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The association between stent type and developing angina pectoris following percutaneous coronary intervention

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Abstract

Background Angina pectoris can occur in up to 40% of patients following percutaneous coronary intervention (PCI). There is limited data assessing whether the type of stent implanted during revascularization can predict post-PCI angina symptoms.

Methods In this study, data regarding revascularization characteristics including the stent type in patients admitted for PCI was collected. Prospective data including occurrence of angina and the presenting class, new onset ST-segment elevation myocardial infarction (STEMI), and other clinical outcomes were collected at 1, 3, and 6-month follow-up intervals. Univariable and multivariable logistic regression models were used to assess the potential predictors of angina symptoms at 6-month follow-up.

Results A total of 787 patients (64.5% males) undergoing PCI with three stent types (Orsiro, Promus, and Xience) were included in the study. The occurrence of post PCI angina pectoris and new STEMI was similar among the stent types ($p > 0.05$). A linear association was found between the development of new STEMI ($p = 0.018$) and stroke ($p = 0.003$) and the worsening of angina class. The stent type was not a predictor of angina during the follow-up period. Other variables including dyslipidemia (odds ratio (OR) (95% CI), 1.51 (1.08; 2.10)), prior coronary artery disease (CAD) (OR (95% CI), 1.63 (1.02; 2.61)), and previous hospitalization (OR (95% CI), 2.10 (1.22; 3.63)) were independent predictors of angina.

Conclusions Although the type of stent may not have an association with the post-PCI angina, other predictors such as dyslipidemia and previous CAD and hospitalization may predict recurrence of cardiac angina. The class of angina severity may have a linear association with new-onset STEMI and stroke.

Keywords Angina pectoris, Percutaneous coronary intervention, Type of stent, Predictors

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Background

Development of angina pectoris following stent implantation in patients undergoing percutaneous coronary intervention (PCI) affects approximately 20–40% of individuals which can be due to numerous etiologies including in-stent restenosis and incomplete revascularization [1–3]. Angina pectoris significantly impacts the quality of life and often leads to repeat revascularization procedures [4]. Previously, smoking, male sex, and residual chronic total occlusion were considered as potential predictors of angina [5, 6]. With numerous options regarding stent selection, comparative data on the incidence of post-PCI angina pectoris are essential to guide optimal stent implantation. Existing data on this matter are not conclusive, highlighting the need for further research to clarify the comparative efficacy of different drug-eluting stents (DES) in reducing post-PCI angina [7, 8]. In the present study, we aimed to compare the incidence of angina symptoms in patients undergoing PCI stratified by three types of DES (Xience, Promus, and Orsiro). We further sought to investigate whether the type of stent can be a predictor of developing angina in 6-month follow-up and to find other potential clinically relevant predictors of angina symptoms.

Methods and materials

Study design

In this study, clinical and procedural data were extracted from the records available from March 2016 up until June 2017 at Al-Zahra Heart Hospital, a tertiary referral center. The follow-up data regarding the occurrence of the outcomes were prospectively collected. Approval for the conduct of this study was obtained from the Institutional Review Board at Shiraz University of Medical Sciences and Al-Zahra Heart Hospital. A written informed consent was obtained from all of the eligible participants prior to inclusion.

Study population and inclusion criteria

Eligible participants were all the patients undergoing PCI and stent implantation with one of the available stents (Orsiro, Promus, and Xience). General data including sex, age, baseline comorbidities, history of previous hospitalizations, reason of prior admission, and previous cardiac procedures were extracted from the database. Data regarding the diagnosis on admission in the specified time and procedural characteristics including type of the implanted stent, number of the involved coronary arteries, and length and diameter of the culprit artery were abstracted for further analyses. Patients were queried through telephone or in-person visits regarding the occurrence of the desired outcomes at 1, 3, and 6-month follow-up interval after angioplasty. Patients were excluded based on the following criteria: [1] no available follow-up data or no contact information, [2] patients undergoing stent implantation with more than one type of stent, [3] patients diagnosed with acute stent thrombosis, and [4] patients who died at the hospital.

