Original Article

Palestinian Medical and Pharmaceutical Journal (PMPJ). 2018; 3(2): 40-49

Characteristics and mortality of percutaneous coronary intervention patients in Palestine: a prospective cohort study

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Received: (17/12/2017), Accepted: (01/04/2018)

ABSTRACT

According to the American Heart Association, cardiovascular diseases are the main cause of death worldwide in 2015 [1]. A common consequence of coronary heart disease is acute coronary syndrome (ACS),which includes ST elevation myocardial infarction, Non ST elevation myocardial infarction and unstable angina [2]. ACS causes more than 2.5 million hospitalizations in the world every year [3].In Palestine, myocardial infarction and ischemic heart disease are the leading cause of death according to the Palestinian health information center. During 2012, twenty percent of the reported deaths among age Group 20 - 59 years were due to myocardial infarction and ischemic heart disease. In the Palestinian older age group, more than 60 years, mortality due to cardiovascular diseases was 19.4% of the overall mortality causes (Palestinian Ministry Of Health/2012) Management of ACS includes both conservative and invasive methods; the earlier consists of medical management, which can be followed by catheterization and revascularization if ischemia persists despite medical therapy. The Invasive method; that's cardiac catheterization, done within 4 to 24 hours after admission, followed by revascularization using percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) [4].The number of PCI procedure performed has been dramatically increasing during the last years in Palestine, this rapid growth in PCI as an alternative to medical therapy or coronary artery bypass graft (CABG) surgery is mainly due to PCI being less invasive and less expensive choice. Factors affect the outcome and the prognosis of PCI including age, gender, hypertension, diabetes, Creatine kinase (CK) [5].Through our research, we found insufficient data among the Palestinian population regarding PCI. We conducted this prospective study to describe patients' characteristics and their outcome in Palestine. The objectives of our study was to assess the relationship between the prognosis of primary PCI procedure and demographic factors, medical history , lab results and PCI data and to follow up each patient readmission due to cardiovascular events "including stroke, revascularization procedures, heart failure and chest pain" using the medical records within 30 days.

Keywords :PCI, Mortality, Palestine

METHODS

Study design

A prospective cohort design was conducted; data were collected from patients who have undergone PCI using structured questionnaire-based interviews as well as patients' medical files for laboratory results and PCI reports.

The patients were followed up in both short term (30 days after the procedure) and long term (6 months after the procedure) periods. Post-procedure cardiovascular related mortality was documented using both medical history obtained by phone calls and medical files.

Study population and Sampling

The sample was taken conveniently; all patients admitted to Al-Arabi Hospital (private hospital) and An-Najah National University hospital (teaching hospital) in Nablus city for PCI procedure during the study period between September 2014 and December 2014. Inclusion criteria were: all males and females, Primary

(Defined as symptoms for less than 12 hours prior to intervention) and secondary patients (symptoms for more than 12 hours

prior to intervention), all types of ACS were included (STEMI, non STEMI and unstable angina) were included.

TOOLS

To collect the data, aquestionnaire composed of three parts was used; the first part consists of demographic factors: age, gender, smoking, marital status, hypertension (HTN), diabetes mellitus (DM), statin intake, degree of pain before and after the procedure, renal insufficiency and primary or secondary presentation, previous history of PCI. The second part includes laboratory tests: Cardiac markers, white blood cells count (WBC), creatinine level. The last part includes PCI procedure variables: number and type of the involved arteries, PCI access and the type of the used stent.

Data collection

The permission was taken from the IRB committee at An-Najah National University as well as the targeted hospitals. Consent form was signed by each patient prior to the data collection. Demographic data were collected by interviewing each patient by the investigators, PCI reports written by interventional cardiologists were reviewed and medical files were used to collect laboratory tests results. Confidentiality and anonymity of participants were assured. Patients' identities were coded in the files instead of using their names. All the records are kept in save closed lockers and will not be used for purposes other than the scientific research by the investigators.

