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Original Research Article

Predictors of angiographic restenosis in patients with coronary artery disease who have undergone percutaneous coronary intervention with drug eluting stents

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ABSTRACT

Background: Percutaneous transluminal coronary angioplasty (PTCA) is now widely accepted as a nonsurgical revascularization procedure for selected patients with CAD. In-stent restenosis (ISR) is a frequent complication after PCI which limits its long-term efficacy. Identification of those clinical and angiographic characteristics that may predict the risk of restenosis is extremely important to eliminate restenosis. In this context we conducted this study to assess the profile of patients with drug eluting stents - ISR with an emphasis on demographic characteristics, risk factors, mode of presentation and coronary angiographic characterization.
Methods: This study was a Case control study based on the catheterization registry of all patients who have undergone PCI with DES during the period from October 2012 to April 2015. All patients who have undergone PCI with DES and repeat coronary angiogram for evaluation of symptoms and detected to have ISR during same period were taken as case and age matched patients who had previously undergone PCI with DES and repeat coronary angiogram for evaluation of symptoms between 1/10/2012 to 30/4/2015 and detected to have fully patent stents were taken as control.
Results: A total of 26 patients were detected to have ISR during the study period as per the study protocol with equal number of age matched controls. The most common presentation of ISR was as chronic stable angina (70%). Binary logistic regression analysis of 6 factors namely diabetes, hypertension, lesion type, stent diameter, stent length and stent overlap found significant in univariate analysis, showed only the lesion type to be statistically significant with p value of 0.023.
Conclusions: Patients who have undergone PCI with DES particularly for complex lesions, diabetics with longer stents, lesser diameter stents and overlapping stents need to be meticulously followed up to rule out the possibility of restenosis, as in a small number of patients the presentation could be ACS with comparatively bad prognosis.

Keywords: Drug eluting stents, In-stent restenosis, PTCA

INTRODUCTION

Coronary Artery disease (CAD) represents the leading cause of death in adults in India. Since the introduction of stents for the treatment of CAD, the number of coronary interventions performed each year has increased considerably. Coronary artery stenting has been used to optimize the coronary lumen and reduce peri-procedural complications since 1987 circumventing the issues of acute vessel closure associated with plain old balloon

angioplasty. Percutaneous transluminal coronary angioplasty (PTCA) is now widely accepted as a nonsurgical revascularization procedure for selected patients with CAD. Its long-term efficacy is limited by coronary restenosis or in-stent restenosis (ISR), reported to be as high as 17 to 40% in the early studies.[1-7] Reactive neointimal tissue proliferation as a consequence of arterial barotrauma during stenting leads to reduction of arterial lumen. Binary angiographic restenosis generally refers to a luminal narrowing of 50% or greater as measured by follow up angiography.[8] The most widely accepted definition of clinical restenosis at the present time is the one proposed by the Academic Research Consortium. This definition requires either a luminal narrowing of at least 50% of the vessel diameter with associated evidence of functional significance by symptoms of ischemia or abnormal fractional flow reserve or luminal narrowing of at least 70% or greater in the absence of ischemic symptoms. It is well known that most cases of restenosis occur within 6 months after coronary angioplasty.

In-stent restenosis is the major limitation hampering the medium-term efficacy of coronary stenting. Several reports have evaluated the impact of baseline and procedural characteristics on the risk of subsequent restenosis after bare metal stent implantation, with a number of high-risk parameters, such as diabetes, lesion length, and vessel size, being consistently identified in most studies. Sirolimus-eluting and paclitaxel-eluting stents, the 2 drug-eluting stents most extensively studied so far, have markedly altered the outcome of patients undergoing coronary angioplasty, mainly because of their effect on the reduction of restenosis. However, the efficacy of these drug-eluting stents has not been uniform across different patient populations, which suggests that specific characteristics still confer an increased risk of restenosis after drug-eluting stent placement.[9-11] Identification of those clinical and angiographic characteristics that may predict the risk of restenosis and repeated revascularization procedures in the new era of drug-eluting stents may be of particular interest, because it may assist in the improvement of existing or the development of new tools and strategies to eliminate restenosis. The current study aims to assess the profile of patients with drug eluting stents – ISR with an emphasis on demographic characteristics, assessment of the risk factors, mode of presentation and coronary angiographic characterization.

