Ticagrelor or Prasugrel in Patients with Acute Coronary Syndromes

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Risk of bias table

trial	design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Sch√ºpke S, 2019	RCT	+	+	+	+

Trial summaries

n	Participants	Interventions	Outcomes	punchline	finding
? ? ?	Patients with Acute Coronary Syndromes, patients who presented with acute coronary syndromes and for whom invasive evaluation was planned to receive either, patients with acute coronary syndromes	ticagrelor, ticagrelor or prasugrel, prasugrel, Ticagrelor or Prasugrel	composite of death, myocardial infarction, or stroke at 1 year, bleeding	There were no sig- nificant differences in baseline characteristics between patients with complete 1-year follow-up and those with incomplete 1-year follow-up, ex-	‚Äï no diff

Characteristics of studies

Sch√ºpke S, 2019

Population	1. Similar Cox propor-Ticagrelor or Pr asugrel in Acute Coronary Syndromes tional-hazards models were used for the analysis of prespecified subgroups defined according to age (<75 years or ‚â•75 years), sex (male or fe- male), smoking status (active smoker or not an active smoker), weight (<60 kg or ‚â•60 kg), the presence of diabetes mellitus (yes or no), renal function (dichotomized at the median creatinine

	value), cardiogenic shock (yes or no), clinical pre- sentation (unstable angina, NSTEMI, or STEMI), and management strategy (PCI, coronary-artery bypass grafting [CABG], or conservative treatment). 2. Patients who met all the inclusion criteria and none of the exclusion criteria were randomly assigned in consecutive order to either ticagrelor or prasugrel, with a randomization ratio of 1:1. 3. A reduced maintenance dose of 5 mg daily was recom- mended in patients who were 75 years of age or older and in those who had a body weight of less than 60 kg.
Interventio n	1. m e dicine Trial Protocol Therapy with ticagrelor was started at a loading dose of 180 mg and continued at a maintenance dose of 90 mg twice daily. 2. Therapy with prasugrel was started at a load- ing dose of 60 mg and continued at a mainte- nance dose of 10 mg once per day. 3. Patients who were assigned to ticagrelor received the loading dose as soon as possible after randomization.
Outcomes	1. The primary end point was the composite of death, myocardial infarction, or stroke at 1 year. 2. Secondary end points in- cluded the safety end point, which was the inci- dence of bleeding at 1 year (type 3, 4, or 5 on the Bleeding Academic Research Consortium [BARC] scale, which ranges from 0 to 5, with higher values indicating more severe bleeding), 11 the incidence of the individual components of the primary end point at 1 year, and the incidence of definite or probable stent thrombosis at 1 year. 3. The primary end point was the composite of death, myocardial infarction, or stroke at 1 year after randomization.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Randomization In each participating center, treatment assign- ments were made with the use of sealed, opaque envelopes containing a computer-generated se- quence that had been created at the coordinating center. 2. Randomly permuted block sizes (of four, six, or eight) were used in each stratum. 3. In patients with a coronary angiography- confirmed acute coronary syndrome who were not considered to be candidates for PCI but who were considered to be candidates for conserva- tive therapy, dual antiplatelet therapy (aspirin and the randomly assigned trial medication) was recommended.
Allocation concealment	low	1. Randomization In each participating center, treatment assign- ments were made with the use of sealed, opaque envelopes containing a computer-generated se- quence that had been created at the coordinating center. 2. Patients who met all the inclusion criteria and none of the exclusion criteria were randomly assigned in consecutive order to either ticagrelor or prasugrel, with a randomization ratio of 1:1. 3. Com- mercially available ticagrelor or prasugrel tablets were prescribed by the treating physician and purchased by the patients.
Blinding of participants and personnel	low	1. All pri- mary and secondary end points were adjudicated and classified according to source data (e.g. dis- charge letters, laboratory values, catheterization reports, electrocardiograms, and angiograms) by two members of the event adjudication commit- tee who were unaware of the trial-group assign- ments. 2. The analysis was performed in a modified intention-to-treat population, which included all patients who received at least one dose of the randomly assigned trial drug and were assessed for

		bleeding events up to 7 days after discontinuation of the trial drug. 3. Com- mercially available ticagrelor or prasugrel tablets were prescribed by the treating physician and purchased by the patients.
Blinding of outcome assessment	low	1. The analysis was performed in a modified intention-to-treat population, which included all patients who received at least one dose of the randomly assigned trial drug and were assessed for bleeding events up to 7 days after discontinuation of the trial drug. 2. All pri- mary and secondary end points were adjudicated and classified according to source data (e.g. dis- charge letters, laboratory values, catheterization reports, electrocardiograms, and angiograms) by two members of the event adjudication commit- tee who were unaware of the trial-group assign- ments. 3. Although the ad- judication of end points was performed in a blinded manner, the open-label nature of the trial remains a limitation.

References

1. Sch√ºpke S et al. Ticagrelor or Prasugrel in Patients with Acute Coronary Syndromes N. Engl. J. Med. 2019. 16(11); 1524-1534 PMID: 19717846