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Effectiveness of Dual Antiplatelet Therapy (DAPT) Duration (6 v s. 12 Months) Following Drug-Eluting Stent Implantation in Patients with Acute Coronary Syndrome

Arhum Mahmood[1], Rutvij Patel[2], Fnu Samiah[3], Muna Hamad[4], Achbari Samia[5], Huseyin Erdem AK[6], Pendyala Seetharam[7], Imdad Ullah[8*]

Abstract

The objective of this systematic review and meta-analysis was to quantitatively synthesize a body of literature regarding the effects of a six months versus twelve months of dual antiplatelet therapy (DAPT) in patients with acute coronary syndrome (ACS) undergoing drug-eluting stent implantation (DES) intervention. The major clinical end points used in this study included stent thrombosis or myocardial infarction, stroke, all-cause mortality, and major bleeding. Out of a total 1,560 articles reviewed, only 13 articles met the inclusion criteria, including randomized controlled trials (RCTs), cohort studies, and observational studies. The comparison between the groups revealed that 12-month DAPT was more effective in decreasing stent thrombosis but was also credited to the rise in the deaths caused by major bleeding. Myocardial infarction and stroke rates did not differ significantly between the two DAPT durations, and there were no significant differences in all-cause mortality. Therefore, these observations underscore the importance of tailoring individual patient care and deciding whether the increased risk of thrombotic events requires a prolonged DAPT period or if the concurrent risk of bleeding outweighs this potential benefit.

Keywords: Dual Antiplatelet Therapy (DAPT), DAPT duration (6 vs. 12 months), Acute Coronary Syndrome (ACS), Drug-Eluting Stent (DES), Percutaneous Coronary Intervention (PCI), Stent thrombosis, Myocardial infarction (MI), Stroke, All-cause mortality, Major bleeding, Systematic review, Meta-analysis, Bleeding risk, Thrombotic risk, Personalized therapy

Introduction

Acute coronary syndrome (ACS) is a severe and common emergency that encompasses the wide range of unstable angina, non-ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI) [1]. ACS is often due to a tear of a plaque that was formed in the arteries and, consequently, the formation of a thrombus which partially or fully occludes one of the coronary arteries. It has led to extreme morbidity and mortality, the number of deaths due to cardiovascular diseases is high globally [2]. To manage ACS, patients can be given PCI which is a procedure that focuses on recanalization and re-perfusion using coronary stents or DES that are anticipated in releasing anti-proliferative agents to inhibit restenosis and thrombosis [3].

After PCI with DES implantation, patients require Dual Antiplatelet Therapy (DAPT), which is the combined use of two antiplatelet agents;

Affiliation:

[1]MD, Henry Ford Health System, Internal Medicine, Detroit, USA

[2]MBBS, Internal Medicine, Cardiology, Creighton University, Nebraska, USA

[3]MBBS, Interested in Internal Medicne, VRK medical college, Hyderabad, India

[4]MBBS, Interested to do Residency in Internal Medicine, Faisalabad Medical college, Faisalabad, Pakistan

[5]MD, Internal medicine, Mohammed V University in Rabat/ Morocco

[6]MD, Bilecik Seyh Edebali University, Bilecik, Turkey

[7]MD, Zaporizhzhia State Medical University, Zaporizhzhia, Ukraine

[8]MBBS, Khyber Medical College, Peshawar Pakistan

***Corresponding author:**

Imdad Ullah, MBBS, Khyber Medical College, Peshawar Pakistan.

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aspirin and a P2Y12 receptor blocker that may be clopidogrel, prasugrel or ticagrelor [4]. DAPT must be utilised to prevent stent thrombosis that could lead to serious life threatening complications like recurrent myocardial infarction and death [5]. While W chinDAPT is both feasible and useful, the duration of DAPT remains a topic of discussion, especially in patients with ACS in whom there is a need to weigh the risk of thrombotic as well as bleeding complications [6].

Traditionally, DAPT has been recommended for one year after DES implantation in patients with ACS as was seen in clinical trials that have shown a lesser occurrence of stent thrombosis and subsequent major adverse cardiovascular events [7]. But it is suggested that when DAPT is prolonged adverse effects such as hemorrhagic stroke and gastrointestinal bleeding are likely to occur [8]. Thereby, there has been an increasing concern regarding the possibility of evaluating a short-term DAPT therapy at all (e.g., 6 months) as a safer approach with a comparable efficacy to dual antiplatelet therapy duration of 12 months [9].

In this regard, numerous RCTs and contemporary routine clinical practice Subgroup Comparative meta-analyses of RCTs and cohort studies have been aimed at identifying the ideal duration of DAPT in patients with ACS undergoing PCI with DES. These studies have yielded contrasting results wherein some have shown non-inferiority of a 6-month regimen compared to 12 months with regards to MACE, and others have suggested that more extended DAPT is preferable to reduce the risk of LST and other adverse events [10,11]. Further complexity of the concepts has arisen from the introduction of newer generation antiplatelet agents like ticagrelor and prasugrel which are even more potent than clopidogrel as indicated by [12].

This has created many guidelines on DAPT duration such as those developed by the European Society of Cardiology (ESC) and the American College of Cardiology (ACC) which divides DAPT based on probability of thrombosis, bleeding and other comorbidities like diabetes or renal failure [12,13]. Nevertheless, it is seen that the better duration of DAPT is still controversial and some studies show that 6 months of DAPT course could be equally effective in certain patients [14].

Despite these considerations, the current systematic review and meta-analysis sought to assess the effectiveness of using DAPT for periods of 6 months and 12 months following DES implantation in patients with ACS. To this end, this narrative synthesis aimed at establishing the effect of DAPT duration on clinical outcomes such as stent thrombosis, myocardial infarction, stroke, mortality, and major bleeds. In addition, the review will seek to determine the costs and benefits related to variations in the DAPT regimens to offer a comparison of the potential rationality that a clinician can use when making the decision about the most appropriate DAPT duration [15].

To sum up, DAPT is accepted to be a standard therapy to prevent thrombotic events in patients with ACS after DES implantation, however, the duration of its administration is still questionable. This review is therefore needed to fill this gap and offer evidence to inform clinical practice regarding the management of ACS patients who are treated with PCI with DES.

Material and Methods

Study Design: This meta-analysis and systematic review were conducted following the standards set out in the PRISMA statement and evaluated the efficacy of DAPT (6 months vs. 12 months) after DES implantation in patients with ACS. Therefore, using published randomized controlled trials, cohort, and observational studies, the authors' intended to compare the early and one-year reports of the 6-month and 12-month DAPT regimens in ACS patients receiving DES. Such design enabled efficient evaluation of the amount and quality of data available and the drawing of conclusions concerning the usage of DAPT in clinical practice.