Study outcomes

Primary outcome of this study was occurrence of any angina pectoris, new onset ST-segment elevation myocardial infarction (STEMI), and unstable angina (UA) recorded at 1, 3, and 6 months of follow-up. Secondary outcomes included clinical events including mortality, revascularization, and stroke during the follow-up period. All the outcomes were categorized based on the type of the implanted stent during angioplasty. New-onset STEMI was defined as the presence of a new ST-segment elevation at the J point ≥ 2 mm in males and ≥ 1.5 mm in females in V2-3 and ≥ 1 mm in other leads in two contiguous leads on a 12-lead electrocardiogram. The angina symptoms were graded by the Canadian Cardiovascular Society (CCS) scoring system from 1 to 4. All the patients were contacted via telephone or visited in outpatient clinics and were required to provide information regarding occurrence of the outcomes of interest.

Statistical analysis

Categorical variables were presented as counts and percentages and continuous variables were shown as either mean ± standard deviation (SD) or median (1st – 3rd quartiles) based on their distribution. The data were presented and compared based on the implanted stent into three groups. The categorical variables were compared using Pearson Chi-square test or Fisher's exact test, as appropriate. For clinical outcomes including mortality, revascularization, stroke, and new-onset STEMI we classified patients into three groups based on their worst angina CCS class severity (class 0, class 1 or 2, and class 3 or 4). A chi-square test for trend was performed to assess any potential linear association between the mentioned outcomes and the worsening angina class. Other variables were compared using a one-way analysis of variance (ANOVA) test. In case of a between-group difference, post-hoc test (Scheffe's method) was performed to determine the source of difference. A univariable binary logistic regression was performed by entering the stent types and other potentially relevant variables into a model one by one to assess the possible predictors of angina pectoris. To adjust for confounders, the variables with a statistically significant p-value were entered into a multivariable logistic regression analysis and the significant ones were presented as independent predictors of angina at 6-month follow-up. An odds ratio (OR) with 95% confidence interval (CI) was presented as the effect size of the logistic regression analysis. For better interpretation of the ORs, we used the margins of 1.32, 2.38, and 4.70

Table 1 General characteristics by stent type

	Total ($n=787$)	Orsiro ($n=416$)	Promus ($n=202$)	Xience ($n=169$)	*p*-value
Male	508 (64.5)	261 (62.7)	135 (66.8)	112 (66.3)	0.749
Age	59.71 (10.60)	59.98 (10.52)	59.49 (10.68)	59.33 (10.76)	0.529
Diabetes mellitus	139 (17.7)	82 (19.7)	31 (15.3)	26 (15.4)	0.280
Hypertension	419 (53.2)	232 (55.8)	101 (50)	86 (50.9)	0.317
Dyslipidemia	299 (38)	174 (41.8)	70 (34.7)	55 (32.5)	0.058
Smoking	230 (29.2)	109 (26.2)	56 (27.7)	65 (38.5)	**0.011**
Opioids	74 (9.4)	39 (9.4)	15 (7.4)	20 (11.8)	0.350
Chronic renal insufficiency	15 (1.9)	7 (1.7)	6 (3.0)	2 (1.2)	0.405
Previous CAD	246 (31.2)	130 (31.3)	68 (33.7)	48 (28.4)	0.553
Previous CABG	21 (2.7)	12 (2.9)	6 (3.0)	3 (1.8)	0.717

Values are presented as either counts (percentage) or mean (standard deviation) (CAD: coronary artery disease, CABG: coronary artery bypass grafting)

Table 2 Procedural characteristics and the diagnosed condition on presentation

		Orsiro ($n=416$)	Promus ($n=202$)	Xience ($n=169$)	*p*-value
Diagnosis on presentation	STEMI	130 (31.3)	53 (26.2)	42 (24.9)	0.207
	CHF	54 (13)	31 (15.3)	25 (14.8)	0.687
	ACS	232 (55.8)	118 (58.4)	102 (60.4)	0.542
Number of vessels involved*	1 vessel	357 (85.8)	170 (84.2)	147 (87.0)	0.788
	2 vessels	32 (7.7)	18 (8.9)	9 (5.3)	
	3 vessels	2 (0.5)	0 (0.0)	1 (0.6)	
Length of the culprit vessel lesion		26 (18; 35)	28 (20; 32)	23 (15; 33)	**0.008**
Diameter of the culprit vessel lesion		3 (2.5; 3)	2.75 (2.5; 3)	3 (2.5; 3)	0.347
Length of the stent		27 (19; 35.5)	28 (18; 33)	24.5 (19.5; 33.7)	0.079
Diameter of the stent		3 (2.5; 3.5)	2.75 (2.4; 3)	3 (2.5; 3.1)	0.881
Bifurcation lesion		36 (8.7)	13 (6.4)	12 (7.1)	0.588

