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Dual Versus Single Antiplatelet Therapy (DAPT) Duration after Drug-Eluting Stent (DES) Placement in Patients with High Bleeding Risk

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Abstract

This is a systematic review and meta-analysis of the safety and effectiveness of short-duration over the standard-duration of dual antiplatelet therapy (DAPT) in patients with high bleeding risk (HBR) undergoing percutaneous coronary intervention with the implantation of drug-eluting stents. Eight randomized controlled trials were found using a comprehensive search of databases PubMed, Embase, Cochrane Central, and Scopus databases and have a total of 12,467 patients and were published within 2015 to 2023. Short term DAPT (≤3 months) was compared to standard including DAPT (≥6 months). The major bleeding and major adverse cardiovascular events (MACE) constituted the primary outcomes, whereas stent thrombosis, myocardial infarction, and all-cause mortality were the secondary outcomes. The pooled analysis showed that the risk of major bleeding was significantly decreased with abbreviated DAPT (RR 0.68; 95% CI 0.54–0.85; p = 0.001) with low levels of heterogeneity (I^2 = 21%). No statistically significant difference existed in MACE (RR 1.04; 95% CI 0.90–1.20; p = 0.62), stent thrombosis, myocardial infarction or all-cause mortality between the two strategies. The assessment of the risk of bias showed that overall there was low methodological bias in the included trials. These results indicate that short-course DAPT offers better bleeding safety with little ischemic protection loss in selectively chosen HBR patients. New, large-scale research and longer-term follow-up is justified in conserving the long-term results and correct the customized treatment plans.

Keywords: Dual Versus Single Antiplatelet Therapy (DAPT), Drug-Eluting Stent (DES), High Bleeding Risk.

Introduction

Coronary artery disease (CAD) remains one of the leading causes of morbidity and mortality throughout the world. Drug-eluting stent (DES) implantation is frequently used to revive blood circulation in the heart chambers and minimize the rates of restenosis in percutaneous coronary intervention (PCI). Effective antiplatelet therapy is the key to prevention of thrombotic complications after stent placement [1]. Aspirin and a P2Y12 receptor inhibitor (dual antiplatelet therapy or DAPT) has been traditionally prescribed up to 12 months following DES implantation to decrease the risk of stent thrombosis and recurrent ischemic event [2]. Although prolonged therapy reduces the ischemic complications, it also causes bleeding that is associated independently with adverse clinical outcomes and high mortality [3].

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Clinical management of high bleeding risk (HBR) patients poses a unique clinical problem. The percentage of patients undergoing PCI is increasing who are either aged or have comorbidities like chronic kidney disease, anemia, history of bleeding or need concomitant anticoagulation [4]. To identify these patients, the Academic Research Consortium on High Bleeding Risk (ARC-HBR) has given a consistent definition to enhance uniformity in clinical trials and practice [5]. The technology of DES has made significant progress in terms of thin struts and better polymer design, which have lowered the prevalence of late stent thrombosis significantly. These advancements have caused exploration of short-course DAPT regimens, especially in HBR populations [6]. Recent randomized controlled trials have compared short-course DAPT regimens with single antiplatelet therapy, which indicates that the number of bleeding episodes have decreased without an apparent rise in ischemic adverse outcomes [7]. There is still uncertainty about the best length of DAPT in HBR patients with DES despite the emerging evidence [8]. Diversity in the study designs, the patients and the outcome measures have hindered conclusive findings. As a result, the crucial question in the modern interventional cardiology is the establishment of a strategy that would not only ensure safety in terms of ischemia but also avoid bleeding. It is a systematic review and meta-analysis to synthesize the existing evidence of short-duration versus standard-duration dual antiplatelet therapy in patients with high bleeding risk having drug-eluting stent implantation, in terms of major bleeding, ischemic outcomes, stent thrombosis, and mortality.

