Immediate and Six-month Clinical Outcome of Percutaneous Coronary Intervention in a Tertiary Hospital in the Sultanate of Oman

Panduranga Prashanth, Mohamed Mukhaini, Abdulla A. Riyami, Kadhim Sulaiman, Rashid Shahrabani, Abdulla M. Riyami

Abstract

Objective: To evaluate the clinical characteristics, angiographic profile, in-hospital and six-month clinical outcome of patients who underwent percutaneous coronary intervention in a tertiary hospital in the Sultanate of Oman.

Methods: Two hundred and five consecutive patients with both acute coronary syndrome and stable coronary artery disease, who underwent percutaneous coronary intervention between January 2007 and June 2007, were retrospectively analyzed. Follow-up information was obtained from outpatient visits of these patients at six-months.

Main outcome measures: The primary end point in this study was the occurrence of major adverse cardiovascular events (MACE), defined as cardiac death, any myocardial infarction (MI), cerebrovascular accident (CVA) and target vessel revascularization (TVR) with either repeat percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG). Secondary end points included angiographic success rate, procedural success rate, angina status, and the rate of clinical and angiographic restenosis.

Results: The angiographic and procedural success rate was 98% and 95% respectively. Fifty-one percent of patients surveyed had single vessel disease, 34% had double vessel disease and triple vessel disease was seen in 15% of patients. Type A lesion was found in 16%, Type B in 55% and Type C in 29% of patients. The majority of patients had single vessel stenting (83%). The mean ± SD number of stents per patient was 1.6 ± 0.9.There were four in-hospital deaths (2%) and six patients (2.9%) had non-ST elevation myocardial infarction before hospital discharge. Out of 205 patients, 53 patients were lost to follow-up. Among the 148 patients followed up, 105 patients (71%) were asymptomatic at follow-up, 36 (24%) patients had stable angina and 7 (5%) had a late myocardial infarction including three patients with stent thrombosis (2%). Among the 43 patients with angina or late infarction, 28 patients underwent coronary angiogram. Angiographic in-stent restenosis was seen in 14 patients. Of them, 8 patients underwent CABG and 6 patients repeat PCI. Fourteen patients had patent stents.The remaining fifteen patients were on optimal medications including two patients with stent thrombosis as they refused coronary angiogram. Overall, 132 of 148 patients (105 asymptomatic/14 patent stents/13 with angina) (89%) were free from major adverse cardiac events. Considering anginal status and repeat angiograms, composite clinical (15 patients) and angiographic (14 patients) six-month restenosis rate in percutaneous coronary intervention patients (29/148) was 19.5%.

Conclusion: Results of percutaneous coronary intervention in our setup is excellent with good immediate results, low complication rate, good six-month clinical outcome and is comparable to international standards.

Keywords: Percutaneous coronary intervention; Major adverse cardiovascular events; Stent; Clinical restenosis; Angiographic restenosis.

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From the Department of Cardiology, Royal Hospital, Muscat, Sultanate of Oman.
Address correspondence and reprint request to: Dr. Panduranga Prashanth, Department of Cardiology, Royal Hospital, P.O. Box 1331, PC 111, Muscat, Sultanate of Oman.
E-mail: prashanthp_69@yahoo.co.in

Introduction

Cardiovascular disease has become a dominant cause of morbidity and mortality in most countries. Coronary artery disease (CAD) has a spectrum of presentations ranging from stable angina, acute coronary syndrome (ACS), asymptomatic disease and sudden cardiac death. It is prudent to know the coronary anatomy, in order to design effective treatment strategy and prevent future cardiac events. Catheter-based interventions are well-recognized techniques for obstructive CAD.

Percutaneous coronary intervention is now an established treatment for patients presenting with acute coronary syndrome or stable angina.[1] The aim of this study was to review the clinical and angiographic profile both as in-hospital and six-month clinical outcome in a group of unselected patients undergoing PCI at Royal Hospital. This hospital is a single high volume angioplasty centre (>400/year) in the Sultanate of Oman.

Methods

The study population included 205 unselected, consecutive patients with both acute coronary syndrome and stable coronary artery disease who underwent PCI at our institution between January and June 2007. Study population consisted of patients presenting to Royal Hospital as well as those referred from

peripheral hospitals in Oman. Patients with previous PCI presenting with in-stent restenosis of previous stent or those who had only plain balloon angioplasty without stenting were excluded from the study.