*: The minimum and maximum percentage of missing data accounts for 6.0-7.1% of the reported results, respectively (values are presented as either counts (%) or median (1st ; 3rd quartile)) (STEMI: ST-segment elevation myocardial infarction, CHF: congestive heart failure, ACS: acute coronary syndrome, 1VD: one vessel disease)

as the areas having small, medium, and large association with the outcome [9]. A two-tailed p-value<0.05 was considered statistically significant throughout the analyses. All the statistical analyses were performed using SPSS statistical software version 26.0.

Results

Patient and procedural characteristics

During the study period, a total of 787 patients met the inclusion criteria and were hospitalized for PCI and stent implantation. A total of 416 (52.9%) patients underwent coronary revascularization with Orsiro stent whereas 202 (25.7%) and 169 (21.5%) patients underwent stent implantation with Promus and Xience stent, respectively. No intravascular imaging was used for guidance of PCI in the patients. The majority of the study sample size comprised of the male participants (64.5%) and the mean age of the population was 59.71 ± 10.60 years. There was no between-group differences regarding the prevalence of baseline comorbidities including diabetes mellitus, hypertension, dyslipidemia, and chronic renal insufficiency. A total of 31.2% of patients were previously diagnosed with coronary artery disease (CAD) prior to the study period and there was no statistically significant difference between the groups (p-value$=0.55$). Also, 21 (2.7%) patients underwent coronary artery bypass grafting (CABG) before the current hospitalization and no difference was observed between the groups (p-value$=0.72$) (Table 1).

A total of 225 (28.6%) patients were diagnosed with STEMI on admission. The occurrence of acute coronary syndrome (ACS) other than STEMI (452 patients (57.4%)) as the primary diagnosis was the highest cause of hospitalization among the participants. Also, 110 (14.0%) patients were admitted with congestive heart failure on admission. The studied groups were similar regarding the primary diagnosis (p-value>0.05). On angiography, the diameter of the culprit vessel was similar among the groups (p-value$=0.35$). Regarding the culprit lesion vessel size, the Xience group showed a shorter length (23 (15; 33)) compared to the Orsiro (mean difference (MD) (95% CI) = -2.73 (-5.00; -0.47)) and Promus (MD (95% CI) = -2.77 (-5.36; -0.18)) stent groups (p-value$=0.01$). The groups were not different in terms of the rate of bifurcation lesions (p-value$=0.59$) (Table 2).

Primary outcomes (angina pectoris, new-onset STEMI, and unstable angina)

One month following stent implantation, 213 (27.1%) patients had at least one episode of angina pectoris which

Table 3 Cumulative incidence of primary outcomes at 1-, 3-, and 6-month follow-up

		Orsiro ($n=416$)	Promus ($n=202$)	Xience ($n=169$)	*p*-value
1 month	**Angina pectoris**	117 (28.1)	52 (25.7)	44 (26.0)	0.783
	New STEMI	0 (0.0)	0 (0.0)	0 (0.0)	-
	UA	4 (1.0)	1 (0.5)	2 (1.2)	0.883
3 months	**Angina pectoris**	125 (30.0)	55 (27.2)	48 (28.4)	0.499
	New STEMI	1 (0.2)	0 (0.0)	1 (0.6)	0.449
	UA	7 (1.7)	2 (1.0)	2 (1.2)	0.920
6 months	**Angina pectoris**	130 (31.3)	56 (27.7)	50 (29.6)	0.433
	New STEMI	4 (1.0)	0 (0.0)	1 (0.6)	0.420
	UA	12 (2.9)	3 (1.5)	3 (1.8)	0.565

(UA: unstable angina, STEMI: ST-segment elevation myocardial infarction)

