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In-Hospital and One-Year Clinical Outcome of Percutaneous Coronary Intervention in a Tertiary Hospital in Oman: Oman PCI Registry

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ABSTRACT

Objectives: The aim of the study was to investigate the in-hospital and one-year clinical outcome of patients treated with percutaneous coronary intervention (PCI) in a tertiary hospital in Oman. ***Methods***: We conducted a retrospective, single-center, observational study looking at patients > 18 years old who underwent a PCI from 1 January to 31 December 2013. The primary end point was the occurrence of a major adverse cardiovascular event (MACE), defined as death, any myocardial infarction (MI), cerebrovascular accident (CVA), and target vessel revascularization (TVR) with either repeat PCI or coronary artery bypass surgery (CABG). Secondary end-points included procedural success rate, angina status, stent thrombosis, and the rate of redo-PCI/CABG for in-stent restenosis. ***Results:*** A total of 1 045 consecutive patients were analyzed. The mean age of the cohort was 58.2±11.2 years. Hyperlipidemia (66.8%), hypertension (55.1%), and diabetes mellitus (45.9%) were the predominant risk factors. Stable angina, ST-elevation MI, non-ST-elevation MI, and post-acute coronary syndrome (ACS) were common indications (approximately 20.0% each). The angiographic and procedural success rate was 95.0%. Forty-six percent of patients had single-vessel disease, 34.4% had double vessel disease, and triple vessel disease was seen in 19.1% of patients. Ninety-eight percent had balloon angioplasty with stenting, and only 1.9% of patients had balloon angioplasty without stenting. The majority of patients had single-vessel stenting (81.3%). A drug-eluting stent was used in 88.4% of patients, and a bare-metal stent in 11.6%. In-hospital MACE was 3.6%. There were 19 in-hospital deaths (1.8%), and four patients (0.4%) had CVA/MI. Out of 1 026 patients discharged, 100 patients were lost to follow-up. Among the 926 patients followed-up, 673 patients (72.7%) were asymptomatic. One-year MACE was 17.0%, including 5.0% death and 6.0% MI. Repeat revascularization was performed in 53 patients (5.7%) for documented in-stent restenosis. Definite stent thrombosis was documented in 10 (1.1%) patients. At discharge, the majority of patients were on post-ACS evidence-based medications, aspirin (100%), clopidogrel (99.6%), statin (97.6%), beta-blocker (88.7%), and angiotensin-converting-enzyme inhibitors (83.9%). ***Conclusions:*** Omani patients treated with PCI were much younger than Western patients with a high prevalence of risk factors. Successful PCI was achieved in a large percentage of patients with a low incidence of in-hospital complications and mortality. At one-year follow-up, the majority patients had a good clinical outcome.

Percutaneous coronary intervention (PCI) is the major treatment strategy recommended for patients presenting with acute coronary syndrome (ACS) or stable coronary artery disease (CAD).[1] Of late, two large ACS registries from the Middle East and Oman, namely Gulf registry of acute coronary events (Gulf-RACE I) and II have reported a high incidence and prevalence of ACS in the Middle East population including Oman.[2,3] Two striking results from these registries are the occurrence of ACS in a younger population in the Middle East (mean age 59 years) and low implementation of coronary intervention including PCI (11%).

Presently in Oman, Royal Hospital is one of the two public hospitals with catheterization facilities and performs a large number of procedures annually. Patients either present directly to the hospital or are transferred from peripheral hospitals. However, there is a paucity of data about the short- and long-

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term results of PCI in this institute. However, there was a study from this hospital about the PCI results published in 2008 involving a small number of patients.[4] Recently, the number of intervention procedures has increased markedly, and as a result, a registry of PCI procedures was initiated.

At present, there is a need to know the PCI outcome using this registry data and any deficiencies in patient management to help formulate improvement strategies. The objective of the registry was to determine the current practice of PCI at our hospital including clinical characteristics, angiographic profile, and in-hospital and one-year clinical outcomes. Furthermore, the registry could be used to determine adherence to published guidelines for PCI management including deficiencies and gaps in the performance of PCI at our hospital.