Conventional risk factors including age, gender, diabetes, hypertension, dyslipidaemia, current smoking (within one year) and family history of CAD were noted. Previous conditions such as myocardial infarction, percutaneous coronary intervention, coronary artery bypass surgery, peripheral vascular disease (PVD), cerebrovascular accident (CVA) or transient ischemic attack (TIA) and chronic kidney disease (CKD) were also noted.

Angiographic and procedural notes were reviewed by cardiologists not involved in the PCI. In our study, single vessel disease was present if there was more than 70% diameter stenosis on visual assessment in the left anterior descending (LAD), left circumflex (LCX), or right coronary (RCA) arteries, or a major branch. Coronary flow was graded according to Thrombolysis in Myocardial Infarction (TIMI) criteria viz. TIMI flow grades 0 (no flow), 1 (minimal flow), 2 (partial flow), or 3 (complete flow).

The lesion location, morphology, stented segment, number of stents used, size, length and type of the stent, procedural success and complications were noted. The lesion morphology was classified according to American College of Cardiology/American Heart Association (ACC/AHA) classification - Type A: concentric noncalcified, <10 mm in length, not bifurcated or angulated. Type C: >20mm in length, proximal tortuosity, angulated segment >90^0 or total occlusion. Type B: all others (ACC/AHA).[1]

Complex lesion morphology was noted including: thrombus, calcification, tortuosity, lesion eccentricity, ostial location and bifurcation lesions. A total occlusion was defined as the absence of a discernible luminal channel with TIMI flow grade 0 or 1.

Chronic total occlusion (CTO) was defined as >3 months in duration of an index event or from previous coronary angiography (CAG) report. Left ventricular ejection fraction was noted from echocardiographic or catheterization records. Multiple coronary stenting was defined as implantation of two or more stents in one or more vessels during the same procedure. Stent thrombosis (ST) was assumed when either occlusive thrombus formation was visualized angiographically within the stented vessel segment, or clinical symptoms and electrocardiographic changes revealed acute MI, either within 24 hours (acute ST) or within thirty days (subacute ST) after stent implantation

PCI was done according to standard clinical practice through the femoral approach using 6 F guiding catheters routinely, except in one patient with PVD who underwent PCI by the radial route. Intra-aortic balloon pump (IABP) was inserted in patients with cardiogenic shock. Patients with intracoronary thrombus received tirofiban (Gp IIb/IIIa antagonist) along with unfractionated heparin infusion. Patients received either a bare-metal stent (BMS) or a drug-eluting stent (DES) according to the indication. All patients received 75 to 300 mg of aspirin within 24 hours before the procedure and postprocedure 300 mg for one month in patients with BMS and for three to six months in patients with DES, after which 75 mg was advised indefinitely. Clopidogrel was administered for all patients (300 mg oral loading dose within 24 hours of the procedure, followed by 75 mg daily for one month in patients with BMS and for one year in patients with DES).

Main outcome measures

The primary end point in this study was the occurrence of major adverse cardiovascular events, defined as cardiac death, any MI, CVA and TVR with either repeat PCI or CABG. Death was considered as cardiac unless otherwise demonstrated. Myocardial infarction was documented by the Troponin T rise (>0.1microgm/L) with either ischemic symptoms or ST elevation/depression or new pathologic Q waves on the electrocardiogram. For post-PCI infarction,Troponin T rise more than 5 times from baseline was considered.[1] Secondary end points included (1) angiographic success rate, defined as less than 20 percent residual stenosis and TIMI-3 flow; (2) procedural success rate, defined as successful angioplasty without the occurrence of clinical events during the hospital stay; (3) anginal class at six months; (4) rate of in-stent restenosis (ISR) was defined as either recurrence of angina(clinical restenosis) or stenosis >50 percent (angiographic restenosis) on follow-up at six-months.

Data collection and statistical analysis

The clinical and angiographic data of patients who had undergone PCI were obtained from the hospital computer records and entered on a database. Follow up information was obtained from outpatient visit at six-months. Categorical variables are expressed as absolute numbers and percentage values. Continuous variables are expressed as the mean value ± SD. Fischer's exact test was used to compare MACE in diabetics and nondiabetics. P value of <0.05 was considered to be significant.

Results

Table 1 shows patient demographic and clinical characteristics. PCI was attempted in 208 patients and performed in 205 patients. In three patients it was unable to cross the lesion and they underwent CABG electively. Among the studied patients, 71% were males and 29% females. The mean age was 54.7 ± 10.5 years and 12% of the total patients were under 40 years of age. 182 patients were Omanis and 23 expatriates.

