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Percutaneous coronary interventions in Assam, North East India: procedure indications and outcome

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Abstract :
Objective: *There is a paucity of data on the procedure indications and outcome of Percutaneous Coronary Interventions (PCI) performed in centres from North East India. Therefore, this study was conducted to determine the procedure indications and in hospital and 30 days outcome of PCI procedures performed in the cardiac catheterization laboratory of Gauhati Medical College Hospital during the early period of its inception.*
Methods: *We conducted an observational descriptive study on 151 symptomatic coronary artery disease patients, who underwent primary, rescue or elective PCI with stent deployment in Gauhati Medical College Hospital, from January 2010 to December 2011. The primary objective of the study was to identify the procedure indications, clinical profile, pattern of stent use and to document the in hospital and 30 days adverse outcomes. The patients were followed for one month and complications were noted.*
Results: *The mean age of sample was 54.9 ±10.6 years, 87.4% of them were male. The indications for PCI were stable angina (59.6%), unstable angina (4.6%), Post MI (21.19%), Primary PCI (11.92%) and Others (CHF) (2.6%). The outcomes were mortality (0.66%), Peri procedural MI (0.66%), Contrast induced-acute kidney injury (0.66%), Arrhythmia requiring treatment-VT/VF (2.64%), Complete heart block (1.98%), Local vascular complications (1.32%), probable sub acute stent thrombosis (0.66%) and Discharge from hospital after a successful PCI procedure (99.33%). None required referral for CABG surgery or reported any major bleeding.*
Conclusion: *Our in hospital and 30 days outcome after PCI are comparable with the National data. Stable angina was a major indication in our study probably reflecting a more conservative approach towards patient selection during the initial period of starting the cardiac cath lab. Brady and tachy-arrhythmias were the major complications observed. The results of our study suggest that favourable outcome with PCI can be achieved in our setting, which is at par with the National level.*

Keywords: *Coronary artery disease, Percutaneous coronary interventions, Indications, Outcomes, Coronary stents*

I. Introduction

Cardiovascular disease is currently the leading cause of morbidity and mortality in India. Coronary artery disease (CAD) has reached epidemic proportions and appears to be due to genetic predisposition of our people and acquisition of traditional risk factors (smoking, tobacco use, hypertension, dyslipidemia and diabetes mellitus) at a rapid rate as a result of urbanization. The ever increasing burden of patients with symptomatic and life threatening manifestations of CAD is posing a major challenge to the Governments and healthcare providers. Efforts to develop modern facilities to treat these patients by contemporary methods like percutaneous coronary revascularization and surgical methods have shown a very promising trend during the last decade. Facilities of modern diagnostic methods and new proven techniques to offer symptomatic relief and improve their prognosis are available in most parts of the country.

There are presently over 500 centers with cardiac cath lab facilities for coronary angiography and coronary angioplasty in the country and these numbers are steadily increasing [1] . Most metropolitan cities have these facilities available and even smaller cities are acquiring these at a rapid rate. However, high treatment costs, lack of social security and insurance for the large majority of the patients are a major hurdle for the economically deprived seeking medical help. They usually have to rely on Government hospitals, which are situated in metros for quality care at affordable rates. Often Government hospitals have long waiting lists causing much unwanted delay in treatment due to high patient load.

The use of percutaneous coronary interventions (PCI) to treat ischemic coronary artery disease has expanded dramatically and the number of coronary interventions are increasing each year in India. The estimated PCI procedures performed annually in India exceed the number of coronary artery bypass graft (CABG) procedures. The rate of growth of coronary interventions in India during the period 2006 to 2012 was to the tune of 16.4%. The number of smaller centres, like ours, performing <200 PCI's per year in India increased from 85 in 2010 to 101 in 2011 and accounted for 30.4% of total number of PCI procedures performed [2].

There is a paucity of data on the demographic and clinical profile, procedure indications and outcomes from centres in this part of the country. Therefore, this study was undertaken to analyse critically the data of coronary artery disease patients who underwent PCI during the initial period of starting cardiac cath lab facility in Gauhati Medical College Hospital, Guwahati, Assam, the premier teaching hospital of North East India.