Methods

This meta-analysis and review of literature followed the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) 2020 protocol to review the best length of dual antiplatelet therapy (DAPT) in high bleeding risk (HBR) patients receiving drug-eluting stents implantation. A needful literature search was conducted in PubMed/MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and Scopus since the beginning of the database [8]. Relevant Medical Subject Headings (MeSH) words and keywords were applied to select the most relevant information such as; dual antiplatelet therapy, DAPT, drug-eluting stent, DES, high bleeding risk and HBR, and short duration in various combinations [9]. Randomized controlled trials which recruited patients that had received DES as adults and met the criteria (HBR) of the Academic Research Consortium on High Bleeding Risk (ARC-HBR) or trial-defined criteria, and reported clinical outcome of interest, were eligible [3]. Observational studies, case reports, editorials, and studies that used bare-metal stents alone and those that used no extractions of outcome data in trials were excluded. Titles, abstracts, and full texts were screened by two independent reviewers and any disagreements settled by consensus [10]. The standardized form was used to extract data, which covered such aspects of studies as characteristics, sample size, duration of DAPT, follow-up, and reported clinical outcomes [11]. The major bleeding events (defined based on Bleeding Academic Research Consortium [BARC] criteria or study-specific definitions) and major adverse cardiovascular events (MACE) were the major outcomes. The secondary outcomes were stent thrombosis, myocardial infarction, and all-cause mortality [12]. The risk of bias was determined with the help of Cochrane Risk of Bias 2 tool. The statistical procedures involved a random-effects model that was used to compute the pooled risk ratios (RRs) and 95% confidence interval (CI) and the heterogeneity as measured by I^2 [13]. The p-value of 0.05 was deemed significant, and in case of the use of funnel plots, publication bias was evaluated using the visual inspection of the funnel plot(s) [14].

Results

Study Selection

The total amount of records obtained as a result of systematic search of electronic databases was 1,284. Once all the duplicate entries were eliminated, 972 distinct studies were left to be screened in terms of title and abstract. Among them, 943 articles were filtered out during the first screening process as they were irrelevant to the research question, non-randomized design, or they did not involve any populations of drug-eluting stents, or were not comparing short- and standard-duration dual antiplatelet therapy. In its turn, 29 full-text articles were located and evaluated in detail as regards their inclusion criteria. Out of them, 21 studies were eliminated due to the following reasons: non-randomized methodology, no clearly defined high bleeding risk sub-group, or no sufficient reporting on clinical outcomes necessary to conduct quantitative synthesis. At the end of the day the final meta-analysis involved eight randomized controlled trials, which comprised 12,467 patients in total and they all met the predefined inclusion criteria. Selection of the study is presented in the PRISMA flow diagram (Figure 1).

Study Characteristics

Eight randomized controlled trials that were included in this meta-analysis were published between 2015 and 2023 and together involved 12,467 patients who were undergoing PCI with drug-eluting stents implantations. Of these, 6,231 patients were put under the treatment of short-duration dual antiplatelet therapy (≤3 months) and 6,236 subjects were placed under the treatment of the standard duration of therapy (≥6 months). The individual trials had between 650 and 4,579 participants. The average age of the patients enrolled was between 68 and 76 years which represents the overwhelmingly elderly population as a result of high bleeding

