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PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH SEVERE LEFT VENTRICULAR DYSFUNCTION

Cardiology

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ABSTRACT

Aim: To study clinical and epidemiological parameters of patients undergoing percutaneous coronary intervention (PCI) with severe left ventricular dysfunction (LVD) and to follow them up for understanding outcomes of procedure.

Materials & methods: This is retrospective data analysis of 157 patients who underwent PCI from January 2016 to November 2017 at the department of cardiology in our institute and were followed up at July 2018. Patients who were in cardiogenic shock or required vasopressors or support ventilation before or at the time of PCI were excluded from the study. Epidemiological variables considered were age, gender, diabetes, hypertension, smoking, alcohol intake & tobacco chewing. Clinical parameters taken into account were Left ventricular ejection fraction (LVEF), ST elevation myocardial infarction (STEMI) or non ST elevation myocardial infarction (NSTE-ACS) or chronic stable angina (CSA), thrombolysed or not. Angiographic data considered were chronic total occlusion (CTO), single vessel disease (SVD) or double vessel disease (DVD) or triple vessel disease (TVD) and stent dimensions. Follow-up was done to report incidence of local site complications, stent thrombosis, in-stent restenosis, NYHA class and death.

Results: Out of 157 patients, 113 (71.97%) were male & 45 (28.66%) were female, with both median age and mean age being 56. 51 (32.48%) were diabetic, 52 (33.12%) were hypertensive, 22 (14.01%) patients were tobacco chewer, 42 (26.75%) were smokers & 30 (19.10%) were alcoholic. 151 (96.17%) patients had STEMI, 6 (3.82%) had NSTE-ACS, 1 had CSA. 60 patients were thrombolysed (38.21%) before being referred to our centre. AWMI was diagnosed in 145 (92.35%) patients & IWMI in 11 (7%) patients. 14 (8.91%) patients were CTO, out which only one attempt of PCI failed. 113 (71.97%) were SVD, 40 (25.47%) were DVD & 5 (3.18%) were TVD. 146 (92.99%) patients had LAD involvement and among DVD patients, LAD & RCA were most commonly involved in 22 (55%) patients. LAD PCI was done with average stent diameter of 2.96 mm & length of 26.8 mm, LCX PCI was done with average stent diameter of 2.25 mm & length of 30 mm and RCA PCI was done with average stent diameter of 3.32 mm & length of 27 mm. On follow-up of mean 604.42 days (minimum 268 days, maximum 909 days), no episodes of subacute stent thrombosis or ISR occurred and no mortality was reported. Majority of patients belonged to class III NYHA pre PCI 92 (58.59%), while post PCI majority of patients were in NYHA class II 82 (52.29%).

Summary: As per our knowledge this is the first study to report data of PCI in severe LVD from Indian subcontinent. The study shows affection of young male population predominately. SVD is the most common angiographic diagnosis with LAD predominately affected vessel. This real world-data on clopidogrel with aspirin as dual anti-platelet therapy and second generation stent in patients with severe LVD shows no episode of stent thrombosis or ISR and significant improvement in NYHA class.

Condensed Abstract:

1. The data of PCI in severe LVD from Asian subcontinent is lacking. No study could be searched at the time of writing manuscript in either PubMed or Google Scholar on this topic from Indian origin except for the data for CABG in severe LVD. Hence, it is the need of hour to collect data regarding outcomes of PCI with severe LVD. This study, though observational becomes pioneer for this context.
2. This registry being real-world scenario has shown very promising outcomes of PCI despite use of second-generation stents and clopidogrel as a second antiplatelet in combination to aspirin.
3. As per our knowledge this is the first study to report data of PCI in severe LVD from Indian subcontinent.

Limitation: Due to non-invasive follow-up, exact amount of stent restenosis can not be calculated.

Impact on daily practice: This real world-data on clopidogrel with aspirin as dual anti-platelet therapy and second generation stent shows negligible event of stent thrombosis & ISR even in patients with severe LV dysfunction. This can help reduce cost burden on society and help better distribution of health budget.

KEYWORDS

Severe left ventricular dysfunction; revascularization; PCI; India

INTRODUCTION:

Percutaneous coronary intervention has been in practice since almost 40 years but till today in 2018 no randomized controlled trial has been undertaken to compare PCI versus coronary artery bypass grafting in patients with severe LVD. To the best of our knowledge and search on PubMed and Google scholar at the time of writing manuscript there is no data of PCI in severe LVD patients from Indian subcontinent. This study, hence becomes the first observational study of PCI in patients with severe LVD from India. Balloon angioplasty evolved into angioplasty with stenting and from bare metal stents (BMS) to drug eluting stents (DES). DES is constantly undergoing changes from the type of drug being used to the amount of metal, thickness of struts, platform design, etc. Stent classification system developed by Dr. Sundeep Mishra helps in understanding the importance of newer stent

with newer drugs. (1) Also at the same time when stents are undergoing evolution, newer antiplatelet drugs with improved efficacy & potency are being launched. American college of cardiology has put newer antiplatelets ticagrelor and prasugrel as first line antiplatelet for patients undergoing PCI. (2) But the real-world data is quite different from trials data which are done in controlled environment. Hence, came the concept of registry to maintain real world data which is usually free from pharmaceutical industry bias. Reviewing the registry helps us understand real world scenario and analysing it makes one more competent in dealing with patients in one's locality.

