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Prolonged Dual Antiplatelet Therapy in High-Risk ACS Patients: Insights from the OPT-CAD Study

Faraaz Zaveri[1*], Saria Naser[2]
[1]*Department of Cardiology, Texila American University, Nicaragua*
[2]*Department of General Medicine, Soochow University, China*

Abstract

This review delves into the discussion of the "Effect of dual antiplatelet therapy prolongation in acute coronary syndrome patients with both high ischemic and bleeding risk" explored in the OPT-CAD study. The research was directed at identifying patients with acute coronary syndrome who presented a bi-risk profile of high ischemic and bleeding risks and further evaluated the safety and efficacy of extended use of DAPT beyond 12 months post-PCI. The current review, through post hoc analysis of the OPT-CAD trial data, discusses the five-year incidence of ischemic and bleeding events in bi-risk patients. Indeed, extended DAPT has reduced the incidence of stroke without significant major bleeding risks. This review will cover the methodology of the findings presented, the results, and their clinical implication in real-world practice for the management of ACS.

Keywords: *ACS, Bleeding Risk, DAPT, Ischemic Risk, OPT-CAD Study, Stroke Prevention.*

Introduction

Dual antiplatelet therapy (DAPT) represents the cornerstone in the management of acute coronary syndrome (ACS), especially following the implantation of drug-eluting stents (DES). Traditionally, DAPT has been recommended for at least 12 months to prevent stent thrombosis and recurrent ischemic events. However, the optimal duration of DAPT, in particular in patients at both high ischemic and bleeding risk or so-called bi-risk, is still a matter of debate. However, longer DAPT may reduce ischemic events but increases the concern about increased bleeding complications. The OPT-CAD study addresses this specific issue regarding the feasibility of DAPT in extending bi-risk ACS patients.

This review of findings is based on the OPT-CAD study, which involved stratification of patients by the OPT-BIRISK criteria. These criteria identified those patients who were at high risk both from ischemic and bleeding complications. The primary objective was to evaluate the benefit of DAPT duration beyond 12 months to prevent ischemic events, with special reference to stroke, maintaining an acceptable safety profile regarding bleeding risks [1].

Materials and Methods

The OPT-CAD study was a post hoc analysis of a large-scale, prospective registry consisting of 7,049 ACS patients who have undergone PCI. This registry allowed the investigators to apply the criteria according to OPT-BIRISK, classifying patients at risk for ischemic and bleeding events. They divided the study population into two groups: continued DAPT beyond 12 months versus switching to single antiplatelet therapy.

Data Sources

Data were derived from the Optimal Antiplatelet Therapy for Chinese Patients with Coronary Artery Disease (OPTCAD) registry [2]. Ethical approval was obtained from all

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****Corresponding Author: drfaraazzaveri@outlook.com***

participating centers and written informed consent was collected from each patient.

Risk Assessment

OPT-BIRISK criteria were used to define patients at high ischemic and bleeding risk. These included age, multivessel coronary disease, previous ischemic events-myocardial infarction or stroke-diabetes mellitus, chronic kidney disease, and the total length of the stents used during PCI. Bleeding risk was defined by advanced age, prior ischemic stroke, iron deficiency anaemia, and some medications. The patient distribution within the study population is illustrated in Figure 1, showing that 58.8% of patients had a bi-risk profile (see Figure 1).

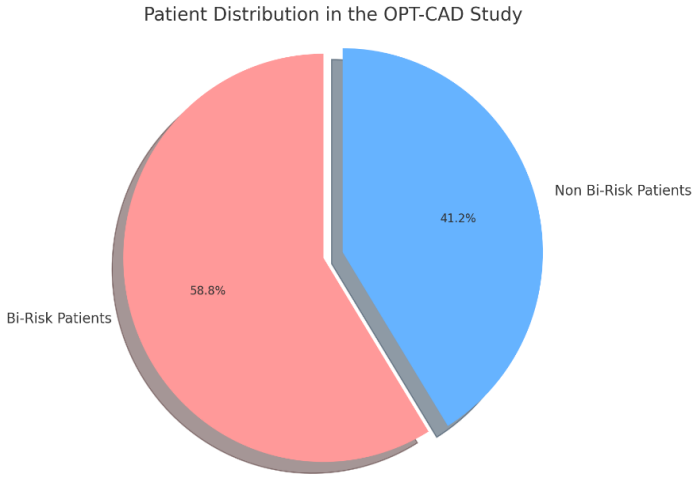

Figure 1. Patient Distribution in the OPT-CAD Study

Statistical Analysis

The propensity score matching was applied to balance the two groups according to demographic and clinical characteristics. The time-to-event outcomes, including ischemic events (composite of stroke, myocardial infarction, and cardiac death), as well as bleeding events according to the Bleeding Academic Research Consortium (BARC) classification, have been studied using Kaplan-Meier curves and the log-rank test.

Results

Accordingly, the present study demonstrated that in bi-risk patients, prolonged DAPT resulted in a lower incidence of ischemic events, mainly stroke, compared to SAPT: 1.10% versus 2.10%, P=0.036. Major bleeding, BARC 2, 3, and 5, did not differ significantly between the two groups, with bleeding rates for the DAPT and SAPT groups being 1.26% and 0.79%, respectively (P=0.282). However, it did not show a significant difference in the risk of all-cause mortality and MI. A comparison of ischemic and bleeding events between the extended DAPT and SAPT groups is presented in Table 1, highlighting the lower incidence of ischemic events in the DAPT group (see Table 1). The Kaplan-Meier curve illustrates the stroke-free survival probability over a 24-month follow-up period for patients on extended DAPT compared to SAPT (see Figure 2).