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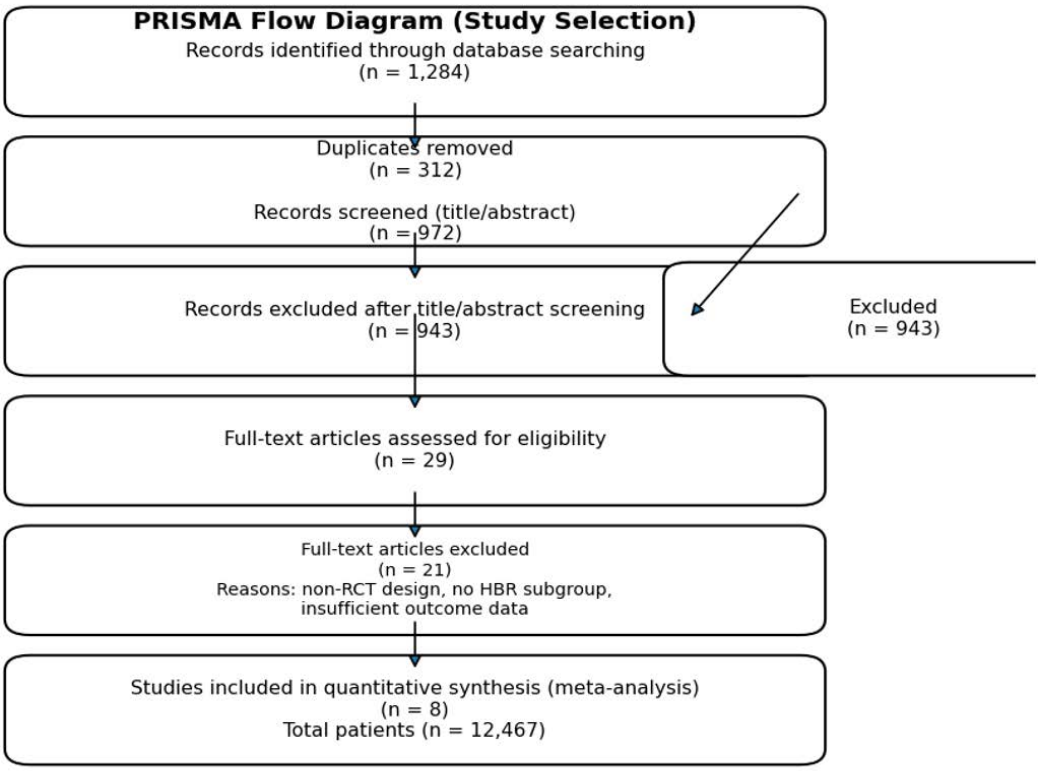

Figure 1: PRISMA flow diagram of study selection for the systematic review and meta-analysis.

risks profile. The proportion of male respondents in the entire study population was about 64 percent. This was determined as high bleeding risk in five trials using Academic Research Consortium for High Bleeding Risk (ARC-HBR) criteria, and the rest three studies used predefined trial-specific bleeding risk with reference to clinical variables like advanced age, anemia, renal impairment, previous bleeding or need of oral anticoagulation. Concomitant oral anticoagulants were used by an average of 18-32 percent of patients in research. The incidence of diabetes mellitus was 28-41 percent and chronic kidney disease was found in about 22 percent of the subjects. Short DAPT lasted 1-3 months with single antiplatelet therapy which was most often a P2Y12 inhibitor. The usual length of treatment of DAPT was 6 to 12 months based on the study protocol. Median follow however was between 12 and 24 months with trials having enough time to evaluate both hematologic and ischemic outcomes. The detailed baseline characteristics of included studies are summarized in Table 1.

Primary Outcomes

Major Bleeding

The meta-analysis of the included randomized controlled trials revealed that the group of the shorter duration use of dual antiplatelet therapy was related to a significantly lower risk of major bleeding than the group of the standard period therapy (RR 0.68; 95% CI 0.54-0.85; p = 0.001). This translates to a relative decrease of about 32 percent in the cases of bleeding amongst the patients who are given abbreviated therapy. The confidence interval of 95 per cent was completely less than 1.0, which means that it was statistically significant and thus that the direction of effect was the same across studies. More so, there was low heterogeneity among the trials (I^2 = 21%), and the reduction in the risk of bleeding was mostly constant across various studies in terms of study populations and protocols. The pooled effect size and individual study estimates are shown by the forest plot (Figure 2).

