% [0.26%,0.44%]	0.39% [0.23%,0.65%]	0.32% [0.24%,0.44%]	1.22 [0.66,2.24]	0.5242	0.89 [0.46,1.74]	0.7373	0.87 [0.45,1.66]	0.6636
	180 Day	0.41% [0.32%,0.53%]	0.45% [0.27%,0.73%]	0.40% [0.30%,0.53%]	1.13 [0.64,1.99]	0.6705	0.82 [0.44,1.52]	0.5271	0.79 [0.44,1.45]	0.4502
	1 Year	0.49% [0.39%,0.61%]	0.61% [0.40%,0.93%]	0.45% [0.35%,0.59%]	1.34 [0.81,2.22]	0.2539	0.94 [0.55,1.63]	0.8349	0.89 [0.52,1.52]	0.6713

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.14 Outcomes in Patients with no previous TIA or Stroke and <75y or ≥ 75 years with DM or prior MI

Subgroup: ACS-PCI patients with no prior TIA or stroke and <75 or =>75 years of age and have diabetes mellitus or a history of MI										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 15891)	Prasugrel (N= 3765)	Clopidogrel (N=12126)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	5.16% [4.82%,5.52%]	3.45% [2.90%,4.10%]	5.69% [5.28%,6.13%]	0.60 [0.50,0.73]	<.0001	0.85 [0.68,1.06]	0.1470	0.91 [0.74,1.12]	0.3651
	90 Day	8.07% [7.64%,8.52%]	5.55% [4.84%,6.36%]	8.86% [8.35%,9.40%]	0.62 [0.53,0.72]	<.0001	0.89 [0.75,1.06]	0.1806	0.93 [0.78,1.09]	0.3623
	180 Day	11.79% [11.27%,12.34%]	7.96% [7.10%,8.92%]	13.00% [12.38%,13.65%]	0.60 [0.53,0.68]	<.0001	0.91 [0.78,1.05]	0.1818	0.90 [0.78,1.03]	0.1237
	1 Year	17.16% [16.54%,17.80%]	11.51% [10.47%,12.65%]	18.94% [18.20%,19.71%]	0.59 [0.53,0.65]	<.0001	0.86 [0.76,0.97]	0.0141	0.86 [0.76,0.96]	0.0105
Death	30 Day	0.98% [0.84%,1.16%]	0.26% [0.13%,0.49%]	1.21% [1.02%,1.43%]	0.21 [0.11,0.41]	<.0001	0.63 [0.30,1.30]	0.2093	0.71 [0.35,1.45]	0.3475
	90 Day	1.81% [1.61%,2.04%]	0.61% [0.40%,0.94%]	2.19% [1.93%,2.48%]	0.28 [0.18,0.43]	<.0001	0.76 [0.46,1.24]	0.2668	0.78 [0.48,1.25]	0.3007

Subgroup: ACS-PCI patients with no prior TIA or stroke and <75 or =>75 years of age and have diabetes mellitus or a history of MI										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 15891)	Prasugrel (N= 3765)	Clopidogrel (N=12126)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
	180 Day	2.85% [2.59%,3.14%]	1.02% [0.73%,1.42%]	3.44% [3.11%,3.80%]	0.29 [0.20,0.41]	<.0001	0.77 [0.52,1.13]	0.1844	0.77 [0.53,1.11]	0.1642
	1 Year	4.32% [3.99%,4.67%]	1.50% [1.14%,1.98%]	5.21% [4.80%,5.66%]	0.28 [0.21,0.38]	<.0001	0.74 [0.54,1.02]	0.0653	0.72 [0.53,0.99]	0.0412
Myocardial infarction	30 Day	2.55% [2.31%,2.81%]	1.58% [1.23%,2.04%]	2.85% [2.56%,3.17%]	0.56 [0.42,0.74]	<.0001	0.82 [0.60,1.12]	0.2100	0.84 [0.62,1.13]	0.2467
	90 Day	3.14% [2.87%,3.43%]	1.85% [1.46%,2.34%]	3.54% [3.22%,3.90%]	0.53 [0.41,0.68]	<.0001	0.83 [0.62,1.11]	0.2183	0.85 [0.64,1.13]	0.2687
	180 Day	3.93% [3.63%,4.26%]	2.26% [1.82%,2.80%]	4.46% [4.09%,4.87%]	0.51 [0.40,0.64]	<.0001	0.83 [0.64,1.08]	0.1741	0.81 [0.62,1.05]	0.1053
	1 Year	5.00% [4.65%,5.37%]	3.12% [2.58%,3.76%]	5.59% [5.17%,6.05%]	0.55 [0.45,0.68]	<.0001	0.87 [0.69,1.09]	0.2290	0.86 [0.69,1.08]	0.1845
Unplanned Revascularization	30 Day	2.07% [1.85%,2.31%]	1.74% [1.36%,2.23%]	2.17% [1.92%,2.46%]	0.80 [0.60,1.06]	0.1158	0.93 [0.68,1.29]	0.6805	0.96 [0.71,1.31]	0.8054
	90 Day	4.11% [3.79%,4.45%]	3.58% [3.01%,4.26%]	4.27% [3.91%,4.67%]	0.83 [0.68,1.02]	0.0726	1.00 [0.80,1.25]	0.9910	1.02 [0.82,1.27]	0.8443
	180 Day	6.82% [6.41%,7.25%]	5.42% [4.70%,6.24%]	7.26% [6.78%,7.78%]	0.74 [0.63,0.87]	0.0003	0.96 [0.80,1.15]	0.6771	0.92 [0.77,1.10]	0.3738
	1 Year	10.74% [10.23%,11.28%]	8.36% [7.45%,9.37%]	11.51% [10.90%,12.16%]	0.72 [0.63,0.82]	<.0001	0.91 [0.78,1.05]	0.1989	0.89 [0.77,1.03]	0.1058
Bleeding	30 Day	1.85% [1.65%,2.08%]	1.23% [0.92%,1.64%]	2.04% [1.80%,2.31%]	0.60 [0.43,0.82]	0.0014	0.92 [0.64,1.32]	0.6430	0.93 [0.66,1.32]	0.6796
	90 Day	2.48% [2.24%,2.74%]	1.71% [1.33%,2.19%]	2.72% [2.43%,3.03%]	0.62 [0.47,0.81]	0.0006	0.94 [0.69,1.28]	0.6934	0.96 [0.71,1.30]	0.8061
	180 Day	2.93% [2.67%,3.21%]	1.92% [1.52%,2.44%]	3.24% [2.93%,3.59%]	0.59 [0.45,0.76]	<.0001	0.89 [0.67,1.19]	0.4389	0.90 [0.68,1.20]	0.4749
	1 Year	3.90% [3.59%,4.23%]	2.72% [2.22%,3.32%]	4.27% [3.91%,4.68%]	0.62 [0.50,0.78]	<.0001	0.89 [0.70,1.15]	0.3853	0.91 [0.71,1.16]	0.4398
Stroke	30 Day	0.27% [0.20%,0.37%]	0.19% [0.09%,0.39%]	0.30% [0.21%,0.42%]	0.64 [0.28,1.44]	0.2815	0.65 [0.25,1.69]	0.3779	0.86 [0.35,2.06]	0.7278
	90 Day	0.42% [0.33%,0.54%]	0.28% [0.15%,0.51%]	0.46% [0.35%,0.61%]	0.61 [0.31,1.20]	0.1519	0.72 [0.33,1.56]	0.4051	0.84 [0.40,1.73]	0.6312
	180 Day	0.53% [0.43%,0.67%]	0.40% [0.24%,0.68%]	0.57% [0.45%,0.73%]	0.70 [0.39,1.25]	0.2274	0.91 [0.47,1.75]	0.7724	0.98 [0.52,1.84]	0.9521
	1 Year	0.82% [0.68%,0.98%]	0.66% [0.44%,1.01%]	0.87% [0.70%,1.07%]	0.76 [0.48,1.21]	0.2528	1.07 [0.63,1.82]	0.8023	1.06 [0.63,1.76]	0.8336
Def/Prob Stent Thrombosis	30 Day	0.23% [0.16%,0.32%]	0.37% [0.21%,0.63%]	0.19% [0.12%,0.29%]	1.98 [0.99,3.95]	0.0536	1.24 [0.58,2.62]	0.5804	1.18 [0.57,2.45]	0.6508
	90 Day	0.32% [0.24%,0.43%]	0.40% [0.24%,0.67%]	0.30% [0.21%,0.42%]	1.35 [0.72,2.52]	0.3502	0.94 [0.48,1.85]	0.8580	0.89 [0.46,1.73]	0.7393
	180 Day	0.41% [0.31%,0.53%]	0.46% [0.28%,0.75%]	0.39% [0.29%,0.53%]	1.20 [0.68,2.14]	0.5312	0.86 [0.46,1.60]	0.6316	0.81 [0.44,1.49]	0.5040
	1 Year	0.49% [0.39%,0.62%]	0.62% [0.41%,0.96%]	0.45% [0.34%,0.59%]	1.40 [0.84,2.35]	0.1958	0.98 [0.56,1.71]	0.9504	0.91 [0.53,1.56]	0.7313

