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Original Research Article

Clinical and angiographic profile in patients of western Rajasthan undergoing percutaneous coronary interventions: a single centre experience

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ABSTRACT

Background: This study was aimed to evaluate clinical and angiographic profile of patients undergoing percutaneous coronary intervention at the Department of Cardiology, Mathura Das Mathur (MDM) Hospital attached to Dr. Sampurnanand Medical College, Jodhpur.
Methods: This study was hospital based prospective observational study conducted in the department of cardiology at MDM hospital. This study included 1166 patients who underwent percutaneous coronary intervention at cardiac cathlab of MDM hospital from January 2016 to April 2017. Procedural details noted included vascular access route, lesion characteristics, number of lesions intervened, stents used and periprocedural pharmacotherapy administered.
Results: A total of 1166 patients (mean age- 56.3±10.4 years) with 76.5% male and 23.5% female were included in the study. Smoking and hypertension were the most common risk factors, present in 64% and 56% patients respectively. Diabetes mellitus and obesity were observed in 24.5% , 18.0% patients respectively. Anterior wall MI was the most common mode of presentation (36.2%). Single Vessel Disease (SVD) was the most common angiographic pattern observed in 62% patients; left anterior descending artery (LAD) was the most frequently involved vessel (65.9%); and type B lesions were most prevalent (48%). Most of the procedures were elective (61.4%) and femoral route was used in the majority (76%). Radial access was obtained in 24% of patients. Primary PCI was done in 6% of cases while pharmaco-invasive approach was adopted in 32.6% of patients. Drug eluting stents were deployed in 100% of the cases. The overall procedural success rate was 95.4%. Procedural mortality was nil and periprocedural complications occurred in 16.0% patients.
Conclusions: This first PCI study from western Rajasthan provides an overview into the salient features of CAD among regional population and focus on the characteristics of PCIs performed with their outcomes.

Keywords: Angiographic profile, Coronary artery disease, Percutaneous coronary interventions

INTRODUCTION

Coronary artery disease (CAD) is a leading cause of death worldwide and over three quarters of these deaths occur in low and middle income countries.[1] India is turning into the 'global capital' of coronary artery disease (CAD), contributing to 60% of global burden of CAD, and the prevalence is rising unabated.[2] CAD tends to occur at a younger age in Indians with more extensive angiographic involvement.[3] CAD varies across geography, socio-demography, and ethnicity with marked interregional heterogeneity across the country.[4] In the state of Rajasthan the population, like any other developing community, is fast undergoing lifestyle

changes, but the unusual stress and strain due to fast paced changed lifestyle has modified the epidemiology of CAD in this population. Paralleling this increased prevalence, the treatment of ischemic heart disease has also witnessed some revolutionary changes in last couple of decades.[5] In particular, percutaneous coronary interventions (PCI) which include percutaneous trans-luminal coronary angioplasty (PTCA), stenting, and related techniques represent a major therapeutic advance in the management of CAD. PCI is effective in relieving symptoms and it improves survival in certain subsets of CAD patients.[6,7] Through advances in equipment and technical skills the profile of patients undergoing PCI is constantly evolving, with increasingly more complex patients and lesions being treated with this modality.[8,9] Despite this increasing phenomenon, there is serious lack of data regarding risk factors, angiographic profile and clinical outcomes in patients undergoing PCI in India, which formed the basis to perform this study.[10-12] This is the first study from western Rajasthan conducted to explore the clinical profile of patients with CAD undergoing percutaneous revascularization in terms of risk factors, clinical presentation, and angiographic characteristics; and to analyze procedural outcomes at our hospital. Our objective was to determine baseline regional data and compare it to various national and international data available.