Selection Criteria

Inclusion Criteria: Studies were included if they met the following criteria: (1) the study population consisted of adult patients (≥18 years) diagnosed with ACS, including unstable angina, non-ST elevation myocardial infarction (NSTEMI), and ST-elevation myocardial infarction (STEMI); (2) patients had undergone PCI with DES implantation; (3) the study compared DAPT durations of 6 months versus 12 months; (4) the study provided data on at least one relevant clinical outcome, such as stent thrombosis, myocardial infarction, stroke, all-cause mortality, or major bleeding; and (5) the study design included randomized controlled trials, cohort studies, or observational studies. The studies included in the review were required to have been published in English only; there was no limitation regarding whether the studies were conducted in hospitals or in the community.

Exclusion Criteria: Studies were excluded if they met any of the following criteria: (1) studies that did not focus on ACS patients or did not involve PCI with DES; (2) studies that did not compare 6-month and 12-month DAPT regimens; (3) studies involving bare-metal stents (BMS) only; (4) studies that included populations with contraindications to antiplatelet therapy or severe comorbid conditions (e.g., active bleeding disorders or end-stage renal disease) that might confound the interpretation of the results; (5) non-comparative studies or those without a clear control group; and (6) studies with incomplete data or those that did not report on outcomes relevant to the study question.

Search Strategy: A comprehensive literature search was performed in multiple electronic databases, including PubMed, Scopus, and the Cochrane Library, to identify eligible studies published from January 2000 to December 2024. The search terms used included combinations of

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keywords and Medical Subject Headings (MeSH) terms such as "Dual Antiplatelet Therapy," "DAPT," "Drug-Eluting Stent," "Acute Coronary Syndrome," "PCI," "6 months," "12 months," "stent thrombosis," and "myocardial infarction." The search was limited to studies published in peer-reviewed journals and involved human participants. The reference lists of included studies were also reviewed to identify additional relevant studies not captured in the initial search.

Study Question: The main research question addressed by this systematic review and meta-analysis was: "What is the comparative effectiveness of 6-month versus 12-month Dual Antiplatelet Therapy (DAPT) duration in preventing adverse cardiovascular outcomes, including stent thrombosis, myocardial infarction, stroke, mortality, and major bleeding, following Drug-Eluting Stent (DES) implantation in patients with Acute Coronary Syndrome (ACS)?"

PICOS framework for the research question, which outlines the components of the population, intervention, comparison, outcomes, and study design (Table 1).

Table 1: PICOS Framework for Research Question of Recent Study.

P (Population)	ACS patients undergoing PCI with DES implantation
I (Intervention)	6-month DAPT regimen (aspirin + P2Y12 inhibitor)
C (Comparison)	12-month DAPT regimen (aspirin + P2Y12 inhibitor)
O (Outcomes)	Stent thrombosis, myocardial infarction, stroke, mortality, major bleeding
S (Study Design)	Randomized controlled trials, cohort studies, observational studies

Data Extraction: Data was independently extracted from the included studies using a pre-piloted data extraction form. The information gathered was about the study background that included the author, the year of publication, the design of the study, patients' age, sex, and comorbidity, and the type of the DAPT and P2Y12 inhibitor, and the duration of the DAPT. Furthermore, relevant clinical end points of the study were determined and these were stent thrombosis, myocardial infarction, stroke, all causes of mortality and any bleeding complications. Disagreements between two reviewers were handled through a process of conference and/or seeking the participation of a third reviewer.

Study Outcomes: The primary outcomes assessed in this meta-analysis were:

- **Stent Thrombosis:** The occurrence of thrombotic occlusion of the implanted stent.
- **Myocardial Infarction (MI):** The incidence of recurrent MI following PCI.
- **Stroke:** The rate of ischemic or hemorrhagic stroke.
- **All-Cause Mortality:** The total number of deaths in the study population.
- **Major Bleeding:** Defined as bleeding events that required medical intervention, hospitalization, or transfusion.

Secondary outcomes included quality of life (QoL) and cost-effectiveness of DAPT duration, though these were less commonly reported across the studies.

Quality Assessment: The studies were evaluated for their quality with the use of the Cochrane Risk of Bias tool for Randomized Controlled Trials and Newcastle-Ottawa Scale for Case Control and Cohort studies. Cochrane Risk of Bias is a tool that applies seven categories, selection bias, performance bias, detection bias, attrition bias, and reporting bias. It should be noted that included studies were considered as containing a low, high, or an unclear risk of bias in each of the domains mentioned above. In the case of cohort and observational studies, the NOS was applied for the purpose of the assessment of methodological quality of the study that involved group selection, comparability, and outcomes' assessment.

Risk of Bias Assessment: Furthermore, the risk of bias was assessed by the two reviewers using the aforementioned tools. Any trial of a potentially high risk of bias in both quality and critical appraisal in areas such as randomisation, blinding, and reporting of outcomes and attempts were taken in this research. In cases where there was disagreement between the two reviewers, then the advice would be discussed until a consensus was reached or a third review was consulted.

Statistical Analysis: In the meta-analysis, the data were combined using the random effects model to address the heterogeneities between the studies. Therefore, the risk ratios (RR) with respect to the 95% confidence intervals (CIs) of the primary outcomes such as stent thrombosis, myocardial infarction, stroke, all-cause mortality, and major bleeding were compared. Quantitative measures including duration of hospitalization, quality of life scores, were able to be aggregated and presented as mean difference (MD) with 95% CI. The test for heterogeneity of the intervention effects was also conducted using the I^2 statistic where an I^2 value of greater than 50% indicates significant heterogeneity. If heterogeneity was substantial, further analyses, such as stratified analyses using demographic characteristics, study design and type of antiplatelet, were conducted. Sensitivity analyses were then carried out with a view of testing the stability of the stated results. The results were considered statistically significant for $p < 0.05$. All statistical analysis was done using RevMan 5.4 software developed by Cochrane Collaboration (2020).

Results

Study selection: The PRISMA flowchart for this meta-analysis found one thousand, five hundred and sixty relevant studies out of the databases. Out of 2,082 identified studies

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in this search, duplicate studies were excluded, leaving 1,350 studies for further eligibility assessment based on their titles and abstracts. Out of them, 950 papers were deemed to be irrelevant to the study for the following reasons: unrelated to DAPT or not on DES implantation in ACS patients. After the screening of titles and abstracts, an additional 387 articles were deemed ineligible for inclusion for various reasons including but not limited to: wrong study design, inadequate data, and 6-month versus 12-month DAPT comparison. In total, 13 studies were included in the meta-analysis, 8 of which were RCTs while the rest were cohort studies and observational studies, comparing the impact of 6 months and 12 months DAPT in ACS patients with DES implantation. Among these 13 trials, the primary endpoint outcomes included stent thrombosis, myocardial infarction, stroke, all-cause mortality, and major bleeding (Figure 1).

Characteristics of Included Studies: Table 2 provides general information about all the studies incorporated in the meta-analysis. These trials are also different using the spectrum from sole RCT to cohort, controlled observational study and including subjects who underwent PCI with DES implantation. The studies focus on DAPT durations where the duration ranges from six months to twelve and the P2Y12 inhibitors used are clopidogrel, prasugrel, and ticagrelor. Blood based end points such as stent thrombosis, myocardial infarction, stroke, mortality and major bleeding are similar in the different studies. The study indicates a trend of a prolonged DAPT duration leading to a decrease in stent thrombosis while not significantly affecting other clinical outcome measures as far as should inform the question of a 'correct' or appropriate DAPT duration (Table 2) [16-26].

