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Perioperative management of the antiplatelet therapy in patients with ischemic heart disease undergoing noncardiac surgery

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Abstract
Background: Antiplatelet treatment (APT) perioperative care in non-cardiac surgery (NCS) patients who have previously undergone percutaneous coronary intervention (PCI) is still a problem. Our goal was to figure out if serious adverse cardiac and cerebrovascular incidents (MACCE) and serious bleeding events (MBE) are connected with the various perioperative APT regimens, either single APT (SAPT) or dual APT (DAPT).
Methods: This was prospective observational research that was conducted on one hundred adult patients ≥ 21 years known to have ischemic heart disease (IHD) on APT, either SAPT or DAPT, Patients having urgent NCS necessitating at least a 24-hour hospital stay. The incidence of MACCE and MBE during hospitalization or at 30 days after surgery was recorded. Amount and frequency of MACCE and MBE Patients who went through perioperative SAPT or DAPT were contrasted. Identifying the possible MACCE and MBE risk variables. Furthermore, central blockade-related neuraxial haemorrhagic episodes were reported.
Results: The incidence of MACCE was 22.64% in patients on SAPT and 2.13% in patients on DAPT. the incidence of MBE was 3.77% in patients on SAPT and 17.02% in patients on DAPT. No neuraxial haemorrhage events had been recorded. Mortality rate was 5.66% and 4.26% in patients on SAPT and DAPT respectively.
Conclusions: Perioperative DAPT associated with lower incidence of MACCE and a higher prevalence MBE than SAPT. As regard MACCE, their risk factors were BMI ≥30 kg/m^2, previous myocardial infarction, ejection fraction ≤ 50%, RWMA and high-risk surgery. While, DAPT, antihyperlipidemic drugs and beta blocker drugs were protective factors. As regard MBE, their risk factors were BMI ≥30 kg/m^2, high-risk surgery and DAPT and there were no protective factors for MBE.

Keywords: Antiplatelet, myocardial ischemia, percutaneous coronary intervention, bleeding, thrombosis

Introduction
The number of patients having NCS who have coronary stents is considerably rising. Premature APT cessation is linked to a higher likelihood of stent thrombosis, a feared complication that might have severe clinical repercussions, in particular when it takes place in the first few months followed stent placement. APT, however, may substantially raise the risk of intraoperative haemorrhage during surgical or endoscopic operations [1].
Cardiologists, surgeons, and anesthesiologists still face challenges in the perioperative care of patients with APT [2]. Making decisions necessitates careful balance of the dangers of coronary thrombosis following APT cessation and the danger of life-threatening perioperative hemorrhage, even though this is frequently very challenging [2].
On the perioperative management of APT, a number of recommendations and guidelines from experts have been published. Instead, than coming from random research, they mostly come from expert opinion. Our research sought to determine if the various perioperative APT regimens—SAPT or DAPT—were related to MACCE and MBE [3].

Patients and methods
This is an observational prospective study conducted on one hundred adult patients ≥ 21 years known to have IHD requiring hospital admission for at least 24 hrs at Tanta University from June 2021 to August 2022.

After approval from institutional ethics committee Tanta University (Approval code: 34714/5/21), an informed written consent was taken from each patient.

Patient rejection and lack of permission were the exclusion criteria, Patients who are pregnant, those who have serious concurrent illnesses, such as liver and renal problems, individuals who were on oral anticoagulant therapy

Every participant in this trial underwent the preoperative evaluation Detailed history gathering, a physical exam, laboratory investigation, including complete blood count, the prothrombin activity and INR, hepatic function tests, kidney function tests, bleeding time, and coagulation time. Electrocardiograms and echocardiograms were assessed. During hospitalization and 30 days afterwards surgery, the prescribed perioperative APT regimen, either SAPT or DAPT, shall be documented.

Data on PCI and key stent characteristics (type and number of stents, date of implantation) were gathered. It was reported how long it took from implantation to surgery. Potential preoperative warning signs for MACCE included active cardiac diseases (unstable coronary syndromes, decompensated heart failure, significant arrhythmias, and severe valvular disease), clinical risk factors (history of coronary artery disease, chronic kidney disease, congestive heart failure, diabetes mellitus, or cerebrovascular disease), and other minor predictors of ischemic disease (age > 70 years, abnormal ECG, non-sinus rhythm, or hypertension). Further, information on preoperative pharmaceutical therapies and information on the ongoing surgical operation were gathered. Patients received a call 30 days after being released from the hospital to check on their clinical condition and APT schedule.