The aim of this study was to report in-hospital and one-year clinical outcome of consecutive patients undergoing PCI during 2013 at Royal Hospital. The study would also generate local data to be compared with those of other parts of the world and help local health care authorities plan PCI strategies in Oman.

METHODS

We conducted a retrospective single-center observational study of all patients who underwent PCI in Royal Hospital from 1 January to 31 December 2013 with a one-year follow-up from 1 January to 31 December 2014. The study population consisted of patients presenting to Royal Hospital, Oman, and those referred from peripheral hospitals. Males and females > 18 years old, admitted to Royal Hospital who underwent a PCI in 2013 were included in the study. Those who underwent a coronary angiogram were excluded. Each patient was included only once during index PCI admission. Repeat admission for other vessel PCI was excluded from the analysis.

Data was collected from computer medical records and entered in a case report form (CRF) for analysis. One-year follow-up data was collected either from clinic visits or by telephone. Institutional ethical committee approval was obtained. Statistical analyses was done for risk factors, clinical presentation, angiographic profile, PCI details, stents used, medication use, and in-hospital and one-year outcome following PCI. Baseline characteristics of patients are summarized in terms of frequencies and percentages for categorical variables and by means and standard deviation (SD) for continuous variables. All data was processed using SPSS Statistics (SPSS Statistics Inc., Chicago, US) version 15.

Definitions of data variables in the CRF are based on the American College of Cardiology/American Heart Association (ACC/AHA) guidelines.[1,5–7] Conventional risk factors including age, gender, diabetes, hypertension, dyslipidemia, current smoking (within one year), and family history of CAD were noted. Previous conditions such as myocardial infarction (MI), PCI, coronary artery bypass surgery (CABG), peripheral vascular disease (PVD), cerebrovascular accident (CVA) or transient ischemic attack (TIA), and chronic kidney disease (CKD) were also noted.

Diabetes was defined as having a history of diabetes diagnosed and treated with medication and/or insulin or fasting blood glucose 7.0 mmol/L (126 mg/dL) or HBA_{1c} ≥ 6.5%. Hypertension was defined as having a history of hypertension diagnosed and treated with medication, blood pressure ≥ 140 mmHg systolic or 90 mmHg diastolic on at least two occasions. Hyperlipidemia was defined as a history of dyslipidemia diagnosed and/or treated by a physician or total cholesterol > 5.18 mmol/L, low-density lipoprotein ≥ 3.37 mmol/L or high-density lipoprotein < 1.04 mmol/L. Current smoker was defined as smoking cigarettes, water pipe, cigar or chewing tobacco within one year of admission. CKD was defined as estimated glomerular filtration rate (eGFR) < 60 mL/min/1.73m^2 for three months or more, with or without kidney damage or on dialysis. If no eGFR data was available, serum creatinine > 177 mmol/L was marked as CKD.

Angiographic and procedural notes were reviewed. Single vessel disease was considered present if there was more than 70.0% diameter stenosis on visual assessment in the left anterior descending (LAD), left circumflex (LCX), right coronary (RCA) arteries, or a major branch, or > 50.0% left main stenosis or for in-stent restenosis. The stented artery, number of stents used, type of the stent, procedural success, and complications were noted. Left ventricular ejection fraction was noted from echocardiographic or catheterization records. PCI was performed according to standard clinical practice through the femoral approach, except in very few patients who underwent PCI by the radial route. An intra-aortic balloon pump