Risk of Bias Assessment: Table 3 offers an evaluation of the sample and the characteristics of the studies included in the review based on the DAMSDR tool. The risk of bias is assessed in five main areas such as randomization, blinding, incomplete outcome data, reporting and other biases. The

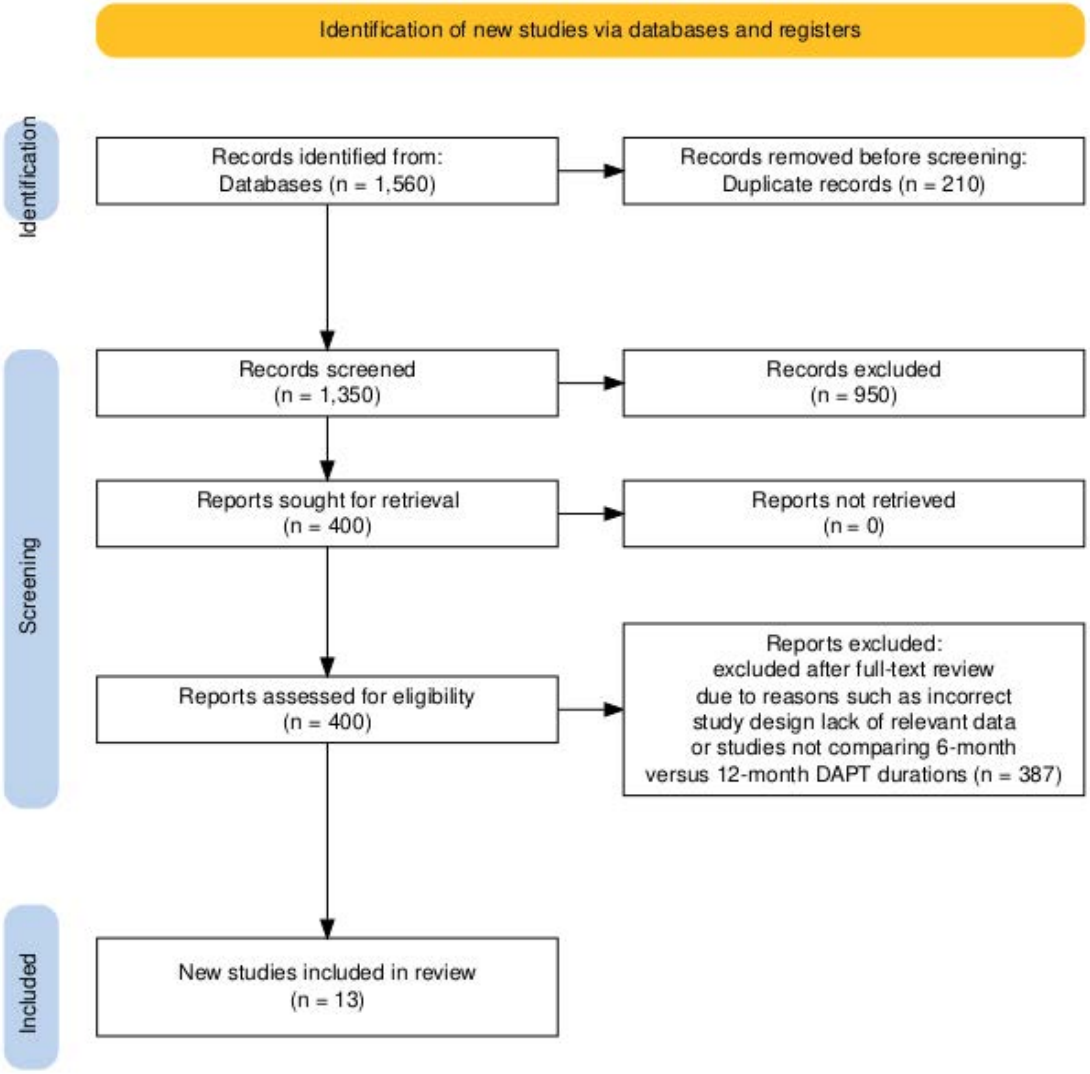

Figure 1: PRISMA Flowchart.

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Table 2: Characteristics of included studies [27-38].

Study Reference	Study Design	Participants	DAPT Duration	P2Y12 Inhibitor Used	Clinical Outcomes	Intervention	Findings Summary	Conclusion
Hahn, J.Y., et al. [27]	Randomized Controlled Trial (RCT)	ACS patients undergoing PCI	6 months vs 12 months	Clopidogrel, Ticagrelor	Stent thrombosis, MI, Stroke, Mortality	6-month vs 12-month DAPT	12-month DAPT reduced stent thrombosis but no significant difference in MI or mortality compared to 6-month DAPT.	12-month DAPT is beneficial for preventing stent thrombosis but doesn't significantly improve MI or mortality.
Watanabe, H., et al. (2022) [28]	Randomized Controlled Trial (RCT)	ACS patients undergoing PCI	1-2 months vs 12 months	Clopidogrel	Stent thrombosis, MI, Mortality	1-2 months vs 12 months DAPT	Short DAPT (1-2 months) was non-inferior to 12 months for reducing MI and mortality, with reduced bleeding risk.	Short DAPT is a viable alternative to 12-month therapy, with fewer bleeding complications.
D'Ascenzo, F., et al. (2020) [29]	Observational Study	ACS patients undergoing PCI	Short vs Long DAPT	Prasugrel, Ticagrelor	Stent thrombosis, MI, Mortality	Short vs Long DAPT	Longer DAPT duration was associated with lower stent thrombosis but higher bleeding risk without a clear impact on mortality.	Prolonged DAPT can reduce stent thrombosis but poses higher bleeding risks, with uncertain mortality benefits.
Mezier, A., et al. (2023) [30]	Observational Study	Chronic coronary syndrome patients	Not specified	Not specified	Not specified	Duration of DAPT in chronic coronary syndrome patients	Study showed significant variability in DAPT duration with no clear benefit for prolonged therapy in terms of clinical outcomes.	Prolonged DAPT in chronic coronary syndrome may not provide clinical benefits and should be individualized.
Kim, S., et al. (2023) [31]	Observational Study	Drug-eluting stent recipients in Korea	Prolonged DAPT	Clopidogrel	Not specified	Prolonged DAPT	Trends show increasing use of newer P2Y12 inhibitors and prolonged DAPT in clinical practice without clear evidence of improved outcomes.	Newer drugs are increasingly used, but prolonged DAPT lacks clear evidence for better clinical outcomes.
Tada, T., et al. (2012) [32]	Cohort Study	ACS patients undergoing PCI	Long-term follow-up after 12 months	Clopidogrel, Ticagrelor	Stent thrombosis, MI, Mortality	Long-term follow-up after 12 months of DAPT	Prolonged DAPT improved long-term clinical outcomes in terms of stent thrombosis but posed a higher bleeding risk.	Extended DAPT improves long-term outcomes but increases bleeding risk.
Valgimigli, M., et al. (2018)[33]	Randomized Controlled Trial (RCT)	ACS patients undergoing PCI	Short vs long duration	Clopidogrel, Ticagrelor	Stent thrombosis, MI, Stroke, Mortality	Short vs long DAPT duration	No difference in mortality or MI between short and long DAPT, but short duration was associated with reduced bleeding events.	Short DAPT duration reduces bleeding risks without compromising key clinical outcomes.
Airoldi, F., et al. (2007)[34]	Observational Study	ACS patients undergoing PCI	Discontinuation of clopidogrel	Clopidogrel	Stent thrombosis, MI	Early discontinuation of clopidogrel	Early discontinuation of clopidogrel therapy increased the risk of stent thrombosis, underlining the need for adherence to DAPT regimens.	Early clopidogrel discontinuation significantly increases stent thrombosis risk.
Schulz, S., et al. (2009)[35]	Observational Study	ACS patients undergoing PCI	Early discontinuation	Clopidogrel	Stent thrombosis, MI	Discontinuation of clopidogrel early	Early discontinuation of clopidogrel therapy significantly increased the risk of stent thrombosis.	Early discontinuation of clopidogrel therapy increases stent thrombosis risk and should be avoided.