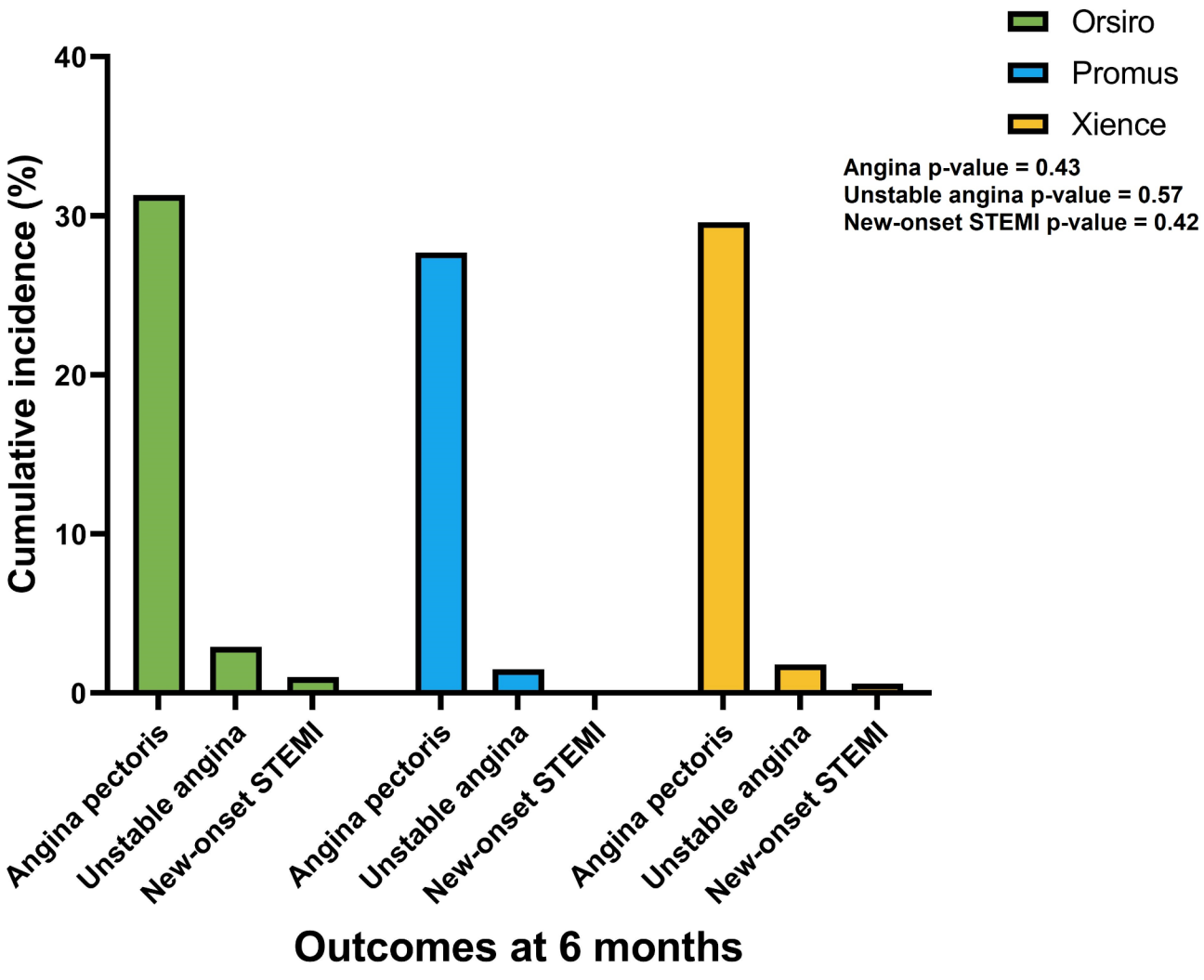

Fig. 1 Cumulative incidence of primary outcomes at 6 months of follow-up (STEMI: ST-segment elevation myocardial infarction)

was similar among the groups (Orsiro=117 (28.1%), Promus=52 (25.7%), Xience=44 (26.0%), *p*-value=0.78). No new-onset STEMI was formed during this period and occurrence of UA was also similar among the groups (*p*-value=0.88). At 3 months, the outcomes were captured and there was no between-group differences regarding the primary endpoints (*p*-value>0.05). After the last follow-up (6-month), a total of 236 (30.1% (26.8; 33.3)) patients experienced at least one episode of angina pectoris which was similar across the studied groups (Orsiro=130 (31.3%), Promus=56 (27.7%), Xience=50 (29.6%), *p*-value=0.43). Five patients developed new STEMI in their electrocardiogram (*p*-value=0.42) (Table 3) (Fig. 1). Fifteen patients with angina in the