(IABP) was inserted in patients with cardiogenic shock as per operator discretion. Per-procedure all patients received unfractionated heparin 1000 units/kg bolus intravenous. Patients undergoing primary angioplasty or those with intracoronary thrombus received intracoronary bolus Tirofiban (glycoprotein IIb/IIIa antagonist) followed with tirofiban infusion for 12–24 hours at operator discretion. Patients received a bare metal stent (BMS) or a drug-eluting stent (DES) according to the indication. All patients received 75–300 mg of aspirin within 24 hours before the procedure. Post-procedure, 75 mg was advised indefinitely. High-dose statin and clopidogrel were administered for all patients; 600 mg oral loading dose pre-procedure followed by 150 mg daily for a week, then 75 mg daily for one month in patients with BMS and for one year in patients with DES. Post-procedure access sheaths were removed according to the department protocol with use of compressors. All patients were followed-up daily until discharge. The access site was examined for any local complications. Contrast nephropathy was defined as either a 25.0% increase in serum creatinine from baseline or 44 µmol/L increase in absolute value within 48–72 hours of PCI. A large hematoma was defined as > 5 cm. Significant bleeding was defined as hemoglobin drop > 5 gm% or required > 2 packs of red blood cells for transfusion. Discharged patients were given clinic follow-up appointments for those in the Muscat region. Those outside of Muscat were followed-up in regional hospitals.

The primary end point of this study was the occurrence of major adverse cardiovascular events (MACE), defined as death (from any cause), any MI, CVA and target vessel revascularization (TVR) with either repeat PCI or CABG.[1,5–7] MI was documented by the highly sensitive troponin T rise (> 14 pg/mL) with either ischemic symptoms or ST elevation/depression, new pathologic Q waves on electrocardiogram, from discharge, or as documented in outpatients notes. Post-PCI infarction was considered as a > 5 times rise in troponin T from baseline levels. TVR was defined as any repeat percutaneous intervention or surgical bypass of any segment of the target vessel which was stented before.

Secondary end points included: (1) procedural success rate, defined as successful PCI without associated in-hospital major clinical complications; (2) angina symptoms at one-year; (3) stent thrombosis, defined as definite stent thrombosis occurring when clinical presentation was consistent with ACS and angiography examination confirmed stent occlusion or thrombus; and (4) rate of in-stent restenosis (ISR), defined as > 50.0% angiographic restenosis on follow-up within one-year resulting in either repeat-PCI or CABG.

RESULTS

We collected data from 1045 consecutive patients who underwent a PCI between 1 January and 31 December 2013. Omani nationals made up 92.2% (n = 964) of patients, and expatriates the

Table 1: Clinical characteristics of patients (n = 1 045) who underwent a PCI at Royal Hospital between 1 January and 31 December 2013.

Characteristics	Number	Percentage
Age, mean±SD, years	58.2±11.2	
Omani	964	92.2
Expatriate	81	7.8
Male	776	74.3
Female	269	25.7
Dyslipidemia	698	66.8
Hypertension	576	55.1
DM	480	45.9
Previous MI	359	34.4
Current smoker	209	20.0
Previous PCI	209	20.0
Family history CAD	176	16.8
Previous CABG	64	6.1
CKD	54	5.2
History of CVA/TIA	38	3.6
PVD	9	0.9
Stable angina	252	24.1
STEMI	229	21.9
Thrombolysed	92	40.1
Transferred	137	59.9
NSTEMI	223	21.3
Unstable angina	98	9.4
Elective post ACS	224	21.4
Cardiogenic shock	19	1.8

DM: diabetes mellitus; 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; STEMI: ST-elevation MI; NSTEMI: Non-ST elevation MI; ACS: acute coronary syndrome.

remaining 7.8% (n = 81 patients). Among the PCI patients, 776 (74.3%) were male and 269 (25.7%) were female. The mean age was 58.2±11.2 years. The most common risk factor was dyslipidemia in 698 (66.8%) patients followed by hypertension in 576 (55.1%) patients and diabetes mellitus in 480 (45.9%) patients. Twenty percent of patients (n = 209) smoked, and 16.8% (n = 176) had a family history of CAD. Three hundred and fifty-nine (34.3%) patients had a history of MI; 209 (20.0%) had previous PCI; and 64 (6.1%) had previous CABG. The most common indication for PCI was stable angina (n = 252; 24.1%) followed by ST-elevation MI (STEMI) (n = 229; 21.9%), non-ST-elevation MI (NSTEMI) (n = 223; 21.3%), unstable angina (n = 98; 9.4%), and elective post-ACS transferred patients (n = 224; 21.4%). Nineteen patients (1.8%) presented with cardiogenic shock [Table 1].

