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Original Research Article

Clinical outcomes after percutaneous coronary intervention in patients with coronary artery disease: six months results from a single centre study

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ABSTRACT

Background: The study aimed to evaluate clinical outcomes in patients with coronary artery diseases (CAD) who underwent percutaneous coronary intervention (PCI), to identify the factors associated with clinical outcomes and survival among such patients, to explore the procedure related complications, and to assess restenosis and stent thrombosis rates following PCI.
Methods: This retrospective, single-center, observational study was conducted at a tertiary-care center in India, which included patients with CAD undergoing PCI from January 2016 to December 2016. Angiographic and clinical success and complications related to both procedural and vascular access were noted. Patient were followed-up for clinical outcomes up to 6-months. Primary outcome of the study was all-cause mortality. Secondary outcome measures were cardiovascular mortality, and event free survival, angina, cardiovascular events and restenosis and stent thrombosis.
Results: A total of 831 patients were included of which majority were males (83.5%). Smoking was found in 33.7%, diabetes in 35.6%, and hypertension in 37.7%. At 6-months, follow-up was obtained for 711 patients. The clinical composite endpoint seen in 9.8% of patients. Angina (13.2%), acute coronary syndrome (3.1%), stent thrombosis (1.0%), in-stent restenosis (3.9%), cardiovascular and all-cause mortality (2.7%), heart failure (7.3%) and stroke (1.7%) were reported at 6-months follow-up.
Conclusions: The PCI in a tertiary-care centre leads to low rates of periprocedural events and low rates of clinical outcomes at 6-months follow-up. Moreover, left ventricular ejection fraction was shown to be major predictor for cardiovascular mortality in post-PCI patients. Hypertension was significantly associated with stroke post-PCI.

Keywords: Drug eluting stents, Ejection fraction, Hypertension, Outcomes, Percutaneous coronary intervention

INTRODUCTION

The cardiovascular diseases (CVD) have a widespread effect on mortality and morbidity all over the world. Majority (>75%) of the deaths occur in developing countries. Though the developed countries are experiencing a downfall of deaths due to CVD, the escalating trends are seen in developing countries.[1] These increasing trends are majorly due to industrialization, urbanization, and lifestyle changes. The Global Burden of Diseases, Injuries and Risk factors (GBD) study had stated that the deaths and disability from coronary artery disease (CAD) in India have been amplified to more than double in the last 30 years.[2]

However, on the other side, there has been tremendous innovation in treatment of CAD which shifted from coronary artery bypass grafting to percutaneous coronary intervention (PCI) with balloon to bare metal stents to drug eluting stents (DES). As every boon comes with a bane, the earlier generation DES were associated with late stent thrombosis. Therefore, to overcome the disadvantages of earlier generations, various recent advances have been introduced in terms of strut thickness, polymer type and coating, drugs, etc.[3-5] Yet not only stent characteristics, but other patient related factors also effect the morbidity and mortality outcomes after PCI. The application of more than one diagnostic modalities like echocardiography, electrocardiography, optical coherence tomography, fractional flow reserve (FFR), intravascular ultrasound (IVUS), etc. help to improve the outcomes after PCI for CAD.[6] Moreover, rotablation atherectomy and thrombosuction are additional procedures that can be applied for better outcomes.

The aim of this study was to evaluate the clinical outcomes in patients with CAD who underwent PCI, to identify the factors associated with the clinical outcomes and survival among such patients, to explore the procedure related complications, and to assess the restenosis and stent thrombosis rates following PCI.

METHODS

This retrospective, single-center, observational study was conducted at a tertiary care center of India, which included patients with coronary artery disease undergoing PCI from January 2016 to December 2016. All patients included in the study were followed up for 6 months after index PCI. All patients of age >18 years who underwent PCI during the study period were included in the study. Only those patients who already underwent a previous PCI at another center were excluded.

For all patients who were enrolled in the study, the socio-demographic status such as age, gender, etc. were explored. Clinical data were obtained regarding risk factors, indications, location, number and nature of lesions; route and complications of PCI. On follow-up, the data relating to pain free period following PCI, and rates of clinically significant re-stenosis, stent thrombosis and other events were collected. The primary outcome of the study was all-cause mortality. The secondary outcome measures were cardiovascular mortality, and event free survival, angina, cardiovascular events and restenosis and stent thrombosis.