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.15 Outcomes in Patients with low body weight (<60 kgs)

In and Out of Hospital Post-Procedural Events by Therapy at PCI. Subgroup: Low Body Weight (<60 kgs)										
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 6304)	Prasugrel (N= 989)	Clopidogrel (N= 5315)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	6.48% [5.89%,7.13%]	4.28% [3.17%,5.77%]	6.90% [6.23%,7.63%]	0.61 [0.44,0.85]	0.0029	0.96 [0.67,1.38]	0.8259	0.99 [0.70,1.41]	0.9690
	90 Day	10.00% [9.26%,10.79%]	6.61% [5.19%,8.40%]	10.64% [9.81%,11.53%]	0.61 [0.47,0.79]	0.0002	0.95 [0.71,1.28]	0.7408	0.98 [0.74,1.31]	0.9158
	180 Day	14.89% [13.99%,15.84%]	9.98% [8.20%,12.12%]	15.83% [14.82%,16.89%]	0.61 [0.49,0.76]	<.0001	0.97 [0.77,1.24]	0.8337	0.96 [0.76,1.21]	0.7146
	1 Year	21.06% [20.01%,22.16%]	13.48% [11.40%,15.92%]	22.50% [21.32%,23.73%]	0.57 [0.47,0.69]	<.0001	0.90 [0.73,1.11]	0.3116	0.87 [0.71,1.06]	0.1702
Death	30 Day	1.72% [1.42%,2.09%]	0.42% [0.16%,1.12%]	1.97% [1.62%,2.39%]	0.21 [0.08,0.58]	0.0025	0.50 [0.18,1.43]	0.1970	0.58 [0.21,1.60]	0.2905
	90 Day	3.02% [2.61%,3.49%]	0.76% [0.36%,1.58%]	3.45% [2.97%,4.00%]	0.22 [0.10,0.46]	<.0001	0.45 [0.19,1.04]	0.0603	0.57 [0.26,1.23]	0.1499
	180 Day	4.82% [4.29%,5.41%]	1.46% [0.85%,2.50%]	5.46% [4.84%,6.14%]	0.26 [0.15,0.45]	<.0001	0.57 [0.31,1.05]	0.0730	0.64 [0.36,1.15]	0.1348
	1 Year	6.97% [6.33%,7.68%]	1.94% [1.21%,3.11%]	7.93% [7.18%,8.76%]	0.24 [0.15,0.39]	<.0001	0.53 [0.32,0.90]	0.0177	0.54 [0.33,0.90]	0.0171

In and Out of Hospital Post-Procedural Events by Therapy at PCI.
Subgroup: Low Body Weight (<60 kgs)