METHODS

This is a Case control study based on the catheterization registry of all patients who have undergone PCI with DES during the time period from October 2012 to April 2015 and repeat coronary angiogram for evaluation of symptoms during the same period. All patients who have undergone PCI with DES and repeat coronary angiogram for evaluation of symptoms and detected to have ISR during a period from 1/10/2012 to 30/4/2015 were taken as case and age matched patients who had previously undergone PCI with DES and repeat coronary angiogram for evaluation of symptoms in the same period and detected to have fully patent stents were taken as control. Sample sizes in each arm were twenty-six. Lesion severity was classified as type A, B1, B2, C as per ACC/AHA task force criteria. The database used for data collection was Microsoft Access, the spreadsheet for export and data conversion was with Microsoft Excel. The Data was analyzed with SPSS (Open source). Comparison of qualitative variables between two groups were done by Chi Square test and comparison of quantitative variables between two groups were done by independent sample T test and Mann Whitney U test and significance was assumed at $p < 0.05$ level.

RESULTS

A total of 52 patients were included in the study with 26 patients each in the case and control arm. The mean age was around 55 yrs in both the groups as age matched controls were selected. The maximum numbers of patients were in the age group 41-50 yrs followed by 51-60 yrs (Table 1).

Table 1: Age wise distribution of patients.

Age	ISR patients (N)	%
31-40	1	3.8
41-50	9	34.6
51-60	8	30.8
61-70	8	26.9
71-80	1	3.8

Age wise distribution of the patients with maximum no. of patients in the age group 40-70.

Table 2: Baseline characteristics.

	ISR patients	%	Non ISR patients	%
Male	18	69.2	18	69.2
Female	8	30.8	8	30.8
Diabetes	18	69.2	9	34.6
Systemic Hypertension	20	76.9	13	50
Dyslipidemia	11	42.3	15	57.7
Renal dysfunction	4	15.4	1	3.8
Smoking	9	34.6	12	46.2

Baseline characteristics showing the predominant population to be males with more diabetics and hypertensives in the ISR group.

There was only one patient in the age group 31-40 yrs as well as in the age group 71-80 yrs in the case arm. Females formed 30% of the study group and were equally distributed in both case and control arms as they were

matched. Five patients in the case arm and eight patients in the control arm had Left ventricular ejection fraction <50% but was not found to be statistically significant (p = 0.286). Three patients among the case arm and two patients from the control arm were found to have haemoglobin less than 10gm% but was not found to be statistically significant. Sixty-nine percentage of the case had diabetes mellitus as a risk factor with only 34.6% in the control arm (Table 2). This was found to be statistically significant with a p=0.012, OR = 4.250, 95% CI (1.332-13.562). Twenty patients in the case arm and thirteen patients in the control arm were hypertensive which showed statistical significance (p=0.044, OR = 3.333, 95% CI = (1.011-10.550).42.3% of the case arm and 57.7 % patients in the control arm had dyslipidemia as a risk factor but this was not found to be statistically significant with a p value of 0.267. Renal dysfunction with Serum creatinine below 1.4 mg/dl were noted in four patients in the case group and five patients in the control group. This was not found to be statistically significant with a p value of 0.158. Smoking as a risk factor was present in 34% of patient in the case arm and 53 % patients in the control arm but was not found to be statistically significant (p = 0.397). In the case arm the most common mode of presentation for the initial angioplasty was Unstable Angina (34.6%), STEMI (30.8 %) and CSA forming 26.9% of the population while in the control arm the major presentation was STEMI (57.7%) followed by CSA (30.8%).

Angiographic characteristics

The most common vessel involved in case arm was LAD (57.8%) followed by RCA (30.8%). There was one patient with LMCA involvement. In the control arm there was no patient with LMCA involvement. The predominant vessel involved was also LAD (77.1%) followed by RCA (7.7%) (Table 3).

Table 3: Angiographic details showing the vessel involved.

Vessel involved	ISR patients		Non ISR patients	
	N	%	N	%
LMCA	1	3.8	0	0
LAD	15	57.7	20	76.9
LCX	1	3.8	1	3.8
RCA	8	30.8	2	7.7
Diagonal	0	0	1	3.8
OM	0	0	1	3.8
RPDA	0	0	1	3.8
RCA+OM	1	3.8	0	0

Table showing the maximum no of lesions in the LAD followed by RCA.