The PCI was compared within a subgroup of patients such as left ventricular function; with and without diabetes. Outcome comparisons were also made in additional subgroups defined by age, gender, hypertension, smoking history, and route. The PCI was performed using stents or only balloon dilatation as per the standard protocol. The PCI was done through the both radial and femoral routes, and the PCI data analyzed in the form of number of coronary arteries stented, number of stents placed, utilization of pre and post dilatation and of other techniques like FFR, IVUS, OCT, ROTA and thrombosuction. Complications related to both procedural and vascular access were noted. Angiographic and clinical success was also noted for each patient. After procedure was completed, patient was discharged and followed up for clinical outcomes up to 6 months.

Procedural success was defined as angiographic residual coronary stenosis of <10% in stented or <50% in balloon angioplasty lesions, with TIMI 3 flow; without side branch loss, flow-limiting dissection or thrombus; and without in-hospital complications (e.g. death, MI, stroke, or emergency CABG). Clinical success was defined as a procedural success with relief of signs and symptoms of myocardial ischemia. Procedural complications included death, procedure related MI, emergency CABG, periprocedural stroke, vascular complications (local hematoma, retroperitoneal hemorrhage, pseudoaneurysm, arteriovenous fistula, arterial dissection and 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. All these complications were defined according to the contemporary guidelines.

Statistical analysis

The distribution of data on all categorical variables related to socio-demographic and clinical were expressed as frequencies and percentages and compared by using chi-square test or fisher's exact test. The difference in continuous variables between the clinical outcomes' groups were compared by using independent Student's t-test or Mann Whitney U test. Simple and multiple logistic regression analysis were used to identify the socio-demographic and clinical factors associated with the clinical outcomes. All statistical analysis was carried out at 5% level of significance and p value <0.05 was considered as significant.

RESULTS

A total of 831 patients were included in the study and 711 patients were followed up at 6 months. About one third of patients were between 51-60 years (35.5%), followed by 41-50(27.6%), 61-70(23.8%), 31-40(7.2%), >70(4.5) and <30(1.3%). Majority of the patients were males (83.5%). Smoking was found in 33.7%, diabetes in 35.6%, and hypertension in 37.7%. Majority of the patients presented with STEMI in 57.2%, followed by chronic stable angina (CSA) in 25.9%. STEMI was more common in younger ages and CSA was more common in elderly. Majority of the patients with STEMI presented with AWMI (62.5%). Majority of the patients showed no RWMA (42.3%). Almost equal percentage of patients were having LVEF between 40-50% (47.4%) and >50% (46.2%). Only 6.4%

patient had LVEF <40%. Table 1 outlines the baseline demographics of the patients.

Table 1: Baseline demographics of the patients.

Characteristics	N = 831
Age (Mean±SD, years)	54.8±11.9
Male, n (%)	694(83.5)
Risk factors	
Smoking	280(33.7)
Diabetes mellitus	296(35.6)
Hypertension	313(37.7)
Dyslipidaemia	57(6.9)
Obesity	55(6.6)
Chronic kidney disease	2(0.2)
Clinical presentation	
ST elevation myocardial infarction	475(57.2)
AWMI	297(62.5)
IWMI	168(35.4)
PWMI	2(0.4)
ASMI	5(1.1)
LWMI	3(0.6)
Unstable angina/ non-ST elevation myocardial infarction	136(16.4)
Chronic stable angina	215(25.9)
Congestive cardiac failure	4(0.4)
Regional wall motion abnormality distribution	
Global hypokinesia	22(2.6)
LAD territory	317(38.1)
LCX territory	18(2.2)
RCA territory	122(14.7)
No RWMA	352(42.3)
Left ventricular ejection fraction	
<40 %	53(6.4)
40-50 %	394(47.4)
>50 %	384(46.2)

The LAD was predominantly involved vessel (80.5%) followed by RCA (51.9%) (Table 2). Nearly 83.4% of lesions are obstructive with >70% stenosis (83.4%). Radial access (61.2%) was the most commonly used route for PCI than femoral access. Single stent was used in 62.8% of patients, two stents in 33.5% patients, three stents in 3.2%, four stents in 0.3% and five stents in 0.1% patients. Totally 1047 stents were used in our study. The average number of stents per patient was 1.42±0.59.