Table 1. Showing clinical characteristics of study group

Characteristic	Patients (n=205)
Age	54.7+/-10.5
Males	145 (71)
Hypertension	103 (51)
Hyperlipidemia	94 (46)
Diabetes	66 (32)
Current smoker	45 (22)
Family history of CAD	30 (15)
Old MI	38 (18)
Previous PCI	18 (9)
Previous CABG	07 (3)
CKD	10 (5)
Old CVA/TIA	5 (2)
PVD	5 (2)
Stable angina	82 (40)
NONSTEMI	42 (21)
Unstable angina	32 (15)
Post MI angina	28 (13)
STEMI	21 (11)

Values are n (%) or mean+/- SD
CAD: Coronary artery disease
MI: Myocardial infarction
PCI: Percutaneous coronary intervention
CABG: Coronary artery bypass surgery
CKD: Chronic kidney disease
CVA: Cerebrovascular accident
TIA: Transient ischemic attack
PVD: Peripheral vascular disease
NONSTEMI: Non ST elevation MI
STEMI: ST elevation MI

The most common risk factor was hypertension (51%) followed by dyslipidaemia (46%), diabetes (32%) and smoking (22%). Seventeen percent of the total patients had more than three risk factors. Incidence of family history was low (15%).

Among the previous conditions 38 (18%) had a history of old MI; 18 had previous PCI; 7 had previous CABG; CKD in 10 patients; PVD in 5; old CVA/TIA in 5.

The most common indication for PCI was stable angina (40%) followed by NONSTEMI (21%), unstable angina (15%), post-MI angina (13%), and lastly STEMI (11%). The majority of stable angina and post MI angina patients were referred from regional hospitals. Among patients with post-MI angina, 22 patients (78%) had received thrombolysis with reteplase or streptokinase. 39% (32/82) patients with stable angina had their treadmill exercise test or nuclear scan positive.

All patients underwent PCI within a week of admission. Table 2 shows the angiographic and procedural characteristics. Analysis of angiographic data revealed single vessel disease (105 patients) to be more prevalent as compared to double vessel disease (69 patients) (51% vs 34%). Thirty-one patients (15%) had triple vessel disease. The lesion types were: 16% Type A; 55% Type B and 29% Type C. Proximal LAD involvement was found in 68 of 123 LAD (55%) lesions, among these ostial LAD disease was seen in 7%. Total occlusion in 31 patients (15%), among whom CTO was seen in 19(9.2%). Clots were seen in 18 patients (8.7%); calcific lesions in 12 (5.8%); eccentric lesions in 8; dissection in 3; tortuous lesions in 5 and bifurcation lesions in 2 patients. Mean LV ejection fraction (EF) was 51 ± 13% among 145 patients in whom EF was documented.

Table 2. Showing Angiographic and procedural results in the study group.

	Results
Angiographic success	201/205 (98)
Procedural success	195/205 (95)
Single vessel disease	105 (51)
Double vessel disease	69 (34)
Triple vessel disease	31 (15)
Type A lesion	39 (16)
Type B lesion	134 (55)
Type C lesion	69 (29)
Single vessel PCI	171 (83)
Double vessel PCI	31 (15)
Triple vessel PCI	3 (2)
Treated lesions	242
LAD lesion	123 (50.5)
RCA lesion	70 (29)
LCX lesion	48 (20)
LIMA lesion	01 (0.5)
Implanted stents	333
Stents per patient	1.6+/-0.9
Stent size-mm	2.9+/-0.35
Stent length-mm	14+/-3.8
Use of high pressure	146 (71)
TIMI 3 flow post PCI	201 (98)
DES	17 (8)
LV EF%(n=145)	51+/-13

Values are n (%) or mean+/- SD
PCI:Percutaneous Coronary Intervention
LAD: Left anterior descending artery
RCA: Right coronary artery
LCX: Left circumflex artery
LIMA: Left Internal Mammary Artery
TIMI: Thrombolysis in Myocardial Infarction
DES: Drug Eluting Stent
LV EF: Left Ventricular Ejection Fraction

Two hundred and five patients with 242 lesions were treated with 333 stents, 1.6 ± 0.9 stents per patient. The mean ± SD stent size was 2.9 ± 0.35 mm and stent length was 14 ± 3.8 mm. The target lesions were 123 in LAD; 70 in RCA and 48 in LCX. One patient had left internal mammary artery stenting. No venous graft or left main stenting was done. Eighty-three percent of patients had single-vessel stenting, 15% had double and 2% patients had triple-vessel stenting. Multiple coronary stenting of a single coronary artery was undertaken in 64(31%) of the patients. CTO stenting was successful in (14/15) 93% of patients. Bare metal stents were deployed in 188 patients (92%) and drug-eluting stents in 17(8%).