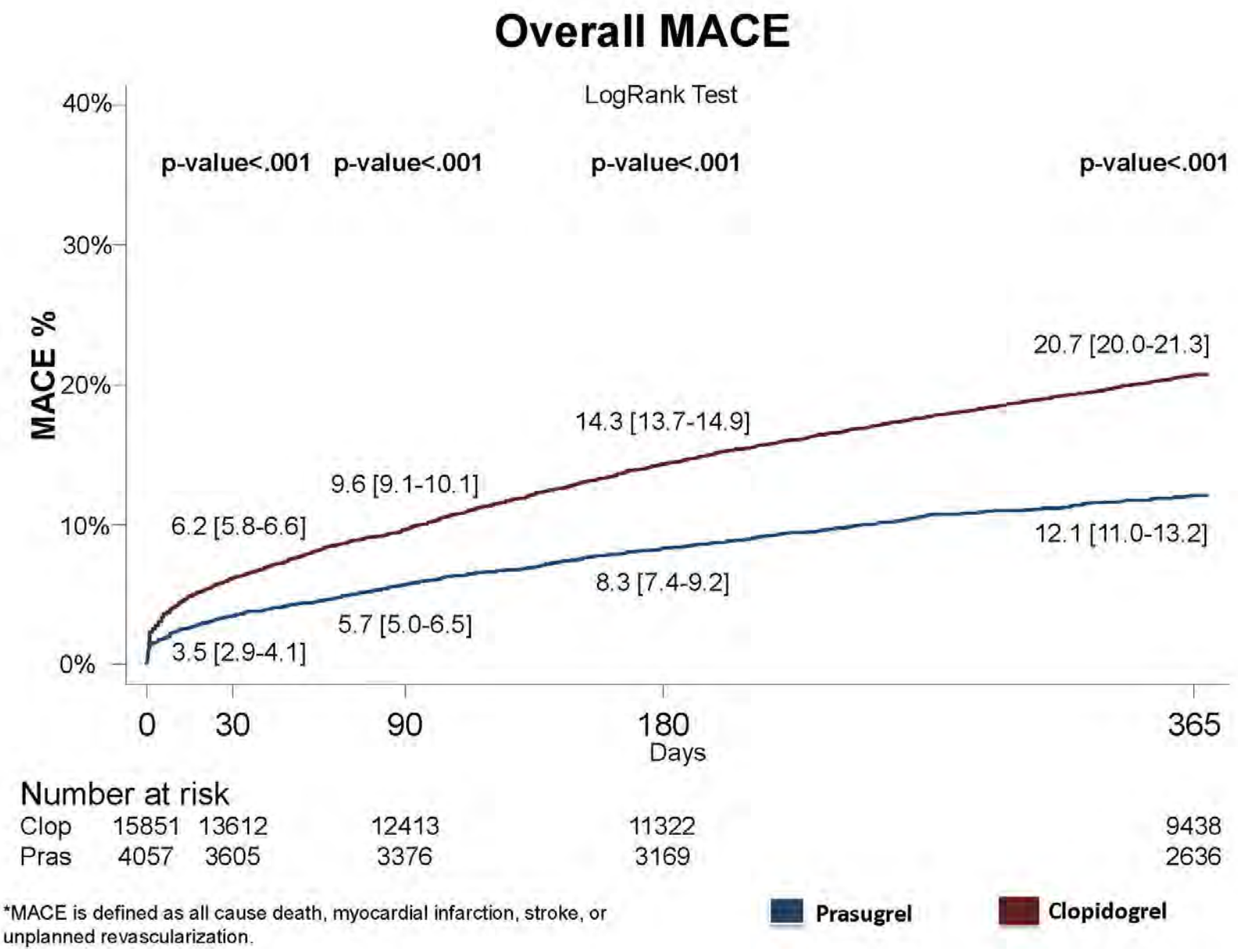
					Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]	
		Overall (N = 6304)	Prasugrel (N= 989)	Clopidogrel (N= 5315)	HR [CI%]	P-value	HR[CI%]	P-value	HR [CI%]	P-value
Myocardial infarction	30 Day	2.97% [2.57%,3.43%]	1.45% [0.86%,2.44%]	3.26% [2.80%,3.78%]	0.44 [0.26,0.76]	0.0034	0.74 [0.40,1.38]	0.3417	0.71 [0.40,1.27]	0.2477
	90 Day	3.86% [3.40%,4.38%]	1.78% [1.11%,2.85%]	4.25% [3.73%,4.85%]	0.42 [0.25,0.68]	0.0005	0.79 [0.45,1.38]	0.4014	0.74 [0.44,1.24]	0.2532
	180 Day	5.04% [4.50%,5.64%]	2.48% [1.66%,3.72%]	5.53% [4.92%,6.21%]	0.44 [0.29,0.68]	0.0002	0.85 [0.53,1.36]	0.4879	0.73 [0.46,1.14]	0.1668
	1 Year	6.52% [5.90%,7.20%]	3.84% [2.76%,5.34%]	7.03% [6.33%,7.81%]	0.53 [0.37,0.75]	0.0004	1.01 [0.68,1.49]	0.9789	0.88 [0.60,1.28]	0.4901
Unplanned Revascularization	30 Day	2.06% [1.72%,2.45%]	2.33% [1.54%,3.52%]	2.00% [1.65%,2.43%]	1.17 [0.74,1.86]	0.5068	1.44 [0.85,2.47]	0.1784	1.34 [0.80,2.24]	0.2724
	90 Day	4.09% [3.61%,4.64%]	4.34% [3.20%,5.87%]	4.04% [3.52%,4.64%]	1.08 [0.77,1.52]	0.6621	1.36 [0.92,2.01]	0.1197	1.29 [0.89,1.89]	0.1791
	180 Day	7.12% [6.46%,7.83%]	6.80% [5.33%,8.66%]	7.18% [6.47%,7.97%]	0.96 [0.73,1.26]	0.7524	1.25 [0.92,1.69]	0.1559	1.14 [0.85,1.54]	0.3783
	1 Year	11.15% [10.33%,12.04%]	9.64% [7.85%,11.80%]	11.46% [10.55%,12.45%]	0.85 [0.67,1.07]	0.1637	1.09 [0.84,1.41]	0.5249	1.01 [0.79,1.30]	0.9327
Bleeding	30 Day	2.81% [2.43%,3.25%]	2.05% [1.32%,3.15%]	2.95% [2.53%,3.45%]	0.69 [0.44,1.10]	0.1233	1.11 [0.65,1.88]	0.7079	1.07 [0.64,1.77]	0.7968
	90 Day	3.66% [3.21%,4.16%]	2.93% [2.03%,4.22%]	3.79% [3.30%,4.36%]	0.77 [0.52,1.14]	0.1887	1.21 [0.77,1.89]	0.4092	1.14 [0.74,1.75]	0.5628
	180 Day	4.38% [3.88%,4.93%]	3.17% [2.23%,4.51%]	4.61% [4.06%,5.23%]	0.69 [0.47,1.01]	0.0557	1.05 [0.68,1.60]	0.8358	0.98 [0.65,1.47]	0.9178
	1 Year	5.72% [5.14%,6.36%]	3.92% [2.84%,5.39%]	6.07% [5.42%,6.79%]	0.65 [0.46,0.92]	0.0142	0.90 [0.61,1.32]	0.5859	0.89 [0.61,1.29]	0.5310
Stroke	30 Day	0.64% [0.47%,0.88%]	0.40% [0.15%,1.07%]	0.69% [0.49%,0.96%]	0.61 [0.22,1.71]	0.3428	0.99 [0.31,3.19]	0.9864	1.18 [0.39,3.61]	0.7706
	90 Day	0.95% [0.73%,1.23%]	0.52% [0.22%,1.24%]	1.03% [0.78%,1.36%]	0.51 [0.21,1.29]	0.1557	0.76 [0.28,2.09]	0.5977	0.90 [0.34,2.41]	0.8390
	180 Day	1.34% [1.07%,1.67%]	0.75% [0.36%,1.57%]	1.45% [1.15%,1.84%]	0.53 [0.24,1.14]	0.1048	0.85 [0.36,2.00]	0.7094	0.96 [0.42,2.20]	0.9199
	1 Year	2.12% [1.77%,2.55%]	0.99% [0.52%,1.91%]	2.34% [1.94%,2.83%]	0.44 [0.22,0.86]	0.0171	0.79 [0.38,1.65]	0.5332	0.81 [0.39,1.67]	0.5697
Def/Prob Stent Thrombosis	30 Day	0.22% [0.13%,0.38%]	0.21% [0.05%,0.85%]	0.22% [0.12%,0.40%]	0.95 [0.21,4.29]	0.9481	0.82 [0.14,4.66]	0.8223	0.97 [0.19,4.90]	0.9708
	90 Day	0.35% [0.22%,0.54%]	0.32% [0.10%,1.00%]	0.35% [0.22%,0.56%]	0.92 [0.27,3.13]	0.8912	0.89 [0.22,3.56]	0.8701	1.00 [0.27,3.73]	0.9985
	180 Day	0.44% [0.30%,0.66%]	0.32% [0.10%,1.00%]	0.47% [0.31%,0.71%]	0.70 [0.21,2.35]	0.5698	0.66 [0.18,2.42]	0.5316	0.64 [0.18,2.28]	0.4945
	1 Year	0.53% [0.37%,0.76%]	0.57% [0.24%,1.37%]	0.52% [0.35%,0.78%]	1.07 [0.41,2.81]	0.8884	0.91 [0.32,2.59]	0.8560	0.93 [0.33,2.58]	0.8830

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

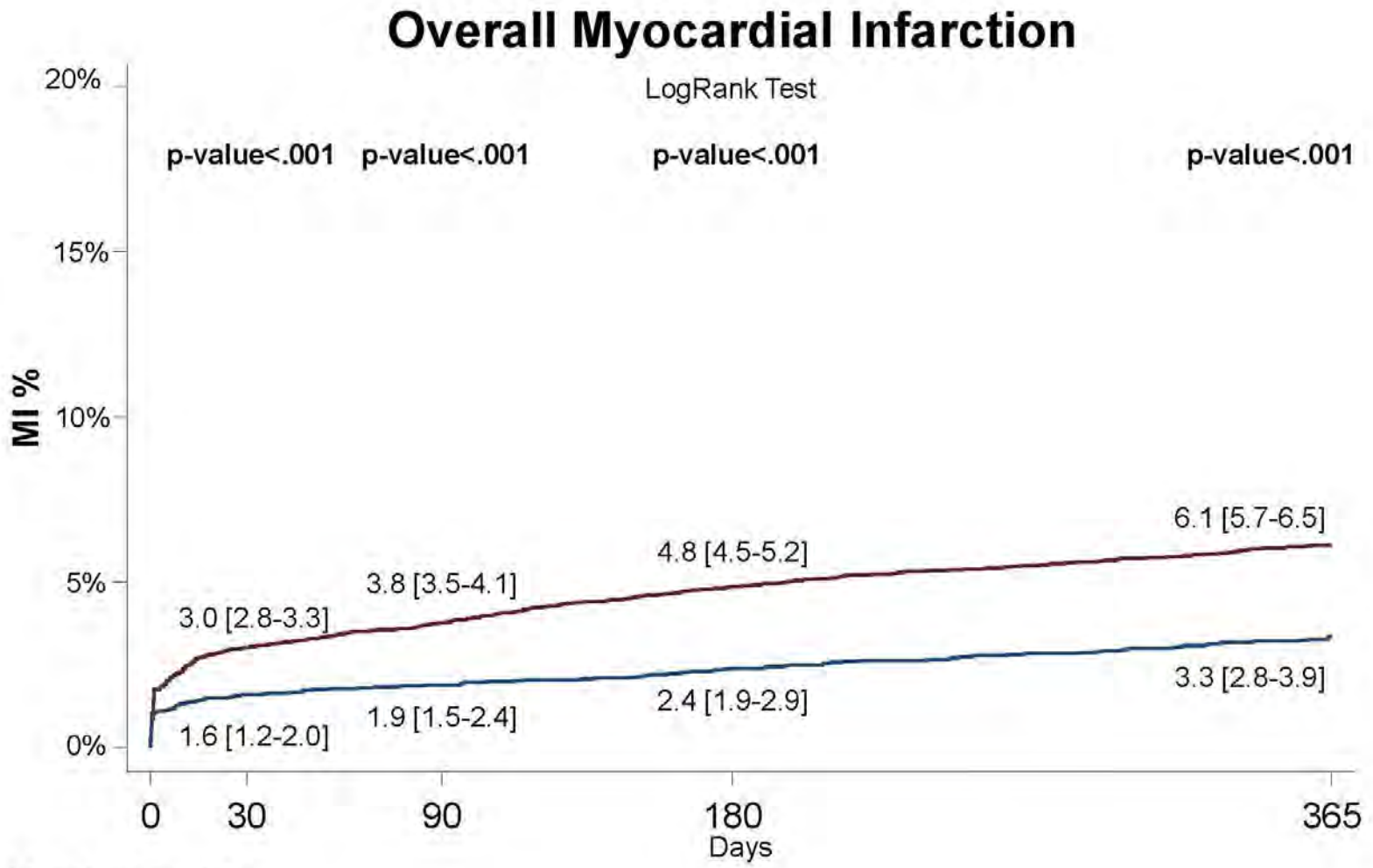
[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

