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RETROSPECTIVE STUDY OF CLINICAL & EPIDEMIOLOGICAL PARAMETERS OF PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION WITH THEIR FOLLOW-UP

Cardiology

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ABSTRACT

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

Materials & methods: This is retrospective data analysis of 862 patients who underwent PCI from January 2016 to November 2017

Results: Out of 862 patients, 611 (70.88%) were male & 251 (29.12%) were female, with mean age being 55. 243 (28.19%) were diabetic, 470 (54.52%) were hypertensive, 158 (18.32%) patients were tobacco chewer, 215 (24.92%) were smokers & 111 (12.87%) were alcoholic. 636 (73.78%) patients had STEMI, 153 (17.74%) had NSTE-ACS, 61 (7.07%) had CSA.578 (67.05%) were SVD, 262 (30.39%) were DVD & 19 (2.20%) were TVD. Out of SVD, 350 (60.55%) patients had LAD involvement and among DVD patients, LAD & RCA were most commonly involved in 107 (40.83%) patients. On follow-up of mean 604.42 days (minimum 236 days, maximum 909 days), 2 (0.23%) episodes of subacute stent thrombosis occurred & 11 (1.27%) patients had ISR but no mortality was reported.

Summary: The study shows affection of young population predominately and gender inequality suggesting primarily male disease. PCI is often sought in ACS and CSA is predominately treated medically. Thrombolysis still remains the first treatment received by STEMI patients. 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 shows negligible event of stent thrombosis & ISR.

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. This can help reduce cost burden on society and help better distribution of health budget.

KEYWORDS

INTRODUCTION:

Percutaneous coronary intervention (PCI) is the cornerstone in treatment of acute coronary syndrome (ACS). PCI is an evolving science and outcomes of which depend on characteristics of individual patient, operator experience, availability of newer & more sophisticated hardwares, improvement in our understanding of science of atherosclerosis, etc. Since the first balloon angioplasty done by Dr. Andreas Gruntzig in 1987, the art of PCI has changed a lot. 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 study the distribution of left ventricular ejection fraction (LVEF) among patients undergoing PCI.
- 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 862 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 604.4 ±161.4 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 therapy 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:

Table 1: Age-wise distribution

Age	Number	Percentage
Teenage (<20)	1	0.11
Very Young (20 to <=35)	30	3.48
Young (35 to <= 55)	405	46.98
Peri-retirement (56 to 64)	222	25.75
Elderly (>= 65)	204	23.66

Out of 862 patients, 611 (70.88%) were male & 251 (29.12%) were female. Patients' age were uniformly distributed from 18 years of age to 85 years of age as shown in table 1, with both median age and mean age being 55. 243 (28.19%) were diabetic & 470 (54.52%) were hypertensive. 158 (18.32%) patients were tobacco chewer, 215 (24.92%) were smokers & 111 (12.87%) were alcoholic. 636 (73.78%) patients had STEMI, 153 (17.74%) had NSTE-ACS, 61 (7.07%) had CSA. Out of 636 patients with STEMI, 302 patients were thrombolysed (47.48%) before being referred to our centre & only 3 patients received PAMI. Also, out of STEMI patients, AWMI was diagnosed in 384 (60.37%) patients & IWMI in 262 (41.19%) patients. Table 2 shows distribution of patients according to LVEF. 47 (5.45%) patients were

Table 2: Distribution according to LVEF

LVEF	Number	Percentage
=<30	158	18.32
30-45	239	27.72
46-60	233	27.03
>=60	232	26.91

CTO, out which 5 (10.63%) attempts failed. As per this PCI registry, 578 (67.05%) were SVD, 262 (30.39%) were DVD & 19 (2.20%) were TVD. Out of SVD, 350 (60.55%) patients had LAD involvement and among DVD patients, LAD & RCA were most commonly involved in 107 (40.83%) patients. 577 times LAD PCI was done with average stent diameter of 2.97 mm & length of 25.68 mm, 186 times LCX PCI was done with average stent diameter of 2.86 mm & length of 22.84 mm and 327 times RCA PCI was done with average stent diameter of 3.20 mm & length of 25.86 mm.