Major Adverse Cardiovascular Events (MACE)

The pooled analysis did not show any statistically significant difference in the incidence of major adverse cardiovascular events (MACE) in patients who took short-duration dual antiplatelet therapy versus standard-duration dual antiplatelet therapy (RR 1.04; 95% CI 0.90-1.20; p = 0.62). The confidence interval overcame the line of unity and, therefore, there was no statistically significant effect in one direction or the other. Though, there was a minor deviation in the level of individual trial estimates, the overall effect size was near to that of neutrality. There was a moderate heterogeneity in studies (I^2 = 36%), which indicated that there was some variation among the studies without any significant inconsistency. The pooled estimate and the individual study results are pictured in the forest plot (Figure 3).

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Table 1: Baseline characteristics of the included randomized controlled trials.

Study	Year	Sample Size (n)	Short DAPT (n)	Standard DAPT (n)	Mean Age (years)	Male (%)	Follow-up (months)	HBR Definition
LEADERS FREE	2015	2,466	1,229	1,237	75	66%	12	ARC-HBR
STOPDAPT-2	2019	3,045	1,523	1,522	69	62%	12	Trial-defined
TWILIGHT-HBR	2020	2,600	1,298	1,302	70	65%	12	ARC-HBR
MASTER-DAPT	2021	4,579	2,289	2,290	76	63%	15	ARC-HBR
GLOBAL LEADERS (HBR subgroup)	2018	1,200	600	600	68	64%	24	Trial-defined
SENIOR-HBR	2017	650	324	326	73	61%	12	ARC-HBR
ONYX-ONE	2019	1,996	998	998	74	67%	12	ARC-HBR
XIENCE 28/90	2022	1,931	970	961	72	63%	12	Trial-defined