13.16 Overall Unadjusted MACE

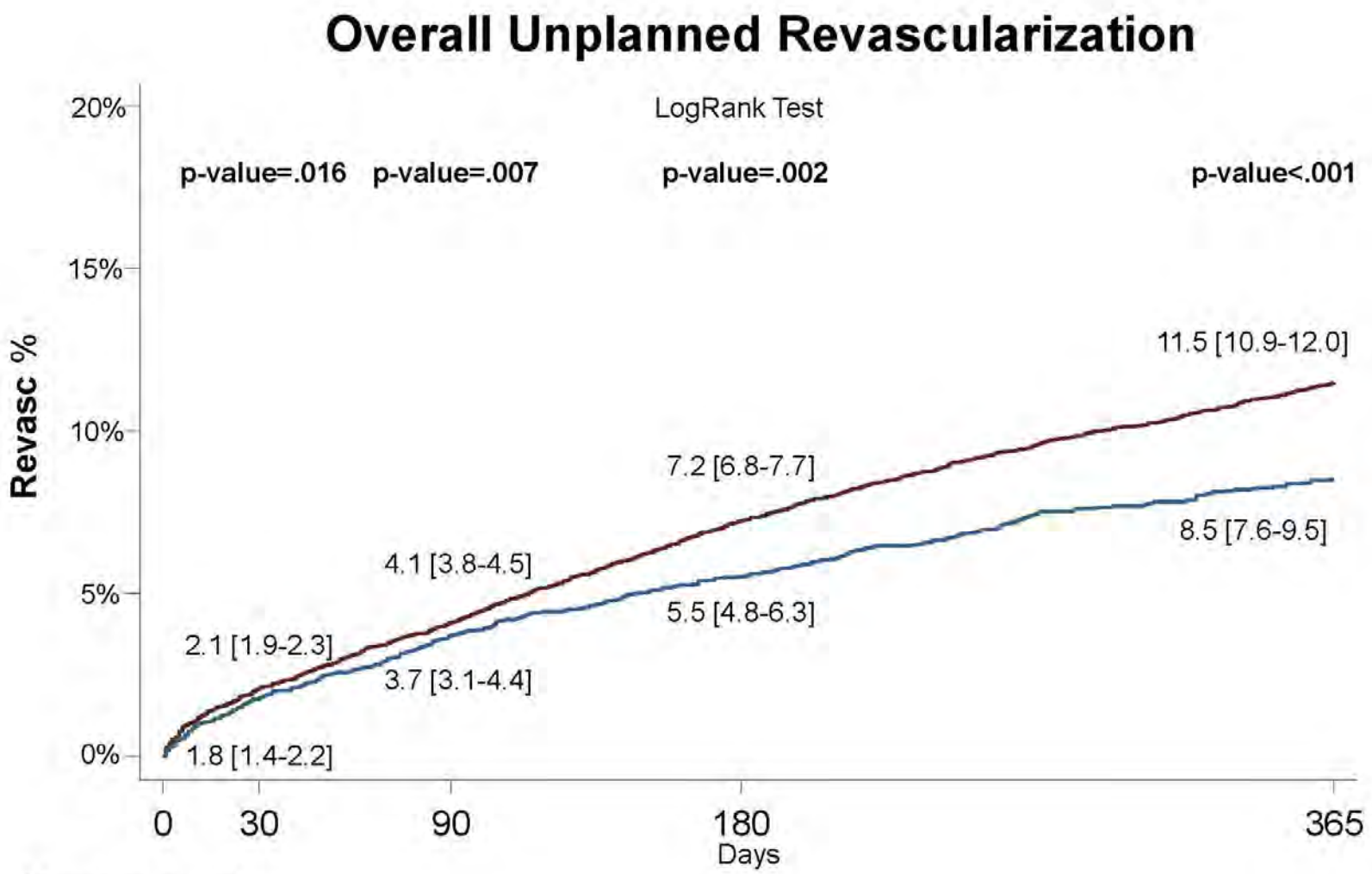


*MACE is defined as all cause death, myocardial infarction, stroke, or unplanned revascularization.