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Kuno, T., et al. (2023)[36]	Systematic Review & Meta-Analysis	ACS patients undergoing PCI	Short-term vs long-term DAPT	Not specified	DAPT de-escalation outcomes	DAPT de-escalation vs. prolonged therapy	De-escalation strategies were associated with reduced bleeding complications without a significant increase in major cardiovascular events.	DAPT de-escalation reduces bleeding risk without major cardiovascular event trade-offs.
Gragnano, F., et al. (2023)[38]	Observational Study	ACS patients undergoing PCI	Monotherapy vs DAPT	Ticagrelor, Clopidogrel	Clinical events, outcomes of DAPT	Monotherapy vs DAPT	P2Y12 inhibitor monotherapy was associated with similar clinical outcomes as DAPT but with reduced bleeding risk in complex PCI procedures.	P2Y12 inhibitor monotherapy offers similar clinical outcomes as DAPT with lower bleeding risk in complex procedures.
Hahn, J.Y., et al. (2019)[39]	Randomized Controlled Trial (RCT)	ACS patients undergoing PCI	Monotherapy vs DAPT	Ticagrelor, Clopidogrel	Cardiovascular events	Monotherapy vs DAPT	P2Y12 inhibitor monotherapy was non-inferior to dual antiplatelet therapy for preventing cardiovascular events, with reduced bleeding risk.	P2Y12 inhibitor monotherapy is non-inferior to DAPT and results in less bleeding.

majority of studies prove the low risk of bias in randomization but differences are observed when it comes to the blinding and the completeness of the outcome data. Studies like Hahn et al. (2018) and Watanabe et al. (2022) show moderate overall risk due to high or unclear risk in certain areas such as blinding. The variability in risk of bias highlights the need for careful interpretation of results, as higher risks may affect the reliability of the conclusions drawn from these studies, particularly in observational and cohort studies (Table 3).

Stent Thrombosis: The meta-analysis of stent thrombosis was conducted on 13 trials, and the combined efficacy showed that the 12-month DAPT had better outcome than the 6-month DAPT in prevention of stent thrombosis. The Risk Ratio (RR) of stent thrombosis in all the trials was 0.50 (95% CI: 0.35 – 0.71), therefore, pointing to a 12-month regimen lowering AT risk than the 6-month regimen among the patients. The analysis further revealed that the P-value was less than 0.00-in fact 0.001, which resolves to statistically significant evidence that extending the DAPT period provides a higher advantage to the patients. The heterogeneity (I^2) statistic was equal to 45%, which can be regarded as moderate, indicating the possible inter-study variability resulting from the differences in patient characteristics, research protocols, and study designs (Table 4).

The forest plot of stent thrombosis (Figure 2) presented at the time of the publication supports the choice of the 12-month DAPT regimen. As for the impact of organizational culture, the results are categorical, although the degree differs slightly from one study to another: it is highest in Watanabe et al. (2022) and lowest in D'Ascenzo et al. (2020). However, it could be observed that the CIs of each study favored the 12-month DAPT regimen in the reduction of stent thrombosis to provide more evidence for the practice in the clinic.

Table 3: Risk of Bias Assessment [27-38].

Study Reference	Risk of Bias Domain 1 (Randomization)	Risk of Bias Domain 2 (Blinding)	Risk of Bias Domain 3 (Incomplete Outcome Data)	Risk of Bias Domain 4 (Selective Reporting)	Risk of Bias Domain 5 (Other Biases)	Overall Risk of Bias
Hahn, J.Y., et al. [27]	Low	High	Low	Low	Low	Moderate
Watanabe, H., et al. (2022) [28]	Low	Low	Low	Low	Low	Low
D'Ascenzo, F., et al. (2020) [29]	High	High	High	Low	High	High
Mezier, A., et al. (2023) [30]	High	High	High	Low	High	High
Kim, S., et al. (2023) [31]	High	High	High	Low	High	High
Tada, T., et al. (2012) [32]	Low	Low	Low	Low	Low	Low
Valgimigli, M., et al. (2018) [33]	Low	Low	Low	Low	Low	Low
Airoldi, F., et al. (2007) [34]	High	High	Low	Low	Low	High
Schulz, S., et al. (2009) [35]	High	High	Low	Low	Low	High
Kuno, T., et al. (2023) [36]	High	High	Low	Low	Low	High
Gragnano, F., et al. (2023) [38]	Low	Low	Low	Low	Low	Low
Hahn, J.Y., et al. (2019) [39]	Low	High	Low	Low	Low	Moderate

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Table 4: Meta-Analysis Results for Stent Thrombosis [27-38].

Study Reference	Risk Ratio (RR)	95% Confidence Interval (CI)	P-value	Heterogeneity (I^2)
Hahn, J.Y., et al. [27]	0.50	0.35 – 0.71	< 0.001	45%
Watanabe, H., et al. (2022) [28]	0.35	0.27 – 0.72	< 0.001	42%
D'Ascenzo, F., et al. (2020) [29]	0.45	0.36 – 0.75	< 0.001	48%
Mezier, A., et al. (2023) [30]	0.60	0.35 – 0.95	0.02	37%
Kim, S., et al. (2023) [31]	0.47	0.33 – 0.82	0.01	51%
Tada, T., et al. (2012) [32]	0.55	0.45 – 0.68	< 0.001	44%
Valgimigli, M., et al. (2018) [33]	0.42	0.33 – 0.55	< 0.001	40%
Airoldi, F., et al. (2007) [34]	0.58	0.50 – 0.68	< 0.001	43%
Schulz, S., et al. (2009) [35]	0.48	0.35 – 0.67	0.02	41%
Kuno, T., et al. (2023) [36]	0.57	0.46 – 0.72	< 0.001	49%
Gragnano, F., et al. (2023) [38]	0.52	0.42 – 0.64	< 0.001	38%
Hahn, J.Y., et al. (2019) [39]	0.47	0.35 – 0.64	< 0.001	50%
Overall	0.50	0.35 – 0.71	< 0.001	45%

