Early outcome of 212 coronary angioplasty procedures our experience at Manmohan Cardiothoracic Vascular and Transplant Centre

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ABSTRACT

A prospective study was carried out to evaluate safety, in-hospital clinical end points and early outcome in a consecutive series of 212 patients with coronary artery disease (CAD) who underwent coronary angioplasty in Manmohan Cardiothoracic Vascular and Transplant Centre from October 2012 to April 2014 over a period of 18 months. All patients who underwent angioplasty during the specified period were included in the study. Majority of the patients were male (84.4%). Hypertension was found in 31%, diabetes in 29%, dyslipidemia in 23% and smoking in 19%. A total of 253 stents were deployed. Patients with single vessel coronary artery disease (SVD) were 75 %, double vessel coronary artery disease (DVD) 23 % and triple vessel coronary artery disease (TVD) was only 1.8%. Indications for stent implantation were stable CAD in 110 (51.8%), unstable angina (UA) in 19 (8.9%), Non ST segment elevation Myocardial Infarction (NSTEMI) in 31 (14.6%) and ST segment elevation Myocardial Infarction (STEMI) in 52 (24.5%). Eighty one percent received drug eluting stent (DES); while 19 % received bare metal stent (BMS). Over all procedural success was obtained in 206 (97.6 %) cases. Mortality occurred in 4 cases (1.9%) during index hospitalization. All these patients were in cardiogenic shock due to acute STEMI. On follow up, one case of sub acute stent thrombosis (0.4%) and 3 cases (6.3%) of instent restenosis were observed among 47 BMS cases. Coronary Angioplasty was found to be a safe and effective method of coronary revascularization with low in-hospital morbidity and mortality even in high risk elective and emergency procedures.

Keywords: Coronary angioplasty, procedural success, early outcome

INTRODUCTION

German cardiologist Andreas Gruentzig introduced Percutaneous Trans-luminal Coronary Angioplasty (PTCA) as a non surgical procedure used to dilate narrowed coronary arteries in 1977 A.D.[1] This procedure is now called Percutaneous Coronary Intervention (PCI) as this term includes the use of wire, balloon and deployment of intra coronary stent and other devices whenever deemed necessary. Since its introduction, PCI has dramatically changed the modalities of treatment in coronary artery disease (CAD). It has replaced the need for coronary artery bypass graft surgery (CABG) in large number of cases.[2] Stent insertion along with angioplasty has become a part of standard cardiac care in treatment of CAD because more and more evidences are in favour of stent implantation. With operator experience, new technology and adjunctive pharmacotherapy, the overall success and complication rate of PCI have improved.[3]

Use of coronary stents have made the job of the interventionists and the lives of the cardiac patients easier and many cases that were previously thought to be surgical, are now being handled increasingly by the cardiologists on account of high primary success rate of stenting procedures.[4-6] However on the other hand instent restenosis has emerged as a challenging problem that is yet to be solved.[7]

Therefore, there is always a need to improve the skills and technology to get the best possible procedural outcomes for the safety and care of the patients. Medical audit of such procedures is an important step towards innovation. This modern effective procedure was introduced in our hospital about 20 months back. As per our knowledge, there is paucity of data regarding early outcome of this procedure. This study represents not only single centre or single operator experience but also includes the initial outcome data in limited resources setting. This study is a result of immediate outcome of percutaneous coronary intervention (PCI) cases of newly setup cath lab in Manmohan Cardiothoracic Vascular and Transplant Centre, a tertiary care government teaching hospital located in capital city , Kathmandu.

MATERIAL AND METHODS:

All the patients who underwent PTCA in our centre during the period of 18 months (October 2012 to April 2014) were included in this study and were followed up to evaluate safety, in-hospital clinical end points and early outcome. Informed consent was taken from all patients.

PTCA was performed in all cases as per the current standard recommendations and guidelines. Before stent implantation, patients were treated with aspirin 300 mg and Clopidogrel 300 mg given at least 12 hrs before the procedure and repeated dose of 150 mg Clopidogrel at least 3 hours before the procedure. A bolus of 5000 unit Heparin was given after sheath insertion, with repeat boluses of Heparin given as needed to maintain an ACT >250 sec. Different types of stents were used, which included bare metal stents (BMS) & Drug eluting stents (DES). DES included Zotarolimus & Everolimus coated stents which were FDA approved. Most of the stents were inflated at high pressure (>14 atm) for final in stent dilatation. Post dilatations were performed with appropriate sized noncompliant balloon within the stent to obtain a near zero residual stenosis. Clopidogrel 150 mg was given for 1 month to all patients and subsequently 75 mg for 12 months and Aspirin 150 mg indefinitely.

The coronary lesions were divided into A, B1, B2 and C, according to the classification of the American College of Cardiology and American Heart Association.8 The characteristics of high risk (type C) were: lesion length > 20 mm, massive calcification, excessive tortuosity of proximal segment, target segment with extreme angulation (> 90 degrees), chronic occlusion in blunt tip, inability to protect significant lateral (≥ 2.5 mm) and stenotic (> 50%) branch, degenerated vein grafts.

