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Comparative Evaluation of Prasugrel vs. Ticagrelor in Patients Undergoing Percutaneous Intervention : A Systematic Review and Meta-analysis of Randomized Controlled Trials

Yash Dharmendra Mehta[1], Nishant Babubhai Prajapati[1], Prajapati Vipul Dhanjibhai[2]*, Sood Shikha Vikram[3], Malhotra Supriya Deepak[4]

[1] Resident, Department of Pharmacology,, Smt. NHL Municipal Medical College,, Ahmedabad, Gujarat
[2]Associate professor, Department of Pharmacology, Smt. NHL Municipal Medical College,, Ahmedabad, Gujarat
[3]Associate professor, Department of Pharmacology, Smt. NHL Municipal Medical College,, Ahmedabad, Gujarat
[4]Professor and Head, Department of Pharmacology, Smt. NHL Municipal Medical College, Ahmedabad, Gujarat

Corresponding Author:
Prajapati Vipul Dhanjibhai, Associate professor, Department of Pharmacology, Smt. NHL Municipal Medical College,, Ahmedabad, Gujarat
E-MAIL: yashdmehta108@gmail.com

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ABSTRACT

Background: Coronary artery disease (CAD) remains a leading cause of morbidity and mortality worldwide, necessitating effective antiplatelet therapy in patients undergoing percutaneous coronary intervention (PCI). Prasugrel and Ticagrelor, both potent P2Y12 receptor inhibitors, have emerged as pivotal components of dual antiplatelet therapy in this setting. Despite their widespread use, there is an ongoing debate regarding the comparative efficacy and safety of Prasugrel and Ticagrelor. This systematic review and meta-analysis aim to compare the efficacy and safety of Prasugrel and Ticagrelor in patients undergoing percutaneous intervention (PCI) through an exhaustive examination of randomized controlled trials (RCTs). **Methods:** A comprehensive search of electronic databases, including PubMed, Embase, and Cochrane Library, was conducted to identify relevant RCTs comparing Prasugrel and Ticagrelor in patients undergoing PCI. Data extraction and quality assessment were performed independently by two reviewers. The composite outcomes assessed were those including death, myocardial infarction, and stroke. Secondary outcomes included bleeding events and dyspnea. The random-effects model was employed for the meta-analysis, and subgroup analyses were conducted based on specific patient characteristics and study characteristics. **Results:**Ticagrelor exhibits a significantly increased risk of dyspnea compared to Prasugrel (OR: 13.929, 95% CI: 3.495 to 55.514). The analysis reveals substantial heterogeneity (I2 = 3.734), indicating variability in the effect estimates across studies.No significant difference in bleeding risk is observed between Ticagrelor and Prasugrel (OR: 1.245, 95% CI: 0.996 to 1.555). The analysis suggests moderate heterogeneity (I2 = 1.926).The odds of death are comparable between Ticagrelor and Prasugrel (OR: 1.166, 95% CI: 0.919 to 1.479). Heterogeneity is low (I2 = 1.263).Ticagrelor is associated with a significantly higher risk of MI compared to Prasugrel (OR: 2.732, 95% CI: 2.155 to 3.465). The analysis indicates low heterogeneity (I2 = 8.294).A significantly increased risk of stroke is observed with Ticagrelor compared to Prasugrel (OR: 2.732, 95% CI: 2.155 to 3.465). Heterogeneity is low (I2 = 8.294).The overall findings suggest that Ticagrelor may be associated with a higher risk of dyspnea, MI, and stroke compared to Prasugrel in ACS patients. However, no significant differences are noted in bleeding and death outcomes. **Conclusion**: This systematic review and meta-analysis suggests that Prasugrel and Ticagrelor exhibit similar efficacy and safety profiles in patients undergoing PCI. The findings may aid clinicians in making informed decisions regarding antiplatelet therapy selection based on individual patient characteristics and preferences. Further research, including large-scale RCTs, is warranted to validate these findings and provide more nuanced insights into the comparative effectiveness of Prasugrel and Ticagrelor in specific patient subgroups. **Discussion:** These findings have important for choosing appropriate antiplatelet therapy. Prasugrel and Ticagrelor can be considered as effective treatment options. However, healthcare providers need to carefully consider the safety profiles and potential side effects of these medications when making treatment decisions. The study relied on aggregated data, which might introduce bias. High attrition rates and heterogeneity among studies limit the findings.

