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CORONARY IN-STENT RESTENOSIS AND CORONARY ARTERY BYPASS GRAFT STENOSIS IN POST MYOCARDIAL REVASCULARISED PATIENTS- SINGLE CENTRE EXPERIENCE FROM NORTH INDIA

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ABSTRACT **Aims and Objective :** To calculate the incidence of coronary artery In-stent restenosis and coronary artery bypass graft stenosis in post myocardial re-vascularised patients in Indian context. **Methods :** This is an observational study , coronary artery disease patients earlier re-vascularized either by coronary stent implantation or by coronary artery bypass graft presented with exertional angina , anginal equivalents , symptoms of heart failure or acute coronary event were enrolled in the study, patient with contraindications to coronary angiogram were excluded. The data collected from CAG was analysed by using quantitative coronary angiography and statistical analysis was performed using SPSS version. **Results :** Study included total 201 patients, 117 in PTCA group , 84 in CABG group. Out of 184 stents, 34 stents showed >50% restenosis with incident rate 14.3% for DES and 47.80% for BMS respectively The incidence rate of restenosis was higher in BMS than DES in PTCA group ,where as the stenosis rate of LIMA graft(8.7%) was minimal in comparison to SVG graft(43.81%). Statistically no difference in restenosis rate between diabetic and non diabetic population in both PTCA and CABG group. **Conclusion:-** Our observational study reflected the rate of In-stent restenosis and coronary artery bypass graft stenosis both in PTCA and CABG groups in concordance with previous studies. In PTCA group BMS have higher incidence of In-stent restenosis in comparison with DES where as in CABG group venous graft have higher stenosis than arterial graft. There is no difference in restenosis rate among diabetic and non diabetic population in our study.

KEYWORDS : coronary artery disease, revascularization , instent restenosis, graft restenosis

INTRODUCTION

"Coronary artery disease is now the leading cause of death worldwide; it is on the rise and has become a true pandemic that respects no borders" World Health organization reports. In India, coronary artery disease (CAD) prevalence has doubled in rural areas and quadrupled in urban areas over the past four decades, and becomes the leading cause of morbidity and mortality.[1,]

Patients of coronary artery disease having significant coronary artery stenosis are revascularized either by percutaneous coronary intervention with stent implantation or by coronary artery bypass graft surgery depending on cardiac function, coronary anatomy, complexity of lesion or number of vessels involved. Both are safe and well-established treatment modalities of invasive revascularization; however conflicting information exists when comparing the long-term efficacy of the two methods.[2]

Patients with significant Coronary artery disease revascularized earlier with Balloon angioplasty were associated with up to 40% risk of restenosis secondary to acute and chronic recoil and constrictive remodeling.[2] The advent of bare metal stents (BMS) appeared to eliminate the issue of acute and chronic recoil but it introduced a new entity, neointimal hyperplasia (NIH), and the rates of ISR remains considerable.[3] In the past decade Drug eluting stents(DES) were conceived as the next step in tackling this iatrogenic entity of neointimal hyperplasia with large-scale reductions in restenosis rates and target lesion revascularization (TLR) compared with bare-metal stents (BMS) but still, a low rate of in-stent restenosis, stent thrombosis and inhibition of vasomotion persists.[4,5]

Coronary angiography remains the standard for identifying the presence or absence of arterial narrowing in atherosclerotic coronary artery disease and also for instent restenosis and graft stenosis. It provides the most reliable anatomic information regarding determining the appropriateness of medical treatment, PTCA or CABG[6]

we conducted a study at our institute to review the incidence of coronary artery In-stent restenosis and coronary artery bypass graft stenosis in post myocardial re-vascularized patients in Indian context with diverse and varied nature of the population in - terms of demography, ethnicity, genetics.

2. Method and Materials

It is an observational study conducted at tertiary care Hospital in t north India, New Delhi from May 2013 to April 2015. After obtaining approval from Scientific and Ethics Committee of hospital, 201 coronary artery disease patients earlier re-vascularized either by coronary stent implantation or by coronary artery bypass graft presented with cardiac symptoms or acute coronary event underwent coronary angiography enrolled in the study.

Inclusion criteria: Patient earlier revascularized either by coronary stent Implantation or by coronary artery bypass graft presented with cardiac symptoms who would undergo coronary angiography included.

Exclusion criteria: Patients not giving consent or had contraindication to coronary angiogram.