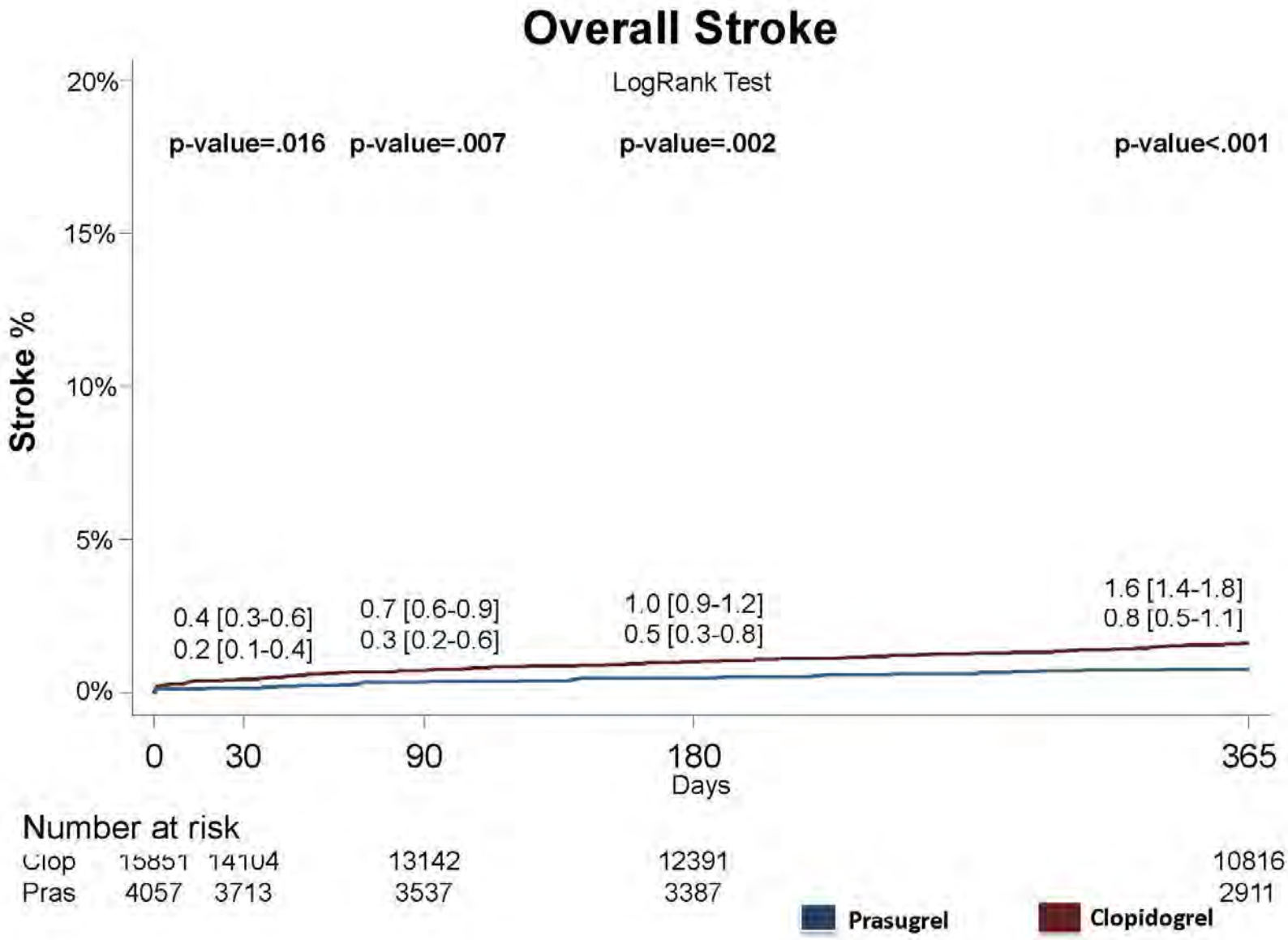
13.17 Overall Unadjusted Myocardial Infarction



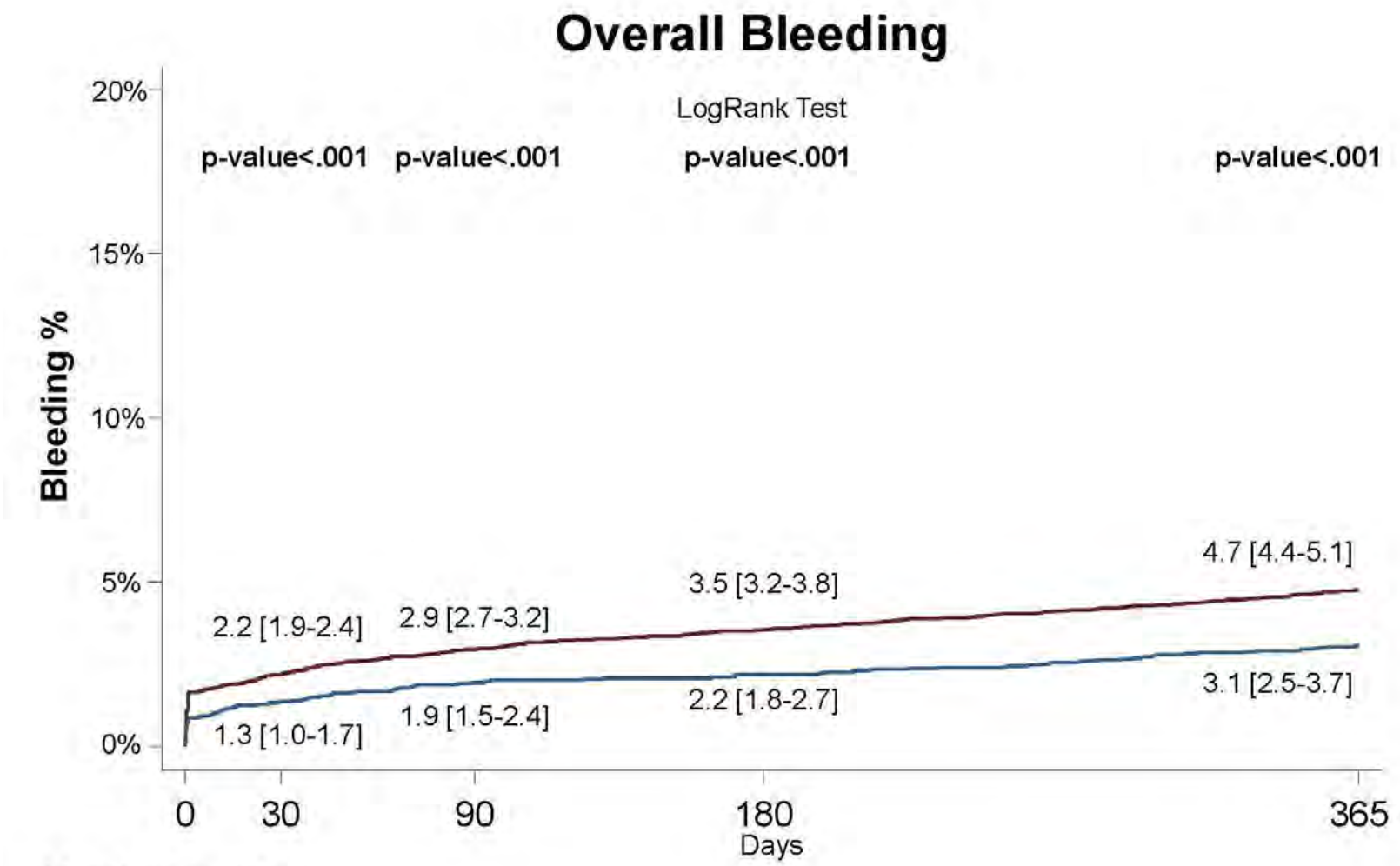
13.18 Overall Unadjusted Unplanned Revascularization