METHODS

This study was hospital based prospective observational all comers study conducted in department of cardiology at MDM hospital. This study included 1166 patients who underwent percutaneous coronary intervention at cardiac cathlab of MDM hospital between January 2016 and April 2017. Patients of coronary artery disease were diagnosed on the basis of clinical history, 12 lead ECG findings, biochemical markers like Troponin I and/or non-invasive tests like treadmill test and 2D echocardiography. Patients with varied clinical presentations (stable angina, unstable angina, ST elevation MI and Non-ST elevation MI) who subsequently underwent coronary angiography with revascularization were included in the study. Patients with severe renal insufficiency defined as creatinine clearance <30ml/min were excluded from the study. Usual atherosclerotic risk factors like smoking, hypertension and diabetes mellitus were identified and documented in each patient. Diabetes mellitus was diagnosed on the basis of fasting plasma glucose >126mg/dl or HbA1c >6.5% or symptoms of diabetes plus random blood glucose level >200mg/dl. Hypertension was considered to be present if the patient was taking antihypertensive drugs at time of presentation or if blood pressure recorded was more than or equal to 140mm of Hg systolic or more than equal to 90mmHg diastolic on at least 2 separate readings. Obesity was diagnosed on the basis of BMI ≥30kg/m^2. Angiographic characteristics including site, severity, type and extent of lesion and numbers of arteries involved were analyzed. Coronary artery disease was categorized as single vessel disease (SVD), double vessel disease (DVD) and triple vessel disease (TVD) according to number of vessels with >50% angiographic stenosis.[13] The angiographic lesions with ≥70% stenosis was stented with drug eluting stents, for left main (LM) disease when it showed ≥50% stenosis. Severe stenosis in smaller vessels (reference vessel diameter ≤2.25mm) were either left alone or plain balloon angioplasty was done depending upon the extent of myocardium supplied by the same. Infarct related lesions with no evidence of viability in respective territories were excluded from the study. Procedural details noted included vascular access route, number of lesions intervened, stents used, peri-procedural pharmacotherapy administered and peri-procedural complications, if any.

Operational terms

Stable angina: It was diagnosed on the basis of clinical (chest pain-typical or atypical) and non-invasive evaluation (≥1mm horizontal or down sloping STdepression on exercise ECG or perfusion defects on technetium 99 sestamibi scan).

Myocardial infarction (MI): It was diagnosed in the presence of two of the following criteria: pain suggestive of myocardial ischemia lasting for at least 30min; unequivocal new electrocardiographic alterations; or positive results of qualitative troponin T or I assay (ROCHE diagnostic kits, Germany). Patients with both STEMI and NSTEMI were included. STEMI was diagnosed when ST elevation of ≥2mm in two or more contiguous precordial leads, or ≥1mm in at least two contiguous limb leads or when new or presumably new left bundle branch block was observed on ECG.

Unstable Angina: It was diagnosed in presence of typical ischemic chest discomfort of increasing severity and ST segment depression of 1mm on limb leads or 2mm on chest leads with negative results of qualitative troponin T or I assay.

Type A Lesions: It included lesions having all of the following characteristics; discrete (<10mm length), concentric, readily accessible, non-angulated segment (<45^0), smooth contour, little or no calcification, less than totally occlusive, non-ostial location, no major side branch involvement, and absence of thrombus.

Type B Lesions (moderate risk): It included lesions having any of the following characteristics: tubular (10 to 20 mm length), eccentric, moderate tortuosity of proximal segment, moderately angulated segment (≥45^0 but <90^0), irregular contour, moderate to heavy calcification, total occlusions <3 months old, ostial in location, bifurcation lesion requiring double guidewires, and some thrombus present.

Type C Lesions: It included lesions having any of the following characteristics; diffuse (>20mm length),

excessive tortuosity of proximal segment, extremely angulated segments >90^0, total occlusion >3 months old, inability to protect major side branches, and degenerated vein grafts with friable lesions.

Coronary artery territories and segments: The left main coronary artery was considered a segment and a territory of its own. Proximal segments comprised the proximal parts of the left anterior descending (LAD), the left circumflex (LCX), and the right coronary arteries (RCA). Mid segments consisted of the mid parts of the 3 main coronary arteries, and of the proximal 1 to 2 cm of major diagonal and obtuse marginal branches. Segments distal to mid segments were considered distal.

Ostial stenosis: A stenosis was classified as "ostial" when the origin of the lesion was within 3 mm of the vessel origin involved.