Clinical profile of each of such patient studied for age, sex, presence or absence of cardiac symptoms of angina, heart failure, palpitation, syncope, risk factors such as past history of CAD, DM, hypertension, chronic kidney disease, physical examination findings and old investigations reviewed. History of previous coronary angioplasty or coronary artery bypass grafting with relevant data from previous papers for date of previous PTCA or CABG , type and number of stents implanted, artery stented, type, number of grafts implanted, artery grafted, reason of readmission recorded. Coronary angiography (CAG) was done using various catheters through femoral or radial artery route and restenosis was assessed via visual estimation and quantitative coronary angiography. Findings of instent- restenosis, graft occlusion, time duration from revascularization to occlusion analyzed.

In-stent restenosis was defined as "renarrowing to a diameter stenosis >50%, either within the stent or within 5 mm proximal or distal to the stent margin[7]. Whereas graft stenosis was

defined as "renarrowing to a diameter stenosis >50%".[8]

2.1. Statistical analysis : Categorical data were expressed as percentages and compared using the chi-square test or student t test. Continuous variables were presented as means and standard deviation (SD). Student t test was used to assess the differences between continuous values. Categorical variables were presented as numbers with percentages. Chi-square test was used to assess the differences between categorical values. Statistical significance was considered when two-tailed p value <0.05. Statistical significance was considered when two-tailed p value <0.05. Statistical analysis was performed using SPSS version 16 software (IBM, Armonk, New York).

3. RESULTS

A total 201 patients were included in this study, of which 117 had been earlier revascularized with PTCA stenting and 84 were revascularized with CABG. Their data was compared after analysing it separately.

3.1 Post PTCA group: Out of 117 patients in this group, 91 were males and 26 females. The mean age of patients was 59.7 years with youngest one 37 years and oldest one 81 years. In these 117 patients total of 184 stents were implanted which include 161 drug eluting stent (DES) and 23 bare metal stent(BMS) Out of 184 stents, 34 stents showed >50% restenosis with incident rate 14.3% for DES and 47.80% for BMS respectively (Table 2). The difference in the restenosis rate between the two stent groups was statistically significant (P=000). Maximum number of patients (46) were in 51-60 years age group(figure1) having 18 stents with >50% restenosis(figure 2) which not only showed that there had been a higher number of patients but also higher rate of restenosis present in this age group. There was an increase in the rate of restenosis with increasing age and this trend was maintained above 70 years of age.

44 patients with diabetics mellitus implanted with 69 stents, and 11 stents among them showed restenosis >50%. Among the PTCA group 9 diabetic and 21 non-diabetic patients developed >50% restenosis which was statistically non-significant(P>0.05).

Similarly 56.4% patients were having hypertension with 94 stents implant of which 19.2% stents developed >50% restenosis with overall restenosis rate 9,8% - statistically non- significant (P=0.682).

3.2 Post CABG group: Out of 84 patients in this group,78 were males and 06 were female with male predominance. Total 258 graft implanted, 79 graft 72 in males , 7 in female had >50% restenosis.(Table -3, Figure -3)

Out of 258 grafts implanted in 84 patients there were 80 LIMA, 7 RIMA, 160 SVG and 11 RA grafts. Total 79 grafts showed >50% restenosis .As shown In figure 3, the incidence rate of LIMA,SVC,RA grafts restenosis was 8.7%, 43.8%,18.2% respectively with overall incidence rate of restenosis 30% including all grafts.

There were 52 patients with diabetes in CABG group having 166 grafts of which 52 grafts showed >50% stenosis. There were 32 non diabetic patients having 92 grafts ,of which 27 showed >50% restenosis. This difference in the restenosis rate between the two groups was statistically non-significant(P>0.05). The most common reason was angina on exertion followed by unstable angina and dyspnoea on exertion.

3.3 Comparison between PTCA and CABG groups : The incidence rate of restenosis was higher in BMS (14.3%) than DES(47.8%) in PTCA group where as in CABG group the rate of LIMA graft(8.7%) stenosis was minimal in comparison to SVG graft(43.81%). In PTCA group, maximum number of patients (46) were in 51-60 years age group having 18 stents with >5o% restenosis which not only showed that there had been a higher number of cases but also higher rate of restenosis present in this age group. Similarly, in CABG group out of 36 patients in 61-70 years age group, 20 patients with 32 grafts were having >5o% stenosis reflecting higher number of patients as well as higher rate of graft stenosis present in this age group along with increase in the rate of graft stenosis with increasing age.

4. DISCUSSION

The coronary stents & bypass grafts stenosis occurs by thrombosis or by intimal proliferation with progression of time causing symptoms of stable angina most commonly, though ignored may lead to an acute coronary event. Predictors of restenosis/stenosis include diabetes mellitus, unstable angina, acute myocardial infarction, prior restenosis, small vessel diameter, long lesion length, SVG .