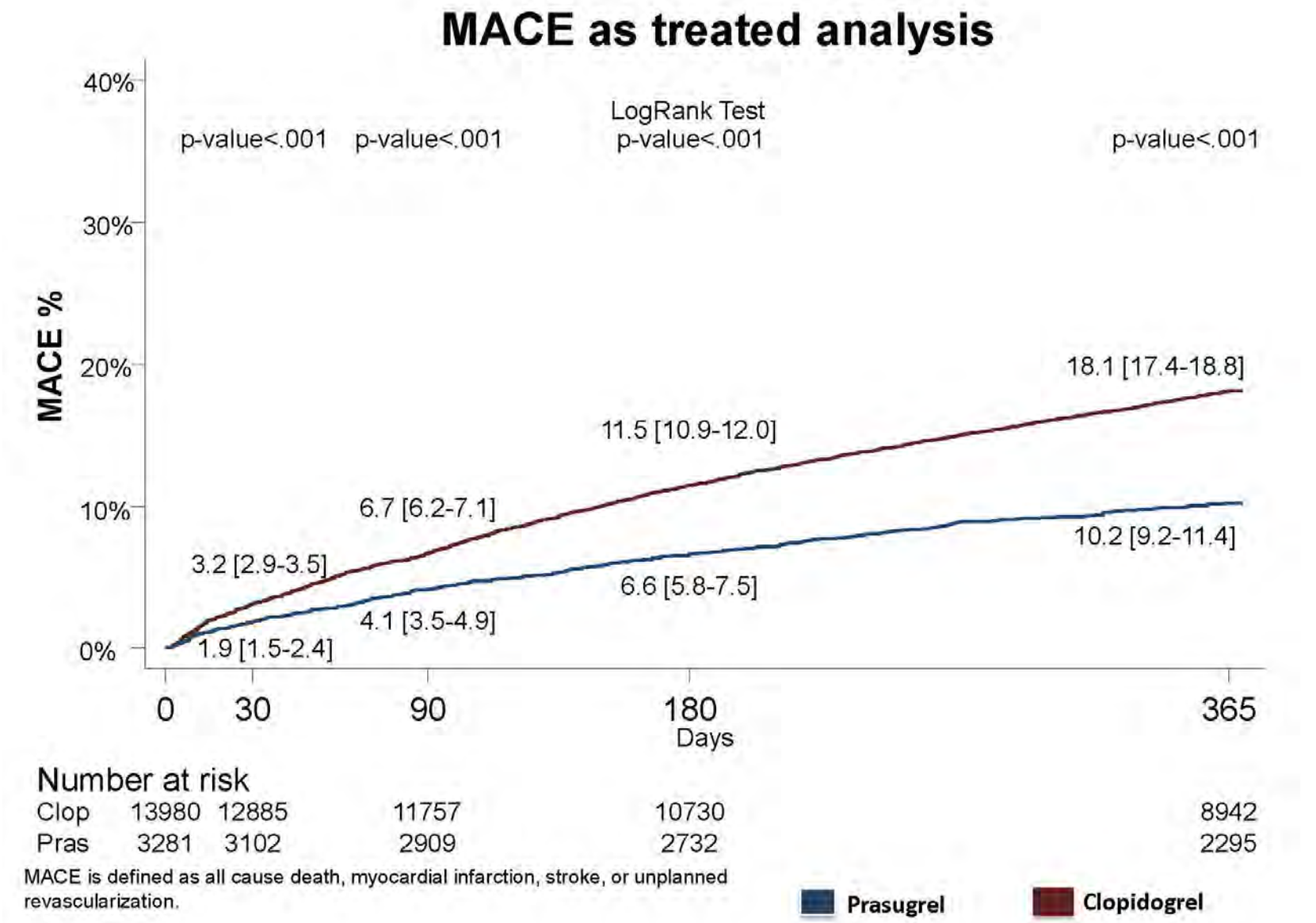
13.19 Overall Unadjusted Stroke



13.20 Overall Unadjusted Bleeding



13.21 Unadjusted MACE As-Treated Analysis



MACE is defined as all cause death, myocardial infarction, stroke, or unplanned revascularization.

13.22 Sensitivity Analysis for Cumulative MACE After Excluding Patients Lost to Follow-up

Lost to Follow-up Sensitivity Analysis									
		Unadjusted		Propensity Stratified[1]		Covariate Adjusted[2]		IPW	
		HR [CI%]	P-value	HR [CI%]	P-value	HR [CI%]	P-value	HR [CI%]	P-value
MACE	30 Day	0.56 [0.47,0.67]	<.0001	0.84 [0.68,1.03]	0.0871	0.90 [0.74,1.09]	0.2884	0.85 [0.65,1.11]	0.2377
	90 Day	0.58 [0.50,0.67]	<.0001	0.89 [0.76,1.05]	0.1783	0.94 [0.80,1.10]	0.4229	0.93 [0.76,1.15]	0.5310
	180 Day	0.56 [0.49,0.63]	<.0001	0.90 [0.78,1.03]	0.1196	0.89 [0.78,1.02]	0.0845	0.96 [0.80,1.14]	0.6299
	1 Year	0.55 [0.50,0.61]	<.0001	0.86 [0.77,0.96]	0.0092	0.85 [0.77,0.95]	0.0046	0.91 [0.78,1.06]	0.2154
Death	30 Day	0.15 [0.08,0.29]	<.0001	0.47 [0.23,0.95]	0.0363	0.57 [0.29,1.13]	0.1048	0.29 [0.12,0.67]	0.0037
	90 Day	0.21 [0.14,0.33]	<.0001	0.63 [0.40,1.00]	0.0481	0.68 [0.44,1.06]	0.0866	0.52 [0.28,0.94]	0.0302
	180 Day	0.25 [0.18,0.34]	<.0001	0.70 [0.49,0.98]	0.0385	0.71 [0.51,0.99]	0.0414	0.67 [0.43,1.06]	0.0853
	1 Year	0.26 [0.20,0.33]	<.0001	0.69 [0.52,0.91]	0.0092	0.67 [0.51,0.88]	0.0036	0.63 [0.43,0.91]	0.0130
Myocardial infarction	30 Day	0.53 [0.41,0.69]	<.0001	0.81 [0.60,1.09]	0.1593	0.82 [0.62,1.09]	0.1719	1.01 [0.69,1.48]	0.9642
	90 Day	0.50 [0.40,0.64]	<.0001	0.84 [0.64,1.11]	0.2167	0.84 [0.65,1.10]	0.2005	1.08 [0.76,1.54]	0.6664
	180 Day	0.49 [0.39,0.61]	<.0001	0.85 [0.66,1.08]	0.1811	0.80 [0.63,1.01]	0.0595	1.09 [0.80,1.50]	0.5874
	1 Year	0.53 [0.44,0.64]	<.0001	0.90 [0.73,1.11]	0.3319	0.86 [0.70,1.06]	0.1641	1.12 [0.85,1.48]	0.4080
Unplanned Revascularization	30 Day	0.86 [0.66,1.12]	0.2579	0.99 [0.74,1.34]	0.9699	0.98 [0.74,1.31]	0.9173	1.19 [0.81,1.75]	0.3686
	90 Day	0.90 [0.75,1.08]	0.2510	1.06 [0.86,1.31]	0.5816	1.05 [0.86,1.29]	0.6214	1.21 [0.92,1.58]	0.1705
	180 Day	0.76 [0.65,0.88]	0.0004	0.98 [0.83,1.16]	0.8003	0.93 [0.79,1.09]	0.3694	1.07 [0.86,1.32]	0.5570
	1 Year	0.73 [0.65,0.83]	<.0001	0.92 [0.80,1.06]	0.2531	0.89 [0.78,1.02]	0.0893	1.00 [0.84,1.20]	0.9831
Bleeding	30 Day	0.61 [0.45,0.81]	0.0008	0.98 [0.71,1.36]	0.9185	1.00 [0.73,1.37]	0.9966	1.01 [0.64,1.59]	0.9715
	90 Day	0.65 [0.51,0.83]	0.0006	1.05 [0.79,1.38]	0.7536	1.04 [0.80,1.36]	0.7763	1.00 [0.69,1.47]	0.9851
	180 Day	0.61 [0.48,0.76]	<.0001	0.97 [0.75,1.26]	0.8321	0.95 [0.74,1.23]	0.7024	0.91 [0.64,1.31]	0.6208
	1 Year	0.63 [0.52,0.77]	<.0001	0.97 [0.78,1.22]	0.8222	0.96 [0.77,1.19]	0.7194	0.86 [0.63,1.17]	0.3242
Stroke	30 Day	0.40 [0.18,0.87]	0.0205	0.55 [0.22,1.38]	0.2038	0.78 [0.34,1.80]	0.5643	0.21 [0.09,0.53]	0.0008
	90 Day	0.46 [0.26,0.82]	0.0083	0.86 [0.44,1.68]	0.6595	1.04 [0.55,1.94]	0.9088	1.40 [0.58,3.42]	0.4535
	180 Day	0.47 [0.29,0.76]	0.0024	0.96 [0.55,1.67]	0.8730	1.03 [0.61,1.77]	0.9016	1.41 [0.66,3.00]	0.3696
	1 Year	0.48 [0.33,0.72]	0.0003	1.03 [0.66,1.62]	0.8867	1.06 [0.69,1.64]	0.7755	1.21 [0.65,2.25]	0.5449
Def/Prob Stent Thrombosis	30 Day	1.62 [0.85,3.09]	0.1463	1.05 [0.52,2.15]	0.8848	1.05 [0.53,2.11]	0.8848	1.27 [0.52,3.14]	0.5977
	90 Day	1.28 [0.71,2.29]	0.4111	0.93 [0.49,1.76]	0.8203	0.88 [0.47,1.65]	0.6931	1.10 [0.49,2.44]	0.8185
	180 Day	1.13 [0.66,1.94]	0.6651	0.83 [0.46,1.49]	0.5319	0.78 [0.44,1.39]	0.4008	1.01 [0.49,2.10]	0.9738
	1 Year	1.33 [0.83,2.14]	0.2380	0.96 [0.57,1.62]	0.8853	0.88 [0.53,1.47]	0.6333	1.08 [0.58,2.03]	0.8059

Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.

