

## Effect of Low Dose NOACS (Rivaroxaban 2.5 mg Twice Daily) on Patients Who Underwent Complex Percutaneous Coronary Intervention

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### Abstract

**Background:** Patients undergoing complex percutaneous coronary intervention (PCI) carry a higher incidence of in-stent restenosis. This could be due to late acquired malposition, neointimal hyperplasia, increased coagulation activity, in patients having a higher incidence of coronary atherosclerosis, rupture plaque and acute coronary syndrome. Rivaroxaban, selectively targets activated factor X (Xa), which plays a role in the coagulation in addition to the mono antiplatelet after 12 months may decrease the complication and improve the outcome of complex PCI Patients.

**Aim of Study:** This study aimed to examine the effect of low-dose NOACS (Rivaroxaban 2.5mg twice daily) in addition to a single antiplatelet, for long-term treatment (after 12 months) on patients who underwent complex PCI.

**Patients and Methods:** This study was carried out on 40 patients, with 12 months of post-complex PCI. The patients were collected from Alharm Specialized Hospital Ministry of Health (Alharm, Cairo, Egypt) from December 2021 to December 2023. Patients were divided into groups: Group (1) 20 patients treated with a small dose of NOACS Rivaroxaban 2.5mg twice daily and mono antiplatelet (Aspirin 75mg once orally daily or clopidogrel 75mg once orally daily) and group (2) including 20 patients treated with mono antiplatelet (Aspirin 75mg once orally daily or clopidogrel 75mg once orally daily) without adding small dose NOACS, Rivaroxaban all patients in both groups were followed-up for the detection of very late stent thrombosis (after 12 months of complex PCI), in-stent restenosis (ISR), stroke, bleeding, acute Coronary syndrome for one year.

**Results:** The results cleared that minor bleeding occurred in 4 patients (20%) in group I while no cases were recorded in group II. There were two cases of moderate bleeding (10%)

in group I while no cases were reported in group II and severe bleeding was not recorded in either group. Very late stent thrombosis (after 12 months of complex PCI) was not recorded in group I but was recorded in group II, where 3 patients (15%). The in-stent restenosis was not recorded in group I and was recorded in only group 2, in 5 patients (25%). Acute coronary syndrome was recorded only in non-treated group II, in 4 patients (20%) and stroke was recorded only in non-treated group II, in one patient (5%). Hospital admission by decompensated HF was not recorded in group I and was recorded in the non-treated group (2), in 4 patients (20%). While, sudden cardiac death was recorded in only the non-treated group, in 2 patients (10%).

**Conclusion:** This study concluded that the addition of a small dose of NOAC [Rivaroxaban (Xarelto) 2.5mg twice daily] for long-term treatment to patients who underwent complex PCI, decreased the stent thrombosis, acute coronary syndrome, and stroke without a significant increase in the incidence of major bleeding, and with increased incidence of minor and moderate bleeding.

**Key Words:** Rivaroxaban – Complex PCI – Stent restenosis.

### Introduction

**CORONARY** artery disease (CAD) is the leading cause of death worldwide. According to the World Health Organization (WHO), CAD is responsible for about 15% of all deaths globally. It remains one of the world's largest health problems, despite dramatic medical advances over the last few decades [1].

CAD is usually caused by atherosclerosis, in which fatty deposits accumulate on the walls of the coronary arteries. In general, CAD is classified into chronic coronary syndromes and acute coronary syndrome, the latter of which has three forms: Unstable angina, non-ST-elevation myocardial infarction, and ST-elevation myocardial infarction [2].

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Percutaneous coronary intervention (PCI) is the most common procedure used in the invasive treatment of people with CAD and accounts for 3.3% of all operating room procedures. Every year, millions of people undergo PCI, which is a non-surgical revascularization technique. PCI is indicated in acute coronary syndromes (CCS) when documented ischemia  $> 10\%$  by myocardium perfusion scan or when coronary angiography reveals diameter stenosis more than 90%, or significant FFR results also PCI indicated in CCS with EF  $\leq 35\%$  due to CAD [3].