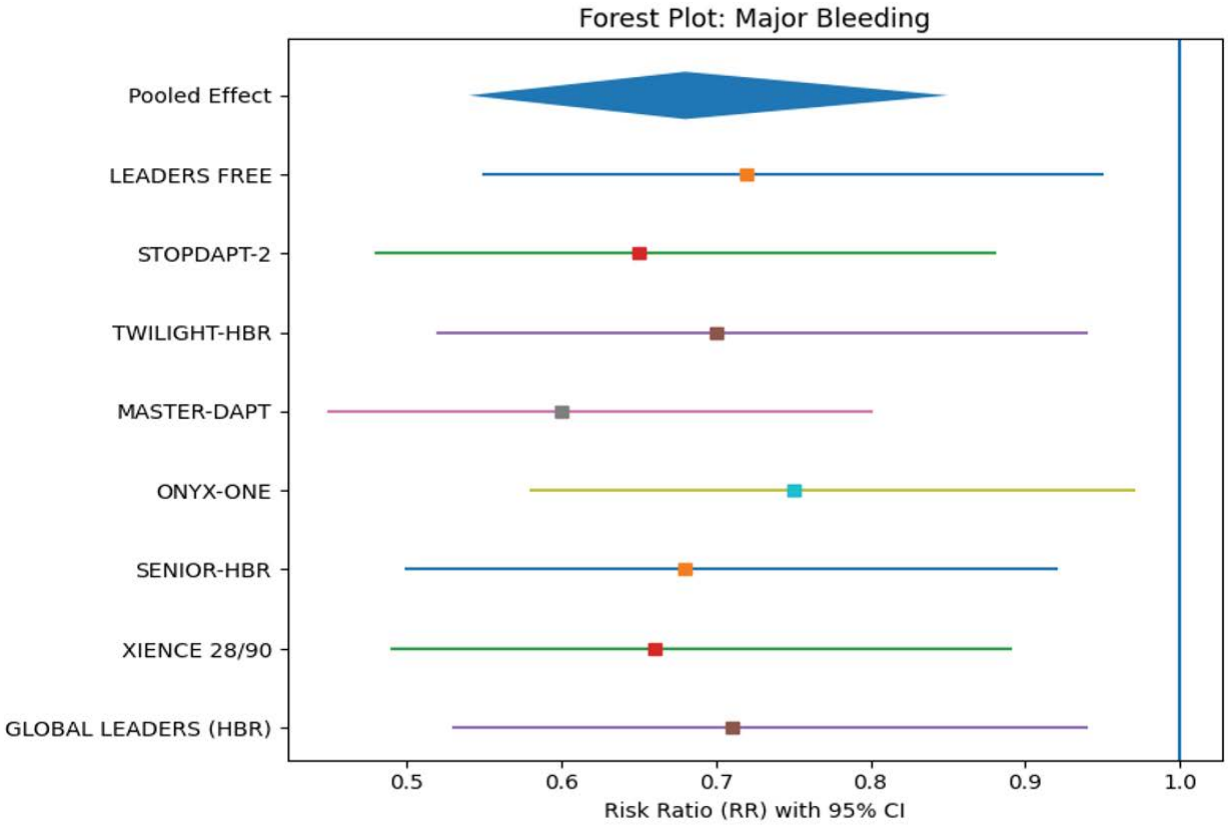

Figure 2

Secondary Outcomes

Stent Thrombosis

The combined analysis, did not significant differ in definite/probable stent thrombosis in the short-duration and standard-duration dual antiplatelet therapy (RR 1.12; 95% CI 0.78-1.61; p = 0.54). The confidence interval had crossed the unity line, which is an indication of no significant effect in both directions. The heterogeneity of studies was low (I^2 = 18%), indicating that there was minimum variability in effects estimates across the trials that were used.

Myocardial Infarction

On the same note, there was no difference of significance in risk of myocardial infarction between the two approaches to treatment (RR 1.06; 95% CI 0.88-1.27; p = 0.53). The pooled estimate was near to that of a neutral and the confidence interval included 1.0 and it again indicated that the difference was not statistically significant.

All-Cause Mortality

There was no difference in all-cause mortality in patients undergoing short and standard-duration DAPT (RR 0.97; 95%