Table 4 Clinical outcomes at 6-month follow-up stratified by the angina class severity

Outcome	CCS class 0	CCS class 1 and 2	CCS class 3 and 4	*p*-value
Mortality	4 (0.7)	1 (0.5)	0 (0.0)	0.714
Revascularization	15 (2.7)	7 (3.3)	0 (0.0)	1.000
Stroke	0 (0.0)	4 (1.9)	1 (3.8)	**0.003**
New-onset STEMI	1 (0.2)	3 (1.4)	1 (3.8)	**0.018**

Data are presented as events (percentage)

Table 5 Univariable and multivariable logistic regression analysis of angina pectoris at 6 months

Univariable analysis			Multivariable analysis		
Variables	**Odds ratio (95% CI)**	***p*-value**	**Variables**	**Odds ratio (95% CI)**	***p*-value**
Orsiro	1.154 (0.849; 1.569)	0.361			
Promus	0.855 (0.599; 1.222)	0.391			
Xience	0.963 (0.662; 1.400)	0.844			
Sex (female/male)	1.184 (0.862; 1.626)	0.296			
Age	1.008 (0.993; 1.022)	0.307			
Number of diseased vessels	1.163 (0.790; 1.714)	0.444			
Diabetes mellitus	1.602 (1.092; 2.350)	**0.016**	**Diabetes mellitus**	1.297 (0.860; 1.956)	0.215
Hypertension	1.216 (0.893; 1.655)	0.214			
Dyslipidemia	1.684 (1.233; 2.299)	**0.001**	**Dyslipidemia**	1.505 (1.080; 2.099)	**0.016**
Chronic renal insufficiency	1.193 (0.403; 3.529)	0.750			
Previous CAD	1.883 (1.188; 2.985)	**0.007**	**Previous CAD**	1.630 (1.016; 2.613)	**0.043**
Prior hospitalization	2.304 (1.348; 3.938)	**0.002**	**Prior hospitalization**	2.102 (1.218; 3.627)	**0.008**
Previous CABG	1.480 (0.605; 3.619)	0.391			
Smoking	0.997 (0.712; 1.396)	0.987			
Opium usage	1.414 (0.857; 2.332)	0.175			
Stent length	1.033 (0.979; 1.092)	0.237			
Stent diameter	0.609 (0.215; 1.588)	0.324			

(CAD: coronary artery disease, CABG: coronary artery bypass grafting, CI: confidence interval)

Orsiro group (11.5%) had the worst angina severity class of 3 or 4 whereas 7 (12.5%) and 4 (8%) patients had a class of 3 or 4 in the Promus and Xience groups, respectively. There was no difference regarding the worst angina severity class between the stent types (p-value=0.414).

Clinical outcomes based on the CCS angina class

During the study period, the incidence of mortality was 5 (2 in Orsiro and 3 in Promus group) and a total of 22 patients underwent repeat revascularization (Orsiro: 16, Promus: 5, and Xience: 2). Two patients in the Orsiro group and 3 in the Promus group suffered from stroke. No association was found between the CCS class angina severity and mortality (p-value=0.71) or revascularization (p-value=0.83). The results of the Chi-square test for trend showed that there was a linear trend towards increasing the stroke rates when the class of angina was higher with patients in class 0 having 0.0% stroke rate whereas 1.9% and 3.8% stroke rates were observed in class 2 or 3 and 3 or 4, respectively (p-value=0.003). A dose-response manner was also found between developing new-onset STEMI and the angina class severity (0.2%, 1.4%, and 3.8% in the groups, respectively) (p-value=0.018) (Table 4).