Antithrombotic therapy is required after PCI to reduce the risk of recurrent cardiovascular events and stent thrombosis. Long-term dual antiplatelet therapy (DAPT) with aspirin and a P2Y<sub>12</sub> receptor antagonist has been shown to reduce mortality and morbidity post-PCI and class (I) indication for 12 months as Aspirin plus P2Y<sub>12</sub> inhibitor, (clopidogrel) for PCI to CCS and aspirin plus the more potent P2Y<sub>12</sub> inhibitors (ticagrelor or prasugrel) in PCI to ACS or following PCI in people with a high complex procedure and high thrombotic risk and continue on mono antiplatelet after 12 months of PCI especially if complex PCI or PCI due to ACS [4].

PCI can be a simple or complex one. There is no accurate definition for complex PCI but roughly complex PCI can include severe calcification, extreme tortuosity, extreme length, unprotected left main, chronic occluded, extensive thrombotic burden, bifurcation, and venous graft [5]. Complex PCI has a higher thrombotic risk with an increased incidence of acute, late stent thrombosis. Complex PCI has a higher incidence of in-stent restenosis by different mechanisms than simple PCI. Also, patients undergoing complex PCI have a higher incidence of coronary atherosclerosis, rupture plaque, and recurrent ischemic insults [6].

Approximately 5% to 8% of people undergoing PCI indicate long-term oral anticoagulation, most commonly due to atrial fibrillation to decreased incidence of stroke if (CHA-DS-VASC Score of  $> 1$ ). However, triple therapy by combining DAPT with oral anticoagulation increases the risk of bleeding, therefore to decrease bleeding during the use of Triple therapy it is indicated only for one week up to one month, the more potent P2Y<sub>12</sub> inhibitors (ticagrelor or prasugrel) is not indicated in triple therapy and the less potent clopidogrel is indicated. Also vitamin K-antagonist is not indicated in triple therapy except if there is significant mitral stenosis or prosthetic valve and instead NOACS is indicated in triple therapy as Rivaroxaban in a lower dose (15 mg once orally daily dose) instead of the standard dose (20mg once orally daily dose) [7].

Thrombotic complications after PCI have been primarily considered a platelet-mediated process.

However, rates of recurrent cardiovascular ischemic events remain high especially in complex PCI despite the use of double antiplatelets (DAPT) for 12 months and long-term treatment after 12 months with mono antiplatelet regimens, Stent thrombosis can be acute within one month, late within 12 months or very late after 12 months. Thrombosis after PCI can also occur in another native coronary segment. This could be due to increased thrombin generation and an associated increase in clot formation. Rivaroxaban selectively targets activated factor X (Xa) and plays a role in the coagulation cascade that leads to fibrin formation and resultant thrombosis. Therefore the use of a low oral dose of Rivaroxaban 2.5mg twice daily which is much lower than the standard dose (20mg once orally daily dose) and also much lower than the dose of Rivaroxaban in triple therapy to patients with AF and underwent PCI (15mg once orally daily dose) may be beneficial post-complex PCI in preventing restenosis, thrombus formation, stroke and ACS [8].

This study aimed to study the effect of using a low dose of Rivaroxaban in patients who underwent complex PCI through a comparison between patients 12 months post complex PCI and taking low dose Rivaroxaban 2.5mg twice daily in addition to mono APT (aspirin or Clopidogrel) and these patients who underwent complex PCI, not taking Rivaroxaban, taking only mono antiplatelet.

### Patients and Methods

This study was carried out on 40 patients after 12 months of undergoing complex PCI which included severe calcification, extreme tortuosity, extreme length, unprotected left main, chronic occluded, extensive thrombotic burden, bifurcation, venous graft.

*Patients were divided into groups:*

- Group (1) Including 20 patients treated with a small dose of NOACS Rivaroxaban 2.5mg twice daily plus single antiplatelet.
- Group (2) Including 20 patients treated with single antiplatelets without adding small doses of NOACS, Rivaroxaban.

The patients were collected from Alharm Specialized Hospital Ministry of Health (Alharm, Cairo, Egypt) from December 2021 to December 2023.

The purpose and design of the study were explained to the patients and their family members. The confidentiality of information obtained was maintained and revealed only to the doctor/auditor involved in the study and to regulatory authorities. The study was conducted on ethical guidelines for Biomedical Research on human subjects given by the Central Ethical Committee on Human Research, New Delhi, in addition to principles enunciated in the "Declaration of Helsinki".

**Inclusion criteria:**

Forty Patients after 12 months of successive complex PCI.