The angiographic and procedural success rate was 95.0% (n = 993; Table 2). Analysis of angiographic data revealed that single-vessel disease (n = 485; 46.4%) was more prevalent than double-vessel disease (n = 360; 34.4%). Two hundred patients (19.1%) had triple-vessel disease. The mean left ventricle ejection fraction (EF) was 46.1±13.7% of the 895 patients in whom EF was documented.

The majority of patients underwent single-vessel stenting (n = 850; 81.3%), 141 (13.5%) had double-vessel and 13 patients (1.2%) had triple-vessel stenting. Twenty-one (2.0%) patients underwent stenting of the left main or venous graft or left internal mammary graft angioplasty. Balloon angioplasty without stenting was performed in 20 patients (1.9%). A total of 1 618 stents were implanted in 1 045 patients with a mean 1.6±0.8 stents per patient. The majority of stents used were

Table 2: Angiographic and procedural results in the study population (n = 1 045).

Procedure	Number	Percentage
Procedural success	993	95.0
Single-vessel disease	485	46.4
Double-vessel disease	360	34.4
Triple-vessel disease	200	19.1
Single-vessel PCI	850	81.3
Double-vessel PCI	141	13.5
Triple-vessel PCI	13	1.2
Other (LIMA, LMCA & SVG)	21	2.0
POBA	20	1.9
Implanted stents	1618	
Stents per patient, mean±SD	1.6±0.8	
DES	1431	88.4
BMS	187	11.6
Target lesions	1 167	
LAD lesion	563	48.2
RCA lesion	318	27.2
LCX lesion	286	24.5
EF, %	895	46.1±13.7

PCI: percutaneous coronary intervention; LIMA: left internal mammary artery; LMCA: left main coronary artery; SVG: saphenous vein graft; POBA: plain old balloon angioplasty; SD: standard deviation; DES: drug-eluting stent; BMS: bare metal stent; LAD: left anterior descending artery; RCA: right coronary artery; LCX: left circumflex artery; EF: ejection fraction.

Table 3: In-hospital and one-year clinical outcomes (n = 1 045).

	Number	Percentage
In-hospital MACE	**38**	**3.6**
Death	19	1.8
MI	4	0.4
CVA	4	0.4
Repeat PCI	11	1.1
Urgent CABG	0	0.0
Contrast mephropathy > 44 µmol/L	13	1.2
IABP	11	1.1
Arteriovenous fistula	7	0.7
Hematoma > 5 cm	5	0.5
Pseudoaneurysm	4	0.4
Hb drop > 5 gm% or > 2 PRBC	1	0.1
Dialysis	1	0.1
Follow-up patients	**926**	**90.3**
Lost to follow-up	**100**	**9.7**
One year MACE (n = 926)	**157**	**17.0**
Death	46	5.0
MI	55	6.0
NSTEMI	36	3.9
STEMI	19	2.1
Redo-PCI	38	4.1
CABG	15	1.6
CVA	3	0.3
Asymptomatic	673	72.7
Medically treated angina	8	0.9
Stent thrombosis	10	1.1
Other vessel revascularization	81	8.7

MACE: major adverse cardiac events; MI: myocardial infarction; CVA: cerebrovascular accident; PCI: percutaneous coronary intervention; CABG: coronary artery bypass surgery; IABP: intra-aortic balloon pump; Hb: hemoglobin; PRBC: packed red blood cell transfusion; NSTEMI: non-ST elevation MI; STEMI: ST elevation MI.

Table 4: Medications at discharge (n = 1 045).

Medication	Number	Percentage
Aspirin	1045	100.0
Clopidogrel	1041	99.6
Statin	1020	97.6
Beta-blocker	927	88.7
ACEI	877	83.9

ACEI: angiotensin-converting enzyme inhibitor.

DES (n = 1 431; 88.4%) with 187 (11.6%) BMSs deployed. There were 563 target lesions in the left anterior descending artery, 318 in the right coronary artery, and 286 in the left circumflex artery.