Thrombus: It was defined as a discrete, intraluminal filling defect with defined borders and largely separated from the adjacent vessel wall. Contrast staining might or might not be present.

Tortuosity: Stenosis distal to two bends >75^0 was considered moderately tortuous, and those distal to three or more bends >75^0 were considered excessively tortuous.

Bifurcation stenosis: Stenosis involving the parent and daughter branch if a medium or large branch (>1.5mm) originated within the stenosis and if the side branch was completely surrounded by stenotic portions of the lesion to be dilated.

Calcification: Calcification was recorded if readily apparent densities were seen within the apparent vascular wall of the artery at the site of the stenosis.

Chronic total occlusion: A total occlusion [thrombolysis in myocardial infarction (TIMI) flow grade 0], judged to be 3 months duration on the basis of clinical and angiographic findings, was considered as a chronic total occlusion (CTO).

Irregular contour: A stenosis was classified as having irregular contour if the vascular margin was rough or had a "saw tooth" appearance.

Procedural success: The procedure was considered successful if the visual angiographic estimate of residual coronary stenosis was <10% in stented segments or <50% in balloon angioplasty segments, with the presence of TIMI III flow in the target vessel; without side branch loss, flow-limiting dissection, or angiographic thrombus; and without associated in-hospital major clinical complications (e.g. death, MI, stroke, or emergency CABG).[15]

Procedural complications: These included death, procedure related MI, emergency CABG, periprocedural stroke, vascular complications (access site hematoma, retroperitoneal haemorrhage, pseudoaneurysm, arteriovenous fistula, arterial dissection and/or occlusion), periprocedural bleeding, coronary perforation, acute stent thrombosis, flow limiting coronary dissection, side branch loss, arrhythmias requiring specific interventions, and contrast induced acute kidney injury (AKI). All these complications were defined according to the recent guidelines.[14]

Statistical methods

Statistical analysis was performed by SPSS software package (version 21.0, SPSS Inc, Chicago, Illinois, USA). All continuous variables were expressed as mean± standard deviation (SD), and categorical variables were reported as frequency and percentages. Continuous variables were analyzed with the help of Student's t-test. A p value <0.05 was considered statistically significant.

RESULTS

Overall, during the period of 16 months, a total of 1166 patients who fulfilled the eligibility criteria were included in the study.

Patient characteristics and clinical presentation

A total of 1166 patients (mean age- 56.3±10.4 years) with 76.5% male and 23.5% female were included in the study (Table 1). The patient population undergoing PCI at our hospital was relatively young mean age 56±10.4 years, with females presenting a decade later than males.[15] Age range for male patient was between 21-74 years and for female patients it was 44-76 years. Smoking and hypertension were the most common risk factors, present in 64% and 56% patients respectively. Diabetes mellitus and obesity were observed in 24.5%, and 18% patients respectively. Dyslipidemia was observed in 14% of the patients with most common pattern being high triglycerides and low HDL.

Anterior wall MI was the most common mode of presentation (36.2%) and total of 1235 lesions were reviewed by angiography. Type B lesions were most prevalent (48%). Drug eluting stents were deployed in 100% of the cases. The overall procedural success rate was 95.4%. Procedural mortality was nil but periprocedural complications occurred in 16% patients which included episodes of hypotension, rigors, respiratory distress attributed to contrast allergy.

Local site complications like haematoma formation occurred in 14.5% and pseudoaneurysm occurred in 6% of patients. Slow flow phenomenon was managed with intracoronary bolus of nicorandil, nitroglycerine, diltiazem, adenosine, eptifibatide or rarely intracoronary adrenaline. Two cases of iatrogenic leftmain coronary artery dissection occurred which were managed with additional stenting of left main.

Table 1: Demographic and clinical profile of the population studied.