Measurements

It was documented when MACCE emerged during hospitalization or 30 days afterwards surgery. Any of the following is a synonym for MACCE: cardiovascular mortality, non-fatal cardiac arrest, any form of acute coronary syndrome, stroke, mini-stroke, transient ischemic attack, congestive heart failure, or sudden severe arrhythmia (4). The occurrence of MACCE was compared in patients who received perioperative SAPT or DAPT. The potential risk factors for MACCE were analyzed.

The MBE occurrence was recorded. MBE was interpreted as any of the following during hospitalization: A demand for transfusion of two or more RBCs, a haemoglobin drop of less than 2 g/dl during or following surgery, or a brain hemorrhage [5]. The occurrence of MBE was compared in patients who received perioperative SAPT or DAPT. The potential risk factors for MBE were evaluated. Neuraxial hemorrhagic events related to central blockade, mortality rate and the cause of death were recorded.

Outcomes

Primary outcome was at least one MACCE happening while in the hospital or 30 days afterwards surgery.

Secondary outcomes were mortality rate, the reason for death, and the frequency of MBE during hospitalization or 30 days afterwards surgery.

Sample Size (Convenient Sample)

Cases that were admitted in Tanta University Emergency Hospital fulfilling inclusion and exclusion criteria in the period from June 2021to August 2022 involved.

Statistical analysis of the data

With the help of IBM, Illinois, Chicago, USA's SPSS version 19 (Statistical Package for Social Studies), the gathered data were arranged, tabulated, and statistically examined. The SPSS chart builder and Microsoft Excel for Windows 2019 were used to create the charts.

Results are shown as the mean, standard deviation (SD), or median with interquartile range (IQR) for continuous variables, while number or % are used to represent categorical data. Based on the chi-square test and Fishers exact test, categorical data were compared between patients with and without MBE and MACCE. The Mann-Whitney U test or the Student's t test were applied to compare continuous data. To identify the risk variables for the emergence of MBE and MACCE, the multivariate logistic regression model was built. The threshold for relevance was set at $p<0.05$.

Results

Seven patients failed to satisfy the criteria for being included in this study's 115 participants, while three patients declined to take part. All inclusion and exclusion criteria were met by the 105 patients who were still present. Since there were missing data after discharge for five patients, they were not taken into account in the statistical analysis. One hundred patients were monitored and analyzed using statistics. Fifty-three patients received perioperative SAPT; 48 patients received aspirin and 5 patients received Plavix. Forty-seven patients received perioperative DAPT. Figure 1

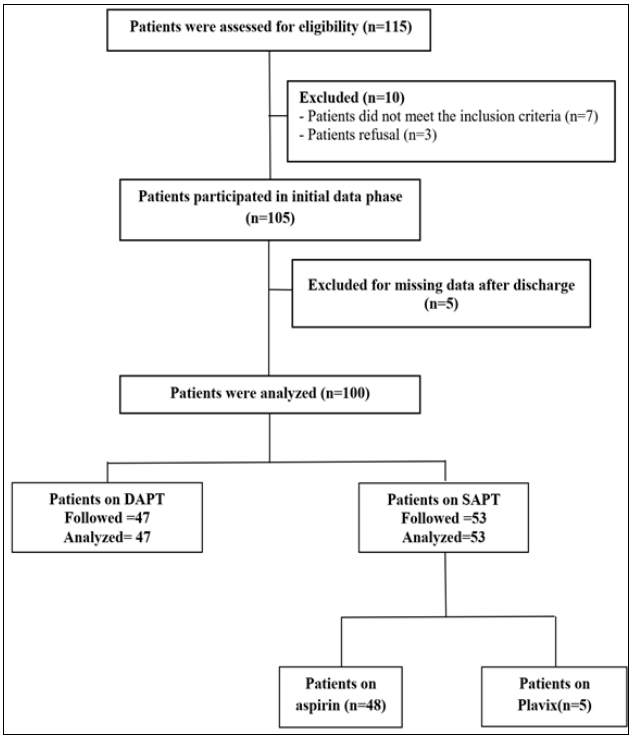

Fig 1: Consent flow chart

The comparison of the demographic data, the comorbidities, pharmacological treatment, type of surgery, risk of surgery and duration of surgery between patients on SAPT and patients on DAPT was insignificantly different. While, type of anesthesia, number of patients required RBCs transfusion and postoperative hemoglobin were significantly different between patients on SAPT and patients on DAPT. Table 1