KEYWORDS: Meta analysis, Ticagrelor, Prasugrel, Dual anti-

platelet therapy

INTRODUCTION

Coronary artery disease remains a leading cause of morbidity and mortality worldwide, necessitating effective antiplatelet therapy in patients undergoing percutaneous coronary intervention (PCI). Prasugrel and Ticagrelor, both potent P2Y12 receptor inhibitors, have emerged as pivotal components of dual antiplatelet therapy in this setting. [1] Despite their widespread use, there is an ongoing debate regarding the comparative efficacy and safety of Prasugrel and Ticagrelor.

Prasugrel is a thienopyridine, an irreversible antagonist of the ADP P_2Y_{12} receptor. Thienopyridine antiplatelet agents interfere with platelet activation and aggregation induced by ADP. [2]Ticagrelor inhibits platelet activation and aggregation by reversibly interacting with the platelet P_2Y_{12} adenosine diphosphate (ADP) receptor to prevent signal transduction. [3]Previous studies and meta-analyses have attempted to address this question; however, discrepancies in trial designs, patient populations, and outcomes measured have contributed to inconclusive evidence. [4]Furthermore, advancements in interventional cardiology and evolving treatment paradigms underscore the need for a contemporary and comprehensive analysis to guide clinical decision-making.

This systematic review and meta-analysis aim to fill this gap by synthesizing the available evidence from randomized controlled trials (RCTs) comparing Prasugrel and Ticagrelor in patients undergoing PCI. By rigorously evaluating major adverse cardiovascular events (MACE), bleeding events, and other clinically relevant outcomes, we seek to provide clinicians with a nuanced understanding of the relative merits of these two antiplatelet agents. The identification of the optimal P2Y12 receptor inhibitor is crucial for individualized treatment strategies, considering factors such as patient comorbidities, risk profiles, and preferences. Ultimately, a comprehensive analysis of existing RCTs will contribute valuable insights to the ongoing discourse on antiplatelet therapy in PCI patients, guiding evidence-based decisions for optimal clinical outcomes.

Objectives: To assess the research comparing the effectiveness and safety of Prasugrel vs Ticagrelor in patients having coronary artery disease. Additionally, we want to describe the composite outcome in terms of MI, Death and stroke with these medications and provide a comparison viewpoint.Also, to describe the adverse effects in terms of Dyspnea bleeding and type of bleeding(BARC/TIMI).

METHODS

In this meta-analysis, we considered Randomized Control Trials. The time frame for the inclusion of studies in this meta-analysis extends from the inception of the earliest relevant studies till 2023. Studies published in the English language were included in this meta-analysis. Only published studies were included.

Inclusion criteria: Randomized controlled trials with adequate method of concealment and single/double-blind trials. For this study, all Randomized controlled trials in which all participants who are undergoing per cutaneous intervention, with or without any co-morbidities and who have been subjected to either Ticagrelor or prasugrel.

Exclusion criteria: Those not fulfilling the inclusion criteria and sudies with incomplete information.

Search strategy: We conducted a comprehensive search of electronic databases ([PubMed, Embase, Cochrane Library, and Scopus) to identify relevant randomized controlled trials (RCTs) published, with no restrictions on the publication language or year.

Selection of studies: The abstracts of all the records that met our predefined inclusion criteria were screened by all the authors, and studies that entirely fulfilled our inclusion criteria, were retrieved with their supplementary appendix, for further analysis. Any ambiguity during the study selection has been resolved by mutual discussions and consensus.

Data collection process: In this study, data collection from reports was conducted by two independent reviewers for each report. Three Reviewers have worked separately to minimize bias and enhance the reliability of data extraction. Any discrepancies or uncertainties in data extraction were resolved through discussion and consensus between the reviewers. To ensure data accuracy and completeness, we employed a process to contact study investigators when necessary. Any missing or unclear data points were clarified through direct communication with the investigators to ensure the integrity of the information collected. Additionally, automation tools were not used in the data collection process. Data extraction was performed manually by the reviewers to maintain the precision and accuracy of the collected information.

Data abstraction: Study design data including design synopsis, treatment comparators, dosage, titration schedule and duration of treatment were abstracted, along with baseline characteristics including summary statistics of BMI, age, and sex.