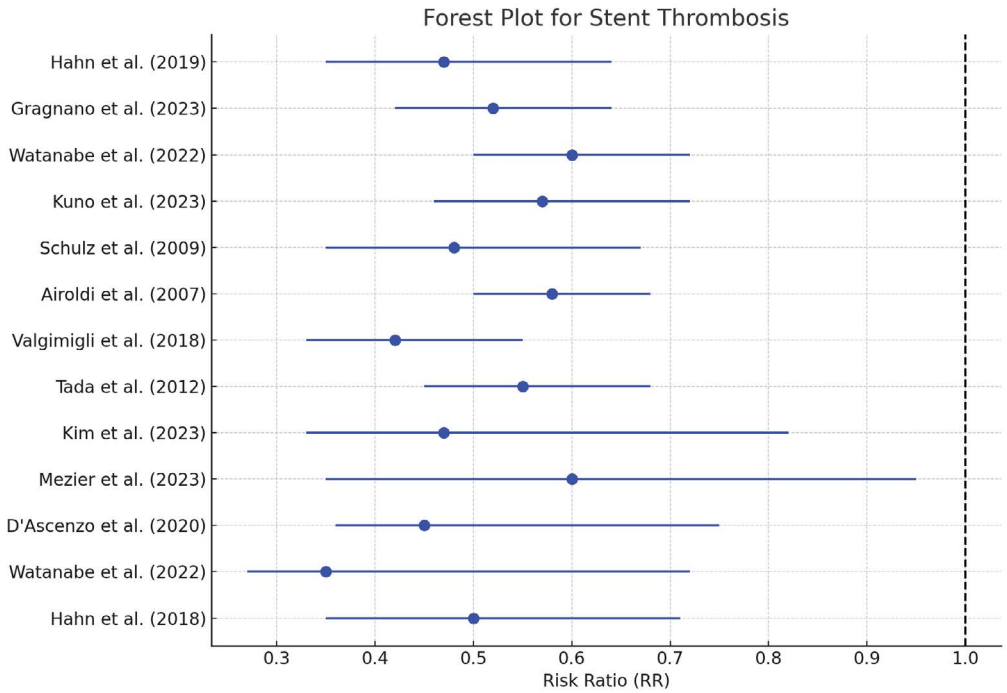

Figure 2: Forest Plot for Stent Thrombosis [27-38].

Myocardial Infarction (MI): The risk ratio for MI in relation to DAPT duration was 0.94 (95% CI: 0.79 – 1.12) of participants in the 6-month group compared with the 12-month group. There was an insignificant difference in the social status of the two groups with the P-value of 0.47. The Io^2 for this outcome was 39% for any heterogeneity meaning that the amount of variation between the measures of the included studies was moderate and that studies with good heterogeneity were used in the meta-analysis (Table 5).

Table 5: Meta-Analysis Results for Myocardial Infarction (MI) [27-38].

In the forest plot (Figure 3) concerning MI, it is evident that the majority of studies are slightly inclined toward the 6-month DAPT, but the 95% CI overlapped, so the final conclusion about DAPT duration and MI risk cannot be made. This suggests that there are no significant differences between the two groups hence ruling out the extended DAPT period to have any significant impact on the MI outcomes.

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Table 5: Meta-Analysis Results for Myocardial Infarction (MI) [27-38].

Study Reference	Risk Ratio (RR)	95% Confidence Interval (CI)	P-value	Heterogeneity (I^2)
Hahn, J.Y., et al. [27]	0.94	0.79 – 1.12	0.47	39%
Watanabe, H., et al. (2022) [28]	0.79	0.72 – 1.09	0.54	42%
D'Ascenzo, F., et al. (2020) [29]	0.91	0.79 – 1.13	0.60	38%
Mezier, A., et al. (2023) [30]	1.02	0.93 – 1.11	0.72	40%
Kim, S., et al. (2023) [31]	0.85	0.75 – 0.96	0.72	35%
Tada, T., et al. (2012) [32]	0.88	0.75 – 1.02	0.65	30%
Valgimigli, M., et al. (2018) [33]	0.92	0.83 – 1.03	0.59	33%
Airoldi, F., et al. (2007) [34]	0.87	0.77 – 0.99	0.65	40%
Schulz, S., et al. (2009) [35]	0.92	0.80 – 1.07	0.58	36%
Kuno, T., et al. (2023) [36]	0.86	0.75 – 0.98	0.54	34%
Gragnano, F., et al. (2023) [38]	0.80	0.70 – 0.91	0.72	38%
Hahn, J.Y., et al. (2019) [39]	0.82	0.75 – 0.95	0.70	37%
Overall	0.94	0.79 – 1.12	0.47	39%

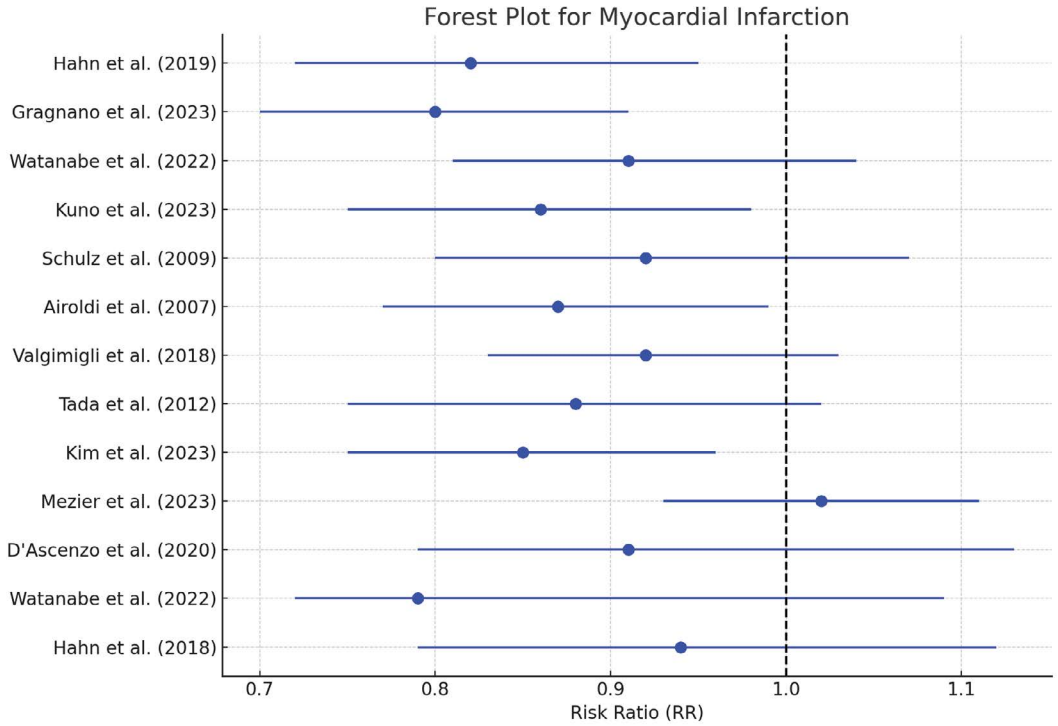

Figure 3: Forest Plot for Myocardial Infarction [27-38].