[1] Stratified by propensity and adjusted for age, stent type, stent length, CAD presentation, ckd, hemoglobin, center, previous mi

[2] Adjusted for age, procedural bivalirudin, smoking, hypertension, ckd, center, previous cvd, prev mi, cat length, CAD presentation, stent type, diabetes, stent diameter, and hemoglobin

30 Day: 18706 patients were included (Prasugrel= 3817, Clopidogrel=14889)

90 Day: 18312 patients were included (Prasugrel= 3741, Clopidogrel=14571)

180 Day: 17480 patients were included (Prasugrel= 3597, Clopidogrel=13883)

365 Day: 16918 patients were included (Prasugrel= 3482, Clopidogrel=13436)

13.23 Rates at 90 Days for Propensity Stratum

Stratum	Total number within stratum	Number (%) of Prasugrel	Number (%) of Clopidogrel	MACE			Bleeding		
				Rate at 90 days for Prasugrel	Rate at 90 days for Clopidogrel	Unadjusted HR	Rate at 90 days for Prasugrel	Rate at 90 days for Clopidogrel	Unadjusted HR
1	5294	159 (3.0)	5135 (97.0)	17.2 [12.1-24.3]	15.2 [14.3-16.3]	1.13 [0.77-1.67]	4.5 [2.2-9.2]	4.6 [4.1-5.3]	0.99 [0.47-2.10]
2	1568	105 (6.7)	1463 (93.3)	9.1 [4.8-16.7]	8.8 [7.4-10.4]	1.03 [0.52-2.02]	2.1 [0.5-8.1]	2.9 [2.2-4.0]	0.70 [0.17-2.88]
3	1764	159 (9.0)	1605 (91.0)	9.6 [5.8-15.6]	7.3 [6.0-8.7]	1.29 [0.74-2.25]	3.3 [1.4-7.9]	2.5 [1.8-3.4]	1.32 [0.52-3.36]
4	1961	276 (14.1)	1685 (85.9)	6.5 [4.1-10.2]	6.0 [5.0-7.3]	1.06 [0.63-1.77]	1.5 [0.6-4.0]	2.2 [1.6-3.1]	0.67 [0.24-1.87]
5	1960	408 (20.8)	1552 (79.2)	4.7 [3.0-7.3]	6.1 [4.9-7.4]	0.75 [0.46-1.26]	2.3 [1.2-4.4]	2.1 [1.5-3.0]	1.08 [0.52-2.28]
6	1568	423 (27.0)	1145 (73.0)	4.6 [2.9-7.1]	5.0 [3.9-6.5]	0.89 [0.52-1.51]	0.8 [0.3-2.4]	1.4 [0.8-2.3]	0.54 [0.15-1.85]
7	1569	535 (34.1)	1034 (65.9)	3.4 [2.2-5.5]	5.8 [4.5-7.4]	0.59 [0.34-1.01]	1.0 [0.4-2.4]	1.5 [0.9-2.5]	0.64 [0.23-1.76]
8	1372	549 (40.0)	823 (60.0)	4.3 [2.9-6.5]	6.3 [4.8-8.2]	0.71 [0.43-1.17]	1.6 [0.8-3.1]	1.2 [0.6-2.3]	1.33 [0.51-3.46]
9	1176	564 (48.0)	612 (52.0)	6.3 [4.5-8.7]	5.9 [4.3-8.2]	1.05 [0.65-1.69]	3.1 [2.0-5.0]	1.9 [1.0-3.3]	1.70 [0.80-3.63]
10	1372	839 (61.1)	533 (38.9)	4.7 [3.4-6.4]	6.7 [4.8-9.2]	0.68[0.43-1.09]	1.6 [0.9-2.8]	1.9 [1.0-3.5]	0.83 [0.36-1.88]

Propensity Matched Analysis

In and Out of Hospital Post-Procedural Events by Therapy at PCI. Propensity Matching						
					Unadjusted	
		Overall (N = 8008)	Prasugrel (N= 4004)	Clopidogrel (N= 4004)	HR [CI%]	P-value
MACE	30 Day	3.75% [3.35%,4.20%]	3.41% [2.88%,4.04%]	4.09% [3.51%,4.77%]	0.83 [0.66,1.05]	0.1153
	90 Day	5.91% [5.39%,6.46%]	5.66% [4.97%,6.45%]	6.15% [5.42%,6.97%]	0.91 [0.76,1.10]	0.3317
	180 Day	8.69% [8.07%,9.36%]	8.21% [7.36%,9.15%]	9.17% [8.28%,10.16%]	0.89 [0.76,1.04]	0.1373
	1 Year	12.87% [12.11%,13.68%]	11.93% [10.90%,13.05%]	13.81% [12.71%,14.99%]	0.86 [0.75,0.98]	0.0214
Death	30 Day	0.33% [0.23%,0.50%]	0.24% [0.12%,0.46%]	0.43% [0.26%,0.70%]	0.56 [0.25,1.27]	0.1640
	90 Day	0.70% [0.53%,0.92%]	0.60% [0.40%,0.92%]	0.79% [0.55%,1.14%]	0.76 [0.43,1.32]	0.3217
	180 Day	1.38% [1.13%,1.68%]	1.13% [0.83%,1.54%]	1.64% [1.27%,2.11%]	0.69 [0.46,1.03]	0.0666
	1 Year	2.11% [1.80%,2.48%]	1.77% [1.38%,2.27%]	2.45% [1.99%,3.03%]	0.71 [0.51,0.99]	0.0454
Myocardial infarction	30 Day	1.80% [1.53%,2.12%]	1.59% [1.24%,2.03%]	2.02% [1.62%,2.51%]	0.78 [0.56,1.09]	0.1483
	90 Day	2.07% [1.77%,2.41%]	1.89% [1.51%,2.37%]	2.24% [1.82%,2.76%]	0.84 [0.61,1.14]	0.2609
	180 Day	2.61% [2.27%,3.00%]	2.36% [1.92%,2.90%]	2.86% [2.37%,3.45%]	0.82 [0.62,1.09]	0.1653
	1 Year	3.43% [3.04%,3.88%]	3.29% [2.76%,3.93%]	3.57% [3.02%,4.23%]	0.90 [0.71,1.16]	0.4267
Unplanned Revascularization	30 Day	1.83% [1.55%,2.16%]	1.79% [1.41%,2.27%]	1.88% [1.49%,2.37%]	0.95 [0.68,1.33]	0.7764
	90 Day	3.65% [3.24%,4.11%]	3.72% [3.15%,4.38%]	3.58% [3.03%,4.24%]	1.03 [0.81,1.31]	0.7858
	180 Day	5.58% [5.08%,6.14%]	5.50% [4.80%,6.30%]	5.67% [4.96%,6.49%]	0.97 [0.80,1.18]	0.7648
	1 Year	8.70% [8.06%,9.39%]	8.40% [7.53%,9.38%]	8.99% [8.08%,10.00%]	0.94 [0.80,1.10]	0.4318
Bleeding	30 Day	1.42% [1.18%,1.71%]	1.31% [1.00%,1.72%]	1.54% [1.19%,1.97%]	0.85 [0.58,1.23]	0.3889
	90 Day	1.90% [1.61%,2.23%]	1.92% [1.53%,2.41%]	1.87% [1.49%,2.35%]	1.01 [0.73,1.40]	0.9444
	180 Day	2.10% [1.80%,2.45%]	2.16% [1.74%,2.67%]	2.05% [1.64%,2.55%]	1.04 [0.76,1.41]	0.8243
	1 Year	2.94% [2.57%,3.35%]	3.05% [2.54%,3.67%]	2.82% [2.33%,3.41%]	1.07 [0.81,1.39]	0.6399
Stroke	30 Day	0.23% [0.14%,0.36%]	0.15% [0.07%,0.33%]	0.31% [0.17%,0.54%]	0.50 [0.19,1.33]	0.1648