Study Settings: In this meta-analysis multiple research contexts were considered. These settings encompass clinical trials conducted within controlled clinical environments. The inclusion of studies from a range of settings will enhance the generalizability and applicability of the findings to both controlled experimental conditions and real-world clinical practice."

Time frame: The time frame for the inclusion of studies in this meta-analysis extends from the inception of the earliest relevant studies till 2023. This duration allows us to capture a comprehensive range of evidence while accommodating

developments and changes in interventions and outcomes over time.

Language: Studies published in the English language were included in this meta-analysis. The decision to limit the review to English language studies is based on resource constraints and the non-availability of qualified translators for other languages.

Publication Status: Only published studies are included in this meta-analysis. The decision to exclude unpublished or grey literature is made to maintain a high standard of evidence and ensure the reliability of data sources.

Report Characteristics: Full-text articles are considered for inclusion in this meta-analysis. Any study that fails to provide essential data was excluded from the analysis.

Risk Bias/Meta-bias(es): We have assessed potential meta-biases in this meta-analysis, including publication bias and selective reporting. Publication bias was evaluated using funnel plots, Egger's regression test and Begg's test. Selective reporting within studies was explored through visual inspection of forest plots and comparison of reported outcomes with pre-specified outcomes in the protocols."

Effect Measures : In this meta-analysis, we employed standardized mean Difference (SMD) as our Primary effect measure. The SMD was calculated by taking the Mean Difference (MD) between the intervention group and the placebo group and dividing it by the Standard Deviation (SD) of the Outcomes. We considered the Mainly Odds ratio for Secondary effect measure.

Synthesis Methods: We conducted a comprehensive search of electronic databases (PubMed, Embase, Cochrane Library, and Scopus) to identify relevant randomized controlled trials (RCTs) published till 2023. Two reviewers independently screened the studies, extracted data and assessed the risk of bias using the Cochrane Risk of Bias tool. Bucher's and Bayesian Meta-regression Simulation Method were used for indirect head-to-head comparison between various active drugs. MedCalc® statistical software, RevMan Version 5.4$^{rcledR;}$ along with A Meta- Analysis Toolkit by Cochrane Methods were used. P-value< 0.05 was considered significant.

Reporting Bias assessment: Visual Inspection of Funnel Plots: Funnel plots were visually inspected to assess the symmetry of data points, where each point represents an individual study's effect size plotted against its standard error. Asymmetry in the funnel plot can be indicative of publication bias, and we assessed the potential impact of this bias on our findings.

Egger's Test and Begg's test: Egger's and Begg's tests were conducted to quantify the degree of asymmetry in the funnel plot, providing statistical evidence for publication bias.

Certainty assessment: We conducted sensitivity analysis to assess the influence of reporting bias on our findings. This involved comparing the outcomes of the primary analysis with adjusted estimates obtained through imputation of potentially missing studies, employing a graphical representation known as a "publication bias assessment plot" (Figure 1) and a "summary plot." (Figure 2)

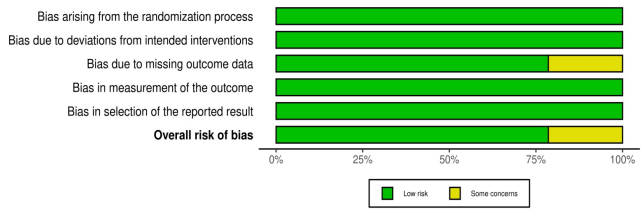


Figure 2: Publication Bias Summary Plot

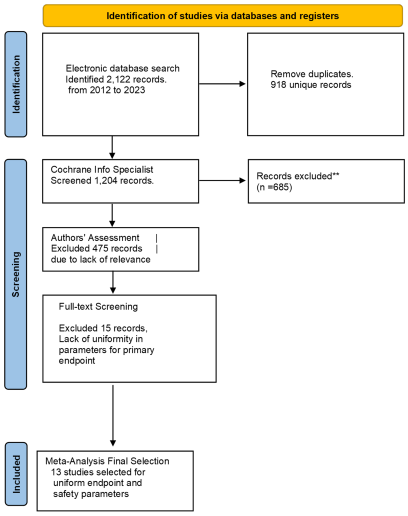


Figure 3: Flow chart-study selection

Study characteristics: "Full-text articles" are considered for inclusion in this meta-analysis.