Logistic regression analysis

The different type of stents were entered into a univariable logistic regression analysis in addition to other clinically relevant variables. None of the stent types were associated with occurrence of angina pectoris at 6 months (Orsiro: OR (95% CI)=1.15 (0.85; 1.57), Promus: OR (95% CI)=0.86 (0.60; 1.22), and Xience: OR (95% CI)=0.96 (0.66; 1.40)). Among the potential predictors, 4 variables were associated with developing angina pectoris including diabetes mellitus (OR (95% CI)=1.60 (1.09; 2.35)), dyslipidemia (OR (95% CI)=1.68 (1.23; 30)), previous CAD (OR (95% CI)=1.88 (1.19; 2.99)), and prior hospitalization (OR (95% CI)=2.30 (1.35; 3.94)). These potential predictors were then entered in a multivariable analysis for adjusting the potential effect of confounders. Among these variables, dyslipidemia (OR (95% CI)=1.51 (1.08; 2.10)), previous CAD (OR (95% CI)=1.63 (1.02; 2.61)), and prior hospitalization (OR (95% CI)=2.10 (1.22; 3.63)) were associated with angina pectoris and considered predictors of angina at 6 months (Table 5).

Discussion

Occurrence of angina pectoris in patients with previous revascularization is a common presentation in up to 40% of patients. The frequent angina symptoms in affected

patients have been associated with detrimental effects of quality of life and physical function [10]. Patients with more frequent angina symptoms are also reported to have more direct and indirect costs [11]. As a result, finding relevant predictors of angina pectoris in patients with CAD is of paramount significance as it can provide valuable insights for improving the management of these individuals. In the present study, we explored the potential association between the implanted stent type during PCI and occurrence of patient-reported angina pectoris. We found that the type of stent was not a predictor of angina pectoris at 6-month follow-up. The rate of unstable angina, new-onset STEMI, and also angina pectoris were similar among stent types at 1, 3, and 6-month interval. The incidence of angina pectoris at 6 months after PCI was 30.1%. This rate is in accordance with previous studies estimating the prevalence of resistant or recurrent angina following coronary angioplasty [12, 13]. Although the type of stent was not associated with angina, some other baseline characteristics including dyslipidemia (OR 1.51), prior CAD (OR 1.63), and previous hospitalization (OR 2.10) were among the predictors of angina although they all had small association with recovery. We also found a linear association between two of the outcomes (stroke and new-onset STEMI) and the CCS angina class as higher classes of angina were linked with increased rates of stroke and new STEMI.

Post-PCI angina places a significant economic burden and a drastic impact on quality of life of the affected patients. Several underlying mechanisms have been proposed as the causes contributing to post-PCI angina including limited flow in epicardial obstructions, coronary vasomotion disorders, progression of atherosclerosis, and neoatherosclerosis [13, 14]. Thus, finding appropriate predictors of angina may be of significant importance and can aid for optimal management of the affected individuals. As the primary aim of this study, we sought to investigate if the type of stent implanted during PCI could predict occurrence of post-PCI angina. We included three drug-eluting stents (DES) (Orsiro, Promus, and Xience) and the results showed that the type of stent is not an independent predictor of patient-reported angina. One can conclude that none of the mentioned DES may be superior to another in terms of angina recurrence. Another finding in our study that should be noted was that the majority of patients developing with angina recurrence, experienced the symptoms following the first month after stent implantation (27.06% (23.99; 30.31)). A previous similar study showed that none of the included stents were associated with angina at 1-year of follow-up. However, some other factors such as previous CABG (OR 1.47) and PCI (OR 1.51), male sex (OR 0.65), and age (OR 0.88) were independent predictors in the multivariable regression analysis and all of them were weak predictors of the outcome [8]. Branch jailing with provisional stenting in coronary bifurcation lesions has also been proposed as a potential source for myocardial ischemia and angina symptoms in patients undergoing PCI [15]. It should be noted that the rate of bifurcation lesions was similar between our studied groups.

The ABSORB IV trial was a randomized study which assessed the clinical outcomes and angina symptoms in patients either with stable coronary artery disease or acute coronary syndrome compared between the Xience stent and the Absorb Scaffold. The authors showed that occurrence of angina was similar among the stents (21%) both after 30 days and 1 year of follow-up. Similar to our findings, they demonstrated that the angina symptoms were likely to develop in short-term and about 60 days after stent implantation [16]. Similar results were observed in the findings of the NORSTENT trial comparing the angina frequency and stability between bare-metal stents (BMSs) and DESs. Their findings demonstrated that the rate of revascularization was significantly higher in BMS group [17]. As BMSs tend to promote the formation of the neo-intima layer, they may contribute to re-stenosis warranting further revascularization compared to DESs having anti-proliferative characteristics [18]. However, the higher rate of revascularization in the NORSTENT trial was not translated into higher angina symptoms and the proportion of patients experiencing symptoms of angina was similar across the groups [17].