In and Out of Hospital Post-Procedural Events by Therapy at PCI. Propensity Matching						
					Unadjusted	
		Overall (N = 8008)	Prasugrel (N= 4004)	Clopidogrel (N= 4004)	HR [CI%]	P-value
	90 Day	0.34% [0.23%,0.50%]	0.32% [0.18%,0.56%]	0.36% [0.22%,0.61%]	0.86 [0.40,1.85]	0.6915
	180 Day	0.47% [0.34%,0.66%]	0.46% [0.29%,0.74%]	0.48% [0.30%,0.77%]	0.94 [0.49,1.83]	0.8576
	1 Year	0.80% [0.61%,1.04%]	0.77% [0.53%,1.12%]	0.82% [0.57%,1.19%]	0.93 [0.55,1.57]	0.7824
Def/Prob Stent Thrombosis	30 Day	0.31% [0.21%,0.47%]	0.34% [0.20%,0.58%]	0.29% [0.16%,0.52%]	1.18 [0.53,2.63]	0.6886
	90 Day	0.40% [0.28%,0.57%]	0.39% [0.24%,0.65%]	0.40% [0.24%,0.66%]	1.00 [0.49,2.04]	0.9952
	180 Day	0.51% [0.37%,0.71%]	0.45% [0.28%,0.73%]	0.58% [0.38%,0.88%]	0.81 [0.43,1.53]	0.5114
	1 Year	0.64% [0.48%,0.85%]	0.64% [0.42%,0.96%]	0.64% [0.43%,0.96%]	1.00 [0.56,1.78]	0.9956
Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.						

13.24 Equipoise Analysis

Equipoise Analysis						
					Unadjusted	
		Overall (N = 4445)	Prasugrel (N= 914)	Clopidogrel (N= 3531)	HR [CI%]	P-value
MACE	30 Day	3.66% [3.14%,4.27%]	2.82% [1.92%,4.15%]	3.88% [3.28%,4.59%]	0.73 [0.47,1.11]	0.1436
	90 Day	6.46% [5.75%,7.25%]	5.33% [4.02%,7.06%]	6.75% [5.94%,7.66%]	0.78 [0.57,1.07]	0.1296
	180 Day	10.11% [9.21%,11.09%]	8.04% [6.38%,10.11%]	10.65% [9.62%,11.77%]	0.75 [0.58,0.97]	0.0298
	1 Year	15.36% [14.26%,16.54%]	12.72% [10.58%,15.26%]	16.04% [14.79%,17.39%]	0.78 [0.63,0.96]	0.0201
Death	30 Day	0.62% [0.42%,0.91%]	0.34% [0.11%,1.05%]	0.69% [0.46%,1.04%]	0.50 [0.15,1.65]	0.2531
	90 Day	1.42% [1.10%,1.83%]	0.82% [0.39%,1.71%]	1.58% [1.20%,2.07%]	0.52 [0.24,1.14]	0.1028
	180 Day	2.05% [1.66%,2.54%]	1.08% [0.56%,2.06%]	2.31% [1.84%,2.90%]	0.47 [0.23,0.93]	0.0313
	1 Year	3.15% [2.64%,3.75%]	2.05% [1.26%,3.33%]	3.44% [2.84%,4.15%]	0.58 [0.34,0.98]	0.0438
Myocardial infarction	30 Day	1.78% [1.43%,2.22%]	1.23% [0.68%,2.21%]	1.92% [1.51%,2.44%]	0.64 [0.34,1.21]	0.1681
	90 Day	2.13% [1.74%,2.61%]	1.46% [0.85%,2.50%]	2.31% [1.85%,2.88%]	0.64 [0.35,1.14]	0.1311
	180 Day	2.84% [2.37%,3.39%]	1.60% [0.95%,2.68%]	3.16% [2.61%,3.82%]	0.52 [0.30,0.91]	0.0210
	1 Year	3.69% [3.15%,4.33%]	2.30% [1.47%,3.60%]	4.05% [3.42%,4.80%]	0.57 [0.35,0.92]	0.0207
Unplanned Revascularization	30 Day	1.46% [1.14%,1.88%]	1.04% [0.54%,1.99%]	1.58% [1.20%,2.06%]	0.66 [0.32,1.33]	0.2431
	90 Day	3.48% [2.96%,4.10%]	3.21% [2.21%,4.64%]	3.56% [2.97%,4.26%]	0.89 [0.59,1.36]	0.5891
	180 Day	6.49% [5.75%,7.31%]	5.56% [4.18%,7.38%]	6.73% [5.89%,7.67%]	0.82 [0.60,1.14]	0.2372
	1 Year	10.33% [9.40%,11.35%]	8.91% [7.09%,11.15%]	10.70% [9.64%,11.87%]	0.82 [0.64,1.07]	0.1447
Bleeding	30 Day	1.35% [1.05%,1.74%]	1.02% [0.53%,1.96%]	1.44% [1.09%,1.89%]	0.69 [0.34,1.41]	0.3076
	90 Day	2.10% [1.71%,2.58%]	1.74% [1.05%,2.87%]	2.19% [1.75%,2.75%]	0.77 [0.44,1.34]	0.3611
	180 Day	2.75% [2.29%,3.30%]	2.00% [1.25%,3.21%]	2.94% [2.41%,3.58%]	0.68 [0.40,1.13]	0.1354
	1 Year	3.89% [3.33%,4.55%]	2.85% [1.90%,4.26%]	4.16% [3.51%,4.93%]	0.68 [0.43,1.05]	0.0829
Stroke	30 Day	0.14% [0.06%,0.32%]	0.23% [0.06%,0.90%]	0.12% [0.05%,0.32%]	1.90 [0.35,10.40]	0.4569
	90 Day	0.22% [0.11%,0.42%]	0.23% [0.06%,0.90%]	0.22% [0.10%,0.46%]	1.08 [0.23,5.22]	0.9200
	180 Day	0.27% [0.15%,0.49%]	0.35% [0.11%,1.09%]	0.25% [0.13%,0.50%]	1.42 [0.38,5.37]	0.6015
	1 Year	0.73% [0.50%,1.07%]	1.04% [0.52%,2.08%]	0.65% [0.42%,1.03%]	1.62 [0.71,3.71]	0.2508
Def/Prob Stent Thrombosis	30 Day	0.19% [0.10%,0.38%]	0.34% [0.11%,1.06%]	0.15% [0.06%,0.36%]	2.29 [0.55,9.57]	0.2573
	90 Day	0.29% [0.17%,0.51%]	0.34% [0.11%,1.06%]	0.28% [0.14%,0.53%]	1.27 [0.34,4.67]	0.7240
	180 Day	0.29% [0.17%,0.51%]	0.34% [0.11%,1.06%]	0.28% [0.14%,0.53%]	1.27 [0.34,4.67]	0.7240

Equipoise Analysis						
					Unadjusted	
		Overall (N = 4445)	Prasugrel (N= 914)	Clopidogrel (N= 3531)	HR [CI%]	P-value
	1 Year	0.35% [0.21%,0.59%]	0.34% [0.11%,1.06%]	0.35% [0.19%,0.63%]	1.04 [0.29,3.73]	0.9515
Note: MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.						