Primary PCI was done in 7 patients (3.4%) including four with cardiogenic shock, rescue PCI in 2 patients and delayed PCI after tirofiban in 2 patients. Primary PCI was angiographically successful in 5 out of 7 patients. Nine patients (4.3%) with intracoronary thrombus were treated with tirofiban.

In-hospital outcome

The angiographic success rate was 98% (201 of 205 patients). The procedural success rate was 95% (195 of 205 patients).

Deaths: There were four (2%) deaths. All deaths occurred in patients presenting with STEMI and cardiogenic shock. They underwent angiographically successful primary PCI (with IABP support) of totally occluded infarct related artery but remained in cardiogenic shock and expired. Three of these patients were diabetics.

Myocardial infarction: Six patients (2.9%) developed post PCI NONSTEMI in which four were due to side-branch occlusion.

CABG: No patient required post-procedural emergency CABG.

Repeat PCI: Four patients had check angiogram done for post-PCI chest pain or hypotension but stents were patent. No patient had repeat angioplasty done before hospital discharge.

Vascular complications: Three patients (1.4%) suffered major peripheral vascular complications: right femoral pseudoaneurysm (treated with thrombin injection), right femoral AV fistula (closed spontaneously on follow-up) and right common iliac dissection but with good distal flow. None of the patients had any major haematoma requiring blood transfusion.

Other complications: one patient developed pseudomonas sepsis (responded to antibiotics) and another patient developed mild pericardial effusion. No patient suffered contrast induced nephropathy or CVA.

Late clinical outcome

Table 3 shows late clinical outcome. Out of 201 patients discharged 53 patients were referred to regional hospitals with no follow-up in our hospital. Clinical follow-up was available in 148 patients at six-months. The six-months MACE in diabetics (8/52) and nondiabetics (8/96) was 15.3% and 8.3% but was not statistically significant (p value 0.26).

Table 3: In-hospital and six-month Clinical outcome

Clinical outcome	N(%)
In-hospital MACE(205 patients)	10 (4.9%)
Death	4 (2%)
MI	6 (2.9%)
TVR	0
Six-month MACE(148 patients)	16 (10.8%)
Death	0
MI	7 (5%)
TVR(including 5 with MI)	14 (9.5%)
Patent stents	14 (9.5%)
Angina/ST	15 (10%)
Asymptomatic	105 (71%)
Clinical/Angiographic six-month ISR	29 (19.5%)

Values are n (%)
MACE: Major adverse cardiac events
MI: Myocardial infarction
TVR: Target vessel revascularization
ST: Stent thrombosis
ISR: In-stent restenosis

Follow-up (Death/Myocardial infarction/Repeat PCI/CABG)

No late deaths occurred. 105 patients (71%) were asymptomatic at follow-up and 43(29%) patients were symptomatic. 36 (24%) of 148 patients had angina class II. 7 patients (5%) presented with MI (5 STEMI, 2 NONSTEMI) including 3 patients with subacute stent thrombosis (ST) (2%). 5 of these patients underwent TVR.

Among the 43 patients with angina or late infarction, 28 patients underwent coronary angiogram. Angiographic in-stent restenosis was seen in 14 patients, among whom 8 patients underwent CABG and 6 patients repeat PCI. Fourteen patients had patent stents among whom 6 patients had another vessel lesion which was stented. The remaining fifteen patients were on optimal medications. Two patients with stent thrombosis refused coronary angiogram.

Overall 132 of 148 patients (105 asymptomatic/14 patent stents/13 with angina) (89%) were free from major adverse cardiac events. The combined six-months MACE was 10.8% (16/148) which included 14 with TVR; 2 patients of ST.

Considering anginal status and repeat angiograms, composite clinical (15 patients) and angiographic (14 patients) six-month restenosis rate in percutaneous coronary intervention patients (29/148) was 19.5%.

Discussion

This study shows that PCI at our center is being performed with a high procedural success rate and good long term clinical outcome. It is not associated with an increased rate of stent thrombosis or late major clinical adverse events. This favorable clinical outcome occurred despite the fact that most patients angiographically had Type B and Type C lesions, which are traditionally considered as high risks for coronary intervention and stent implantation.