In both the arms there was only one patient with Ostial involvement which showed no statistical significance. The predominant type of lesion was type B2 both in the case arm (61.5%) as well as in the control arm (50%) (Table 4).

Table 4: Lesion characteristics and stent details.

Lesion	ISR patients	%	Non ISR patients	%
Ostial location	1	3.8	1	3.8
Type B1 lesion	3	11.5	10	38.5
Type B2 lesion	16	61.5	13	50
Type C lesion	7	26.9	3	11.5
Thrombus aspiration	1	3.8	2	7.7
Predilatation	19	73.1	19	73.1
Stent diameter<3	13	50	6	23.1
Stent length $\geq$ 28 mm	13	50	5	19.2
Post dilatation	11	42.3	10	38.5
Calcification	1	3.8	0	0
Thrombus	2	7.7	1	3.8
Dissection	2	7.7	1	3.8
Stent overlap	6	23.1	1	3.8
Bifurcation lesions	2	7.7	2	7.7
CTO	1	3.8	0	0
Stent thrombosis	1	3.8	0	0

ISR patients with lesions predominantly of type B2 and C. Longer stents and lesser diameter stents are noted in the ISR group.

Type C lesions formed 27% of the total lesions in the case arm and 11.5% in the control arm. Individually the lesions did not show statistical significance but when the type B2 and C lesions were combined it showed statistical significance with a p value of 0.025 and OR of 4.792 95% CI = (1.136-20.211). There was only around 5% of patients with thrombus aspiration together in both the arms which was not statistically significant. Both the arms had equal number of patients with pre-dilatation prior to the deployment of stent (70 %) and were found to be statistically insignificant. Sirolimus stents were the most common deployed stent constituting around 76% in the case arm and 84% in the control arm. The mean stent diameter in the case arm was 2.9 mm compared to 3 mm in the control arm which was found to be statistically significant with p=0.044, OR = 3.333, 95% CI = (1.011-10.990). The mean stent length in case arm was 29 mm compared to 20.7 mm in the control arm. This was found to be statistically significant with a p=0.020 OR = 4.200 95% CI = (1.213-14.541). The predominant stent used in both case arm (46.2%) as well as the control arm (80.8%) were cobalt chromium type with the control arm having no platinum chromium stents. Calcification, Thrombus and Dissection was noted only in < 10% of the patients in both the case as well as control arm and was statistically insignificant. 23% of patients in the case arm had overlapping stents compared to 3.8% in the control arm which was found to be statistically significant p=0.042,

OR = 7.500, 95% CI = (0.833-67.494). There were only 2 cases of bifurcation lesions in each arm which was statistically insignificant. There were no cases of CTO or distal lesions in the control arm and was found to be statistically insignificant. Residual stenosis was noted in 5 cases in the case arm and none in the control arm and reached near statistical significance (p =0.051). Stent thrombosis was noted in one patient in the case arm but was statistically insignificant. The predominant mode of presentation of ISR was as chronic stable angina (73.1 %), five patients had presentation as ACS (19%) with one patient presenting as acute myocardial infarction (Figure 1).

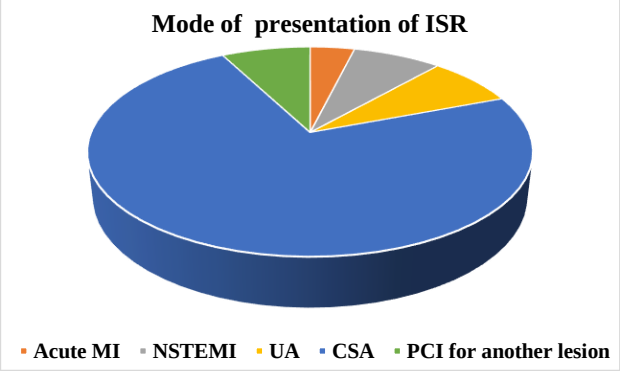

Figure 1: The most common mode of presentation of ISR was as chronic stable angina.

The average duration of symptom appearance was 6.5 months with one patient developing symptoms at 15 months in the form of CSA and one patient developing symptom as early as 1 month in the form of ACS – Unstable angina (Figure 2).