Alexopoulos D, Moulias A et al. [5], Alexopoulos et al. [6], Deharo et al. [7], Laine et al. [8], Bonello et al. [9], Z Motovska et al. [10], Alexopoulos D, Galati A et al. [11], Alexopoulos D, Xanthopoulou I et al. [12], G Parodi et al. [13], Aytekin et al. [14], W Hochholzer et al. [15], and Schupke et al. [16].

Any study that failed to provide essential data was excluded from the analysis. "Only Randomized control trials were included in our Meta analysis. The abstracts of all the records that met our predefined inclusion criteria were screened by all the authors, and studies that entirely fulfilled our inclusion criteria, were retrieved with their supplementary appendix, for further analysis. Any ambiguity during the study selection has been resolved by mutual discussions and consensus. Two independent reviewers were involved in the study selection process. During the initial screening phase, both reviewers independently assessed titles and abstracts of retrieved studies for potential relevance based on the predefined eligibility criteria. Disagree-

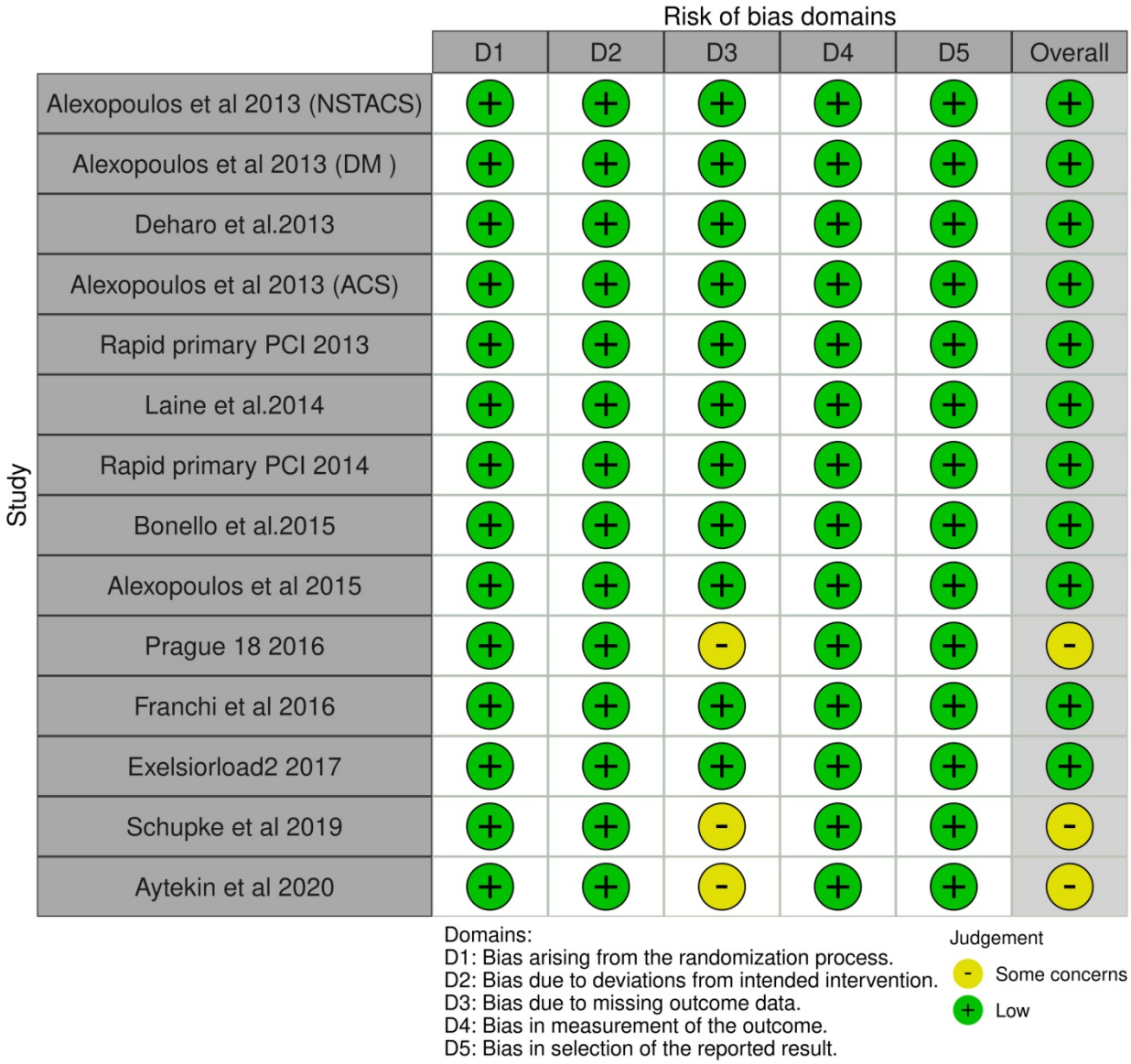


Figure 1: Publication bias assessment plot

ments were resolved through discussion. In the eligibility phase, other three reviewers independently evaluated the full-text articles of potentially relevant studies to determine final inclusion. Consensus reached through discussion among all reviewers. (Figure 1)

Egger's test		Begg's test	
Intercept	-1.64	Kendall 's Tau	0.089
P = 0.11		P = 0.66	

Table 1: Risk of Publication Bias (Ticagrelor vs. Prasugrel)

Egger's Test: The intercept represents the estimate of funnel plot asymmetry. In Egger's test, a non-zero intercept may suggest the presence of publication bias, *p= 0.11.* This is the p-value associated with the Egger's test. If the *p-value* is less than the significance level (commonly set at 0.05), it suggests that there is evidence of publication bias. In this case, *P = 0.11*, which is greater than 0.05, indicating that there is no statistically significant evidence of publication bias. (Table 1)

Begg's Test: Kendall's Tau is a measure of correlation in the Begg's test. It assesses the correlation between the effect size and its standard error. A higher value may indicate potential bias, p = 0.66. Similar to Egger's test, this is the *p-value* associated with Begg's test. A higher *p-value*