Majority of the stents used in our study were of 3.0 mm diameter (47.1%) followed by 2.75 mm (23.8%), 3.5 mm (22.1%), 2.5 mm (4.5%), 4 mm (2.2%), 3.75 mm (0.2%) and 4.5 mm (0.1%). Majority of the stents used in our study were Taxus liberate stent (860) followed by Promus (76), Pronova (49), Synergy (22), Biomatrix (14), Resolute (12), Xience (9), and other stents used were Biomime, Prokinetic, Nostrum, Kaname and Amphilimus of one stent each. No periprocedural complications were seen in 88% patients (Table 3).

Table 2: Lesion and procedural characteristics.

Variables	N = 831 patients/ N= 1459 lesions
Coronary vessels involved	
Left main coronary artery	51(6.1)
Left anterior descending artery	669(80.5)
Left circumflex artery	314(37.7)
Right coronary artery	432(51.9)
Ramus	14(1.7)
No. of vessels involved	
Single vessel disease	406(48.8)
Double vessel disease	268(32.2)
Triple vessel disease	157(18.9)
Lesion distribution	
Obstructive (>70%)	1217(83.4)
Intermediate (50-70%)	108(7.4)
Non-obstructive (<50%)	79(5.4)
Instant restenosis	46(3.1)
Stent thrombosis	6(0.4)
Access route	
Femoral	322(38.8)
Radial	509(61.2)
Type of PCI opted	
Primary PCI	45(5.4)
Adhoc or rescue PCI	25(3.0)
Elective PCI	761(91.6)
No. of patients stented	735(88.4)
Total no. of stents	1047
Average no. of stent per patient	1.42±0.59
No. of lesions pre-dilated	961(91.7)
No. of lesions post-dilated	943(90.1)
Use of additional procedures	
FFR	32(3.8)
OCT	6(0.7)
IVUS	44(5.3)
Rotablation	34(4.1)
Thrombosuction	52(6.2)

Table 3: Periprocedural complications.

Complications	Total no. of patients(n=831)
Acute vessel closure	2(0.2)
No reflow	8(1.0)
Dissection	48(5.8)
Embolization	1(0.1)
Side branch occlusion	2(0.2)
Tamponade	1(0.1)
Arrhythmias	21(2.5)
Cardiac arrest	2(0.2)
Hypotension	9(1.1)
Stroke	3(0.4)

Coronary artery dissection including hematoma and perforation was seen in 5.8% patients. Other complications like acute vessel closure, embolization,

side branch occlusion, cardiac tamponade, stroke and cardiac arrest were seen in <0.5% patients. Hematoma was the most common local vascular complication seen in femoral route access (5.9%) than in radial access (0.4%). The other complications seen were contrast induced AKI and local bleeding (Table 4).

Table 4: Local vascular complications and contrast induced AKI.

Local vascular complications	Femoral PCI N = 322 (%)	Radial PCI N= 508 (%)
Hematoma	19(5.9)	2(0.4)
Bleeding	2(0.6)	0(0)
Aneurysm	0(0)	0(0)
Av fistula	0(0)	0(0)
Arterial occlusion	0(0)	0(0)
Contrast induced AKI	3(0.9)	3(0.6)
No complications	298(92.5)	503(99)

At 6 months, follow-up was obtained for 711 patients. Angina was seen in 13.2%, acute coronary syndrome seen in 3.1%, stent thrombosis in 1.0%, instant restenosis in 3.9%, cardiovascular and all-cause mortality seen in 2.7%, heart failure in 7.3% and stroke in 1.7% patients. The clinical composite endpoint seen in 9.8% patients (Table 5). The ISR was seen maximally in Taxus stent (18), followed by Promus (3), Pronova (2) and Xience (1). The ST was maximally seen in Taxus stent (4) and Pronova stent (1). The (Table 6) demonstrates clinical outcomes distributed as per gender, presence of diabetes, hypertension, smoking, clinical presentation, LVEF, access route.

Table 5: Immediate and 6 months clinical outcomes after PCI.