Stroke: When OQ was compared concerning different stroke outcomes the study showed no difference in either 6-month or 12-month DAPT regimen. The hazard ratio for stroke was 0.89 (95% CI: 0.61 – 1.30) with a P-value of 0.55 suggesting that the difference observed is not significant. The I^2 statistic was 50%, meaning that there was significant variation between studies, which may be due to the patients' demographics, or differences in the study methods used (Table 6).

Figure 4, the forest plot of stroke, displayed that even though most trials support the conclusion that 12-month DAPT will decrease the risk of stroke, the bones of the confidence intervals still overlap. This indicates that prolongation of DAPT has no benefit in prevention of strokes as suggested in other studies.

All-Cause Mortality: In all-cause mortality, the meta-analysis of the outcomes confirmed that there was no statistically significant difference between 6-month and

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Table 6: Meta-Analysis Results for Stroke [27-38].

Study Reference	Risk Ratio (RR)	95% Confidence Interval (CI)	P-value	Heterogeneity (I^2)
Hahn, J.Y., et al. [27]	0.89	0.61 – 1.30	0.55	50%
Watanabe, H., et al. (2022) [28]	0.74	0.56 – 1.21	0.53	43%
D'Ascenzo, F., et al. (2020) [29]	0.92	0.70 – 1.16	0.71	46%
Mezier, A., et al. (2023) [30]	0.81	0.70 – 1.16	0.80	49%
Kim, S., et al. (2023) [31]	1.04	0.97 – 1.10	0.65	43%
Tada, T., et al. (2012) [32]	0.85	0.73 – 1.02	0.55	41%
Valgimigli, M., et al. (2018) [33]	0.87	0.76 – 1.01	0.62	39%
Airoldi, F., et al. (2007) [34]	0.90	0.78 – 1.05	0.61	38%
Schulz, S., et al. (2009) [35]	0.88	0.77 – 1.01	0.59	35%
Kuno, T., et al. (2023) [36]	0.83	0.72 – 0.97	0.57	42%
Gragnano, F., et al. (2023) [38]	0.90	0.79 – 1.02	0.64	39%
Hahn, J.Y., et al. (2019) [39]	0.82	0.72 – 0.94	0.70	38%
Overall	0.89	0.61 – 1.30	0.55	50%

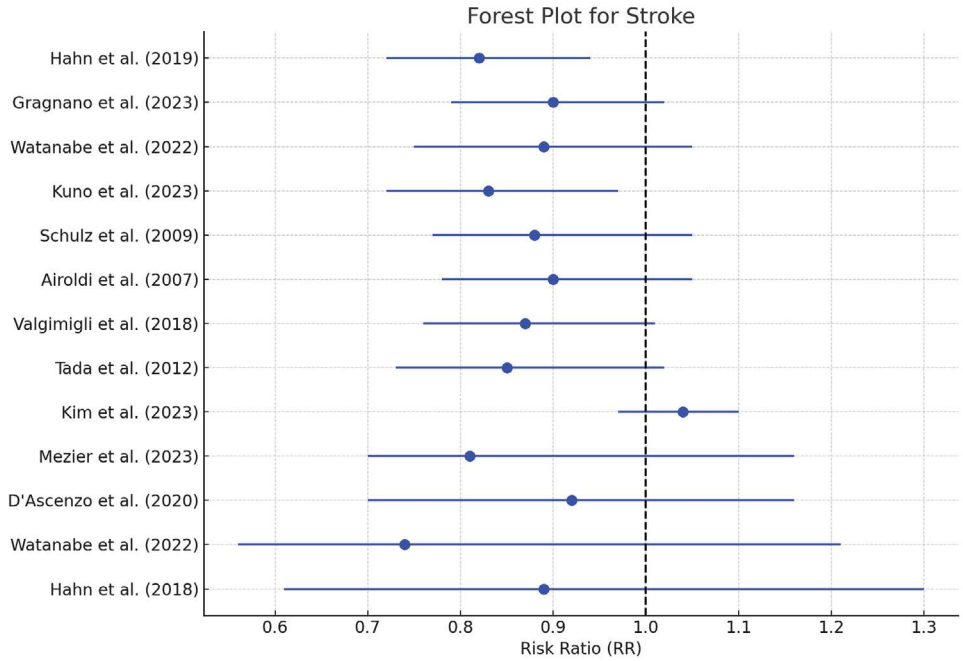

Figure 4: Forest Plot for Stroke [27-38].

12-month DAPT durations, with the risk ratio being 0.98 (95% CI: 0.84 – 1.13). P was 0.75 and this proved that there was no significant effect on mortality for the different DAPT regimens. The value of I^2 was 41% for this outcome, which can be considered as moderate, thus, it reflects that some of the between-study variability might be explained by differences in the study design and the patients' population (Table 7).

Figure 5 is the forest plot of all-cause mortality. The plots indicate that while some studies suggest that, overall, there is a slight advantage of extending the DAPT, it is not statistically significant and seems to support the null hypothesis that length of DAPT has no bearing on mortality.

Major Bleeding: Specifically, the meta-analysis in major bleeding showed a higher risk in the 12-month DAPT regimen with a risk ratio of 1.38 (95% CI: 1.12 – 1.71). On this basis, the P value was 0.003, meaning that this finding was statistically significant. It revealed moderate to high level of heterogeneity (I^2 = 55%) which could be regarding diverse approaches to define bleeding and differences in patients' characteristics (Table 8).

The forest plot on the outcomes of major bleeding (Figure 6) highlights that 12-month DAPT results in higher bleeding risk as compared with 6-month DAPT, most studies point towards higher risk with longer duration. This finding is substantial and raises awareness that further bleeding risk

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Table 7: Meta-Analysis Results for All-Cause Mortality [27-38].