suggests no evidence of publication bias. In this case, *P = 0.6579*, which is greater than 0.05, indicating no statistically significant evidence of publication bias. (Table 1)

In summary, based on the provided results, both tests suggest no statistically significant evidence of publication bias.

Measurement of treatment effect: Direct comparison between active drug and placebo was done using random effect model and Odd's ratio was calculated.

Summary measures: The principal summary measure was the Odd's Ratio (at 95% Confidence Interval) and Funnel Plots as well as Forest Plots were represented. *P-value* less than 0.05 was considered significant.

Data synthesis and statistical analysis: Bucher's and Bayesian Meta-regression Simulation Method were used for head-to-head comparison between various active drugs. RevMan Version 5.4 along with Meta- Analysis Toolkit by Cochrane Methods were used. *P-value* less than 0.05 was considered significant.

RESULTS

Total 13 studies were included for the final analysis.

Ticagrelor vs. Prasugrel	Odds Ratio	95% CL	P value	Z statistic
Dyspnea	13.93	3.50 to 55.51	<0.001	3.73
Bleeding	1.25	0.99 to 1.56	0.054	1.93
Death	1.17	0.92 to 1.48	0.206	1.26
Myocardial Infarction	2.73	2.16 to 3.47	<0.001	8.29
Stroke	2.73	2.16 to 3.47	<0.001	8.29

Table 2: Overall incidence-MI, Death and stroke in terms of primary endpoint and secondary endpoints-Dyspnea, Bleeding,

Dyspnea: The odds of experiencing dyspnea are significantly higher with Ticagrelor compared to Prasugrel. The wide confidence interval suggests a substantial range of uncertainty, but the p-value indicates strong statistical significance. (Table 2)

Bleeding: The odds of bleeding are slightly higher with Ticagrelor compared to Prasugrel, but the difference is not statistically significant at the conventional 0.05 significance level. The p-value is 0.054, indicating a trend but not reaching statistical significance.

Death: There is no significant difference in the odds of death between Ticagrelor and Prasugrel. The p-value is 0.206, suggesting that the observed difference could be due to random chance.

Myocardial Infarction (MI): The odds of experiencing myocardial infarction are significantly higher with Ticagrelor compared to Prasugrel. The p-value is highly significant, indicating a robust and consistent finding. (Table 2)

Stroke: The odds of experiencing a stroke are significantly higher with Ticagrelor compared to Prasugrel. This result is consistent with the findings for myocardial infarction.

