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Review Article

Reasons and clinical outcomes of dual antiplatelet therapy cessation in coronary stenting patients: a systematic review

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ABSTRACT

Percutaneous coronary intervention (PCI) requires dual antiplatelet therapy (DAPT). PCI-related DAPT cessation is prevalent. There are several reasons for DAPT cessation, each with clinical outcomes. A comprehensive literature review was performed across multiple databases, including PubMed, Scopus, Science Direct, and ProQuest for 2018 – 2023. The primary criteria for selected papers were the reported percentage of the study population classified as non-adherence. Secondary criteria include reasons for cessation or clinical outcomes of non-adherence. Quality assessment of the included studies was also evaluated. Eleven articles met the criteria and were analyzed. The extent of DAPT non-adherence was between 4.6% and 55.8%. All studies had no universal agreement regarding the definition of non-adherence and the reasons for DAPT cessation. The PARIS and the NARC studies are the biggest studies correlating the reasons for and the clinical outcomes of DAPT non-adherence. PARIS uses simpler categories for reasons of non-adherence, such as discontinuation, interruption, and disruption, while NARC uses risk profile change, events, surgery, unlisted, logistics, and trauma. Among those reasons, patient-driven non-adherence has the most significant negative impact on cardiac events in both studies. Furthermore, early DAPT discontinuation of at least 30 days had greater cardiac events. Adherence to DAPT after PCI is still challenging for patients undergoing PCI. Even though cardiac events may occur during adherence to DAPT treatment, the healthcare team must be aware of patient-owned decisions regarding non-adherence.

Keywords: DAPT, Reasons, Cessation, PCI, Cardiovascular

Introduction

Percutaneous Coronary Intervention (PCI) is considered a recommended treatment for Acute Coronary Syndrome (ACS) based on the guidelines provided by the American College Cardiology Foundation (ACCF) and the American Heart Association (AHA). It is recommended that DAPT be provided for 6-12 months to treat patients with ACS after PCI. The DAPT regimen combines aspirin with a platelet P2Y12 inhibitor [1, 2]. The utilization of DAPT after PCI is a prolonged therapeutic approach that risks inducing non-adherence to the prescribed medications. According to the World Health Organization, the average patient adherence rate to long-term treatment for chronic diseases in industrialized countries is approximately 50%. This adherence rate is anticipated to be significantly lower in low-income countries [3]. Adherence to DAPT is crucial for enhancing clinical outcomes and cost-effectiveness. However, the exorbitant expenses associated with post-PCI care, particularly DAPT, sometimes lead to premature

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discontinuation of DAPT among numerous patients [4]. A significant proportion of patients (48%) demonstrated non-adherence to DAPT [5]. Early DAPT discontinuation is a strong predictor for stent thrombosis, and a 3-day delay in filling DAPT (clopidogrel) showed higher death/myocardial infarct [6, 7]. Bleeding from DAPT also causes DAPT premature discontinuation [8, 9]. Previously, a review of DAPT adherence showed factors associated with non-adherence [6]. However, the reasons for non-adherence and the association between reasons for non-adherence and their clinical outcomes have yet to be performed. Cardiac events following DAPT cessation occur depending on clinical circumstances and reasons for cessation and attenuate over time [10]. This present review aimed to determine the extent of patient non-adherence to DAPT among individuals after PCI, the reasons for DAPT non-adherence, and the association between the reason for cessation and clinical outcomes.

Materials and Methods

Search strategy

The research design used is a systematic review of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) [11]. A comprehensive literature search was performed across multiple databases, including PubMed, Scopus, Science Direct, and ProQuest. The search methodology employs keywords derived from the research inquiry and Boolean operators (AND, OR, NOT, AND NOT). The search query consists of the following terms: "Acute Coronary Syndrome" or ACS, "Percutaneous Coronary Intervention" or PCI, "Dual Antiplatelet Therapy" or DAPT, and "Cessation" or Medical Adherence" or "Compliance." The present systematic study utilizes secondary data from journals, textbooks, and scientific articles.

Study selection

The literature search findings were documented and categorized, followed by a comprehensive analysis based on the predetermined criteria for inclusion and exclusion. The inclusion criteria encompass the following aspects: 1) The type of article from secondary data must be original research; 2) The research papers must pertain to adherence or non-adherence to DAPT utilization; 3) The articles must be available in either Indonesian or English languages; 4) The study must have been published during the last five years, namely between 2018 and 2022. The exclusion criteria include: 1) Articles that lack open access availability; 2) Reviews of articles; 3) Articles that consist of abstracts; 4) Articles written in languages other than Indonesian or English. The PRISMA flowchart for the study selection process is shown in **Figure 1**.