II. Material And Methods

An observational descriptive study was conducted in the Department of Cardiology, Gauhati Medical College Hospital, Guwahati, Assam from January 2010 to December 2011. One hundred and fifty one (n=151) symptomatic coronary artery disease patients of various ages and both genders who underwent primary, rescue or elective PCI with stent deployment (bare metal or drug eluting) were enrolled. Written informed consent were obtained from all patients. Patients who had a PCI procedure done at other hospitals and all lesions treated with plain old balloon angioplasty (POBA) were excluded.

The primary outcome variables of the study, were indications for PCI that included stable angina, unstable angina (USA), Post MI, Primary PCI and Others (CHF). The PCI outcome included were Death, Emergency CABG, peri procedural MI, contrast induced acute kidney injury (CI-AKI), major bleeding, arrhythmias requiring treatment –VT/VF, complete heart block, local vascular complications, stent thrombosis and discharge from hospital.

Chronic stable angina (CSA) was defined as retrosternal discomfort (heaviness), brought about or increased with exertion and reduced with rest or nitrates lasting less than 10 minutes. All symptomatic patients despite optimal medical therapy and positive tread mill test were considered for coronary angiography with intent to revascularization. Unstable angina was defined by ECG ST-segment depression or prominent T wave inversion and no elevation of cardiac biomarkers of necrosis (Troponins T/I or CPKMB). NSTEMI was defined by ECG ST-segment depression or prominent T wave inversion and/or positive biomarkers of necrosis in the absence of ST-segment elevation. STEMI was diagnosed on ECG changes, i.e., new ST elevation, left bundle branch block or coronary thrombus. In post MI patients, PCI was performed as a part of pharmaco-invasive strategy, in those with post infarct angina or rescue PCI. When PCI was performed in lieu of thrombolytic therapy, it was considered as primary PCI - in patients of STEMI less than 12 hours of symptom onset (or more than 12 hours with persistant symptoms). Other indications for PCI were anginal equivalent (eg, dyspnea, arrhythmia, or dizziness or syncope). Congestive Heart Failure (CHF) was diagnosed clinically by the presence of either paroxysmal nocturnal dyspnoea (PND) or dyspnoea on exertion due to heart failure or chest X-Ray suggestive of pulmonary congestion.

Periprocedural MI was diagnosed when CK-MB was elevated three times normal or higher after the procedure in samples obtained during femoral sheath removal 6 hours after the PCI procedure. Contrast induced-acute kidney injury (CI-AKI) has been defined by the criteria of a 0.3 mg/dl or greater rise in serum creatinine from baseline within 48 hours of intravascular administration of iodinated contrast. Arrhythmia requiring treatment, i.e., ventricular tachycardia was diagnosed on three or more QRS complexes of ventricular origin at a rate exceeding 100 beats/min. Heart Block was diagnosed as complete dissociation of the atrial and ventricular electrical activity on surface ECG. Subacute stent thrombosis was labeled if there was angiographic vessel occlusion, any new Q-wave MI in an area supplied by the stented vessel and/or unexplained death from a cardiac cause from $\geq$24 hours to 30 days of the PCI procedure.

All the selected patients underwent PCI at the cardiac catheterization laboratory (Philips) by consultants of the Department of Cardiology, Gauhati Medical College Hospital. All procedures were done through right femoral arterial approach using 6 French or 7 French guiding catheters as appropriate. The data collected included age, gender, history of hypertension, dyslipidaemia, smoking/tobacco use and diabetes. Procedure indications and in hospital outcomes were recorded. Patients were then followed up in the out-patient department by cardiology fellows after one month, when the final outcome were recorded. Patients who developed any complication during the one month follow-up period, attended the hospital Emergency Department.

Qualitative variables like gender, history of hypertension, dyslipidemia, smoking/tobacco use and diabetes, indications of PCI, distribution of treated vessel, pattern of stent use and in hospital and 30 days outcome were considered. Frequency of indications and outcomes were noted as the primary outcome of the

study. All observations were tabulated accordingly. Results were expressed as percentage, mean, and standard deviation.

III. Results

The sample population of the study was (n=151). The mean age was 54.98 ± 10.65 years. There were 132 (87.4%) male and 19 (12.6%) female patients. Young CAD patients (≤ 40 years) who underwent PCI procedures accounted for 10.59 % of the total patients whereas 89.40% were > 40 years of age. Seven patients (4.6%) were septuagenarians (> 70 years). The most common traditional cardiovascular risk factor was hypertension (66.9%) followed by dyslipidemia (54.3%), smoking/tobacco use (45.03%), and diabetes mellitus (41.7%). The most frequent indication for PCI was chronic stable angina (59.6%) followed by Post MI (21.19%), Primary PCI (11.92%), unstable angina (4.63%) and others (CHF) 2.64%. **Table** 1.