- Meta-analysis does not reveal a statistically significant difference in the risk of death between Ticagrelor and Prasugrel. The low I2 value and non-significant Q statistic support the consistency of the effect estimates across studies, providing a reliable foundation for this conclusion. (Figure 4)
- The meta-analysis results indicate a significantly increased risk of dyspnea associated with Ticagrelor compared to Prasugrel. Under the fixed-effects model, the combined odds ratio for dyspnea is 13.929 (95% CI: 3.495 to 55.514), with a z statistic of 3.734 and a highly significant P-value (<0.001). This suggests a consistent and robust effect across the included studies, supporting the conclusion that the risk of dyspnea is notably higher with Ticagrelor. (Figure 4)

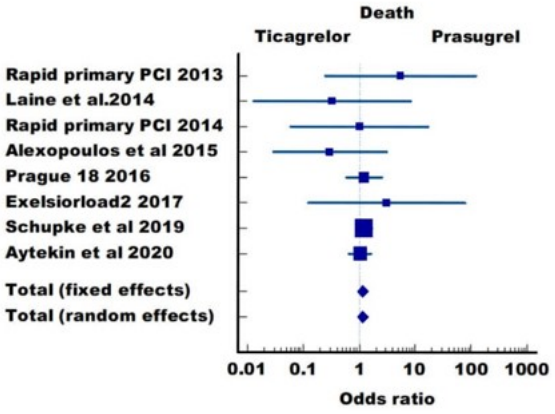
- Meta-analysis does not show a statistically significant difference in bleeding risk between Ticagrelor and Prasugrel. The low I2 value and non-significant Q statistic suggest a consistent effect across studies, providing a stable basis for this conclusion. (Figure 5)

- Meta-analysis reveals a statistically significant elevation in the risk of myocardial infarction with Ticagrelor compared to Prasugrel. The low I2 value and non-significant Q statistic support the consistency of the effect estimates across studies, enhancing the reliability of this conclusion. (Figure 6)
- Meta-analysis reveals a statistically significant elevation in the risk of stroke with Ticagrelor compared to Prasugrel. The low I2 value and non-significant Q statistic support the consistency of the effect estimates across studies, enhancing the reliability of this conclusion. (Figure 6)

DISCUSSION

The comprehensive review of randomized controlled trials (RCTs) comparing Prasugrel and Ticagrelor in the context of acute coronary syndrome (ACS) revealed nuanced insights into their comparative efficacy and safety profiles. The primary composite endpoint, encompassing stroke, myocardial infarction (MI), and death, (Figures 4 and 6)did

Death				
Study	Odds ratio	95% CI	Weight (%)	
			Fixed	Random
Rapid primary PCI 2013	5.426	0.247 to 118.965	0.60	0.60
Laine et al.2014	0.327	0.0130 to 8.215	0.55	0.55
Rapid primary PCI 2014	1.000	0.0591 to 16.929	0.72	0.72
Alexopoulos et al 2015	0.296	0.0289 to 3.042	1.06	1.06
Prague 18 2016	1.222	0.591 to 2.525	10.89	10.89
Exelsiorload2 2017	3.067	0.122 to 77.329	0.55	0.55
Schupke et al 2019	1.238	0.903 to 1.697	57.85	57.85
Aytekin et al 2020	1.038	0.659 to 1.636	27.77	27.77



Dyspnea				
Study	Odds ratio	95% CI	Weight (%)	
			Fixed	Random
Rapid primary PCI 2013	13.683	0.714 to 262.189	26.59	30.64
Rapid primary PCI 2014	105.000	5.684 to 1939.818	27.26	31.00
Franchi et al 2016	2.039	0.217 to 19.187	46.14	38.36