Dyslipidemia was found to be an independent predictor of angina symptoms at 6 months following revascularization in our study and higher lipid levels were associated with higher odds of developing angina (OR: 1.51) although the level of association was not high. The association between dyslipidemia and atherosclerosis has been extensively studied. Abnormally high circulating lipids have been found to be associated with vascular dysfunction and oxidative stress giving rise to atherosclerosis and myocardial ischemia. Therefore, statins have been a mainstay medication in patients with CAD. Statins have demonstrated significant improvement on angina symptoms by decreasing oxidative stress and vascular inflammation and hence, potential beneficial impacts of coronary flow regulation and angina pectoris [19]. This was supported by the findings in a randomized trial showing atorvastatin was a beneficial anti-ischemic agent and its antianginal effects was as effective as amlodipine [20]. Given the above findings and the potential antianginal effects of statins, aggressive lipid management should be a cornerstone for prevention of angina pectoris.

An interesting finding in the present study was that a linear association was observed between higher angina severity class and higher rates of stroke and new-onset STEMI. Patients with higher CCS angina classes

presented with higher stroke and new STEMI rates during the last follow-up. This dose-response manner between angina severity and risk of stroke was previously found in another study showing the rate of ischemic stroke increased in higher CCS angina classes in patients with stable CAD. The authors stated that this may be due to shared risk factors between stroke and CAD and that occurrence of cerebrovascular disease is closely related to coronary atherosclerosis [21]. Our study also hypothesize that patients with more severe angina symptoms may require closer follow-up visits as they are at higher risks of developing new STEMI and patients with CCS classes of 3 and 4 should be closely monitored for presenting with new STEMI in the follow-up period.

Several limitations of the present study should be noted. The primary endpoint of this study was a patient-reported angina pectoris which can be subjected to recall bias. Along with any other observational study, our study may be limited by the lack of adjustment for baseline variables and randomization. There may be potential confounding factors not adjusted in our multivariable analysis such as potential differences in antianginal medications which were lacking in the available information. Data on residual significant CAD post index PCI were not available in our study and it is an important variable as it may have potential impact on the angina symptoms. Only data for mid-term (6-month) follow-up of patients were available. The relatively low rates of clinical outcomes at the follow-up period may limit the reliability of the Chi-square test for trend.

In conclusion, we showed that the frequency of developing angina symptoms in patients undergoing PCI is relatively high (30.1%) and the type of stent (Orsiro, Promus, and Xience) implanted during PCI is not predictive of developing angina pectoris in 6-month follow-up. Other variables including dyslipidemia, prior CAD, and previous hospitalization were independent predictors of angina symptoms. A linear association may be present between angina severity and the rate of stroke and new STEMI. Future large-scale prospective cohorts are needed to confirm our results and find other clinically valuable predictors of long-term angina symptoms.

Abbreviations

PCI	Percutaneous coronary intervention
DES	Drug-eluting stent
STEMI	ST-segment elevation myocardial infarction
UA	Unstable angina
CCS	Canadian Cardiovascular Society
SD	Standard deviation
ANOVA	Analysis of variance
OR	Odds ratio
CI	Confidence interval
CAD	Coronary artery disease
CABG	Coronary artery bypass grafting
ACS	Acute coronary syndrome
MD	Mean difference
BMS	Bare-metal stent

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None.

Author contributions
PI and AN contributed to conceptualization and design. Data collection was performed by AN and PA. Data analysis was performed by AH. Primary draft was written by AH, PI, KA, and AN. The primary draft was reviewed and edited by AA and AH. All the listed authors have contributed to the manuscript substantially and have agreed to the final submitted version.

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Data availability
The data underlying this article will be shared on reasonable request from the corresponding author.

Declarations

Ethical approval
The study protocol of this study has been approved by the Vice Chancellor of Research at Shiraz University of Medical Sciences. A written informed consent was obtained from all of the eligible participants prior to inclusion.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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