Data collection

All relevant articles that satisfy the specified inclusion criteria are compiled into a single repository. The subsequent phase involves doing a thorough examination to identify any instances of article duplication. Subsequently, the articles will go to the screening stage. The data from the research included in the analysis were manually retrieved using a preset format in Microsoft Excel. Data about the features of each study were extracted, including details such as the author's name, year of publication, title, country of origin, study aims, study design, data collection methods, outcome measures, type and duration of DAPT utilized, as well as any additional relevant supporting information. The gathered data is subjected to analysis and subsequent discussion. Moreover, all articles included were analyzed for quality using Study Quality Assessment Tools [12]. Study Quality Assessment Tools consist of fourteen questions either for observational cohort and cross-sectional studies or controlled-intervention studies. Two raters were selected from all the authors of this study review led by the corresponding author to justify the quality of the study selected in this review. The quality of the study was categorized as good, fair, and poor [12]. Additional supporting information for fourteen questions for the assessment of the quality of the study is provided.

Results and Discussion

Based on the literature search results through PubMed, Scopus, ProQuest, and Science Direct publications, the author found 489 related articles published in 2018-2022. Six articles were obtained from the PubMed database, 45 from the Scopus database, 79 from the Science Direct database, and 354 from the ProQuest database. The research articles were then screened by considering the inclusion and exclusion criteria. Four hundred sixty-eight articles are processed into the next stage, namely by reading the full text of the article. Eight relevant studies were obtained. There were two additional articles from Google Scholar, so the total number of articles included in the analysis phase is 10. Nine articles were observational studies [4, 8, 13-18]. Only one article was an interventional study [19]. Quality assessment of selected studies was performed using Study Quality Assessment Tools [12]. The articles that have been reviewed are then summarised in **Table 1** below.

DAPT combines two types of antiplatelet therapy: aspirin and P2Y12 inhibitors consisting of either clopidogrel, prasugrel, or ticagrelor. This DAPT is used in patients with ACS who have undergone cardiac catheterization or PCI. DAPT efficiently reduces platelet aggregation, limiting the risk of stent thrombosis or vascular thrombosis at the stent site. On the other hand, DAPT can increase the risk of severe bleeding associated with increased morbidity and mortality [14]. Adherence to DAPT has resulted in good clinical outcomes. However, non-adherence causes an increase in major adverse cardiovascular events (MACE) [4, 19].

The extent of DAPT non-adherence post-stenting ranges between 4.6% and 55.8%. This figure shows that DAPT non-adherence still poses a great challenge after stenting. The great variability of this prevalence could be due to different populations in those studies, the variability of methods to

measure non-adherence, or the duration of the studies. While most of the selected studies in this review use questionnaires and telephone interviews, some use medical databases. Moreover, big studies such as the PARIS registry monitor patients' non-adherence for 2 years, while the NARC study is for 1 year [8, 16-18].

Furthermore, **Table 2** shows many definitions of non-adherence across clinical trials. DAPT non-adherence can be classified into how many tablets/pills the patient has taken or the timing of non-adherence. The non-adherence definition in some studies used cut-off points of <80% in the proportion of days covered (PDC), early discontinuation of fewer than 270 days, not taking DAPT for the first 6 months, missing two doses in a week, and others. There was no united consensus on the definition of non-adherence in all clinical trials. The Korean study with a cut-off PDC of non-adherence of <80% showed a higher MACE regardless of patient using DES stent. In this Korean study, BMS stents with good adherence to PDC>80% showed less MACE. However, the NARC study showed in another way that besides patient adherence, the patient-oriented composite endpoint (POCE) was also influenced by the advent of DES stent. This supports the fact that adherence to DAPT is crucial. Also, other studies in Germany and India showed that non-adherence resulted in a high incidence of Coronary Artery Bypass Graft (CABG) and mortality [4, 20].