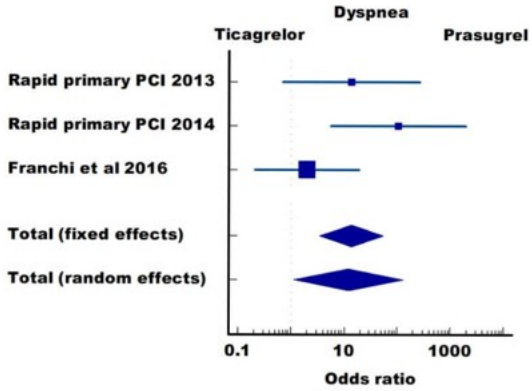


Figure 4: Forest plot of Dyspnea and Death

Bleeding				
Study	Odds ratio	95% CI	Weight (%)	
			Fixed	Random
Alexopoulos et al 2013 (BARC)	0.780	0.324 to 1.877	6.56	6.56
Alexopoulos et al 2013 (TIMI)	0.976	0.131 to 7.261	1.26	1.26
Alexopoulos et al 2013 (TIMI)	0.976	0.131 to 7.261	1.26	1.26
Deharo et al.2013 (BARC)	1.720	0.519 to 5.696	3.53	3.53
Rapid primary PCI 2013 (TIMI)	13.683	0.714 to 262.189	0.58	0.58
Alexopoulos et al 2015 (TIMI)	3.120	0.304 to 32.030	0.93	0.93
Prague 18 2016 (TIMI)	1.608	0.653 to 3.961	6.22	6.22
Schupke et al 2019 (BARC)	1.061	0.783 to 1.439	54.55	54.55
Aytekin et al 2020 (BARC)	1.555	0.993 to 2.437	25.11	25.11

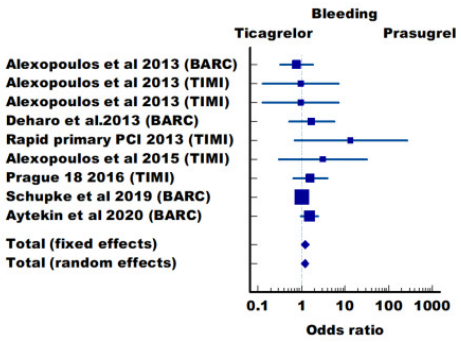


Figure 5: Forest plot of Bleeding (BARC and TIMI)

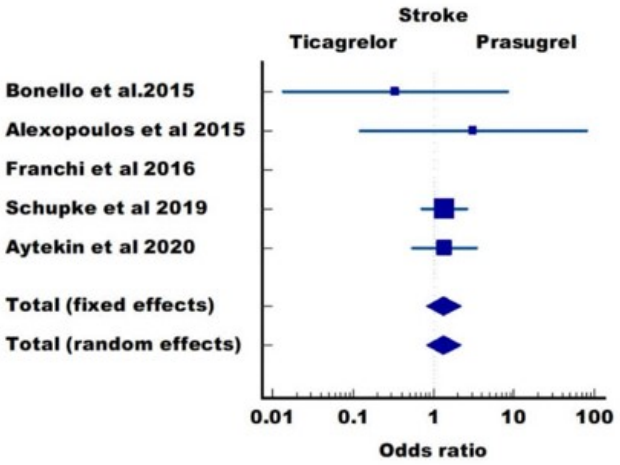
not exhibit a significant risk difference between Prasugrel and Ticagrelor. This finding aligns with the current literature, ,emphasizing the similarity in outcomes between these two antiplatelet agents. [5, 7, 14, 17–20]

Comparison of Prasugrel and Ticagrelor for ACS: The PT-ACS [3] Study reported results consistent with the findings of this meta-analysis. The study concluded that, similar to our meta-analysis, there was no significant difference in efficacy and safety between prasugrel and ticagrelor when combining results from PRAGUE-18 [10] and ISAR-REACT 5. [16]

Contrary to the overall trend, Prasugrel demonstrated superiority over Ticagrelor in reducing the risk of secondary MI, highlighting a potential advantage in specific cardio-vascular outcomes. However, the definition of MI lacked detailed stratification into fatal and nonfatal categories, warranting caution in interpreting these results. Future trials incorporating more refined definitions would enhance the precision of outcome assessments.

While both Prasugrel and Ticagrelor exhibited comparable efficacy and safety profiles with same mechanism of action in most outcomes, the analysis underscored the acute side effect of dyspnea associated with Ticagrelor, The findings

Stroke				
Study	Odds ratio	95% CI	Weight (%)	
			Fixed	Random
Bonello et al.2015	0.333	0.0134 to 8.276	2.57	2.57
Alexopoulos et al 2015	3.109	0.121 to 79.646	2.52	2.52
Franchi et al 2016	-			
Schupke et al 2019	1.373	0.719 to 2.622	63.32	63.32
Aytekin et al 2020	1.358	0.544 to 3.394	31.59	31.59