Statistical analysis

Data analysis was performed using SPSS 20 software. Mean and standard deviation were used for continues variables, whereas frequencies were used for categorical variables. Inferential statistics as chi square and logistic regression were used to analyze the relationship between the variables and outcomes. *P* value less than 0.05 was considered to be significant.

RESULTS

The number of participants was 283, and after applying exclusion criteria, 56 participants were excluded and the total included number was 227.

Demographic factors

Table 1 shows that 157 (69.1%) of the sample were secondary PCI patients and 70 (30.9%) of them were primary PCI patients. Regarding demographic characteristics, most of the patients were in the age group between 30-59 years in both primary and secondary. PCI number of primary PCI patients is 44 (62.8%) when compared to number of secondary PCI patients 84 (53.4%). The dominant gender was male in both primary PCI patients n=63 (90%) and secondary PCI patients n=130 (82%). The greater part of the sample were married; primary PCI patients n=65 (92.9%) and secondary PCI patients n=140 (89.2%). None of these variables were statistically significant.

Table(1): Comparison of demographic characteristics between primary and secondary percutaneous coronary intervention patients.

Variable		Primary (n = 70)	Secondary (n = 157)	χ^2	*P* Value
Age	30-59	44 (62.8%)	84 (53.5%)	4.016	0.547
	60-79	24 (34.3%)	70 (44.5%)		
	80-89	2 (2.9%)	3 (1.9%)		
Gender	Male	63 (90%)	130 (82.8%)	1.969	0.161
	Female	7 (10%)	27 (17.2%)		
Marital Status	Single	1 (1.4%)	6 (3.8%)	1.094	0.579
	Married	65 (92.9%)	140 (89.2%)		
	Widow/er	4 (5.7%)	11 (7.0%)		

* Significant at p value of 0.05.** Significant at p value of 0.01

Cardiovascular risk factors

Most of the patients in both cohorts (primary PCI vs. secondary PCI) were smokers, the percentage of smokers in the primary PCI patients was significantly higher than it is in secondary PCI patients n=48 (68.6%), n=79 (50.3%), respectively with a *p*-value of (0.038). Regarding hypertension, 38 (54.3%) of primary PCI patients were non-hypertensive. In contrary to secondary PCI patients who were mainly hypertensive n=101 (64.3%) with a *p*-value of (.009). The majority of patients in both groups were non-diabetics; primary PCI patients n=45 (64.3%) and secondary PCI patients n=85 (54.1%). Most of the patients in both groups were not on statin prior to PCI procedure; eleven primary PCI patients were on statin (15.7%) when compared to 37 secondary PCI patients (23.6%). Most of the patients in both groups didn't have any level of renal insufficiency, the number of patients who had renal insufficiency in the primary PCI group was 2 (2.9%), and in secondary PCI group was 13 (8.3%). Number of patients without previous history of PCI was more than those who had previous PCI; primary PCI patients were 43 61.4%, secondary PCI patients were 87 (55.4%). There was no statistical difference between both groups regarding diabetes, statin intake, renal insufficiency and history of previous PCI.

Table(2): Comparison of cardiovascular risk factors between primary and secondary percutaneous coronary intervention patients

Variable		Primary (n = 70)	Secondary (n = 157)	χ^2	*P* Value
Smoking	Nonsmoker	12 (17.1%)	44 (28.0%)	6.564	0.038*
	Smoker	48 (68.6%)	79 (50.3%)		
	Ex-smoker	10 (14.3%)	34 (21.7%)		
Hypertension	No	38 (54.3%)	56 (35.7%)	6.916	0.009**
	Yes	32 (45.7%)	101 (64.3%)		
Diabetes	No	45 (64.3%)	85 (54.1%)	2.036	0.154
	Yes	25 (35.7%)	72 (45.9%)		
Statin Intake	No	59 (84.3%)	120 (76.4%)	1.790	0.181
	Yes	11 (15.7%)	37 (23.6%)		
Renal Sufficiency	No	68 (97.1%)	144 (91.7%)	2.307	0.129
	Yes	2 (2.9%)	13 (8.3%)		
Previous History of PCI	No	43 (61.4%)	87 (55.4%)	0.716	0.398
	Yes	27 (38.6%)	70 (44.6%)		