Clinical events were monitored during hospital stay and at 30 days out patient visit. Patients were seen at outpatient clinic. Anginal pain was characterized according to Canadian cardiovascular society classification. Clinical follow up ended when patient developed major adverse cardiovascular event (MACE). Angiographic success was defined as a successful PCI procedure includes- substantial enlargement of the lumen at the target site with the achievement of a minimum stenosis diameter reduction to 20% in the presence of grade 3 TIMI flow (assessed by angiography). Procedural success is a successful PCI should achieve angiographic success without in hospital major clinical complications (e.g. death, Myocardial infarction (MI), emergency Coronary artery bypass graft (CABG) surgery during hospitalization). Clinical success is defined as a clinically successful PCI includes anatomic and procedural success with relief of signs and symptoms of myocardial ischemia after the patient recovers from procedure. Procedural complications were divided into six basic categories: i. Death, ii. MI, iii. Emergency CABG, iv. Stroke, v. Vascular access site complication and vi. Contrast agent nephropathy

Hospital record was reviewed at discharge and follow up was done at 7 days post discharge and every 3 monthly until the end of the study. Data was entered into a Microsoft Excel 2010 spread sheet and imported to SPSS version 17.0 for analysis. Chi square test was applied wherever appropriate and a P value of less than 0.05 was considered significant.

RESULT

A total of 212 patients were included in this study. Mean duration of follow up was 9 ± 5 months. Mean age of the patients was 56 years. Majority of the patients, 84%, were male and 16% female. Regarding baseline prevalence of cardiovascular risk factors, hypertension was found in 31.6% of the study population, while 29.7% had diabetes, 23.1% had dyslipidemia, and 19.8 % of the patients were smokers. (Table 1)

Table 1. Demographic and risk facto profile of the patients.

Total patient (n=212)	Percent	Mean
Age		56 ± 8years
Male	84.8	
Female	15.2	
Cardiovascular Risk factors		
Hypertension	31.6	
Diabetes	29.7	
Dyslipidemia	23.1	
Smoking	19.8	
Family history	28.43	

All procedures were done through femoral route. Most common indication for angioplasty was stable CAD. Coronary Angioplasty was performed as an ad-hoc elective procedure in patients with stable CAD in 110(51.8%), unstable angina (UA) in 19(8.9%) and in NSTEMI in 31 (14.6%) cases. Coronary Angioplasty as an emergency procedure called Primary Angioplasty or Primary Percutaneous Coronary Intervention (PPCI) in 52(24.5%). (Fig 1)

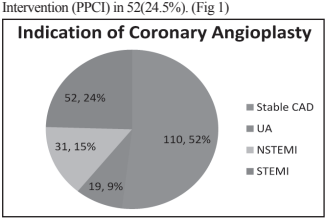

Fig.1 Indication of coronary angioplasty (n, %)

Left anterior descending (LAD) was involved in 56 % of cases and this most commonly involved Epicardial artery. Right coronary artery (RCA) involvement was found in 27%, left circumflex (LCX) in 16% and Left Main coronary artery (LMCA) in 2% of the patients. (Table 2).

Table 2. Types of vessel involved

Type of involved vessel	No. of cases
Left Main coronary artery (LMCA)	3
Left anterior descending (LAD)	142
left circumflex (LCX)	40
Right coronary artery (RCA)	68

75% of the patients underwent single vessel Percutaneous Transluminal Coronary Angioplasty (PTCA). About one fourth of the patients received double vessel PTCA (23.1%). Four patients underwent three vessels PTCA and three patients had successful PTCA to left main coronary artery without peri-procedural complications. Seven percent of the patient received two stents in a single vessel. (Table3).

Table 3 Pattern of vessel involved

Pattern of vessel involvement	No of cases
Triple Vessel Disease (TVD)	4(1.8)
Double Vessel Disease (DVD)	49(23.1%)
Single Vessel Disease (SVD)	159(75%)
Two stents in single artery	15(7%)

PTCA was also performed in patients having complex coronary artery disease. These complex coronary lesions included thirteen (6%) cases of Ostial LAD involvement and 5% bifurcation lesions. Seven cases of Chronic Total Occlusion (CTO), three Left Main coronary artery disease and four triple vessel lesions were also successfully stented. (Table 4)

Table 4. PTCA in in complex lesion

Intervention on complex lesion	No of cases
Ostial LAD lesion	13
Bifurcation lesion	11
Chronic Total Occlusion	7
Left Main Coronary Artery Disease (LMCAD)	3
Triple Vessel Disease (TVD)	4

Majority of the stents used were Drug eluting stents (DES), either Zotarolimus or Everolimus eluting. A majority of patients, 81%, received DES while 19% received BMS. (Fig 2)

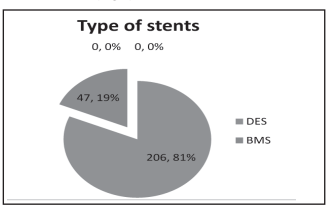

Fig. 2 Type of stents used (n, %)

All types of lesions were treated. Lesion specific characteristic revealed type A lesion in 24 %, type B in 46% and type C in 30%. (Fig 3).