Table 1: Demographic data, Comorbidities, pharmacological treatment and Criteria of surgery of patients on SAPT and patients on DAPT

	Variable	SAPT (53 patients)	DAPT (47 patients)	P-value	CI 95%
Gender	Age in years	61±12.07	57.85± 11.85	0.121	-1; 8.51
	Male	28 (52.8%)	22 (46.8%)	0.548	
	Female	25 (47.2%)	25 (53.2%)		
Medical treatment and comorbidities	BMI(Kg/m^2)	32.47± 5.18	32.6± 4.85	0.897	-2.13; 1.87
	ASA-PS				
	2	9(16.98%)	10(20.28%)	0.939	
	3	23(43.4%)	20(42.55%)		
	4	18(33.96%)	14(29.79%)		
	5	3(5.66%)	3(6.38%)		
	Hypertension	41 (77.36%)	33(70.21%)	0.416	
	Diabetes mellitus	20(37.74%)	20 (42.55%)	0.624	
	Previous myocardial infarction	20 (37.74%)	14 (29.79%)	0.526	
	Insulin	13(24.52%)	12 (56.4%)	0.908	
	oral hypoglycemic drugs	7(13.2%)	12 (56.4%)	0.78	
	Nitroglycerin	38 (71.7%)	33 (70.21%)	0.87	
	Beta blockers	32 (60.38%)	32 (68.09%)	0.423	
	Antihyperlipidemic drugs	25 (47.17%)	22 (46.81%)	0.971	
	Diuretics	5 (13.2%)	3 (2.13%)	0.575	
	Other antihypertensive drugs	10 (18.87%)	10 (21.28%)	0.764	
Type of surgery	▪ Neurosurgery	5 (9.43%)	3 (6.38%)	0.575	
	▪ General	16 (30.19%)	17 (36.17%)	0.526	
	▪ Orthopedic	21 (39.62%)	17 (36.17%)	0.723	
	▪ Vascular	3 (5.66%)	3 (6.38%)	0.879	
	▪ Ophthalmology	4 (7.55%)	6 (12.77%)	0.385	
	▪ Urology	3 (5.66%)	1 (2.13%)	0.368	
	Thoracic	1 (1.89%)	0	0.344	
Risk of surgery	Mild	7 (13.21%)	7 (12.77%)	0.114	
	Moderate	31 (49.06%)	26 (40.43%)		
	High	15 (37.73%)	14 (46.8%)		
Types of anesthesia	General anesthesia	33 (62.26%)	47(100%)	<0.001*	
	Spinal anesthesia	20 (37.74%)	0		
	Duration of surgery(hours)	2± 0.83	1.95±0.898	0.738	-0.285; 0.4
	No. of patients required RBCs transfusion:	6 (11.32%)	15 (31.91%)	0.012*	
	Postoperative hemoglobin (g/dl)	11.62 ± 1.89	10.66±1.72	0.24; 1.68	0.24; 1.68

Statistics are displayed as the percentage of patients or as the mean± SD. ASAPS: Physical Status, American Society of Anesthesiologists

The mean values (±SD) of preoperative HB, platelet count, WBCs count, bleeding time, clotting time, INR, ALT, AST, creatinine and blood were insignificantly different between patients on SAPT and patients on DAPT. Comparing the ECG data; including sinus rhythm, atrial fibrillation, sinus rhythm with premature ventricular contraction, pathological Q wave and T wave inversion; and ECHO data was insignificantly different between patients on SAPT and patients on DAPT. The types of stents, number of stent and duration of stent implantation were insignificantly different between patients on SAPT and patients on DAPT. (Table 2)