The overall in-hospital MACE was 3.6% [Table 3]. There were 19 in-hospital deaths (1.8%), and four patients (0.4%) had a CVA and MI before hospital discharge. Eleven (1.1%) patients had a repeat PCI, and no patients required urgent CABG. Contrast nephropathy was seen in 13 (1.2%) patients with one patient requiring dialysis. IABP was used in only 11 (1.1%) patients. Femoral arteriovenous fistula was detected in seven (0.7%) patients, a large hematomata in five (0.5%) patients, and a pseudoaneurysm in four (0.4%) patients. Only one patient (0.1%) needed a blood transfusion. Out of 1 026 patients discharged 100 patients were lost to follow-up. Follow-up data was available for 926 patients [Table 3]. Overall one-year MACE was 17.0% (n = 157 patients). There were 46 late deaths (5.0%), and 55 patients sustained MI (6.0%) with 36 (3.9%) NSTEMI patients and 19 (2.1%) STEMI patients. Repeat revascularization for target vessel (PCI or CABG) was done in 53 patients (5.7%) for documented in-stent restenosis. A total of 673 patients (72.7%) were asymptomatic at follow-up. Definite stent thrombosis was documented in 10 (1.1%) patients. Late CVA was seen in three patients (0.3%), and 81 patients (8.7%) needed revascularization (either PTCA or CABG) for other vessel involvement. Eight patients (0.9%) with stable angina were medically treated.

At discharge, the majority of patients were on post-ACS evidence-based medications [Table 4].

DISCUSSION

The predominant findings from the first large Oman PCI registry were: (1) Omani patients undergoing PCI were much younger with a high prevalence of risk factors. (2) Successful PCI was achieved in a large percentage of patients with a low incidence of in-hospital complications and mortality. (3) One-year overall MACE was high.

The landmark USA National Cardiovascular Data Registry (NCDR) CathPCI Registry for coronary angiography and PCI results published in 2012 included 941 248 patients undergoing PCI in > 900 centers. Approximately two-thirds of patients were male (67.0%) with a median age of 65 years.[8] In the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) registry the mean age was 67 years.[9] In our study, Omani PCI patients were younger and predominantly male. Hypertension was the predominant risk factor (82.0%) in the NCDR registry followed by diabetes mellitus (36.0%). In the Oman PCI registry, dyslipidemia was the predominant risk factor (66.8%). However, diabetes was highly prevalent (present in 45.9% of patients). This high prevalence of diabetes mellitus has been noted in previous ACS registries from Oman.[2,3] In the NCDR registry, CKD, CVA, and PVD were highly prevalent among PCI patients, but in the Oman registry they were low, which is probably due to the younger age of patients.[8]

In the NCDR data among patients undergoing PCI, approximately 70.0% had ACS at presentation.[8] In the SCAAR data of a total 70 479 patients ACS was the reason for 78.0% of PCIs.[9] In this study, 50.0% of PCI patients had ACS and the rest were elective cases, which differs from Western registry data. This difference may be due to a high number of patients with ACS undergoing immediate PCI in the US and European registry, non-performance of primary PCI at our institute, and non-availability of catheterization facilities at peripheral hospitals for thrombolysed STEMI patients transferred to our institute for PCI.

In the CathPCI registry, procedure success was 96.0%, which is similar to Oman data.[8] Triple-vessel disease was seen in 39.0% of patients compared to 19.1% in the Oman registry. This is probably due to the high prevalence of multivessel disease in elderly; however, in the CathPCI registry, the majority of patients underwent single-vessel stenting (86.0%), which we also observed. The ideal goal in multivessel stable patients with CAD undergoing PCI is complete revascularization; however, this does not happen in practice, and CABG is preferred.[1,10] This is because the rates of MI and late mortality are similar in patients with and without complete

revascularization post-PCI.[1] In addition, in ACS, culprit vessel revascularization is the preferred strategy.[1] In another large registry (the Euro Heart Survey PCI registry), multivessel PCI was associated with a higher rate of post-procedural MI.[11,12] In Portuguese and Greek registries, DES were used in about 75.0% of patients compared to 88.4% in the Oman registry.[13,14] The use of DES has increased exponentially in our hospital compared to 2008 data (8.0%).[4] This is due to the removal of the DES payment option for nationals.