In post PTCA group the mean age was 59.7(±10.47) years with majority of patients in between 50 to 70 years of age. Out of 46 patients in 50-60 years age group, had 18 stents with more than 50% restenosis. This shows that there was a higher number of patients as well as higher rate of restenosis present in this group aged between 51 to 60 years and there was an increase in the rate of restenosis with increasing age. Out of 184 stent, 161(87.5%) were drug eluting stent, (DES) and 23 (2.5%) were bare metal stent (BMS). 34 stent of which 23DES and 11BMS showed >50% restenosis with incidence rate of 14.3% and 47.8% respectively (p=0.000) This was concordant with previous study conducted by Mohan S et al (2010),[9] who found 23% In-stent restenosis in DES and 48.8% in BMS. Similarly, Rathore et al.(2010) [10] reported 14.3% In-stent restenosis in DES and 47% in BMS.

Out of 117 patients there were 44 diabetics. Among 44 diabetics, 11 developed restenosis whereas 21 non diabetic out of 73 also developed restenosis. The difference in the restenosis rate between the two groups was statistically non-significant (P>0.05). However, previous studies have shown a strong risk of restenosis in diabetic patients which may be 1.3 times the risk in nondiabetic patients. Insulin-dependent diabetes mellitus had a stronger relationship with restenosis.[11,12] A recent meta-analysis shown that although diabetes was a risk factor for restenosis after stenting, the apparent effect of diabetes on restenosis rates published in the literature was over rated and reduced to approximately one-half after adjusting for the difference in age[13]. Our small-sized study suggests that diabetes is not a strong predictor of restenosis. Out of 66 (56.4%) patients, 18 hypertensives developed >50% restenosis. 14 non-hypertensives out of 51 developed >50% restenosis. The difference in the restenosis rate between the two groups was statistically non-significant (P=0..682).

Major reason of readmission was angina on exertion (44%) followed by unstable angina (32%). In-stent restenosis was present in 41% of cases presented with angina on exertion and 27% cases presented with unstable angina. Besides this there was an increasing trend of In-stent restenosis with duration of implantation.

CABG group: In this group overall there was male preponderance similar to PTCA group Out of total 258 graft implanted, 79 graft had >50% restenosis. 72 grafts in males and 7 in females had restenosis >50%.

The youngest patient was of 48 years old and oldest one 84. The mean age was 63.18 (± 8.97) years. Maximum number of patients were in 61-70 years age group. Out of 36 patients in 61-70 years age group 20 patients having 32 grafts showed

restenosis which showed that there was a higher number. of patients as well as higher rate of restenosis present in this group of patients aged between 61 to 70 years and there was an increase in the rate of restenosis with increasing age (Figure 4,5)

Out of 258 grafts in CABG group there were 80 (31%) LIMA, 160(62%) SVG, 7(2.7%) RIMA, 11(4.3%) RA grafts. 7out of 80 LIMA, 70 out of 160 SVG, 2 out of 11 RA grafts having >50% restenosis. So, the incidence rate of LIMA restenosis was 8.7%, SVG was 43.8% and 18.2% in RA graft. There was no case of restenosis in RIMA graft which may be because of less number of RIMA graft patients in the study. Overall incidence rate of restenosis was 30.6% including all grafts.

Restenosis was present in 70 (88.6%) grafts in the SVG, 7(8.7%) graft in the LIMA. Arterial versus venous grafts was comparison reflected the difference in the restenosis rate between the two grafts groups which was statistically very significant (P<0.05) which was concordant with previous studies. Sabik JF et al [14] reported unadjusted 1-, 5-, and 10-year patency was 93%, 88%,and 90% for internal thoracic arteries and 78%, 65%, and 57% for saphenous veins. Steven Goldman S.[15] reported patency at 10 years was 61% for SVG and 85% for IMA grafts (p <0.001).

Diabetics showed increased trend with >50% restenosis when compared with non-diabetic. The difference in the restenosis rate between the two groups was statistically non-significant (P>0.05), however Previous studies showed increased rate of restenosis among these groups. Barsness GW et al. reported that diabetes was associated with a worse long-term outcome after both PTCA and CABG in patients with multivessel coronary artery disease[16].

5.CONCLUSION

The study reflects the rate of In-stent restenosis and coronary artery bypass graft stenosis both in PTCA and CABG groups in concordance with previous studies. In PTCA group BMS have higher incidence of In-stent restenosis in comparison with DES ,where as in CABG group venous graft have more stenosis when compared with arterial graft. The stenosis rate of LIMA graft is less than the stenosis of SVG graft with excellence patency rate. However as the duration of disease increase the rate of ISR and graft stenosis also increases. Our study showed no difference in restenosis rate among diabetic and nondiabetic population.