OBJECTIVES:

- To understand the age-wise & gender-wise distribution of patients.
- To know the percentage prevalence of risk factors viz. diabetes mellitus, hypertension, smoking, tobacco chewing and alcohol intake among patients requiring PCI.
- To know the prevalence of ST elevation myocardial infarction (STEMI), non-ST elevation acute coronary syndrome (NSTE-ACS) & chronic stable angina (CSA) among patients who underwent PCI in real-world scenario.
- To learn about the incidence of involvement of type of coronary artery and dimensions of coronary stents required for PCI.
- To follow-up the cohort to calculate incidence of stent thrombosis, in-stent restenosis, other complications or deaths.

METHODS:

This is retrospective data analysis of 157 patients who underwent PCI from January 2016 to November 2017 at the department of cardiology in our institute under Mahatma Jyotiba Phule Jan Arogya Yojana (MJPJAY). This cohort was followed up at July 2018 with mean duration of 604.42 days.

Exclusion criteria:

Patients who were in cardiogenic shock or required vasopressors or support ventilation before or at the time of PCI were excluded from the study.

Age-wise distribution is done as follows: a) teenage – defined as age between 13 years to 19 years; b) very young (3) – defined as age from 20 years to 35 years; c) young (4) – defined as age from 36 years to 55 years; d) peri-retirement – defined as age from 56 years to 64 years; and e) elderly (5,6) – defined as age more than or equal to 65 years.

Risk factors considered in the study were diabetes mellitus, hypertension, smoking, tobacco chewing or alcohol intake. Diabetes mellitus was defined in the study as per WHO guidelines, 2006. (7) Hypertension was defined in the study as those patients who required pharmacologic therapy for hypertension as per Eighth Joint National Committee (JNC 8) guidelines. (8) The individuals were classified as "chewing tobacco" if the patient or his/her relatives answered "yes" to the question on chewing tobacco. Similarly, individuals were categorised as "smokers" if patient or his/her relatives answered "yes" to the question on "smoking tobacco". (9) In the same way, alcohol intake was based on response either "yes" or "no" of question to patients or their relatives when asked about alcohol drinking habit. (10) Acute coronary syndrome either STEMI (11) or NSTE-ACS (12) and chronic stable angina (13) were defined in accordance with American College of Cardiology guidelines (ACC). Thrombolysis whether done in our institute or patient was thrombolysed at other centre and referred for further management was defined thrombolysed irrespective of thrombolytic agent used. Primary angioplasty in myocardial infarction (PAMI) was defined as when patient presented within 6 hours of onset of symptoms of ACS and was taken for PCI directly. STEMI was subclassified into anterior wall myocardial infarction (AWMI) or inferior wall myocardial infarction (IWMI) depending upon whether ST elevation is recorded in anterior chest lead or inferior leads respectively. Chronic total occlusion (CTO) of coronary artery was defined as atleast 3 months of total occlusion of coronary artery or infarct-related artery total occlusion when primary event was recorded 3 months earlier plus use of guide-wire for angioplasty with tip load of more than 4 gm. Single vessel disease (SVD) was involvement of only one coronary artery with significant lesion that requires intervention, while double vessel disease (DVD) was when two coronary arteries required intervention. Similarly, triple vessel disease (TVD) was defined when all the three left anterior descending (LAD), left circumflex (LCX) and right coronary artery (RCA) required stenting during PCI.

Stent details:

The two stents that belong to second generation DES used during this period for PCI at the department were as follows:
1) ProNOVA (Vascular concepts Ltd, India)
2) Endeavor (Medtronic, United States of America)

Antiplatelet details:

Loading dose of 300 mg of aspirin with 600 mg of clopidogrel was used in all patients analysed in the study and dual antiplatelet therapy with aspirin 75 mg and clopidogrel 75 mg once daily post PCI were prescribed.

Stent thrombosis was defined as per timings & definition of academic research consortium. (14) Restenosis was defined in this study as more than 50% diameter stenosis in patient who presents with either ACS or refractory symptoms despite optimal anti-anginal drugs. Local complications considered were pseudoaneurysm, hematoma, arterio-venous fistula. Deaths any reported during this period were classified into cardiac or non-cardiac based on verbal autopsy.

Data regarding all clinical and epidemiological variables was obtained from MJPJAY database of the hospital record. Follow-up of all patients that underwent PCI under MJPJAY scheme at our hospital excluding those mentioned in exclusion criteria was done in the month of July, 2018 at one point in time in cross-sectional manner and any event in the past from the date of PCI was recorded as per protocol. Individual characteristic was expressed using percentage of total event.