A total of 189 lesions were stented in 151 patients. The most common treated vessel was LAD (55.55%) followed by RCA and LCX. Drug eluting stents (DES) were used in 94.17% patients whereas Bare metal stents (BMS) use was 5.82%. Endeavour resolute DES was most frequently used (63.5%) followed by Xience (29.6%). **Table** 2.

Tachy (2.64%) followed by brady arrhythmias (1.98%) requiring treatment were the commonest complications noted. Both were adequately managed with DC cardioversion, i.v. atropine or temporary pacemaker implantation as required . Two patients (1.32%) had mild local site hematoma which subsided with prolonged manual pressure application. Periprocedural MI, contrast induced nephropathy and probable sub-acute stent thrombosis leading to sudden death on the third day of procedure were noted in one patient each (0.66%) each. None of the patients required referral for emergency CABG or reported any major bleeding. Out of the total 151 patients who underwent PCI procedure, 150 (99.33%) were discharged from the hospital in a hemodynamically stable condition after a successful procedure. None of the patients reported any complications at one month follow up visit. **Table** 3.

IV. Figures And Tables

TABLE 1: Demographic and clinical profile and procedure indications of study patients

PARAMETERS	n = 151	%
AGE	54.98±10.65	
(Mean± SD) years		
SEX		
Male	132	87.4
Female	19	12.6
PATIENTS		
Below 40 years	16	10.59
Above 40 years	135	89.40
Above 70 years	07	4.6
RISK FACTORS		
Hypertension	101	66.9
Dyslipidemia	82	54.3
Smoking/tobacco use	68	45.03
Diabetes mellitus	63	41.7
INDICATIONS OF PCI		
Stable angina	90	59.60
Unstable angina	07	04.63
Post MI	32	21.19
Primary PCI	18	11.92
Others (CHF)	04	2.64

TABLE 2 : Distribution of treated vessel and pattern of stent use

TREATED VESSEL	N=189	%
LAD	105	55.55
RCA	61	32.27
LCX	23	12.16
TYPE OF STENT USE		
DES	178	94.17
BMS	11	05.82
DES		
ENDEAVOUR RESOLUTE	120	63.49
XIENCE	56	29.62
EUROCOR	02	1.05
BMS		
DRIVER	06	3.17
INTEGRITY	05	2.64

TABLE 3 : In Hospital and 30 days adverse outcome

Variables	N=151	%
Death	**01**	**0.66**
Emergency CABG	**0**	**-**
Periprocedural MI	**01**	**0.66**
Contrast induced nephropathy	**01**	**0.66**
Major bleeding	**0**	**-**
Arrhythmia requiring treatment –VT/VF	**04**	**2.64**
Complete heart block	**03**	**1.98**
Local vascular complications	**02**	**1.32**
Stent thrombosis	**01**	**0.66**
Discharge from hospital	**150**	**99.33**

V. Discussion

The major value of percutaneous or surgical coronary revascularization is relief of symptoms and signs of ischemic CAD. In acute coronary syndrome (ACS) patients, PCI reduces the risk for mortality and subsequent myocardial infarction when compared with medical therapy. PCI has undergone tremendous growth over the past two decades; partly driven by numerous technological improvements especially coronary balloons, stents and adjunctive devices required to perform safe and effective PCI. Controversies have existed in the past over the appropriate use of PCI in general in the management of CAD.

Our study represents the analysis of PCI performed in a tertiary care cardiac center in the premier teaching hospital of North East India during the early phase of its inception. The data on coronary interventions in India are largely available through two sources - The National Intervention Council (NIC) and the Industry. Our demographic variables were comparable with National Interventional Council Registry data 2012 i.e, for the period 2010 and 2011, which is same as our study period. The major differences being the number of PCI procedures performed in females, which was much less compared to the National data (12.% vs 26%). The possible reasons for this difference may be due to lack of recognition of CAD in women due to differences in clinical presentation leading to delay in proper diagnosis, health beliefs and cultural values [3]. Several studies have revealed that women are less likely than men to receive recommended therapies [4]. The number of PCI procedures performed in young CAD (< 40 years age) in our study (10.59%) compared well with the NIC data which was 8.80% in 2010 and 13.57% in 2011. Although it appears from the NIC data that septuagenarians are being taken up for angioplasty more readily (11.04% in 2010 and 14.45 in 2011), only 4.6% of the patients were more than 70 years age, possibly indicating a more conservative approach towards case selection for PCI during the early period of starting our cath lab services.