Variable	Subgroup	Males		Females		Total		P value
		N (892)	100%	N (274)	100%	N (1166)	%	
Age (years)	<40	62	7	0	0	62	5.3	<0.0001
	41-70	785	88	192	70	977	83.8	
	>70	45	5	82	30	127	10.9	
Smoking	Present	721	80.8	25	9.1	746	64.0	<0.0001
	Absent	171	19.2	249	90.9	420	36.0	
Hypertension	Present	486	54.5	167	61	653	56.0	0.625
	Absent	406	45.5	107	39	513	44.0	
Diabetes mellitus	Present	190	21.3	96	35	286	24.5	0.024
	Absent	702	78.7	178	65	880	75.5	
Dyslipidemia	Present	59	6.6	105	38.2	163	14.0	0.005
	Absent	833	93.4	169	61.8	1003	86.0	
Obesity	Present	65	7.2	145	53	210	18.0	<0.0001
	Absent	827	92.8	129	47	956	82.0	
Family History	Present	42	4.7	14	5.1	56	4.8	0.692
	Absent	850	95.3	260	94.9	1110	95.2	
Clinical Presentation	AWMI	356	39.9	66	24.1	422	36.2	0.003
	IWMI	234	26.2	55	20	289	24.8	
	UA/NSTEMI	195	21.9	69	25.1	264	22.6	
	CSA	107	12.0	84	30.8	191	16.4	
Angiographic Profile	SVD	560	62.8	121	44.1	681	58.4	0.011
	DVD	259	29.0	77	28.2	336	28.8	
	TVD	71	8.0	76	27.7	147	12.6	
	LMCA	2	0.2	0	0	2	0.2	

Note: AWMI, Anterior Wall Myocardial Infarction; IWMI, Inferior Wall Myocardial Infarction; UA, Unstable Angina; NSTEMI, Non ST elevation Myocardial Infarction; CSA, Chronic Stable Angina; SVD, Single Vessel Disease; DVD, Double Vessel Disease; TVD, Triple Vessel Disease; N, Number; %, Percentage.

Coronary angiographic profile

Amongst the patients taken up for angioplasty Single Vessel Disease (SVD) was the most common angiographic pattern, observed in 682 patients (58.4%), followed by Double Vessel Disease (DVD) in 336 patients (28.8%), and Triple Vessel Disease (TVD) in 147 patients (12.6%). Most common vessel involved was the LAD, seen in 63.6% patients, followed by RCA in 51.5% and LCX in 29.2%. LMCA disease was seen in 44 patients (3.8%), all of whom had multi-vessel CAD (Table 2).

Table 2: Angiographic profile of the patients.

Vessel involved	SVD	DVD		TVD		Total	
	N (682)	%	N (336)	%	N (147)	%	N (1166)	%
LMCA	0	0	8	2.6	36	24.5	44	3.8
LAD	355	52	245	72.8	143	97.1	742	63.6
LCX	66	9.7	141	42.0	133	90.6	340	29.2
RCA	259	38	202	60	140	94.9	600	51.5
Ramus	2	0.3	7	2.2	21	14.6	31	2.7

Note: SVD, single vessel disease; DVD, double vessel disease; TVD, triple vessel disease; LMCA, left main coronary artery; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; N, number; %, percentage.

Table 3: Lesion classification and characteristics.

Angiographic Findings		LMCA	LAD	RCA	LCX	Ramus	Total
		N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
ACC/AHA Lesion Type	Type A	3	137	101	66	12	319
		11.5	28.4	26.6	20.9	37.5	25.8
	Type B	22	239	208	170	16	655
		84.6	49.6	54.9	53.8	50.0	53.0
	Type C	1	106	70	80	4	261
		3.8	22.0	18.5	25.3	12.5	21.1
Lesion Characteristics	Ostial Stenosis	12	41	28	36	3	120
		46.2	8.5	7.4	11.4	9.4	9.7
	Bifurcation Stenosis	14	118	56	69	2	259
		53.8	24.5	14.8	21.8	6.3	21.0
	Calcification	7	17	9	11	2	46
		26.9	3.5	2.4	3.5	6.3	3.7
	Chronic Total Occlusion	0	33	21	16	0	70
		0	6.8	5.5	5.1	0.0	5.7
	Thrombus	1	77	95	22	0	195
		3.8	16.0	25.1	7.0	0.0	15.8
	Eccentricity	14	257	191	175	12	649
		53.8	53.3	50.4	55.4	37.5	52.6
	Diffuse/Small vessel disease	0	21	19	28	2	70
		0.0	4.4	5.0	8.9	6.3	5.7

Note: ACC, American College of Cardiology; AHA, American Heart Association; LMCA, Left Main Coronary Artery; LAD, Left Anterior Descending Artery; LCX, Left Circumflex Artery; RCA, Right Coronary Artery; N, Number; %, Percentage.