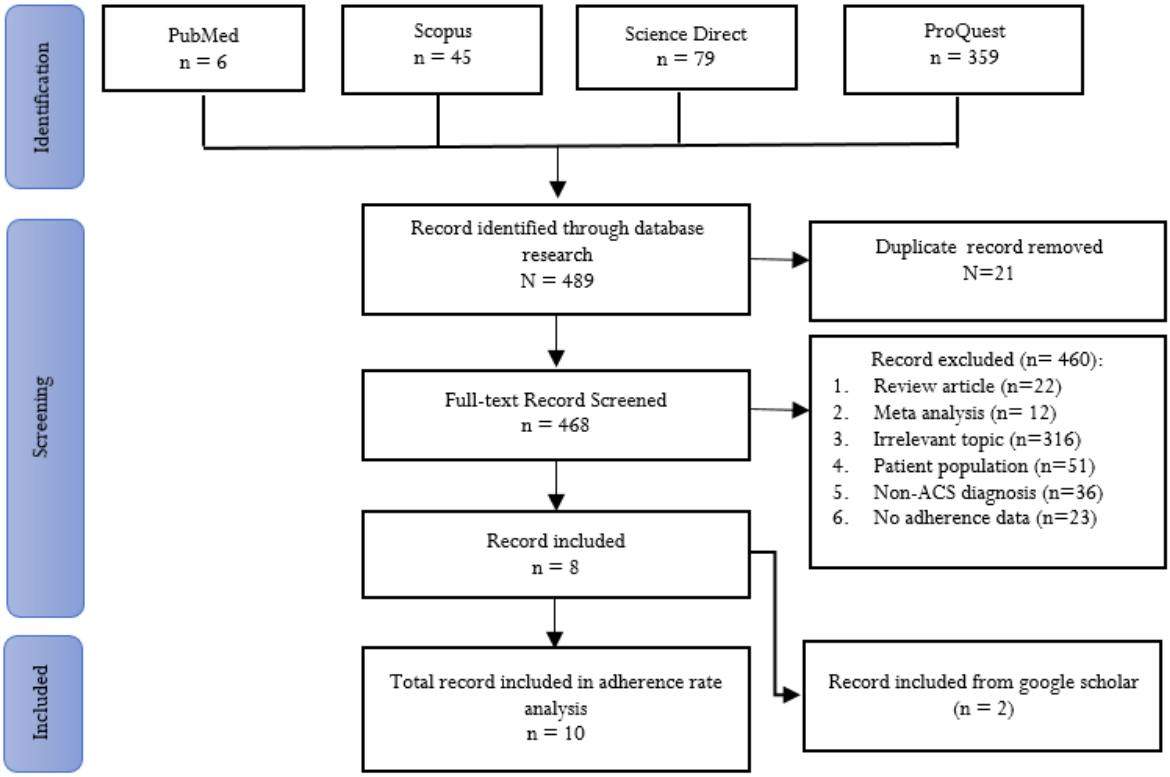

Figure 1. PRISMA Flowchart

Table 1. General Characteristics of Included Study

Author	Aims	Research Design	Research Sites	Method of Collecting data (duration of observation)	Sample Totals	Quality of the study
[4]	Investigate the effectiveness of DAPT adherence on all-cause mortality and potential determinants of DAPT adherence among post-PCI patients.	Prospective Study	India	Medical Records and interviews by phone (12 months)	2,064 patients	Good
[8]	Evaluate the influence of the underlying risk of bleeding on the occurrence, pattern, and association between DAPT discontinuation and adverse events	Prospective, international, multicenter, observational study	Multicenter	Questionnaire and telephone interview (2 years)	5,018 patients	Good
[13]	Investigate the outcomes of patients undergoing PCI using DES or BMS concerning DAPT adherence using National Healthcare Insurance Service data.	Retrospective - Cohort Study	Korea	The Korean National Health Insurance Service database. (5 years)	934 patients	Good
[19]	Determine adherence to DAPT and the switching pattern in ACS patients prescribed DAPT. Also, the impact of close surveillance telephone calls should be evaluated.	Prospective Interventional Cohort Study	Washington, DC	Electronic medical records and telephone interview (12 months)	655 patients	Good

[15]	Evaluate the long-term use of ticagrelor in patients with ACS and evaluate the reasons for premature discontinuation of ticagrelor.	Prospective observational study	Germany	Questionnaire and telephone interview (12 months)	614 patients	Good
[16]	Compare the clinical outcome between DAPT cessation due to non-compliance vs bleeding Investigate the predictors of DAPT cessation due to non-compliance or bleeding.	Prospective observational study	Multicenter	Questionnaire and telephone interview (2 years)	5,018 patients	Good
[17]	Examine the association between discontinuation of DAPT therapy and cardiovascular risk after PCI in relation to age.	Prospective, international, multicenter, observational study	Multicenter	Questionnaire and telephone interview (2 years)	5,018 patients	Good
[18]	Assess patient knowledge, adherence to DAPT use, trends in DAPT use over time, and factors of nonadherence in patients with acute coronary syndrome (ACS).	Prospective Study	Vietnam	Telephone interview (6 months)	200 patients	Good
[20]	Assess the prevalence of NARC self-reported non-adherence to P2Y12 inhibitors and its impact on clinical outcomes in patients undergoing PCI	Prospective Study	Switzerland	Questionnaire and medical records (12 months)	3,896 patients	Good
[21]	To determine the antiplatelet compliances six months after primary PCI in a rural satellite center.	Descriptive Study	Pakistan	Direct interview at the follow-up session, six months after PCI	241 patients	Good