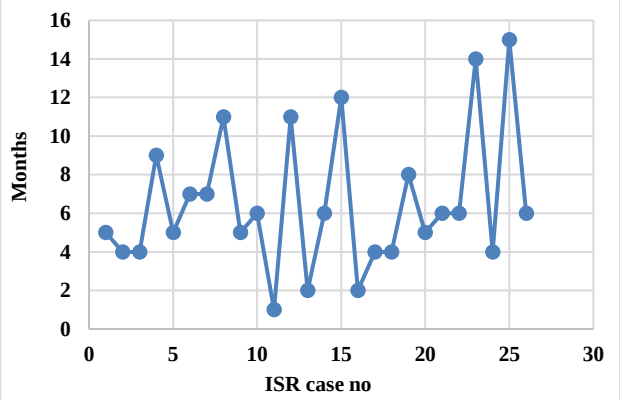

Figure 2: The average duration of symptom appearance was 6.5 months with one patient developing symptoms at 15 months in the form of CSA and one patient developing symptom as early as 1 month in the form of ACS –Unstable angina.

The most common angiographic pattern of restenosis was Type IV or the total occlusion type (30%) followed by type II -intra stent type (27 %) and type I focal type was noted in 23 % of the patients (Figure 3).

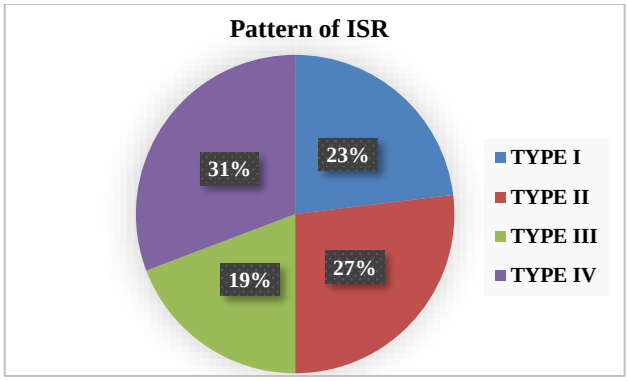

Figure 3: The most common angiographic pattern of restenosis was Type IV or the total occlusion type (31%) followed by type II -intra stent type (27%) and type I focal type was noted in 23% of the patients.

Binary logistic regression analysis of 6 factors namely diabetes, hypertension, lesion type, stent diameter, stent length and stent overlap found significant in univariate analysis showed only the lesion type to be statistically significant with p value of 0.023 (Table 5).

Table 5: Binary logistic regression analysis.

Factors	B	SE	p	OR
DM	1.278	0.768	0.096	3.59
HTN	1.107	0.771	0.151	3.026
Lesion type	2.067	0.91	0.023	7.903
Stent diameter	0.679	0.81	0.402	1.972
Stent length	0.855	0.825	0.3	2.352
Stent overlap	1.308	1.301	0.315	3.698
Constant	-5.761	1.882	0.002	0.003

Binary logistic regression analysis of six factors found significant in univariate analysis showed only the Lesion type to be statistically significant with p value of 0.023.

DISCUSSION

This study was a case control study which analysed the various factors related to ISR in 52 patients over a period of 31 months from 1/10/2012 to 30/4/2015 who had undergone PCI with drug eluting stent and a repeat coronary angiogram done for various presentations. 26 patients were detected to have ISR and included in the case arm and an equal number of age and sex matched patients who on repeat angiogram had patent stents were included in the control arm. The patients were studied for baseline characteristics, Stent related parameters and angiographic details. The mean age of the patients were 55yrs and females formed only around 30% of the study population. In the RESEARCH study by Lemos et al males constituted 73% of the population and the mean age was 60 $\pm$ 12.[12] In a study by Kastrati et al on Drug-Eluting Stents and Predictors of Restenosis the mean age of the population was 67 $\pm$ 10.3 with women constituting 27% of the study population.[13] In the Indian study by S.