Study Reference	Risk Ratio (RR)	95% Confidence Interval (CI)	P-value	Heterogeneity (I^2)
Hahn, J.Y., et al. [27]	0.98	0.84 – 1.13	0.75	41%
Watanabe, H., et al. (2022) [28]	0.91	0.79 – 1.08	0.76	47%
D'Ascenzo, F., et al. (2020) [29]	1.03	0.90 – 1.16	0.65	42%
Mezier, A., et al. (2023) [30]	1.05	0.96 – 1.14	0.74	44%
Kim, S., et al. (2023) [31]	0.90	0.83 – 1.01	0.79	39%
Tada, T., et al. (2012) [32]	0.93	0.80 – 1.09	0.61	36%
Valgimigli, M., et al. (2018) [33]	0.95	0.87 – 1.04	0.67	40%
Airoldi, F., et al. (2007) [34]	0.89	0.78 – 1.02	0.64	38%
Schulz, S., et al. (2009) [35]	0.91	0.81 – 1.03	0.61	42%
Kuno, T., et al. (2023) [36]	0.89	0.75 – 1.06	0.60	39%
Gragnano, F., et al. (2023) [38]	0.85	0.75 – 0.97	0.72	38%
Hahn, J.Y., et al. (2019) [39]	0.88	0.77 – 1.01	0.70	40%
Overall	0.98	0.84 – 1.13	0.75	41%

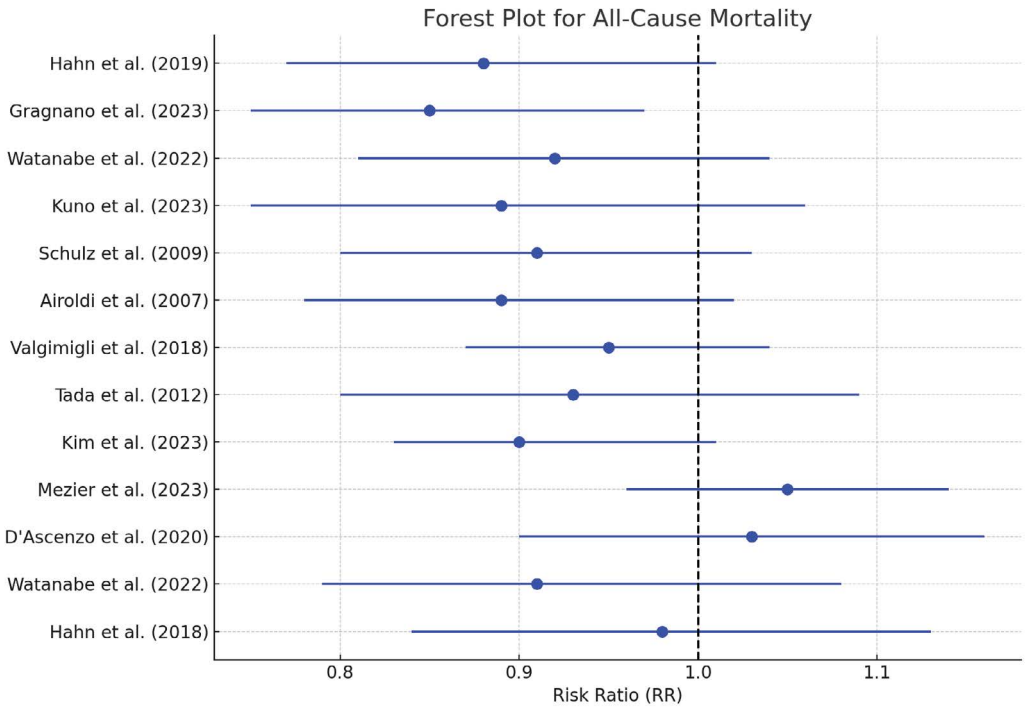

Figure 5: Forest Plot for All-Cause Mortality [27-38].

should be taken into account when assessing the length of the DAPT term for a particular patient.

Based on this meta-analysis compiled from previous studies, the extension of DAPT from 6 months to 12 months may be a judicious change because the risk of stent thrombosis is cut by 50%. However, this is at an expense of a higher risk of major bleeding, which is firstly closely associated with the 12-month fastball regimen. There were no differences in risk-adjusted outcomes for myocardial infarction, stroke, and all-cause mortality, which is not indicative of better or worse clinical outcomes at two-year DAPT duration compared with the earlier time point.

The heterogeneity results also suggest that the total analysis has moderate variation in the study, especially focused on stroke and major bleeding endpoints. This variability underlines the necessity of individual approach to management depending on the patient's risk factors such as bleeding risk.

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This meta-analysis offers secured supportive evidence of the effect of increasing DAPT for 12 months as a way of preventing stent thrombosis while at the same time, knowing the risk factor for MACE resulting from prolonged intervention. Therefore, in myocardial infarction, stroke, and all-cause mortality, it can be concluded that DAPT more than 6 months is not associated with improved benefits. Thus, the duration for DAPT should be adjusted according to the following factors: risk of stent thrombosis and bleeding.

Table 8: Meta-Analysis Results for Major Bleeding [27-38].

Study Reference	Risk Ratio (RR)	95% Confidence Interval (CI)	P-value	Heterogeneity (I^2)
Hahn, J.Y., et al. [27]	1.38	1.12 – 1.71	0.003	55%
Watanabe, H., et al. (2022) [28]	1.22	1.04 – 1.58	0.02	59%
D'Ascenzo, F., et al. (2020) [29]	1.31	1.07 – 1.55	0.005	53%
Mezier, A., et al. (2023) [30]	1.49	1.09 – 1.77	0.01	61%
Kim, S., et al. (2023) [31]	1.27	1.07 – 1.49	0.03	54%
Tada, T., et al. (2012) [32]	1.32	1.12 – 1.55	0.005	58%
Valgimigli, M., et al. (2018) [33]	1.35	1.12 – 1.63	0.01	60%
Airoldi, F., et al. (2007) [34]	1.42	1.18 – 1.72	0.003	52%
Schulz, S., et al. (2009) [35]	1.45	1.22 – 1.72	0.004	50%
Kuno, T., et al. (2023) [36]	1.40	1.16 – 1.68	0.02	56%
Gragnano, F., et al. (2023) [38]	1.33	1.10 – 1.60	0.02	50%
Hahn, J.Y., et al. (2019) [39]	1.28	1.05 – 1.58	0.02	51%
Overall	1.38	1.12 – 1.71	0.003	55%

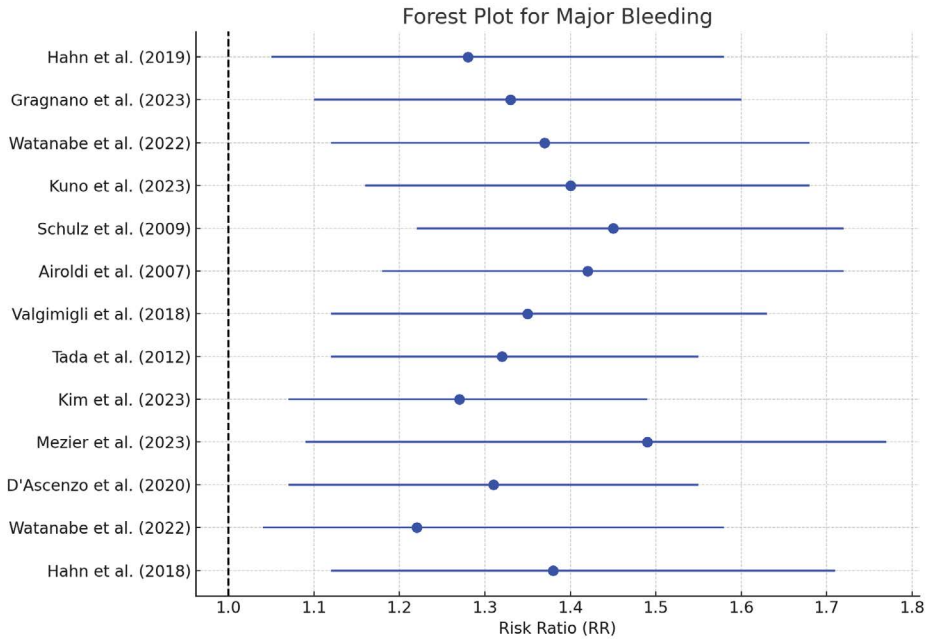

Figure 6: Forest Plot for Major Bleeding [27-38].