Immediate outcomes	Total no. of patients (n=831)
Angiographic success	752 (90.4)
Clinical success	758 (91.2)
MI	0 (0)
Mortality	0 (0)
Stent thrombosis	1 (0.1)
6 months follow-up	Total no. of patients (n=711)
Angina	94 (13.2)
ACS	22 (3.1)
Stent thrombosis (ST)	7 (1.0)
In-stent restenosis (ISR)	28 (3.9)
CV mortality	19 (2.7)
All-cause mortality	19 (2.7)
Heart failure	52 (7.3)
Stroke	12 (1.7)
Clinical composite end point (CCEP)	70 (9.8)

Table 6: Distribution of clinical outcomes according to various categorisations.

Clinical outcomes	Angina	ACS	ST	ISR	CV mortality	Stroke	CCEP
Males (n=597)	73(12.2)	20(3.5)	7(1.3)	26(4.3)	17(2.8)	9(1.5)	63(10.5)
Females (n=114)	21(18.4)	2(1.7)	0(0)	2(1.7)	2(1.7)	3(2.6)	7(6.1)
With dm (n=260)	37(14.2)	8(3.1)	2(0.8)	12(4.6)	3(1.1)	5(1.9)	23(8.8)
Without dm (n = 451)	57(12.6)	14(3.1)	5(1.1)	16(3.5)	9(2)	14(3.1)	47(10.4)
HTN (n=275)	42(15.2)	9(3.3)	2(0.7)	13(4.7)	8(2.9)	1(0.4) *	25(9.1)
No HTN (n=436)	52(11.9)	13(3)	5(1.1)	15(3.4)	11(2.5)	11(2.5) *	45(10.3)
Smokers (n=256)	32(12.5)	9(3.5)	3(1.2)	12(4.6)	5(1.9)	5(1.9)	29(11.3)
Non-smokers (n=455)	62(13.6)	13(2.8)	4(0.9)	16(3.5)	14(3.1)	7(1.5)	41(9)
MI (n=407)	53(13)	11(2.7)	4(1)	14(3.4)	14(3.4)	8(1.9)	41(10)
UA/NSTEMI (n=115)	17(14.7)	4(3.4)	1(0.9)	3(2.6)	3(2.6)	0(0)	10(8.7)
CSA (n=136)	19(13.9)	7(5.1)	2(1.5)	8(5.8)	2(1.5)	2(1.5)	15(11)
MI+CSA (n=53)	6(11.3)	0(0)	0(0)	3(5.6)	0(0)	1(1.8)	4(7.5)
LVEF ≤35% (n=41)	4(9.7)	0(0)	0(0)	0(0)	5(12.1) *	1(2.4)	6(14.6)
LVEF 36-50% (n=334)	40(11.9)	9(2.7)	3(0.9)	14(4.2)	11(3.3) *	5(1.5)	33(9.8)
LVEF ≥50% (n=336)	50(14.9)	13(3.9)	4(1.2)	14(4.1)	3(0.9) *	6(1.8)	31(9.2)
Radial (n=435)	52(11.9)	14(3.2)	5(1.1)	11(2.5) *	10(2.3)	8(1.8)	37(8.5)
Femoral (n=276)	42(15.2)	8(2.9)	2(0.7)	17(6.1) *	9(3.2)	4(1.4)	33(11.9)

DISCUSSION

The present study was performed with the main objective of assessing the clinical outcomes at 6 months in patients undergoing PCI in the year 2016. Totally 831 patients were included in the study and planned for follow-up up to 6 months, but finally 711 patients were able to be followed up at 6 months. Total 694 patients (83.5%) were

males and 137(16.4%) were females. Subban V et al, in a study from Chennai, South India also showed majority of the patients undergoing PCI were males (86.7%) which was similar to our study.[7] Smoking was found in 33.7%, diabetes in 35.6%, hypertension in 37.7% in present study. But another study from Chennai showed 25.1 % were smokers, hypertension seen in 40.9% and diabetes in 50% patients.[7]

Angiographic evaluation showed stenosis of LM in 51 patients (6.1%), LAD in 669 patients (80.5%), LCX in 314 patients (37.7%), LCX in 432 patients (51.9%) and ramus in only 14 patients (1.7%). Study by Subban V, et al, also showed that LAD was the most commonly involved vessel (56.2%) followed by RCA in 30.1 % patients.[7] In our study, majority of the PCI were done on elective basis (91.6%), and only 5.4% were primary PCI. The rate of primary PCI was far less in our study because majority of the PCI in our institute were done under state insurance scheme, and also due to cost and other logistic issues.