Table 1 – Baseline characteristics of patients

	PTCA GROUP	CABG GROUP
TOTAL NO OF PATIENTS	117	84
MALE	91	78
FEMALE	26	06
DIABETES MELLITUS	44	52
HYPERTENSION	66	50
DYSLIPIDEMIA	49	37

Table 2- Total number of stents and restenosis

	DES	BMS	TOTAL
Stents implanted	161 (87%)	23 (12.5%)	184
ISR > 50%	23	11	34

Table 3- Total number of grafts and restenosis

	LIMA	RIMA	SVG	RA	TOTAL
GRAFTS IMPLANTED	80	7	160	11	258
RESTENOSOS > 50%	7 (8.7%)	0	70 (43.7%)	2 (18%)	79 (30.6%)

Table 4- Restenosis Implanted stent/Graft >50% Restenosis

	present	absent	total	P value
PTCA	34	150	184	0.004
CABG	79	179	258	

Table 5 - Diabetic patients among both groups

	present	absent	total
PTCA	44	73	117
CABG	52	32	84

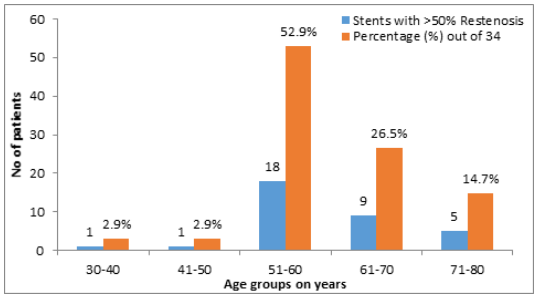

Figure 1: Age Distribution in PTCA Group (117 patients)

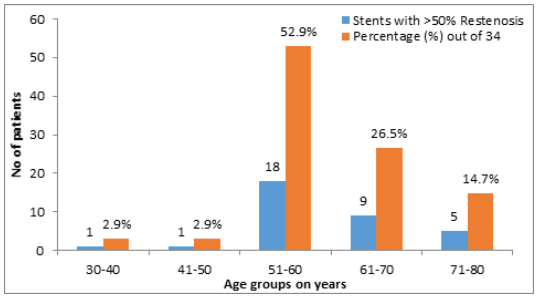

Figure 2: Age distribution PTCA group (Total no. of stents = 184)

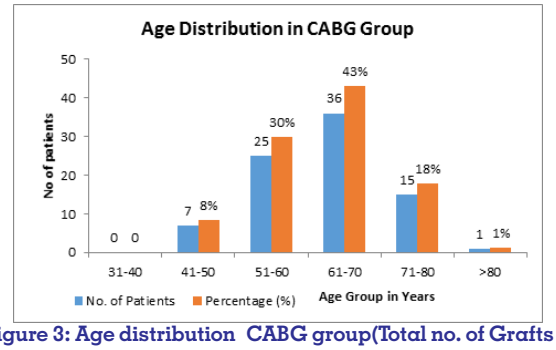

Figure 3: Age distribution CABG group(Total no. of Grafts= 183)

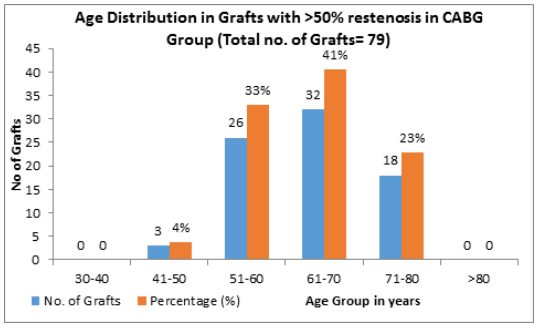

Figure 4- Age distribution among grafts with stenosis > 50%

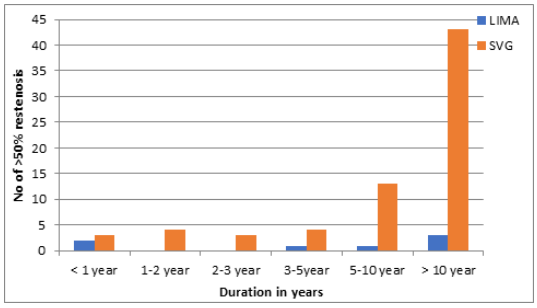

Figure 5- distribution of duration and graft stenosis

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