Mohan et al also age was not found to be statistically significant but sex was found to be statistically significant with 23 of 71 (32.4%) were men and six of nine (66.7%) were women (p=0.04).[14] In the current study age and sex matched controls were selected. Sixty nine percentage of the case had DM as a risk factor when compared to control arm (34.6%). This was found to be statistically significant with a p=0.012 OR = 4.250 95% CI (1.332-13.562). 20 patients in the case arm and 13 patients in the control arm were hypertensive which showed statistical significance (p=0.044 OR = 3.333 95% CI = (1.011-10.550). 42.3% patients of the case arm and 57.7 % patients in the control arm had Dyslipidemia as a risk factor but this was found to be statistically non significant with a p value of 0.267. The SIRIUS trial had 25% patients diabetic, 68% hypertensive and 73% patients with dyslipidemia in the sirolimus eluting stent arm.[15] In the study Mohan S et al of the 29 patients with restenosis 51.7% were hypertensive ,6.9% were diabetics and 31% had dyslipidemia of which only hypertension showed statistical significance (0.048).[14] In the RESEARCH study diabetes was associated with ISR (OR 2.63, 95% CI 1.14 to 6.31; *P*< 0.02).[12] In a study by Cassese S et al of around 2643 patients with angiographic restenosis DM was detected to be an independent predictor of restenosis with OR of 1.32 (95% CI 1.19-1.46).[16] Smoking as a risk factor was present in 34% of patient in the case arm and 53 % of patients in the control arm ,but was not found to be statistically significant (p = 0.397) in the current study. In the study by Kastrati et al current smokers constituted 13 % and the SIRIUS study 18% of the study population were smokers. 10 out of the 29 patients with restenosis were smokers in the study by Mohan S et al and was found to be not statistically significant (p=0.27).[13-15] In the case arm the most common mode of presentation for the initial angioplasty was Unstable Angina (34.6%), STEMI (30.8 %) and CSA forming 26.9% of the population while in the control arm the major presentation was STEMI (57.7%) followed by NSTEMI (11.5%). In the research study the initial presentation was stable angina in 54% of the patients and 26% as Acute Myocardial Infarction.[12] In The study by Kastrati et al 27% patients had prior Unstable angina and 42% had previous Myocardial Infarction but on univariate analysis these were not significant.[13]

Angiographic parameters

The most common vessel involved in case arm was LAD (57.8%) followed by RCA (30.8%) and one patient with LMCA involvement. In the control arm there was no patient with LMCA involvement, the predominant vessel involved was LAD (77.1%) followed by RCA (7.7%). In both the arms there was only one patient with ostial involvement which showed no statistical significance (p =1) Predominant type of lesion was type B2 both in the case arm (61.5%) as well as in the control arm (50%). Type C lesions formed 27% of the total lesions in the case arm and 11.5% in the control arm. Individually the lesions did not show statistical significance but when the type B 2 and C lesions were combined it showed statistical significance with a p value of 0.025 and OR of 4.792 95% CI = (1.136-20.211) There was only around 5% of patients with thrombus aspiration together in both the arms which was not statistically significant (p =0.552). In the research study LAD involvement was 43%, RCA 30% and LMCA involvement was noted only in 3%.[12] On multivariate analysis LAD involvement had an OR 0.30 (95% CI 0.10-0.69). Type B 2 and C lesions together constituted 71% of the lesions and ostial location was noted in 22% of the patients. On multi variate analysis the OR for ostial involvement was 4.84 (CI 1.81-12.07 p<0.01). Fifty percent of patients with angiographic restenosis in the study by Kastrati et al had LAD involvement and 79% had complex lesions (type B2/C).[13]

Sirolimus stents were the most common deployed stent constituting around 76% in the case arm and 84% in the control arm. The mean stent diameter in the case arm was 2.9 mm compared to 3 mm in the control arm which was found to be statistically significant with p=0.044 OR = 3.333 95% CI = (1.011-10.990). The mean stent length in case arm was 29 mm compared to 20.7 mm in the control arm. This was found to be statistically significant with a p=0.020 OR = 4.200 95% CI = (1.213-14.541). The predominant stent used in both case arm (46.2%) as well as the control arm (80.8%) were cobalt chromium type with the control arm having no platinum chromium stents. In the RESEARCH study, 2.25 mm sirolimus stents were deployed in around 18% of the population and the mean total stented length was 26.0 $\pm$ 20.3 with a total stented length of > 36 mm in 17% of the patients.[12] On multivariate analysis a total stented length (per 10-mm increase) showed an OR of 1.42 (95% CI 1.21–1.68 P <0.01) and reference diameter (per 1.0-mm increase) an OR of 0.46 (95% CI (2.24-0.87) P =0.03). A 0.5-mm decrease in vessel size was associated with adjusted odds ratios (ORs) of 1.74 (95% CI, 1.31 to 2.32) for angiographic restenosis and 1.65 (95% CI, 1.22 to 2.23) for target lesion revascularization in the study by Kastrati et al.[13] Post-dilatation was noted in 42.3 % patients in the case arm and 38.5% among the control arm which was found to be statistically non-significant. Calcification, Thrombus and Dissection was noted only in <10% of the patients in both the case as well as control arm and was found to be statistically non significant. There were only 2 cases of bifurcation in each arm which was statistically insignificant.23% of patients in the case arm had overlapping stents compared to 3.8% in the control arm which was found to be statistically significant p=0.042 OR= 7.500 95% CI= (0.833-67.494). Moderate calcification was noted in 7% of the patients, 22% patients had bifurcation involvement, 8 % cases had CTO and 39% patients had overlapping stents in research study.[12] In the study by Kastrati et al calcification was noted in 15%, CTO 13% and bifurcation lesions were treated in 14% of the patients.[13] In the study by Mohan S et al no significant relation was noted with the vessel involved and restenosis.[14] The restenosis rate was the highest in tubular lesions (37.9%) and in chronic total