Table 2: Preoperative laboratory parameters, ECG data, ECHO data and Criteria of stents that used of patients on SAPT and patients on DAPT

	Variable	SAPT (53 patients)	DAPT (47 patients)	P-value	CI95%
	HB (g/l)	12.2± 1.9	11.5± 1.73	0.058	0.029; 1.47
	Platelet count/(µl)	216755±66200	236851± 65803	0.132	-46344; 6151
	WBCs / µl	8839.62±3963.16	9247.02± 4284.83	0.623	2044; 1229
	Bleeding time(min)	4.4±0.43	4.48± 0.639	0.419	-.301; 0.126
	Clotting time (min)	5.9±0.95	5.78±1.36	0.642	-0.353; 0.57
	INR	1.09± 0.12	1.1± 0.14	0.547	-0.66; 0.035
	ALT (u/l)	32.13±20.01	31.68± 21.61	0.914	-7.81; 8.71
	AST (u/l)	30.6±17.58	34.68±19.43	0.275	-11.4; 3.29
	Creatinine (mg/dl)	0.94±0.2	0.95± 0.23	0.94	-0.081; 0.088
	Blood urea (mg/dl)	30.68±6.4	30.47± 6	0.866	-2.26; 2.68
rhythm	**Sinus Rhythm**				
	Atrial Fibrillation	46(86.79%)	42(89.36%)	0.963	
	Sinus rhythm with premature	4 (7.55%)	3(6.38%)	0.82	
	ventricular contraction	3 (5.66%)	2 (4.26%)	0.748	
	Pathological Q wave presence	18(33.96%)	13(27.66%)	0.496	
	T wave inversion	2(3.77%)	5(10.64%)	0.179	
Types of stents	Ejection Fraction (%)	57.1±8.45	59.34± 8.21	0.182	-5.56; 1.07
	RWMA Hypokinesia	16(30.19%)	14(29.79%)	0.9	

	Akinesia	2(3.77%)	2(4.26%)		
	DES	49 (92.45%)	44 (93.62%)	0.819	
	BMS	4 (7.55%)	3 (6.36%)		
Number of stents	**1stent**			0.391	
	2 stents	25 (47.17%)	22 (46.8%)		
	3 stents	24 (45.28%)	20 (42.55%)		
	4 stents	1 (1.89%)	4 (8.51%)		
		3 (5.66%)	1 (2.13%)		
	Duration of stent implantation (years)	3 (2-8)	3(1-5)	0.142	

Data presented as number of patients (%).

Patients on DAPT had lower incidence MACCE and higher incidence MBE than patients on SAPT (P=0.002 and 0.028 respectively). The mortality rate was insignificantly different between patients on SAPT and patients on DAPT (P=0.748). No Neuraxial haemorrhage events had been recorded. (Table 3)

Table 3: The incidence of MACCE, MBE and mortality in patients on SAPT and patients on DAPT

Variable		SAPT (53 patients)	DAPT (74 patients)	P-value
MACCE		12 (22.64%)	1(2.13%)	0.002*
MBE		2(3.77%)	8(17.02%)	0.028*
Mortality rate		3(5.66%)	2(4.26%)	0.748
cause of death	Pulmonary embolism	1(1.89%)	0	0.63
	Septic shock	2(3.77%)	1 (2.13%)	0.344
	Brain hemorrhage	0	1 (2.13%)	0.286
Neuraxial hemorrhage events		0	0	

Data presented as number of patients (%).

The significant risk factors for MACCE were BMI ≥30, previous myocardial infarction, ejection fraction ≤50%, presence of RWMA and high-risk surgery. While DAPT, antihyperlipidemic drugs and beta blocker drugs were protective factors for MACCE. (Table 4)

Table 4: Applying a multivariate logistic regression analysis, the subsequent risk variables were examined in patients who had major adverse cardiovascular and cerebrovascular events:

Variable	MACCE (13 patients)	No MACCE (87 patients)	P-value	OR
Age ≥ 65(years)	7 (53.85%)	34 (39.1%)	0.538	1.82
Gender: Male	9 (69.23%)	41 (47.1%)	0.415	2.52
BMI ≥ 30(kg/m^2)	12 (92.31%)	53 (60.9%)	0.036*	7.7
Hypertension	13 (100%)	61 (70.11%)	0.251	11.63
Diabetes Mellitus	8 (61.5%)	32 (36.8%)	0.410	2.75
Previous Myocardial infarction	11 (84.62%)	23 (26.4%)	0.003*	15.30
Number of stents ≥ 2	8 (61.53%)	45 (51.7%)	0.718	1.493
Duration of stent ≥ 3(years)	7 (53.85%)	48 (55%)	0.946	1.138
Nitroglycerine	11 (84.6%)	60 (68.97%)	0.542	4.62
Antihyperlipidemic drugs	1 (7.7%)	46 (52.9%)	0.018*	0.642
Beta blocker	3 (23.08%)	61 (70.11%)	0.012*	0.534
EF ≤50%	4 (30.77%)	9 (10%)	0.025*	4.85
RWMA	10 (76.92%)	24 (27.6%)	0.01*	8.750
High risk surgery	9 (69.23%)	20 (11.5%)	0.015*	7.54
Transfusion of ≥ 2 unites packed RBCs	1 (7.7%)	8 (9.2%)	0.965	0.823
DAPT	1 (7.7%)	46 (52.9%)	0.018*	0.642

Data presented as number of patients (%). DAPT: dual antiplatelet therapy.

The significant risk factors for MBE were BMI ≥30 kg/m^2, high risk surgery and DAPT. (Table 5)

Table 5: The following risk variables for patients with major bleeding episodes were investigated employing multivariate logistic regression analysis:

Variable	MBE (10 patients)	No MBE (90 patients)	P-Value	OR
Age ≥ 65(years)	4 (40%)	37 (41.11%)	0.945	0.955
Gender: Male	4 (40%)	46 (51.11%)	0.825	0.637
BMI ≥ 30(kg/m^2)	10 (100%)	56 (61.11%)	0.032*	12.82
Hypertension	10 (100%)	64 (71.11%)	0.122	8.63
Diabetes Mellitus	5 (50%)	35 (38.89%)	0.758	1.57
Previous Myocardial infarction	6 (60%)	28 (31.11%)	0.184	3.32
Number of stents ≥ 2	6 (60%)	47 (52.22%)	0.935	1.37
Duration of stent ≥ 3(years)	6 (60%)	49 (54.44%)	0.847	1.26
Nitroglycerine	7 (70%)	64 (71.11%)	0.941	0.947
Antihyperlipidemic drug	7 (70%)	40 (44.44%)	0.425	2.92

Beta-blocker	9 (90%)	55 (61.11%)	0.274	5.73
Ejection fraction ≤50%	2 (20%)	11 (12.22%)	0.715	1.8
RWMA	6 (60%)	28 (31.11%)	0.214	3.32
High-risk surgery	7 (70%)	22 (24.44%)	0.021*	6.73
DAPT	8 (80%)	39 (43.33%)	0.035*	5.23

Data presented as number of patients (%). RWMA: Regional wall motion abnormalities. DAPT: dual antiplatelet therapy.

Discussion

Our results revealed that patients who received perioperative DAPT had lower incidence of MACCE and higher MBE than patients received SAPT without a difference in the mortality rate between both groups. The risk factors for MACCE were BMI ≥30 kg/m^2, Previous MI, ejection fraction ≤50%, RWMA and high-risk surgery. While, the risk factors for MBE were BMI ≥30 kg/m^2, high-risk surgery and DAPT.

There are challenging methodological restrictions and inconsistent findings in published research that examine the connections between perioperative APT control and outcomes in patients with ischemic coronary artery disease obtaining NCS. The ACC/AHA's most recent recommendations for handling cardiovascular risk during the non-cardiac perioperative phase are available [6]. There are unique hazards related to the kind and urgency of the operation as well as the patient's clinical condition, even though the recommendations on perioperative cardiac risk assessment and antiplatelet therapy have mostly been written by cardiologists [7].