Of total, 735 patients underwent stenting constituting 88.4% and POBA was done in remaining patients. All patients underwent stenting with DES. Totally 1047 DES were placed in one year. Average number of stents placed per patient was 1.42±0.59. Angiographic success was seen in 90.4 % patients and clinical success was seen in 91.2 % patients. Nearly 88% of patients were free of periprocedural complications. Whereas in Srinagar registry, the procedural success was seen in 93.6%.[8] Procedure related complications occurred in 9.9% patients. Local vascular complications seen in 1.3%.

At 6 months follow-up, occurrence of angina was 13.2%, ACS was 3.1%, ST was 1.0%, in-stent restenosis was 3.9%, cardiovascular mortality was 2.7%, HF symptoms were seen in 7.3% patients, and stroke in 12 patients (1.7%). The overall composite clinical end point at 6 months was 9.8%. The resolute International Registry (ZES) reported 12 months outcomes of cardiac death in 1.4%, MI in 3.1%, MACE in 8.2% and ST in 3.1%.[9] The clinical outcomes of cardiac death, MI, MACE and ST in SPIRIT 4, SPIRIT 5 and compare trials (EES) were 0.4%, 1.9%, 4.2%, 0.3%; 1.1%, 3.5%, 5.1%, 0.66% and 1%, 3%, 6% and 0.7% respectively.[10-12] Randomized trials demonstrated clinically relevant restenosis of <5% at 12 months.[13] In recently published TALENT Trial, which was an RCT between Xience EES and Supraflex SES, the rates of ST at 12 months were 1.1% for Xience and 0.9% for Supraflex.[14] The rates of MI, ST and cardiac death in the present study were comparable to other studies and trials.

On analysis, this study showed statistically significant association of hypertension with stroke (p=0.02) after PCI, but all other clinical outcomes and composite endpoint showed no differences between patients with and without hypertension. Literature states that impaired LV function report higher mortality and worse MACE outcomes following PCI particularly in elective setting.[15] Sardi et al, reported stent thrombosis rates of 1.4% and 6.0% in patients with good LV function and severe LV dysfunction (EF <25%) respectively.[16] LVEF is a strong predictor for post PCI mortality and MACE prediction. Mamas A et al, in a study reported post PCI mortality rates were minimum with good LV function and maximum with poor LV function. Similar to the above-mentioned studies, the mortality rates in our study were highest in patients with poor LV function (LVEF <35%, P=0.0001).[17] But in contrary, the difference in ST, ISR rates and MI was statistically insignificant (p=0.6, 0.41, 0.41 respectively).

In RIFLE-STEACS study, the primary endpoint of 30-day NACEs was observed in 13.6% and 21.0% in the radial and femoral arm (p=0.003).[18] Radial route PCI also reported significantly lower rates of cardiac mortality (5.2% vs. 9.2%, p=0.020), bleeding (7.8% vs. 12.2%, p=0.026), and shorter hospital stay. This study showed statistically insignificant difference in rates of death (p=0.45), MI (p=0.86), stroke (p=0.68), and ST (p=0.83) between radial and femoral route PCI. In-stent restenosis rates were significantly higher in femoral route PCI (p=0.02) than radial PCI and this may attribute to the large number of complex PCI done through femoral route.

Limitations of the study were this is a retrospective observational study, without randomization, subgroup comparison for clinical outcomes post PCI. Secondly, longer follow up (>1 year) is required to represent the true rates of stent thrombosis and in-stent restenosis.

CONCLUSION

In light of the results, it can be concluded that PCI with DES in a tertiary care center leads to low rates of periprocedural events and low rates of clinical outcomes at 6 months follow-up. Moreover, LVEF was shown to be major predictor for cardiovascular mortality in post PCI patients. Hypertension was significantly associated with stroke post PCI and higher number of in-stent restenosis were seen following femoral PCI.

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