occlusion (CTO) (13.8%). Restenosis was seen more often in proximal lesions (10.3%), and ostial and bifurcation lesions (6.9%). In the study by Cassese et al[16] at multivariate analysis, smaller vessel size (OR 1.59, 95% CI 1.52 to 1.68, for each 0.5 mm decrease), total stented length (OR 1.27, 95% CI 1.21 to 1.33, for each 10mm increase) and complex lesion morphology (OR 1.35, 95% 1.21 to 1.51) were independently associated with restenosis

ISR presentation

The predominant mode of presentation of ISR was as chronic stable angina (73.1%). Five patients had presentation as ACS (19%) with one patient presenting as A/C MI. The average duration of symptom appearance was 6.5 months with one patient developing symptoms at 15 months in the form of CSA and one patient developing symptom as early as 1 month in the form of ACS – Unstable angina. In the study by Mohan S et al of the 29 patients who developed restenosis, 10 (34.5%) initially presented with CSA and seventeen patients (21.2%) initially presented with UA.[14] When they were followed up, 10 (58.8%) had developed restenosis; this was found to be statistically significant (P=0.029). The restenosis rate was higher when the initial presentation was UA compared with CSA. A study of 1958 patients with BMS ISR and 190 patients with DES ISR it was reported that 78.1% presented with unstable angina, 1.8% presented with acute myocardial infarction, and 20.1% presented with stable angina.[17] 60% to 70% of patients with DES ISR either had stable angina or were asymptomatic in two retrospective analyses.[18,19] Patients present late with ISR after PCI with DES; the mean time for patients with DES to have treatment for ISR ranges from 7.5 months to 13 months after PCI compared to BMS ISR who present around 5 months.[18,19] More extensive ISR is noted with patients presenting with early ISR and recurrence of restenosis is also high.[20] The most common angiographic pattern of restenosis was Type IV or the total occlusion type (31%) followed by type II -intra stent type (27%) and type I focal type was noted in 23% of the patients. In the original study by Mehran et al were a total of 288 ISR lesions in 245 patients were studied and angiographic accuracy verified by IVUS, pattern I was found in 42% of patients, pattern II in 21%, pattern III in 30%,and pattern IV in 7% of the patients.[21] Angiographic pattern was predominantly focal with SES ISR (47% SES ISR vs. 19% BMS ISR; p<0.001) and diffuse with BMS ISR (SES ISR 16% vs. BMS ISR 36%; p=0.003) in a study by Rathore et al comparing 487 BMS ISR patients with 351 SES ISR patients.[22] He reported that a focal pattern of SES ISR was an independent predictor of lower recurrent restenosis rate, with a hazard ratio of 0.47.

CONCLUSION

To conclude in this study the most common mode of presentation of ISR was chronic stable angina followed by ACS. The average duration of symptoms appearance in case of ISR was 6.5 months. The most common angiographic pattern of restenosis was Type IV or the total occlusion type. The predictors of ISR found significant on univariate analysis were diabetes mellitus, stent diameter, stent length, stent overlap and intervention on complex lesions. On multivariate analysis only, a single parameter - intervention on complex lesions was found to be statistically significant. Patients undergoing PCI with DES should be meticulously followed up for symptoms of ISR especially in diabetic patients and patients with intervention on complex lesions with shorter diameter and longer stents. Non-invasive evaluation followed by invasive angiography is recommended, as ISR patients can remain asymptomatic and can present as ACS. Further large sample prospective studies are needed to assess the impact of third generation stents with regard to ISR.

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