Table 4: Stent deployment locations.

LMCA	Ostial (n = 2)	Shaft (n = 2)	Distal (n-4)		Total (n = 8)
Ramus	**Ostial-Proximal (n = 1)**		**Mid-Distal (n = 1)**		**Total (n = 2)**
LAD	Ostial (n = 20)	Proximal (n = 163)	Mid (n = 136)	Distal (n = 12)	Total (n = 331)
RCA	Ostial (n = 10)	Proximal (n = 100)	Mid (n = 83)	Distal (n = 60)	Total (n = 253)
LCX	Ostial (n = 10)	Proximal (n = 54)	Mid (n = 62)	Distal (n = 30)	Total (n = 156)

Note: LMCA, Left Main Coronary Artery; LAD, Left Anterior Descending Artery; LCX, Left Circumflex Artery; RCA, Right Coronary Artery; N, Number; %, Percentage.

When these lesions were categorized according to the ACC/AHA lesion classification system, 319 (25.8%) were Type A lesions, 655 (53.0%) were Type B lesions, and 261 (21.1%) were type C lesions. The lesion characteristics are described in Table 3. Notably, calcified lesions were distinctly infrequent, constituting 3.7% of all lesions; while eccentric, and thrombus containing lesions were common, accounting for 52.6%, and 15.8% of all lesions respectively. Bifurcation lesions and CTOs accounted for 21% and 5.7% of all lesions respectively.

Coronary interventions

Out of patients undergoing PCI 746 (64%) were elective, 373 (32%) were pharmaco-invasive, 47 (4%) was primary. Femoral access was obtained in majority (76%) while radial route utilized in 24% of patients. A total of 1355 stents were deployed, all were drug eluting stents (DES). Plain old balloon angioplasty (POBA) without stenting was performed on 30 lesions, all of which were distally located with small reference vessel diameter (<2.25mm). LAD was the most common vessel stented with 331 stents used. Post dilatation with non-compliant balloons was performed in 1300 out of 1355 stents (96%).

The most common antiplatelet regimen used was the combination of aspirin and clopidogrel in 64% patients. Prasugrel and Ticagrelor were used in 28% and 8% patients respectively. High dose statins (atorvastatin 40/80mg or rosuvastatin 40mg) were routinely given to all the patients before and after the procedure. Glycoprotein IIb/IIIa inhibitors were used in 36% of patients, mostly used as a bolus for slow flow/no flow

and in those with high thrombus burden. Thrombus aspiration devices were used in 8.0% patients.

Procedural outcomes

The overall procedural success rate was 95.4%. Major reason for failed procedure was failure to cross the lesionwith guidewire. Procedure related complications occurred in 187 (16.0%) patients (Table 5). Most common among these were slow flow/no reflow (9.1%) which was managed during the procedure by intracoronary administration of nitroglycerine, nicorandil and eptifibatide and vascular complications (2.7%) like haematoma formation and development of pseudoaneurysm.

Table 5: Procedural outcomes and complications.

Complications	Total patients: 1166	16% (187)
Stroke	2	0.2
Slow flow/No Reflow	106	9.1
Flow limiting dissection	1	0.1
Major side branch loss	4	0.3
Coronary Perforation	4	0.3
Vascular complications	32	2.7
Major bleeding	5	0.4
Arrhythmias	2	0.2
Contrast induced hypersensitivity	31	2.7

DISCUSSION

The present study provides an insight into the profile of patients undergoing PCI at our institute, and analyses the procedural indications, technical intricacies and clinical outcomes in these patients.