RESULTS:

Out of 157 patients, 113 (71.97%) were male & 45 (28.66%) were female. Patients' age were distributed from 20 years of age to 85 years of age as shown in table 1, with both median age and mean age being 56. 51 (32.48%) were diabetic & 52 (33.12%) were hypertensive. 22 (14.01%) patients were tobacco chewer, 42 (26.75%) were smokers & 30 (19.10%) were alcoholic. 151 (96.17%) patients had STEMI, 6 (3.82%) had NSTE-ACS, one had CSA. Out of 151 patients with STEMI, 60 patients were thrombolysed (38.21%) before being referred to our centre. Also, out of STEMI patients, AWMI was diagnosed in 145 (92.35%) patients & IWMI in 11 (7%) patients. Table 2 shows distribution of patients as per New York Heart Association (NYHA) symptom grade pre PCI and at follow-up. 14 (8.91%) patients were CTO, out which only attempt of PCI to RCA failed. As per this PCI registry, 113 (71.97%) were SVD, 40 (25.47%) were DVD & 5 (3.18%) were TVD. 146 (92.99%) patients had LAD involvement and among DVD patients, LAD & RCA were most commonly involved in 22 (55%) patients. LAD PCI was done with average stent diameter of 2.96 mm & length of 26.8 mm, LCX PCI was done with average stent diameter of 2.25 mm & length of 30 mm and RCA PCI was done with average stent diameter of 3.32 mm & length of 27 mm.

On follow-up of mean 604.42 days (minimum 268 days, maximum 909 days), there was no episode of subacute stent thrombosis or ISR or any death. Majority of patients belonged to class III NYHA pre PCI 92 (58.59%), while post PCI majority of patients were in NYHA class II 82 (52.29%).

DISCUSSION:

Ischemic heart disease is the most common cause of LVD and at times reversible. Left ventricular function is powerful prognostic marker in patients with ischemic heart disease. Poor left ventricular function is associated with significant morbidity and mortality. Resultant heart failure is the major health care cost issue. Revascularization in patients with severe left ventricular dysfunction has never had unequivocal consensus. Viability scans to look for reversibility of left ventricular function are also of questionable benefit in decision making. (15) Coronary artery bypass surgery (CABG) in patients with severe LVD has been observed to be associated with lower morbidity and mortality in retrospective data analysis of APPROACH study. (16) Gioia et al, showed comparable outcomes of PCI and CABG in patients with severe LVD in terms of MACE and mortality rates. (17) Further advancement in stent designs have also shown improvement in outcomes of PCI with severe LVD. (18,19) However randomized controlled trials comparing CABG and PCI in patients with severe LVD head to head are lacking. A metanalysis of 19 clinical studies have shown comparable outcomes of PCI versus CABG in severe LVD in terms of in-hospital and long-term mortality. (20) The data of PCI in severe LVD from Asian subcontinent is lacking. No study could be searched at the time of writing manuscript in either PubMed or Google Scholar on this topic from Indian origin except for the data for CABG in severe LVD. (21,22) Hence, it is the need of hour to collect data regarding outcomes of PCI with severe LVD. This study, though observational becomes pioneer for this context.

CONCLUSION:

The study shows PCI is very legible option of revascularization in patients with severe LVD. LAD is the most common culprit and majority of times to be the only vessel which needs to be addressed during PCI in such cases of severe LVD. Almost 3 years of follow-up with no mortality, stent thrombosis or in-stent restenosis proves the stand of PCI in severe LVD. Also, this registry being real-world scenario has shown very promising outcomes of PCI despite use of second-generation stents and clopidogrel as a second antiplatelet in combination to aspirin. Hence, the hope of almost replacing CABG with newer generation stents and improved technology as well as pharmacotherapy with PCI in severe left ventricular dysfunction awaits strong data from real world.

Conflict of Interest: Nil

Abbreviations:

1. ACC - American College of Cardiology
2. ACS - acute coronary syndrome
3. AWMI - anterior wall myocardial infarction
4. BMS - bare metal stents
5. CABG – coronary artery bypass grafting
6. CSA – chronic stable angina
7. CTO - Chronic total occlusion
8. DES – drug eluting stents
9. DVD - Double vessel disease
10. IWMI – inferior wall myocardial infarction
11. JNC 8 - Eighth Joint National Committee
12. MACE – major adverse cardiovascular event
13. LAD - left anterior descending artery
14. LCX – left circumflex artery
15. LVEF - left ventricular ejection fraction
16. MJPJAY - Mahatma Jyotiba Phule Jan Arogya Yojana
17. NSTE-ACS - non-ST elevation acute coronary syndrome
18. PAMI - Primary angioplasty in myocardial infarction
19. PCI - undergoing percutaneous coronary intervention
20. RCA – right coronary artery
21. STEMI - ST elevation myocardial infarction
22. SVD - Single vessel disease
23. TVD – Triple vessel disease

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