* Significant at p value of 0.05** Significant at p value of 0.01

PCI characteristics

In both cohorts, most of the patients in both groups presented with 1 diseased coronary vessel (primary PCI patients were 51 [72.9%] and secondary n=110 [70.1%]) where the LAD artery was the most common vessel to be involved (primary PCI patients with diseased LAD n=41 [58.6%] and secondary PCI patients were n=85 [54.1%]). Radial access was used in 36 (51.4%) primary PCI patients, meanwhile femoral access was used in 103 (65.6%) secondary PCI patients, and this is statistically significant with a *p* value of (0.015). Drug eluting stents were the main type in both primary PCI n= 39 (55.7%) and secondary PCI patients n= 109 (69.4%), and this is statically significant with a *p* value of 0.045. Majority of patients in both groups reported cessation of cardiac pain after revascularization; 37 (54.4%) in primary PCI patients and 98 (67.6%) in secondary PCI patients.

Table(3): Comparison of PCI characteristics between primary and secondary percutaneous coronary intervention patients

Variable		Primary (n = 70)	Secondary (n = 157)	χ^2	*P* Value
Number of Diseased Epicardial Vessels	One	51 (72.9%)	110 (70.1%)	1.261	0.738
	Two	16 (22.9%)	42 (26.8%)		
	Three	3 (4.3%)	4 (2.5%)		
	Four	0 (0.0%)	1 (0.6%)		
Type of Vessels Involved	LAD	41 (58.6%)	85 (54.1%)	0.385	0.535
	RCA	27 (38.6%)	58 (63.9%)	0.055	0.815
	Circumflex	18 (52.7%)	48 (30.6%)	0.554	0.457
	OM	5 (7.1%)	18 (11.5%)	0.319	0.993
Percutaneous Coronary Intervention Access	Femoral	34 (48.6%)	103 (65.6%)	5.871	0.01**
	Radial	36 (51.4%)	54 (34.4%)		
Type of Used Stent	Bare metal	31 (44.3%)	48 (30.6%)	4.012	0.045*
	Drug eluting	39 (55.7%)	109 (69.4%)		
Persistence of cardiac pain after revascularization	No	37 (54.4%)	98 (67.6%)	3.462	0.063
	Yes	31 (45.6%)	47 (32.4%)		

* Significant at p value of 0.05, OM; Obtuse marginal .** Significant at p value of 0.01

Laboratory results

Cardiac markers (CK-MB and troponin) were positive in majority of primary PCI patients n= 49 (70.0%), whereas majority of secondary PCI patients had negative cardiac markers n= 80 (51.0%), this is statistically significant (*p* value< 0.001). White blood cells counts were normal (ranging between 4000 cell/mm³and 11,000 cell/mm³) in both PCI patients primary n= 43 (61.4%), secondary n=114 (72.6%), elevated WBC counts were seen in 37.1% of primary PCI patients and in 24.8% of secondary PCI patients. Creatinine level were elevated (more than 1.2 mg/dl) in four primary PCI patients (5.7%) and twenty three secondary PCI patients (14.6%) whereas the rest of the PCI patients had normal creatinine levels (*p* value= 0.05).