Table 2. Definition, percentage, the reasons for, and clinical outcomes of DAPT non-adherence

Author	Non-adherence definition	Percentage of Non-adherence	Reasons for DAPT non-adherence	Clinical outcomes for DAPT non-adherence	Predictors for non-adherence
[4]	Less than 6 months of using DAPT	22,8%	NA	Premature discontinuation had higher one-year-all-cause mortality	NA
[8]	PARIS category: DAPT *cessation* (discontinuation, interruption, or disruption)	High vs intermediate vs low bleeding risk: 17.7% vs 10.4% vs 7.8% (1 year) 22.0% vs 15.1% vs 12.0% (2 years)	Discontinuation, interruption, or disruption	DAPT disruption increases MACE irrespective of the underlying patient's bleeding risk	NA
[13]	The proportion of days covered (PDC) <80%	DES vs BMS patients: 22% vs 40%	NA	DES and BMS patients with PDC<80% showed higher MACE risk. DES patients with PDC<80% had higher MACE risk than BMS patients with PDC>80%	NA
[19]	DAPT cessation/switching	Close surveillance arm (enrolled) 22.00% Historical control Arm 31.70%	Physician decision Adverse reaction (including dyspnea) Bleeding Financial Burden Patient decision	NA	NA
[15]	Early discontinuation (<270 days or reported bleeding)	21.7%	Dyspnoea Bradycardia Bleeding Costs Other side effects Other reasons Unknown	CABG or bleeding is more frequent in patients with early discontinuation	Early discontinuation: Age≥75 years old Prior stroke/TIA Atrial Fibrillation
[16]	PARIS category: DAPT *Disruption* (non-compliance or bleeding)	*Non-compliance*: 1.6% (30 days), 6.5% (12 months), 9.1% (2 years) *Bleeding:* 0.6% (30 days), 3.1% (12 months), 4.6% (2 years)	Non-compliance or bleeding	*Non-compliance*: Greater risk of MACE and spontaneous MI *Bleeding*: Greater risk for all-cause death	DAPT Disruption: *Non-compliance*: Female, smoking, ACS, US patients *Bleeding*: Elderly, prior MI, warfarin discharge

[17]	PARIS category: DAPT *cessation* (discontinuation, interruption, or disruption)	Elderly ≥75 yo had a higher DAPT cessation rate than those 56-74 and <55 yo (10% – 40%)	Discontinuation, interruption, or disruption	Disruption was associated with increased MACE in patients <75 yo	NA
[18]	Premature discontinuation or two or more missed doses per week	5.8% (1 month) 55.8% (3 months) 53.2% (6 months)	NA	NA	Rural locations Inactive occupation Poor knowledge
[20]	NARC Level 1 type of non-adherence Level 2 person responsible for non-adherence Level 3 reasons for non-adherence Level 4 timing for non-adherence	17% Level 1 Permanent discontinuation 84% Level 2 physician-driven (94%), patient-driven (6%) Level 3 risk profile change (43%), unlisted (25%), surgery (17%) and adverse events (14%) Level 4 early (<30 days) 21%, late (30-180 days) 45%, very late	Risk profile change Adverse events Surgery Unlisted reasons Logistic Trauma	Permanent discontinuation, physician-driven non-adherence, and risk profile change were associated as independent predictors for POCE. A discontinuation-guided physician of DAPT is safe, irrespective of HBR.	NA
[21]	Do not take DAPT	10,4%	NA	NA	NA

Later, DAPT non-adherence focused on reasons for cessation and correlated each reason with cardiovascular outcomes. The Patterns of Non-Adherence to Antiplatelet Regimens in Stented Patients (PARIS registry) in 2013 tried to classify the reason for cessation into three categories: discontinuation, interruption, and/or disruption. Discontinuation is doctor-recommended; interruption is temporary cessation due to surgery, while disruption is cessation due to compliance or bleeding [10]. Each reason for cessation in the PARIS registry has been studied in correlation with cardiovascular outcomes. The PARIS registry categories for cessation have been used in other studies [20, 22]. The PARIS registry is followed by the 2019 Non-Adherence Academic Research Consortium (NARC), in which the NARC authors try to reach a consensus on the definition of non-adherence in cardiovascular clinical trials [23]. The NARC definition principally categorizes into four levels of non-adherence. Level 1 is non-adherence, which includes adherence (type 0), deviation from medication prescribed (type 1), temporary discontinuation (type 2), or permanent discontinuation (type 3). Next, level 2 describes the person responsible for non-adherence, either investigator-driven, medical doctor-driven, or patient-driven. Moreover, level 3 is the reason for non-adherence, which includes risk profile change, events, surgery, unlisted, logistics, or trauma. The final level 4 is the timing of non-adherence, which includes early, late, and very late non-adherence.