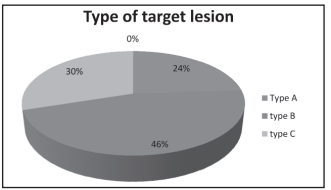

Fig .3. Type of target lesions

Angiographic success was achieved in 100% of the cases. Overall procedural success (Thrombolysis in Myocardial Infarction, TIMI flow grade 3) was obtained in 206 (97.6 %) cases. Clinical success was achieved in 97% cases. There were very few minor complications (6%) & MACE was seen in 3% during study period in entire study population. There was no procedure related death at 30 days follow up. Four patients (1.9%) died during index hospital admission. Cardiac tamponade occurred in one patient with primary PCI which was successfully managed with pigtail drainage. Coronary dissection occurred in 5 patients but none had perforation. Two patients had side branch compression requiring intervention and two patients had plaque shift. Pseudo aneurysm of femoral artery was found in one patient who was managed with ultrasound guided compression. Eight patients had groin hematoma which was treated conservatively. Two patients had subconjunctival haemorrhage and one patient had Foleys catheter induced haematuria not requiring blood transfusion. On follow up, 2 hospitalizations occurred because of cardiovascular events – one because of subacute stent thrombosis and another due to upper Gastrointestinal (GI) bleeding. GI bleeding was managed conservatively and blood transfusion was not required. Subacute stent thrombosis (SAT) occurred in one patient (0.4%). SAT was managed with balloon Angioplasty with achievement of TIMI 3 flow. Three patients had instent restenosis (1.4%) and all these patients had received BMS. One of them had Left Main PTCA done with BMS as a bail out procedure in emergency situation while patient was in cardiogenic shock. Two other cases of instent restenosis were observed, one in Left circumflex and other in LAD artery.

DISCUSSION

This study shows that PTCA was performed with lower rate of morbidity and mortality. Results of this study were generally consistent with most of the published literature as regards the immediate and short term outcomes. Our study had a high angiographic success of 100%, Procedural

success rates were also high at 97.6% and clinical success was 97%. In our study mortality was 1.9%.In a study done by Asaraf Raza, mortality was 0.6%.[9] Rahman et al in 2004 reported 96% clinical success with 2% mortality.[10] Angiographic success rates ranged from as low as 59% in the early days of 1970s to as high as 100% in 2008.[11,12] Though many studies show angiographic success was better among patients with single vessel disease (SVD) than patients with multi-vessel disease, in this study angiographic success was 100% irrespective of vessel involved which was similar to a study by Shahabuddin.[12]

Slightly higher mortality in our study may be due three reasons. First, due to inclusion of cases of acute STEMI, which have higher mortality compared to elective cases. Second, STEMI cases also involved those with cardiogenic shock. Third, in our study complex coronary artery lesions (Table 4) were also treated. Unsuccessful procedures were mainly due to inability to cross the lesions (usually total occlusions). All mortality occurred during index hospitalization. No other mortality occurred during follow up. All mortality occurred in patients who had undergone primary PTCA in acute STEMI cases. All these patients had features of shock during presentation. Despite immediate procedural success in all mortality cases, death was also attributed to presence of diabetic ketoacidosis in two cases, ventilator associated pneumonia in one, severe sepsis in one and complete heart block in one case.

Stable CAD was the most common cause of stenting followed by STEMI. LAD was the most common culprit vessel while RCA was the second most common. These results are consistent with other studies.[9] Most commonly stenting was done for single vessel disease (75%). Stenting of triple vessel disease was performed less in our set up. Most of the patients with TVD and LMCAD were sent for Coronary Artery Bypass Graft (CABG) surgery or kept on medical management as per recommended guidelines. Significant numbers of complex coronary stenting were done in our study including ostial, bifurcation, TVD, LMCAD and CTOs. Most common type of lesion stented was type B lesion. Drug eluting stent was used in majority of the patients (80%) while remaining received BMS. This is consistent with the usual practice in other centres.

In our study, subacute stent thrombosis (SAT) occurred in one patient (0.4%). Three patients had instent restenosis (1.4%). These MACE were comparable to other studies. Eechout et al in 1996 & Serruys et al in 1994 reported the main limitation of coronary stenting is sub-acute in-stent thrombosis which occurred in 4 patients (2%) and lead to myocardial infarction.[13,14] Braim M Rahel et al reported 1% instent thrombosis & Islam et al in 2003 reported 0% instent thrombosis in their series of 100 & 60 patients respectively.[15,16]

The findings of the present study support the previous reports of high angiographic, procedural & clinical success with low in-hospital complications and high short term survival after PCI. Coronary Angioplasty was found to be a safe and effective method of coronary revascularization irrespective of lesion morphology and type of stent used with low in-hospital morbidity and mortality even in high risk elective and emergency procedures.

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