The BENESTENT (BElgian NEtherlands STENT study) and STRESS (STent REStenosis Study) trials had shown the effectiveness of elective coronary stenting using single stents in selected de novo lesions in stable CAD.[2,3] Our patients who underwent PCI consisted of a nearly equal number of ACS and stable CAD. The angiographic success rate was 98% in our study. According to ACC/AHA/SCAI 2005 PCI guideline document, reported rates of angiographic success now range between 82% and 98% depending on the device used and the types of lesions attempted.[1] Formal comparisons demonstrate that success rates are now higher (91% to 92%) in the era of new technology, which includes stents and contemporary drug therapies. The chance of dilating a chronic total occlusion averages 65%, and specific clinical and anatomic factors have been identified that affect this rate. In our study, CTO was successfully stented in 93% of patients probably due to the use of new guidewires and techniques.

Quite different are the success rates for total occlusions associated with STEMI. Success rates over 90% can be expected in this subgroup but it was less in our study at 71%.This may be due to the low number of primary PCI in our study and the lack of an established primary PCI interventional programme. All patients with NONSTEMI and UA who were high risk underwent PCI within a week of admission, which was in accordance with the present guidelines which state that a clear benefit from early angiography and, when needed, PCI or CABG has been reported. Deferral of intervention does not improve outcome.[4] In the current era of stents procedural success rates range from 90% to 95% and it was 95% in our study.

In our study the in-hospital major cardiac event rate was 4.9% including in-hospital death rate of 2% and this was mainly seen in patients with emergency PCI and cardiogenic shock, conditions that are normally considered as very high risk. Reported rates for death after analyses of large registries indicate overall unadjusted in-hospital rates for PCI of 0.4% to 1.9 %.[1] According to the ACC/AHA/SCAI 2005 document, in a combined analysis of PCI as primary reperfusion therapy for STEMI, the short-term mortality rate was 7%. Even after exclusion of patients with cardiogenic shock, in-hospital mortality was 5%. Rates of peri-procedural MI have ranged from 0.4% to 4.9%, and was 2.9% in our study. The rate of emergency CABG in a more contemporary time period and with the availability of stents has been reported in 0.4% of patients but we had no patients needing emergency CABG.

The combined six-month MACE in our study was 10.8% and the composite in-stent restenosis rate was 19.5% which is similar to that reported in previous studies.[2, 3, 5] In our study, patients did not undergo routine follow up angiography and therefore we could not assess the exact angiographic restenosis rate. Repeat angiography was performed only on clinical grounds and if patients agreed. The initial stent trials documented that stents significantly reduce angiographic restenosis compared with balloon angioplasty (BENESTENT: 22% vs 32%; STRESS: 32% vs 42%, respectively). These results were further corroborated in the BENESTENT II trial, in which the six-months angiographic restenosis rate was 16%.[5] With use of drug-eluting stents, the ISR rates are between 8-9 %.[6,7] In the TARGET trial 4,809 patients with similar patient population as in our study were randomized to tirofiban or abciximab during PCI with stent placement and were compared according to whether they received 300 mg of clopidogrel before PCI (93.1%) versus immediately after the procedure.[8] MACE at six months (death, MI, any TVR) was 14.6% vs. 19.8% respectively. In our study the six-month MACE of 10.8% is less than this study even though only a few patients in our study (4.3%) received tirofiban but all received clopidogrel before the PCI.

In our study the six-month stent thrombosis rate was 2% and seen in bare metal stents. All patients (100%) in our study were treated with dual antiplatelet treatment before and after stent implantation. In early studies, definite stent thrombosis at 9 months was 0.4-0.6% of the DES group and in 0.8% of the BMS group.[6, 7] In a recent Denmark study consisting of 12,395 consecutive patients, 8,847 patients were treated with BMS, 3,548 patients received DES and followed up for 15 months.[9] Definite, probable, or possible ST was found in 2.15% patients treated with BMS and in 1.80% patients treated with DES. In another study (TRITON-TIMI 38) comparing prasugrel and clopidogrel in 12,844 patients with ACS followed up for 6-15 months, stent thrombosis was significantly reduced with prasugrel(1.13 vs 2.35%).[10] The incidence of stent thrombosis of 2% is similar to above studies in patients with BMS and receiving clopidogrel.

Our report represents a single centre observational study with no randomized comparison. The study reports early and intermediate term outcome after single and multiple coronary stenting in patients with stable CAD and ACS in the current era of bare metal and drug-eluting stents in our setup.

Conclusion

Results of percutaneous coronary intervention in our setup is excellent with good immediate results, low complication rate, good six-month clinical outcome and is comparable to international standards.

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