The PARIS registry and the NARC study found that adverse clinical outcomes might occur while patients adhered to the prescribed P2Y12 inhibitors. Therefore, in the NARC study, non-adherence had a modest relation with adverse clinical outcomes of POCE with an estimated 5%. This modest relation is supposed to be using a new generation of drug-eluting stent (DES) with improved efficacy and safety. The PARIS registry showed that the DAPT disruption by patients or bleeding has significantly increased MACE. On the other hand, there was no association between clinical outcomes and non-adherence driven by patients or events in the NARC study. But, considering other studies, adherence to DAPT is still an important issue. Moreover, the PARIS registry and the NARC study concluded that the physician-decision discontinuation of DAPT was safe.

The timing of cessation is critical. There were many cut-off points for early DAPT cessation, such as less than 90 days, less than 270 days, or others. Principally, 30 days post-stenting is a critical time frame. DAPT disruption due to non-adherence has a greater effect on MACE and spontaneous myocardial infarction, whereas disruption due to bleeding impacts all-cause mortality. Also, early cessation resulted in more bleeding. Another study shows that stent thrombosis occurred at an early 3-day delay of clopidogrel [7]. The first week of DAPT disruption after PCI is a major risk factor for MACE, including stent thrombosis. While observational data cannot establish causation, these findings are biologically feasible, as the highest risk aligns with the elevated residual prothrombotic/inflammatory risk following an ACS and when the stent surface remains non-endothelialized and prothrombotic [24]. Additionally, one out of twelve patients prematurely terminated DAPT within one year following acute coronary syndrome. Compared to physician-directed discontinuation, DAPT disruption presented a greater risk of MACE. This connection was not influenced by the selection of P2Y12 inhibitors, whether ticagrelor or clopidogrel [25].

Enhancing awareness of patients' predisposition for non-adherence may be crucial. Healthcare systems must recognize and promptly address patients exhibiting nonadherence to DAPT. Smartphone applications and specialized clinics may enhance medication adherence, yet their practical application remains constrained. The absence of suitable measures complicates the assessment of nonadherence risk in daily practice. Employing artificial intelligence algorithms in electronic health records to identify patients at risk of

nonadherence to dual antiplatelet therapy and alerting the treating physician and the patient may be noteworthy. Clinicians should assess biological aspects (e.g., elevated bleeding risk, ischemia risk, and the necessity for surgery/invasive procedures) and social factors (e.g., cost, accessibility, illness comprehension, and environmental support) to select safe and effective DAPT regimens customized for each patient. Several practical considerations include: a) implementing short-DAPT regimens for patients with elevated bleeding risk, diminished ischemic risk, or those necessitating surgery/invasive procedures to prevent premature cessation or interruption of DAPT; b) utilizing genotyping to identify polymorphisms in CYP2C19*2 or CYP2C19*3 alleles to facilitate clopidogrel-based DAPT or guided de-escalation, particularly in patients with high bleeding risk and/or ACS; c) evaluating the risk of dyspnea in ticagrelor users (e.g., those with concurrent respiratory conditions) and enhancing patient education to mitigate unnecessary transitions to prasugrel or clopidogrel; and d) recognizing patients at significant risk of nonadherence and implementing strategies that do not necessitate strict DAPT adherence (e.g., coronary artery bypass grafting or medical management) to avert adverse events resulting from premature DAPT disruption such as elderly, who suffered previous bleeding, or underwent PCI [18, 22, 24].

Conclusion

The percentage of DAPT cessation varies across clinical trials due to different characteristics across studies. Even though there was a modest association between DAPT cessation and clinical outcomes, non-adherence plays an important part in adverse cardiac events. The main reasons for DAPT cessation include physician discontinuation, surgery interruption, and DAPT disruption due to bleeding or patient-owned decisions of non-adherence. The patient-owned DAPT non-adherence has a greater risk for cardiac events, while physician-guided discontinuation is safe. Overall, healthcare system efforts should be made to prevent DAPT non-adherence.

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