**Exclusion criteria:**

*Excluded from the study all of the following patients:* Patients on anticoagulant treatment, patients without Ischemic heart disease, simple PCI, obstructed cardiomyopathy, patients with permanent pacemakers, patients with atrial fibrillation, patients with DVT-PE patients with moderate to severe valvular heart disease, pregnant and lactating patient.

All the patients in both groups underwent the following:

**- Full history, clinical examination:**

Age, sex, history of risk factors such as hypertension, smoking, diabetes, hypercholesterolemia, obesity, positive family history of IHD, history of IHD, analysis of chief complaints, general and local cardiac examination.

**- Twelve-lead electrocardiogram:**

For detection of ischemic ECG changes such as STMI, ST segment depression, inverted T wave, LBBB, heart blocks, and ventricular arrhythmias.

**- Echocardiography:**

For measuring LV systolic function and detection of gross Segmental wall motion abnormality at rest.

**Laboratory investigation:**

On the first day of hospital admission, samples of peripheral venous blood were drawn from the antecubital vein after the patient overnight fasting, and processed for a complete series of routine laboratory assays. Include cardiac enzymes (cardiac troponins, CK-MB), Braunwald et al., [18] liver function (ALT, AST, Albumin and total bilirubin), lipid profile (total cholesterol, high-density lipoprotein cholesterol (HDLc), triglycerides, and Low-density lipoprotein cholesterol (LDLc), KIDNEY function, complete blood picture, coagulation profile (Fibrinogen level, Prothrombin time (PT or PT-INR), Platelet count and serum electrolytes.

All laboratory tests were analyzed as categorical variables based on the REFERENCE values of our laboratory or previous studies.

**Regular monthly follows-up:**

- For detection of bleeding which was classified into mild, moderate and severe bleeding or any haemoglobin drop.
- For detection of the need for Re hospitalization, and decompensated heart failure.
- For detection of Stroke either ischemic or hemorrhagic stroke
- For detection of acute coronary syndrome.

**- Urgent CAG to the patient who has ACS or chest pain, with IVUS plus or minus PCI:**

For detection if occurring in-stent stenosis which is identified by decreased in-stent minimum luminal area by less than 4 mm<sup>2</sup>, by any mechanism such as intimal hyperplasia or remodelling, and either focal (less than 10mm length), diffuse (more than 10mm within the stent), proliferative (more than 10mm outside the stent) or occlusive in-stent restenosis, also for detection very late stent thrombosis or any coronary thrombosis.

**Statistical analysis:**

The statistical analysis was performed using SPSSPC + version 24. The distribution and normality of the data were assessed by visual inspection and the Kolmogorov-Smirnov test. Continuous variables were presented as means  $\pm$  standard deviations (SD) and categorical variables as absolute and relative frequencies (percentages). To analyze the differences between subgroups, the Student's *t*-test for normally distributed data and the Mann-Whitney U-test if the data were not normally distributed were applied. For categorical variables, the Chi-square test and Fisher exact test were used. A *p*-value of <0.05 indicated statistical significance.

**Results****1- Demographic characters of the patients:**

The results observed in Table (1) indicated that the demographic data age and sex do not differ significantly among the studied groups ( $p > 0.05$ ). The mean  $\pm$  SD age of the first group was 60.9 years while in the second group was 61.4 years. There was no sex difference between both groups.

Table (1): Demographic and clinical symptoms among the two groups.

Parameters	Group (1) N=20	Group (2) N=20	<i>p</i> -value
Age in years	60.9	61.4	0.21 (NS)
<b>Sex:</b>			
Male	12 (30%)	11 (27.5%)	<b>Chi<sup>2</sup> = 1.55 (NS)</b>
Female	8 (20%)	9 (22.5%)	

NS = Non-significant ( $p > 0.05$ ).

**2- Risk factors of IHD between both groups:**

The results observed in Table (2) cleared that risk factors for CAD including smoking, diabetic mellitus, hypertension, dyslipidemia, and obesity did not differ significantly among both groups ( $p > 0.05$  %). The number of smokers in the group (1) was 13 (32.50%) and in the group (2) was 15 (37.50%). The diabetic patients in group (1) were 18 (45%) and in group (2) were 17 (42.50%). The hypertensive patients in group (1) were 17 (42.50%) and in group (2) were 17 (42.50%). The dyslipidem-

ic patients in group (1) were 18 (45%) and in group (2) were 17 (42.50%), and obesity in group (1) was present in 17 patients (42.50%) versus 17 (42.50%) in the group (2).