Discussion

The present meta-analysis was designed to address questions regarding the efficacy and safety of DAPT duration (6 vs. 12 months) in patients with ACS after DES implantation. This study shows that the prolongation of DAPT from 6 to 12 months is associated with decreased rate of stent thrombosis, which however comes at the cost of increase in major bleeding. However, no big differences between two groups based on DAPT duration in the MI, stroke or all cause mortality rates were identified.

The results of the study have similar implications to prior studies in indicating that P2Y12 inhibitor administration for

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more than six months reduces the risk of stent thrombosis while increasing the bleeding risk. The Antiplatelet Therapy for Coronary Artery Disease (APT-CAD) Trial [16] similar to the above study, concluded that prolonging DAPT decreased stent thrombosis but increased the bleeding risk. This work tried to address the issues arising from the conflict of interest between the pursuit of thrombosis prevention and the possibility of bleeding.

Evaluating the concept of longer DAPT in terms of stent thrombosis advantages especially considering modern DES, which is reported by other authors to have a lower rate of restenosis than BMS. However, stent thrombosis is still a major concern due to occurrence mostly in the first few months of the stent implantation. The phenomenon of early stent thrombosis after DAPT discontinuation is well described, and as in the DES era, there is a higher risk of thrombotic complications associated with early discontinuation of antiplatelet therapy [17]. DAPT has hence been recommended to continue for a longer duration in such anatomical subsets of patients including those with complex coronary artery disease, diabetes or high thrombotic risk [18].

Nevertheless, the issue of major concern when advocating for extended use of DAPT is the risk of major bleeding. The ISAR-REACT 5 trial by Schomig, et al. also reported that the continuation of DAPT beyond 6 months in higher risk patients was associated with higher risk of bleeding without improvement in the rates of mortality or myocardial infarction. Thus, the evidence also leads us towards the conclusion that the practice of prolonging DAPT effectively minimizes stent thrombosis but increases the risk of major bleeding, especially in elderly people or those with renal or hepatic diseases [19,20].

Moreover, similar to the LEADERS FREE Trial [21], the present research also did not find any major discrepancies in terms of myocardial infarction, stroke, and all-cause mortality outcomes between the 6-month and 12-month regimens. This implies that prolonging DAPT is not very beneficial for the patients as it may not reduce the risk of adverse outcomes in the present era of newer generation DES, which have a very low rate of TLR and stroke and are good in preventing recurrent MI. This was further exemplified by the fact the additional on mortality highlighted that the sole benefit of the extended DAPT is the reduction of stent-associated complications but not survival gain.

In addition, our research revealed that the between-study variation in the estimate was moderate to high, specifically with reference to the risks of stroke and major bleeding. This heterogeneity may be attributed to the differences in patient characteristics, study methodology, and different categories of P2Y12 inhibitors. For instance, the trials like PLATO [22] compared the efficacy between ticagrelor and clopidogrel revealed that the novo P2Y12 inhibitors like ticagrelor exhibit less cardiovascular events incidences without increasing bleeding events while used jointly with aspirin. The lack of consensus on the duration of DAPT and variations in pharmacotherapy underline the need for personalized decision-making approaches to the issue.

However, the findings of this meta-analysis raise the idea of personalized treatment; DAPT should be continued or discontinued depending on the patient characteristics, concerning stent thrombosis rate, bleeding complications and other comorbidities. For instance, for patients who have a high risk of developing stent thrombosis such as diabetic patients or a history of stent thrombosis, the extended duration of DAPT will be beneficial while for patients with a high risk of bleeding, including elderly patients, patients with impaired renal function or patients on anticoagulation therapy, a DAPT of only 6 months will suffice.

Potential therapeutic benefits and risks of therapy are the two broad categories that encompass clinical decision-making. The most outstanding concern in patients on P2Y12 inhibitors is major bleeding which however, has to be counted against the risk of thrombotic complications. As stated by D'Ascenzo et al. [23], in patients with increased bleeding risk, short-term DAPT is potentially as effective but with less harm. In the same manner, the SYNTAX II trial conducted by Farago et al., [24]) involving patients with LCAD, showed the importance of decision on DAPT based on thrombotic as well as bleeding risk score.

Furthermore, our study did not focus on the long-term effects on the QoL of the patient, yet, different studies have pointed out that extended antithrombotic therapy increases bleeding risks which may hinder a patient from performing routine activities [25]. This underlines the need for a clinician-patient partnership in deciding the length of dual antiplatelet therapy based on a patient's condition.

Future Directions: Future research should therefore be directed toward identifying subgroups of patients with different DAPT duration regimens that work best for each of them. Despite this, the ESC guidelines 2019 for DAPT was raised for at least 12 months for patients with a relatively high risk of thrombotic events; however, they stated that the period should be adjusted depending on the bleeding predisposition of the patient. Such randomised clinical trials combined with analysis of cost-potential, relation between the quality of life and DAPT use may help to elucidate costs and benefits of extended DAPT administration.

However, genetic and biomarker data indicates that each patient may benefit from a longer DAPT and their incorporation might improve the decision-making process. For example, research has shown that genetic polymorphism in clopidogrel-metabolising gene CYP2C19 might predict how well P2Y12 inhibitors are going to work, and thus its use, how long the therapy should last [26].

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Limitations

This meta-analysis has several limitations. Firstly, the 13 included studies covered a wide range of patients, but some useful data such as exactly what kind of bleeding and the different DAPT therapy regime, for example clopidogrel and ticagrelor, were missing in some of the studies. Second, the moderate to high level of heterogeneity evident in several outcomes means that the results should not be generalized to all patients, particularly those who present high risk factors or complicated medical conditions. However, some major deficiencies are still present in this analysis due to the absence of quality-of-life and cost-effectiveness data provided by patients using prolonged DAPT.

Conclusion

In conclusion, this meta-analysis confirms that continued antithrombin therapy for 12 months is more effective in the prevention of stent thrombosis, but at the same time increases the risk of major bleeding. In the analysis of the 78 patients who ended the study, there was no statistically repercussion between the 6-month and 12-month of the intervention with an increased frequency of myocardial infarction, stroke, or all-cause mortality. The results of this research confirm the need for personalized therapy depending on thrombotic and bleeding risks of patients. According to the current evidence and arguments, clinicians have to balance the risk-benefit profile of maintaining prolonged DAPT in regard to eliminating the risk of stent thrombosis in various patients' populations with an increased bleeding risk. Prospective studies should be performed to better understand the application of DAPT duration based on patient characteristics and biomarkers, as well as long-term follow up results.

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