Table(4): Comparison of laboratory results between primary and secondary percutaneous coronary intervention patients

Variable		Primary (n = 70)	Secondary (n = 157)	χ^2	*P* Value
Cardiac Markers	Negative	17 (24.3%)	80 (51.0%)	35.83	< 0.001**
	Positive	49 (70.0%)	44 (28.0%)		
	Missing	4 (5.7%)	33 (21.0%)		
White Blood Cell	< 4000 cell/ mm³	1 (1.4%)	4 (2.5%)	3.71	0.156
	Normal	43 (61.4%)	114 (72.6%)		
	> 11.000 cell/mm³	26 (37.1%)	39 (24.8%)		
Creatinine Level	Normal	66 (94.3%)	134 (85.4%)	3.68	0.05*
	Elevated (> 1.2 mg/dl)	4 (5.7%)	23 (14.6%)		

* Significant at p value of 0.05 ** Significant at p value of 0.01

Follow up outcomes

At the end of the follow up periods (short term period of 30 days and long term period of 6 months post procedure), four (6.1%) of primary PCI patients and four (2.8%) of secondary PCI patients were dead by the end of the short term period, while the mortality rate for both groups was 0% by the end of long term follow up. Follow up was missed in 4 of primary PCI patients and in 16 of secondary PCI patients.

Table(5): Comparison of the follow up outcomes between primary and secondary percutaneous coronary intervention patients

Variable		Primary (n = 66)	Secondary (n = 141)	χ^2	*P* Value
Mortality in Short term	No	62 (93.9%)	137 (97.2%)	1.257	0.262
	Yes	4 (6.1%)	4 (2.8%)		
Mortality in Long term	No	66 (100%)	141 (100%)	NA	NA
	yes	0%	0%		

MORTALITY

Logistic regression showed that adverse outcomes were significantly associated with positive history of previous PCI, hypertension, statin intake and femoral PCI access in the overall

sample (there was no statistical difference between primary and secondary PCI follow up outcomes):

Table 6 represents the risk of mortality among primary and secondary PCI patients in terms of previous history of PCI, hypertension, statin intake and PCI access. PCI patients who didn't have previous history of PCI were significantly 0.057 times less likely to die (*p* value=0.037). Those without hypertension were 0.107 times less likely to die with a significance of (*p* value=0.039). A significant increase in mortality (7.00 times) was found among PCI patients who were not on statin therapy prior to the procedure when compared to PCI patients who were on statin therapy (*p* value=0.001). PCI patients who undergone PCI through femoral access were 1.885 times more likely to die when compared to radial access (*p* value= 0.461).

Table(6): Mortality among primary and secondary percutaneous coronary intervention patients

Variable	B	Significance	Exp (B)	95% C.I.for EXP (B)	
				Lower	Upper
Previous History of PCI	-2.858	0.037*	0.057	0.004	0.837
Hypertension	-2.238	0.039*	0.107	0.013	0.890
Statin Intake	3.158	0.001**	7.00	3.350	165.011
PCI Access	0.634	0.461	1.885	0.349	10.190

* Significant at p value of 0.05 .** Significant at p value of 0.01

DISCUSSION

Demographic factors

In the Palestinian population, the age group 30-59 years represented the majority of primary PCI patients (62.8%) and secondary PCI patients (53.4%). While patients between 60-79 years represented 34.3% of primary and 44.5% of secondary patients which is consistent with Feldman study in USA that compared the PCI outcomes based on age groups [6]. Male gender was predominant in both primary and secondary patients, which is consistence with other studies that focused on PCI outcomes in Germany and Netherlands [7, 8]. This could be due to higher prevalence of cardiovascular risk factors (as smoking, DM, HTN, dyslipidemia and diabetes) among males when compared to females in the Palestinian population and

a minority (21.1%) of the Palestinian other countries as the USA [9].

Smokers were more predominant in both primary and secondary PCI patients when compared to nonsmokers; this is mainly because smoking is a risk factor of atherosclerosis and the subsequent acute coronary syndrome [10]. This is also consistent with the results from the Gulf Registry of Acute Coronary Events study in Oman which found that smoking is one of the important modifiable risk factors [11].