Table 1. Comparison of Ischemic and Bleeding Events in Patients Treated with Extended DAPT Versus SAPT

Outcome	Extended DAPT (%)	SAPT (%)	P-Value
Ischemic Events (Stroke)	1.10	2.10	0.036
BARC 2,3,5 Bleeding Events	1.26	0.79	0.282
Cardiac Death	0.72	0.52	0.572
Myocardial Infarction (MI)	0.51	0.26	0.539

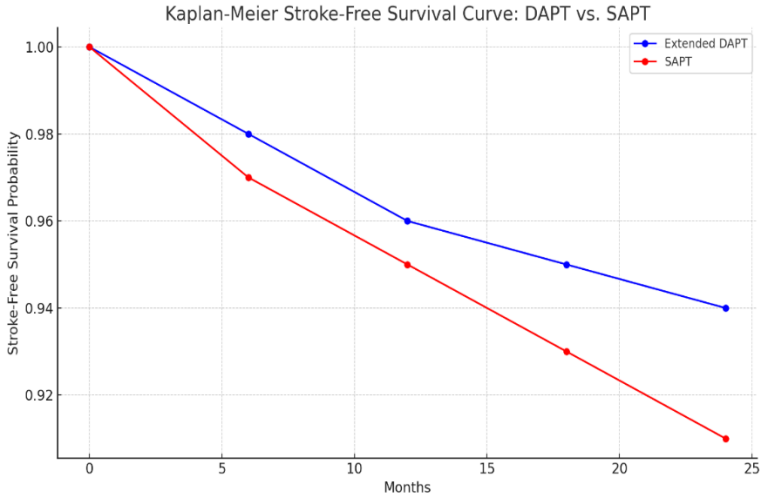

Figure 2. Kaplan-Meier Stroke-Free Survival Curve: DAPT vs. SAPT. This Curve Shows the Stroke-Free Survival Probability over a 24-month Follow-up Period for Patients on Extended DAPT Compared to those on SAPT. The Extended DAPT Group Maintained a Higher Probability of Stroke-Free Survival.

Clinical Implications

The results of the OPT-CAD study thus confirm the need for individual risk stratification in ACS patients who will benefit from extended DAPT. Given the dramatic reduction in stroke incidence observed with extended DAPT, in bi-risk patients, this is especially true for those patients at higher risk of cerebrovascular events in whom prolonged therapy may confer substantial clinical benefits [3]. However, this modest increase in bleeding events underlines careful monitoring and careful patient selection if one considers an extension of DAPT beyond the 12-month standard.

Discussion

Results from the OPT-CAD study showed that in bi-risk ACS patients, prolonged DAPT could reduce ischemic events, especially stroke, without a significant excess of major bleeding [4]. The hazard ratios and confidence intervals for key clinical outcomes in the extended DAPT versus SAPT groups are detailed in Table 2 (see Table 2). These results therefore support extended DAPT as a plausible treatment strategy for those high-risk patients who could tolerate 12 months of DAPT without adverse events. This study also draws on the consideration of individualized treatment approaches focused on patient-specific ischemic and bleeding risks.

Considering somewhat less optimistic conclusions from previous studies, such as the DAPT trial results showing increased bleeding risk after prolongation of the therapy, OPTCAD gives evidence for supposing that protracted DAPT may have a better risk profile in certain populations [5]. However, the major limitations of this study are related to the observational design and the highly specific Chinese population. Major randomized trials, therefore, should be undertaken with the purpose of confirmation of these findings in more heterogeneous populations.

Table 2. Hazard Ratios and Confidence Intervals for Key Clinical Outcomes in Extended DAPT vs SAPT

Outcome	Hazard Ratio (DAPT vs. SAPT)	95% Confidence Interval	P-value
Stroke	0.51	0.25–1.02	0.036
Major Bleeding	1.26	0.79–1.58	0.282

Conclusion

The OPT-CAD study extends insights into important aspects of managing ACS patients with both a high ischemic and bleeding risk [6]. One point it raises is that DAPT extended beyond the usual 12-month period, leads to important clinical benefits regarding the reduction of stroke risk in these high-risk populations. In this regard, this study identified that long-term DAPT reduces ischemic events, principally a stroke, but the bleeding risk was not statistically significant, hence probably making it a valuable approach in well-chosen patients.

However, the decision to extend DAPT has to be markedly individualized. This current investigation fully supports prolonged DAPT, but clinicians should be very aware of the complexities of managing patients with high ischemic and bleeding risks. Thus, clinicians have to balance stroke prevention benefits against the potential for bleeding complications using particular tools, such as the OPT-BIRISK criteria, guiding the treatment choices.

The 2 major limitations of the OPT-CAD study were its observational design and selected population. Therefore, the results presented here will need additional confirmation in larger randomized controlled trials that also involve more diverse patient populations. Additional data are also needed for which patient subgroups extended DAPT confers the most benefit and to fully elucidate the long-term consequences of the therapy.

In relation, while OPT-CAD supported the extension of DAPT in high-risk ACS, this underlined the need for personalized medicine. The need is to provide personalized approaches toward individual risk profiles to maximize benefits while minimizing adverse effects. Clinicians must therefore remain watchful in weighing ischemic event risk against bleeding in each patient when seeking to determine the optimal duration of DAPT therapy. The present study represents a very important contribution to the current active debate concerning the duration of DAPT and thus sets the stage for further studies with the goal of refining strategies in the management of these very complex patients.

Conflict of Interest

The authors declare no conflict of interest.

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