The NCDR registry recorded total MACE four-times higher than our data.[8] STEMI MACE was high probably due to primary PCI performed in STEMI patients, whereas primary PCI in Oman was performed in a negligible number of patients (exact data not available due to inconsistency in reporting primary PCI). The unadjusted in-hospital mortality was 1.8% in Oman registry and 1.4% in the NCDR registry.[15] Contrast nephropathy (1.2%) and the need for dialysis were very low (0.1%) in Oman registry. In another NCDR analysis, 7.0% of PCI patients developed acute kidney injury with 0.3% requiring new dialysis.[16] Cardiogenic shock was present in 1.9% of patients undergoing PCI during admission in the NCDR registry with use of IABP in 2.9%.[8] Shock was seen in 1.8% of patients with use of IABP at 1.1% in our study.

The use of IABP has reduced in Oman after various studies and guidelines downgraded its use in cardiogenic shock.[1] In a study using high sensitivity troponin T (hs-TnT), peri-procedural MI was observed in 4.3% of patients compared to 0.4% in this study .[17] In the Euro Heart Survey (EHS) PCI registry, stroke was observed in 0.4% of procedures in the total population, in 0.3% of PCIs in elective patients, and 0.6% in PCIs performed for ACS.[18] In a contemporary analysis from the NCDR, the incidence of PCI-related stroke was 0.22%. This number was 0.4% in the Oman registry, which was very similar to EHS PCI registry.[19] Recently the NCDR reported the rate of emergency CABG at 0.4%, which was nil in the Oman registry.[20] The incidence of femoral access vascular complications in various reports ranges from 2% to 6%.[1,21] In the Northern New England PCI Registry vascular complications were noted in 6% of patients, which was 1.7% in this registry.[21]

In the SCAAR registry, the overall mortality rate one year after a PCI was 4.6%.[9] In the Oman registry, overall one-year mortality was 5.0%. We observed a one-year MI rate of 6.0% of patients compared to 7.7% in the SCAAR registry. One-year post- PCI, definite stent thrombosis occurred in 1.05% of patients in the SCAAR registry compared to 1.1% in our study. In a large registry of 18 334 PCI patients, the cumulative incidence of definite stent thrombosis at 1–3 years was 1.0% with second generation DES, which was similar to our findings where we used second generation stents during 2013.[22] Our data showed a one year TVR for documented in-stent restenosis rate of 5.7%, which compares favorably to published data from the SCAAR registry (3.4%) and Germany (10%).[9,23]

In our study, the majority of patients were asymptomatic (72.7%) with angina reported in 27.0% of patients, which was less than that reported in other studies (range = 28– 32%).[24,25] In an European study, the percentages of patients on antiplatelet therapy and other medications at the time of hospital discharge was lower than that observed in our study (aspirin 100% vs. 98.0%, clopidogrel 99.6% vs. 99.0%, statins 97.6% vs. 81.0%, beta-blockers 88.7% vs. 73.0%, and angiotensin II receptor blockers/angiotensin-converting enzyme inhibitors 83.9% vs. 64.0%).[26]

The major limitation of this study is its observational and retrospective analysis of PCI and the possible confounding variables not controlled for in the study. There may have been selection bias when selecting PCI cases, and the number of post-interventional complications may be underreported. Patients lost to follow-up may have had MACE. Since we reported only patients admitted to Royal Hospital, the results are not generalizable to other hospitals in Oman.

CONCLUSIONS

Omani patients undergoing PCI were much younger and had a high prevalence of risk factors compared to data from other registries. Successful PCI was achieved in a high percentage of patients with a low incidence of in-hospital complications and mortality. At one-year follow-up, the majority of patients had good clinical outcomes.

Disclosure
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