On follow-up of mean 604.42 days (minimum 236 days, maximum 909 days), 9 (1.04%) had local complication which included one event of pseudoaneurysm and one event of radial artery thrombosis both of which were treated conservatively. There were 2 (0.23%) episodes of subacute stent thrombosis & 11 (1.27%) patients had ISR.

DISCUSSION:

The PCI registry data described here comes from patients who underwent PCI under government health scheme for poor at academic/university government hospital. Epidemiology of ischemic heart disease in India is of concern. According to the present PCI registry almost of half of the population belonged to young age strata in contrast to United States National Cardiovascular Data Registry (US NCDR) database were mean age of PCI patients was 64.6 ±12.1 and Japanese PCI registry where mean age was 68.2 ±9.8 (15). Also, as per the report of National Interventional Cardiology (NIC) 2011 for data on Indian coronary heart disease, 13.6% patients were below 40 years of age. (16) Almost one quarter i.e. 23.66% patients undergoing PCI were elderly. This data shows significant increase in elderly population undergoing PCI for coronary artery disease but still young population is the majority affected. 70.88% of males are affected which is almost similar across the world statistics. More than half were hypertensive & more than one quarter were diabetic. Smoking, tobacco chewing and alcohol intake were involved as a risk factor in decreasing order. Three-fourth of patients undergoing PCI had STEMI which is way beyond described in US NCDR (14.44%), Japanese registry (23.01%) & NIC data (29.5%). Almost half of STEMI still undergo thrombolysis, and PAMI is occasional treatment received by the patient. Elective PCI for CSA is the least proportion of population (~ 7%) while 22.3% population had CSA in NIC PIC registry, 31.69% in US NCDR & 50.59% in Japanese registry. 5% CTO intervention is equitable to 2.2% CTO in NIC registry, 3.2% US NCDR & 6.4% in Japenese registry. Patients undergoing PCI had LVEF as normal, mild, moderate and severe left ventricular dysfuntion approximately one quarter in each level. LAD is the most common coronary artery that requires stenting and LAD with RCA is the most common double vessel disease encountered. Incidence of stent thrombosis and ISR is negligible to make out any inferences.

Summary:
The epidemiological study of PCI data is of huge concern as it shows affection of young population predominately and gender inequality suggesting primarily male disease. PCI is often sought in ACS and CSA is predominately treated medically. Thrombolysis still remains the first treatment received by STEMI patients and PAMI is occasional. Single vessel disease is the most common form of coronary artery involvement with left anterior descending artery being the most commonly involved vessel. No mortality reported in approximately 2 years of follow-up with negligible incidence of stent thrombosis or in-stent thrombosis shows the skill & knowledge of the operators of the centre and also presents real world data for the second generation stents and anti-platelet therapy used.

Conflict of Interest: Nil
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Abbreviations:
ACC - American College of Cardiology
ACS - acute coronary syndrome
AWMI - anterior wall myocardial infarction
BMS - bare metal stents
CSA – chronic stable angina
CTO - Chronic total occlusion
DES – drug eluting stents
DVD - Double vessel disease

IWMI – inferior wall myocardial infarction
JNC 8 - Eighth Joint National Committee
LAD - left anterior descending artery
LCX – left circumflex artery
LVEF - left ventricular ejection fraction
MJPJAY - Mahatma Jyotiba Phule Jan Arogya Yojana
NIC - National Interventional Cardiology
NSTE-ACS - non-ST elevation acute coronary syndrome
PAMI - Primary angioplasty in myocardial infarction
PCI - undergoing percutaneous coronary intervention
RCA – right coronary artery
STEMI - ST elevation myocardial infarction
SVD - Single vessel disease
TVD – Triple vessel disease
US NCDR - United States National Cardiovascular Data Registry

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