Hypertension was the major cardiovascular risk factor seen in 66.9% of our patients undergoing PCI whereas diabetes mellitus was the least common (41.7%). Less prevalence of diabetes in our study patients may be because such patients have lesions not suitable for PCI, and were referred more for CABG surgery. Since CAD is multifactorial in etiology, PCI should be coupled with optimal medical therapy such as control of hypertension and diabetes, smoking cessation and regular physical exercise. Lipid management, particularly statin use, is also an important component.

The commonest indication for PCI in our study was stable angina (59.60%), followed by Post MI (21.19%) and primary PCI (11.92%). In contrast, NIC data for the same period showed that unstable angina (31.63%), followed by post MI (29.54%) and chronic stable angina (23.59%) were the commonest indications. Primary PCI were being done in 12.04% of patients as per National data which compared well with our data for that period. A more conservative approach may explain the higher number of cases of chronic stable angina in our study being considered for PCI. Compared to optimal medical therapy for chronic stable angina, relief of symptoms [5] and improvement of ischemia [6] are better with PCI. Greater than 5% improvement in the ischemic burden is achieved more often with PCI, and the magnitude of the residual ischemia correlates with less frequent death and MI [6].

Out of the 151 CAD patients who underwent PCI, LAD was the most commonly treated vessel (55.55%), followed by RCA (32.27%) and LCX (12.16%). A similar trend was also observed in the NIC data.

A total of 189 lesions were stented in our study patients, out of which 94.17% were DES and 5.82% BMS. The National data for the same period noted that the percentage of DES use was 62.75% in 2010 and 81.1% in 2011. Large randomized clinical trials have confirmed the benefits of DES over BMS in terms of decreasing the incidence of in-stent restenosis and the need for repeat revascularization [7-9]. As a result, there has been a very rapid worldwide shift in the treatment of coronary stenosis from BMS to DES, including in most Asian countries. However, concern remains over late-occurring stent thrombosis after DES implantation [10-12]. To thrive for better outcomes after PCI, the number of DES use may have been higher compared to BMS in our study. This may also explain the higher use of internationally approved DES like Endeavour Resolute (Medtronic) and Xience (Abbott Vascular) similar to the National trend. BMS are currently used in 10 to 30% of patients undergoing PCI and are mostly indicated for larger vessels (>4.0mm) and for those who are unable to

take long term dual antiplatelet therapy. Because of the peculiar pattern of CAD in Indian patients (small vessel disease, diffuse disease, etc.) may further explain the less number of eligible patients for BMS implantation.

Procedural success and complication rates are used to measure outcomes after PCI. Early (<30 day) success (e.g., relief of angina; freedom from death, MI, and urgent revascularization) is generally related to the safety and effectiveness of the initial procedure, whereas late (30 days to 1 year) success (e.g., freedom from recurrence of angina, target vessel revascularization, MI, or death) depends on both clinical restenosis and progressive atherosclerosis at remote sites. Among the major complications noted in our study, death, periprocedural MI, probable sub-acute stent thrombosis and contrast induced- acute kidney injury accounted for 0.66% each and this was similar to the National data. Although the incidence of acute renal failure was less than the National data of 3.27% probably because of the lesser number of patients in our study, however, this does reflect the good clinical practice adopted by most of the operators in our centre. None of the patients required referral for CABG surgery or reported any major bleeding.

VI. Conclusion

Our study represents the analysis of the indications and outcomes of PCI procedures performed in the cardiac catheterization laboratory of Gauhati Medical College Hospital, the premier teaching hospital of North East India during the early period after its inception. We found that the most common indication for performing PCI in our population was chronic stable angina. Brady and Tachy arrhythmias were the most frequently encountered procedural complications which were adequately managed. The occurance of major complications in our study including death, peri procedural MI, sub-acute stent thrombosis and contrast induced- acute kidney injury was similar to the National data. None of our patients required referral for CABG surgery or reported any major bleeding. The results of our study suggest that favourable outcome with PCI can be achieved in our setting, which is at par with the National level.

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