Retrospective research and expert opinions dominate when making recommendations since prospective randomized clinical trials are lacking [6]. The proviso that the choice of continuing or ceasing administering APT should be based on assessing the risks of bleeding and stent thrombosis in each person is outlined in the European Society of Cardiology and ACC/AHA recommendations. Classifying thrombotic and hemorrhagic risks for each kind of operation, type of coronary stent, and clinical and angiographic features has been recommended by multidisciplinary techniques discussing perioperative ATP during NCS. While in a typical circumstance, this is fair. The surgeon, cardiologist, anesthesiologist, and patient may all work together to personalize the choice to the circumstances [8].

Our result revealed that patients received DAPT had lower incidence of MACCE and a higher incidence of MBE than patients received SAPT.

The result meta-analysis performed by Bittl *et al*., [9] revealed that sustaining DAPT for a further 18 to 48 months after PCI contributed to a reduced likelihood of stent thrombosis and MI but a greater likelihood of severe hemorrhage.

Yamamoto *et al*., [6] contrasting the impacts of DAPT and SAPT on NCS outcomes for those who had received either BMS or DES. They looked at 198 individuals who had previously had NCS after obtaining PCI. Among them, 88 patients had surgery on SAPT, and 63 patients had DAPT g operation. Between the two groups, they contrasted cardiovascular and bleeding events that took place during the perioperative period. Their results demonstrated that neither group had stent thrombosis. In comparison to the SAPT group, the DAPT group saw a considerably greater number of bleeding incidents.

Howell *et al*., [10] Our prospective cohort research comprised 847 individuals who needed either elective or urgent NCS and had undergone PCI in the prior 4 years. Prior to surgery, they looked at the rates of MACE and haemorrhage in patients who got DAPT, monotherapy, and no APT. Their results revealed that 32 patients suffered MACE; 3 patients no APT, 16 patients on monotherapy and 13 patients on DAPT. In contrast to those employing aspirin just, bleeding happened much more commonly in patients taking DAPT. They were unable to establish that DAPT prevented stent thrombosis, and they found that maintaining to use two antiplatelet drugs appeared to boost the chance of clinically significant bleeding. They indicated that it is challenging to maintain DAPT in patients having PCI which necessitates NCS and that it is uncertain if the risk of bleeding exceeds protection against perioperative MACE.

The discrepancy between two previous studies and our study regarding the effect of DAPT on MACCE may be due to the nature of surgeries in our study, all our operations were urgent, and our small sample size may be underpowered to detect this effect.

They came to the conclusion that even with perioperative APT, those with coronary stents obtaining NCS are still at elevated risk for MACCE. The major contributing factors to MACCE were preexisting medical issues and perioperative MBE.

Regarding the incidence of MBE in our study, our results revealed that the incidence of MBE was 10% and its risk factors were BMI ≥30 kg/m2, high-risk surgery and DAPT.

The results of a prospective multicenter observational study carried out by Rodriguez *et al*., [11] indicated that 37% of the 432 individuals with coronary stents who underwent NCS also had MBE. Complete discontinuation had been linked with a rise in MBE in patients who were given preoperative aspirin monotherapy. The mean time interval of antiplatelet cessation prior to surgery was unrelated to MBE. Nevertheless, the frequency of MBE postponed the start of APT during surgery.

In a meta-analysis by Burger *et al*., [1], 49,590 individuals had NCS in all, and it turned out that keeping aspirin caused a 1.5-fold increase in bleeding incidents. With the exception of intracranial surgery and potentially transurethral prostatectomy, this rise did not, however, result in a greater level of the severity of issues with bleeding or fatal hemorrhage.

Conclusion Ischemic cardiac patients on APT undergoing urgent NCS are at risk for MACCE and MBE. Perioperative DAPT associated with lower incidence of MACCE and higher prevalence MBE than the SAPT. As regard MACCE, their risk factors were BMI ≥30 kg/m^2, previous myocardial infarction, ejection fraction ≤ 50%, RWMA and high-risk surgery. While, DAPT, antihyperlipidemic drugs and beta blocker drugs were protective factors. As regard MBE, their risk factors were BMI ≥30 kg/m^2, high risk surgery and DAPT and there were not protective factors for MBE. Therefore, it is safer to continue DAPT in perioperative individuals who have MACCE risk indicators.

Conflict of Interest
Not available

Financial Support
Not available

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