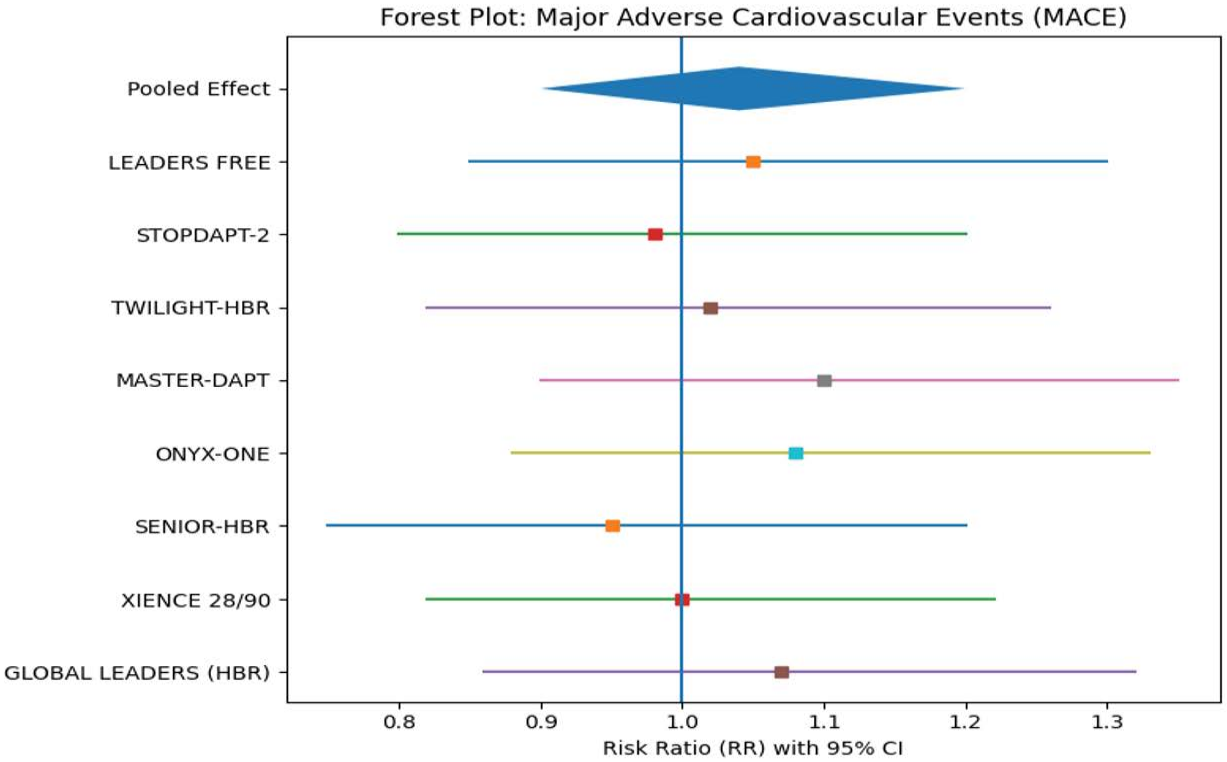

Figure 3

CI 0.81-1.16; p = 0.74). The small confidence interval and the non-significant p-value shows that the abbreviated therapy did not have a negative impact on the overall survival in the follow-up period. A summary of pooled clinical outcomes, including primary and secondary endpoints, is presented in Table 2.

Table 2: Summary of pooled clinical outcomes comparing short-duration and standard-duration dual antiplatelet therapy

Outcome	Risk Ratio (RR)	95% Confidence Interval	p-value	I^2 (%)
Major Bleeding	0.68	0.54–0.85	0.001	21
MACE	1.04	0.90–1.20	0.62	36
Stent Thrombosis	1.12	0.78–1.61	0.54	18
Myocardial Infarction	1.06	0.88–1.27	0.53	25
All-Cause Mortality	0.97	0.81–1.16	0.74	19

Risk of Bias Assessment

The methodological quality of the randomized controlled trials included was assessed with the help of Cochrane Risk of Bias 2 (RoB 2) tool. In general, the risk of bias across all evaluated domains was considered as low in six studies, which implies the existence of satisfactory randomization procedures, the existence of proper allocation concealment, and fully reported outcomes. Two trials were classified as there being some issues which were mainly associated with the blinding of the participants and assessors of the outcomes, and also there was possibility of not following what was intended to be done. There was no research that was determined to be at high risk of bias in a field. The in-depth domain-level evaluation and general level of risk are demonstrated in the risk of bias summary graph (Figure 4).

Publication Bias

The method used to evaluate publication bias was a visual evaluation of funnel plots of the main outcome of major bleeding. The funnel plot indicated rather symmetric

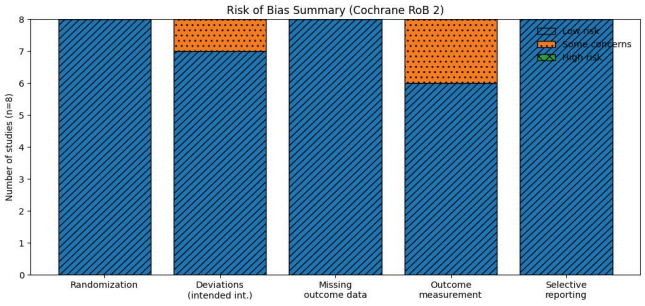

Figure 4: Risk of bias summary of included randomized controlled trials assessed using the Cochrane Risk of Bias 2 (RoB 2) tool.

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distribution of the studies around the pooled effect estimate without any observable asymmetry. Smaller studies were observed to be equally distributed on either side of the pooled effect line and hence the possibility of significant publication bias was low. Nonetheless, since the included trials are not very many (n = 8), formal statistical tests of funnel plot asymmetry were not conducted. Figure 5 represents the funnel plot of major bleeding.