Myocardial Infarction				
Study	Odds ratio	95% CI	Weight (%)	
			Fixed	Random
Rapid primary PCI 2013	0.333	0.0133 to 8.379	0.63	7.32
Laine et al.2014	0.327	0.0130 to 8.215	0.63	7.32
Prague 18 2016	17.122	8.267 to 35.462	12.42	22.31
Franchi et al 2016	-			
Exelsiorload2 2017	0.372	0.0683 to 2.028	2.29	15.01
Schupke et al 2019	1.711	1.225 to 2.388	59.09	24.43
Aytekin et al 2020	1.932	1.156 to 3.230	24.93	23.61

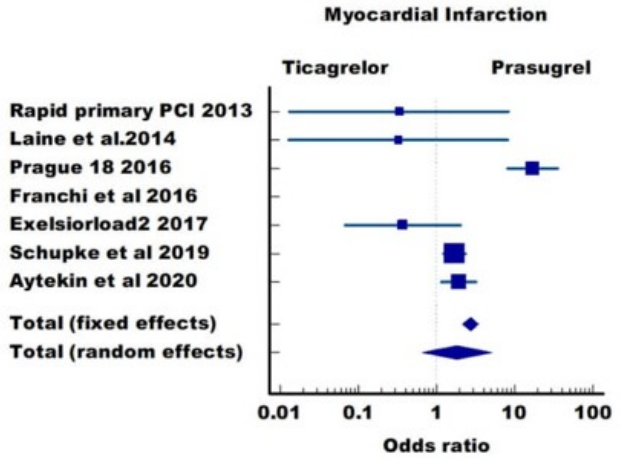


Figure 6: Forest plot of Stroke and MI

align with prior meta-analyses that have investigated the comparative use of Prasugrel and Ticagrelor in patients with acute coronary syndrome (ACS). The chronicity of dyspnea remains uncertain due to limited long-term data. Sensitivity analysis stratifying trials by follow-up duration yielded no significant results in the long-term outcome group, emphasizing the need for further investigations into extended durations of Prasugrel and Ticagrelor use.

Interestingly, the PT-ACS Study also found that prasugrel demonstrated superiority over ticagrelor specifically in the secondary outcome of myocardial infarction (MI) with low heterogeneity (RR = 1.38; 95% CI = 1.05–1.81; p = 0.02, I2 = 0%). However, our meta-analysis suggests a need for better stratification in the definition of MI, considering the potential impact of fatal and nonfatal events. Transparency about the classification of MI events in studies is crucial for enhancing the robustness of methodology. Our study values will be incorporated to provide a more comprehensive comparison.

The conflicting results observed between ISAR-REACT 5 and PRAGUE-18trials could be attributed to methodological issues such as premature termination, underpowering, and variations in patient populations. Notably, the PRAGUE-18 trial's high switching rate to clopidogrel, premature termination, and statistical underpower raised concerns about the robustness of its conclusions.

The meta-analysis's limitations include concerns about the integrity of allocation concealment in over half of the trials, potential asymmetry in funnel plots (though not supported by Egger's test), and the limited number of events for secondary outcomes due to the small number of included studies. Stratified data by patient groups (STEMI vs. NSTEMI) were not provided by the included studies, limiting insights into the differential efficacy of Ticagrelor and Prasugrel among specific subsets of ACS patients. Ongoing research is crucial to address these limitations and provide more nuanced insights into the comparative effectiveness of these antiplatelet agents.

CONCLUSION

In summary, our meta-analysis sheds light on the nuanced comparison between Ticagrelor and Prasugrel in the context of percutaneous coronary intervention. While both antiplatelet agents exhibit comparable bleeding risks, our results hint at a concerning elevation in adverse cardiovascular events, particularly with Ticagrelor.

The study's robustness stems from a meticulous examination of various clinical endpoints across a spectrum of trials. Nevertheless, it is crucial to acknowledge the study's limitations, including inherent trial variations and the potential influence of publication bias.

These findings underscore the necessity for clinicians to weigh the risks and benefits carefully when choosing between Ticagrelor and Prasugrel in clinical practice. Future research endeavors should focus on refining our understanding of the safety profiles of these agents, emphasizing the imperative to enhance patient outcomes in the realm of percutaneous coronary intervention.

REGISTRATION: The registration is under process.

COMPELLING INTEREST: The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants, or patents received or pending, or royalties.

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