Epidemiological studies have shown that prevalence of CAD is increasing rapidly with increase of conventional risk factors. Indians have one of the highest rates of heart disease in the world. The disease also tends to be more aggressive and manifests at younger age. In our study, the mean age of patients were 56±10.4 years which is comparable to other studies done in India that is, CREATE registry (56±13 years) and Jose and Gupta study (57±12 years) but lower than the western populations as in COURAGE trial (62±5 years).[16-18] Male sex is more prone to CAD when compared to their pre-menopausal females. This finding was also observed in INTERHEART study in South Asian men with AMI.[19]

There is no clear cut definition of young MI; various authors have defined different age limits for young CAD. Coronary Artery Surgery Study (CASS Registry) defined young men as below 35 years and young women as below 45 years of age.[20] In our study, we defined young males as below age of 40 years which accounted for about 7% of patients undergoing PTCA.

There is strong correlation between cigarette smoking and CAD and smoking was found more commonly in young adults than older individuals (72% vs 44%). Smoking increases platelet aggregation, fibrinogen levels, coronary vasospasm and decreases fibrinolytic activity and coronary flow reserve. Cessation of smoking at any point of time is beneficial. Autopsy studies have revealed that coronary arteries of smokers have more extensive fatty streak lesions and develop at an early age than the non-smokers.

Indians now constitute the largest population of diabetics in the world. The number of people with diabetes in India is projected to cross 57 million by 2025.[21] In our study, diabetes was present in 21.3% of males and 35% of females and these patients had increased prevalence of DVD and TVD.

Hypertension is another important risk factor for CAD. In our study 56% of patients were hypertensive which was higher than the prevalence of hypertension in South Asian cohort of INTERHEART Study (31.1%).[19]

Dyslipidemia was more frequent in older males than young patients; Chen et al observed that hypertriglyceridemia and low HDL levels were common in younger patients.[22]

MI without previous episodes of angina pectoris was more common in younger patients with CAD. Studies on histopathology have shown that atheromatous plaques seen in young patients are lipid rich with relative lack of acellular scar tissues. These plaques are more unstable and likely to rupture. The most common presentation among young patients is STEMI in comparison to UA or NSTEMI.

In current study, younger patients were found to have higher incidence of non obstructive lesions, SVD, DVD, while incidence of TVD was more in older patients. Mohammed et al also observed that SVD was more common in young patients and TVD was more common in older patients.[23] Young patients in most studies presented with less number of vessels involved than older patients.

Procedural mortality and peri-procedural MI was nil in our study as compared to 1% and 1.9% in Srinagar registry.[24] In our study, procedures were relatively safe and minor complications which occurred were managed conservatively. As around 84% of our study population was admitted with diagnosis of ACS, having slow flow/ no reflow as most common complication can well be explained by thrombotic milieu. Procedural outcome was good with patients doing well on dual antiplatelet therapy with regular follow up in OPD.

Based on the observation from present study, screening of risk factors for CAD could start at an earlier age in Indian male, cessation of smoking, promotion of physical

activities and limitation of saturated fat and salt intake should be strongly encouraged. Adequate control of blood pressure and normal glycemic status is imperative. Since atypical presentations are common, high index of suspicion is necessary for early diagnosis.

The present study had some important limitations. First, this was a single center study with a relatively small sample size and thus may be with referral bias. Second, we only included patients undergoing PCI in this study with many patients, who could not undergo coronary angiography or PCI for a variety of reasons, being excluded. Thus, some of our findings may not be accurately reflective of the spectrum of CAD in the population at large.

Thirdly, because of the limited sample size the procedural outcomes were reported in general and distinction of results between simple vs complex or emergent vs selective procedures was not made. Lastly, no data on follow up, in whom it was performed, were collected in this study.

Hence, further short term and long term follow up data needs to be collected in this patient cohort to provide further insight into their clinical outcomes.

CONCLUSION

This is first study from region of western Rajasthan which provides such detailed overview of not only epidemiological characteristics but also an insight of procedural outcomes, safety and complications. With exponential increase in number of patients developing coronary artery disease, it is imperative that this study would enable us to upgrade our information system and work towards improving quality of care by providing feedback on wide range of performance indices and recognizing lacunae.

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