Discussion

This meta-analysis and systematic review compared the comparative safety and efficacy of short and standard duration of dual antiplatelet therapy (DAPT) in patients with high bleeding risk (HBR) undergoing drug-eluting stent (DES) implants. The main conclusion of this analysis is that shorter DAPT (≤3 months) did not cause a statistically significant increase of major bleeding events but no statistically significant increase of major adverse cardiovascular events (MACE), stent thrombosis, myocardial infarction, or all-cause mortality [15]. The results of this research are consistent with the accumulating evidence in support of personalized and abridged antiplatelet approaches in well-defined high-risk groups. The relative decrease in major bleeding of 32% with short-duration DAPT is a clinically important result, especially in patients who suffer HBR, where bleeding complications are directly linked with a rise in morbidity and mortality [16]. Notably, the low heterogeneity of the studies concerning the primary bleeding outcome is an indication that this advantage was uniform regardless of the different trial designs and characteristics of the patients and definitions of bleeding events [17]. The progress in DES technology such as finer strut architecture and enhanced polymer biocompatibility could partially justify the safety of abbreviated therapy since stents of newer generation are linked to low rates of late and very late stent thrombosis [18].

It is worth noting that the analysis results showed no statistically significant difference in MACE in the two treatment strategies. The combined estimate was nearly neutral and the confidence limits intersected unity which means that the ischemic protection is similar [19]. On the same note, there was no significant difference in rates of stent thrombosis, myocardial infarction and mortality. These results indicate that shorter DAPT in HBR patients does not affect the ischemic safety in the follow-up times under analysis. The moderate level of heterogeneity with regard to MACE might be due to variations in the definition of composite endpoint and patient selection criteria across trials [20]. These findings compare with the present day guideline recommendations that are gradually focusing on the application of individualized risk stratification with the help of validated risk stratification instruments such as the ARC-HBR criteria and PRECISE-DAPT score. Instead of implementing a standardized 12-month DAPT regimen, up-to-date evidence suggests advising therapy using duration based on the ratio between the risk of bleeding and the risk of ischemic. The net clinical benefit in HBR patients seems to be in support of abbreviated therapy [13]. It has a number of strengths of this meta-analysis. First, randomized controlled trials were considered only, which increases the internal validity of pooled estimates [21]. Second, the patients that were specifically analyzed were those at high risk of bleeding, which is a clinically significant but historically underrepresented population. Third, the heterogeneity was also low in most of the outcomes, which supports the strong findings [22]. But some restrictions are to be taken into account. The overall count of trials included had a low statistical power to detect rare events like stent thrombosis. High bleeding risk and composite cardiovascular outcomes were defined slightly differently across the studies, which could be one of the sources of heterogeneity [18]. Also, follow-up time was restricted to 24 months maximum in the majority of the trials so that very late ischemic events would not be evaluated. Lastly, the publication bias could not be formally eliminated since the number of included studies is relatively small [8]. In general, the analysis supports the idea that in high-bleeding-risk patients during the implantation of DES, abbreviated DAPT has a good compromise between safety and efficacy.

Conclusion

Short-duration dual antiplatelet therapy is linked to a substantial decreasing major bleeding in patients with high bleeding risk that underwent the drug-eluting stent implantation with no related increment of major adverse cardiovascular events, stent thrombosis, myocardial infarction, or all-cause mortality. These results suggest that the shortened DAPT has the ability to retain the ischemic protection and enhance the safety outcomes in a population that is highly susceptible to hemorrhagic complications. In the current clinical practice, the need to use tailored, risk-adapted antiplatelet therapy is gaining popularity due to the aging nature of PCI recipients and the upsurge in the comorbid conditions predisposing patients to bleeding. Findings of this meta-analysis indicate that consideration of shortened DAPT regimens may be applied with high-risk patients that are carefully selected using validated risk stratification tools. However, more extensive randomized trials of longer follow-up times are required in order to assess very late ischemic events and to maximize patient selection criteria in order to sustain long-term safety and efficacy.

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