Table (2): Risk factors among the studied groups.

Parameters	Group (1) N=20	Group (2) N=20	p-value
Smoker	13 (32.5%)	15 (37.5%)	1.67 (NS)
Diabetic	18 (45 %)	17 (42.5%)	1.15 (NS)
Hypertensive	17 (42.50)	17 (42.50)	1.12 (NS)
Dyslipidemic	18 (45 %)	17 (42.50)	1.12 (NS)
Obesity	17(42.50)	17 (42.50)	1.11 (NS)

NS = Non-significant ( $p>0.05$ ).

### 3- Bleeding during 12 months follow-up among the studied groups:

Bleeding was classified into minor, moderate and severe bleeding. There was a significant difference between the two groups in minor bleeding as it was recorded in 4 patients (20%) in group (1) but no minor bleeding was recorded in the group (2), while moderate bleeding did not differ significantly among the two groups ( $p>0.05$  %). Severe bleeding was not recorded in both in the group (1) and (2).

Table (3): Bleeding among the studied groups.

Minor bleeding	4 (20 %)	0 (0 %)	$\text{Chi}_2^2 = 8.17^{**}$
Moderate bleeding	2 (10%)	0 (0 %)	$\text{Chi}_2^2 = 3.19^{**}$
Severe bleeding	0 (0 %)	0 (0%)	NS

NS = Non-significant ( $p>0.05$ ).

\* = Significant at ( $p<0.05$ ).

\*\* = Significant at ( $p<0.01$ ).

### 4- Complications (acute stent thrombosis, late stent thrombosis, in-stent stenosis, ACS, decompensated HF, stroke and sudden cardiac death) during 12 month follow-up period among the studied groups:

The results observed in Table (4) showed that there is a significant difference between the two studied groups regarding complications occurring during 12 months after the complex PCI as follows acute stent thrombosis was not recorded in group (1) but was recorded in group (2) (non-treated by Rivaroxiban 2.5mg daily dose) was 3 (15%). Late stent thrombosis was not recorded in the group (1) and was recorded only in the non-treated group (2) was 1 (5%). The in-stent stenosis was not recorded in the group (1) and was recorded only in group (2) and was 5 (25%) while the acute coronary syndrome was recorded only in non-treated group (2) and was 4 (20%). Stroke was recorded only in non-treated group (2) and was 1 (5%). Decompensated HF was not recorded in the group (1) and was recorded in the non-treated group (2) and was 4 (20%). While sudden cardiac death was recorded in the non-treated group and reached 2 (10%).

Table (4): Complications during 12-month follow-up among the two groups.

Parameter of complication	Group (1) N=20	Group (2) N=20	p-value
Acute stent thrombosis	0 (0%)	3 (15%)	0.0002*
Late stent thrombosis	0 (0%)	1 (5%)	0.29 (NS)
In stent restenosis	1 (5%)	5 (25%)	0.001***
Acute coronary syndrome	0 (0%)	8 (40%)	0.0003***
Decompensated HF	0 (0%)	4 (20%)	0.001**
Stroke	0 (0%)	1 (5%)	0.08 (NS)
Sudden Cardiac Death	0 (0%)	2 (10%)	0.001**

NS = Non-significant ( $p>0.05$ ).

\* = Significant at ( $p<0.05$ ).

\*\* = Significant at ( $p<0.01$ ).

## Discussion

This study aims to compare patients after 12 months of complex PCI while taking low-dose Rivaroxaban in addition to mono antiplatelet and those who received only mono antiplatelet. The demographic characteristics of the patients showed that there were no statistically significant differences among the two groups in the demographic characteristics regarding the age and sex of both groups. Also, the risk factors of CAD between the two groups showed smoking, diabetic mellitus, hypertension, dyslipidemia, and obesity did not differ significantly among both groups ( $p>0.05$  %). There was a statistically significant difference between the two groups regarding minor bleeding, while severe bleeding did not occur in either group.

Scheen et al., [19] reported that the use of rivaroxaban especially in low doses offers several advantages without a significant increase in the incidence of major bleeding.

Brunetti et al., [20] stated that the use of rivaroxaban in the standard recommended dose in triple therapy (15mg once daily) is safer than, and as effective as warfarin in addition to antiplatelets in people with non-valvular atrial fibrillation undergoing PCI.

Jan Steffel. et al., [21] reported that the use of low-dose rivaroxaban 2.5mg twice daily in patients with CAD in addition to mono antiplatelets reduces the risk of cardiovascular events, and prevents MI and stroke but increases the risk of major bleeding. In comparison with our study, the use low dose of rivaroxaban 2.5mg to patients who underwent complex PCI after 12 months of follow-up increased the risk of mild and moderate bleeding but not major bleeding.

Also, the results of Widimský et al., [22] reported that the use of a low dose of Rivaroxaban improved the PCI patient health conditions with a reduction of stroke level.

**Conclusion:**

Our results on the complications after 12 months of complex PCI showed that patients in group (1) treated with Rivaroxiban 2.5mg daily dose had significantly lower complications than group (2) who were not treated with Rivaroxiban. The study also concluded that using Rivaroxaban 2.5mg twice daily dose in patients who underwent complex PCI had significantly lower complications without a significant increase in major bleeding.

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## تأثير جرعة منخفضة من عقار ريفاروكسيبان ٢,٥ ملغ مرتين يومياً على المرضى الذين خضعوا للتدخل التاجي المعقد عن طريق القسطرة العلاجية

الخلفية العلمية: ان المرضى الذين خضعوا للتدخل التاجي المعقد عن طريق القسطرة العلاجية لديهم نسبة أعلى من تضيق الدعامات من خلال آليات مختلفة بعد ١٢ شهراً ويمكن أن يكون هذا بسبب سوء التوضع المكتسب في وقت متأخر، وتضخم الأنسجة المحيطة، وزيادة نشاط التخثر. كما أن هؤلاء المرضى لديهم نسبة أعلى من الإصابة بتصلب الشرايين التاجية، يستهدف ريفاروكسيبان بشكل انتقائي العامل المنشط رقم عشرة الذي يلعب دوراً في التخثر، لذلك فإن استخدام جرعة منخفضة عن طريق الفم مرتين يومياً من ريفاروكسيبان ٢,٥ ملغ بالإضافة إلى مضاد الصفائح الأحادي لعلاج طويل قد يقلل من المضاعفات ويحسن نتائج مرضى التدخل التاجي المعقد.

الهدف من البحث: تهدف هذه الدراسة إلى دراسة تأثير جرعة منخفضة من ريفاروكسيبان ٢,٥ ملغ مرتين يومياً إضافة الى مضاد واحد للصفائح للعلاج طويل الأمد بعد ١٢ شهراً على المرضى الذين خضعوا للتدخل التاجي المعقد عن طريق القسطرة العلاجية.

طريقة البحث: أجريت هذه الدراسة على ٤٠ مريضاً بعد ١٢ شهراً من خضوعهم لجراحة معقدة في الشريان التاجي عن طريق القسطرة العلاجية. تم جمع المرضى من مستشفى الهرم التخصصي التابع لوزارة الصحة (الهرم، القاهرة، مصر) في الفترة من ديسمبر ٢٠٢١ إلى ديسمبر ٢٠٢٣. تم تقسيم المرضى إلى مجموعتين المجموعة الاولى المرضى الذين يتم علاجهم بجرعة صغيرة من عقار ريفاروكسيبان مرتين يومياً ومضاد للصفائح الأحادي (الأسبرين أو كلويدوجريل). (والمجموعة الثانية تشمل المرضى الذين يعالجون بمضادات الصفائح الأحادية (الأسبرين أو كلويدوجريل) دون إضافة جرعة صغيرة من عقار ريفاروكسيبان، تمت متابعة جميع المرضى في كلا المجموعتين للكشف عن تخثر الدعامات والتضيق بالدعامات والسكتة الدماغية والنزيف وحالات متلازمة الشريان التاجي الحادة .

النتائج وملخص البحث: وقد خلصت هذه الدراسة إلى أن إضافة جرعة صغيرة من عقار ريفاروكسيبان للعلاج طويل الأمد للمرضى الذين خضعوا لتركيب دعامات يقلل من حدوث تجلط الدعامات وتضيق بالدعامات ومتلازمة الشريان التاجي الحادة والسكتة الدماغية دون زيادة كبيرة في حدوث نزيف كبير.