Non-diabetic patients represented the majority of both cohorts and non-hypertensive patients were the majority of primary PCI patients. This is inconsistent with other studies and it could be due to undiagnosed patients or because history only was used to identify diabetic and hypertensive patients in our study.

Many studies show that statin intake decreases the risk of ACS [12, 13]. Statins are found to decrease plaque volume which is the underlying pathology of coronary artery disease [14].We found that only patients are on statin medications which could explain the increased incidence of ACS in the Palestinian population.

A small proportion of the patients had renal insufficiency and these were mainly among secondary PCI patients. Renal insufficiency itself can be a risk factor of ACS since traditional risk factors for renal injury (age, DM, HTN, dyslipidemia) are common with those of ACS, also chronic kidney disease is common in cardiovascular patients [15, 16].

PCI characteristics

The majority of both primary and secondary PCI patients had only one diseased coronary vessel which was mostly LAD, however about one third of the total sample (28.6%) have more than one diseased vessel which is consistent with finding that patients with one vessel disease are at high risk of having multiple vessel disease [17].

Drug eluting stents are used in most patients in both cohorts when compared to BMS use, this could be explained by the recommendation that using this type of stents has a better prognosis than BMS use [18, 19].

Of the total patients, about one third of the patients (34.4%) complained of post PCI chest pain which could be due to coronary vessel wall stretching, vessel spasm and/or non-cardiac chest pain [20, 21].

Laboratory results

Most of the patients in both cohorts had positive cardiac biomarkers at admission; however, post PCI cardiac biomarkers are not measured routinely in Palestine although many studies showed that elevated markers are associated post PCI myocardial necrosis and adverse outcomes [22, 23].

Most of the patients had normal WBC count, however, elevated WBC counts were seen more in primary patients when compared to secondary patients (37.1% vs. 24.8%), many studies show that elevated WBC count after PCI are associated with impaired myocardial reperfusion and poor prognosis [24, 25].

Mortality

Eight patients out of 207 (3.86%) were dead by the end of the 30 days period (short term) whereas the remaining patients survived till the end of the long term follow up, this is consistent with 5-year post PCI follow up study that found that patients who survive the first 30 days post PCI had good prognosis and they were less likely to die due to cardiovascular events [26]. Of the eight patients who died, four patients were primary PCI patients (6.1%) and four were secondary PCI patients (2.8%), the higher percentage of mortality in primary PCI patients is inconsistent with other studies [27, 28]. This could be explained by the type of patients in each group, where most of the primary PCI patients presented as acute MI patients and most of secondary PCI patients were elective patients with stable angina and staged PCI.

The number of female patients who died was 2 which is 5.8% of the total number of females [34] when compared to male mortality which was less than 3% (6 patients out of 173 given that 20 male patients were dropped out during the follow up period), this

is consistence with a meta-analysis that shows higher incidence of mortality in women when compared to men [29]. This could be explained due to delay in doctor visit and consultation due to psychological fear [30].

Mortality was less likely in patients without previous history of PCI when compared to patients with previous history of PCIP=0.037, this is consistent with other studies [31]. Hypertension increased the risk of mortality when compared to non-hypertensive patients which support other studies that ensure the adverse effect of hypertension on PCI outcome [32, 33].

Patient who were not on statin therapy prior to PCI procedure showed 7 times more risk to die when compared to patients on statins, this finding is consistent with other studies that show the effect of statin therapy in decreasing mortality [13, 34, 35].

Femoral access was associated with increased risk of mortality; this finding is consistent with other studies showing that using the femoral access is associated with poor prognosis due to increased risk of bleeding, complications and longer hospitalization [36- 38].This also could be due to selection bias of patients undergoing PCI by the cardiologists since we found a significant difference between the access used in primary and secondary PCI patients. The follow up of 20 patients was missed due to inability to contact the patients by phone or medical records at the hospitals.

LIMITATIONS

The sample size was small (227 Patients) and was taken conveniently. Furthermore, the follow up period was only 6 months which is shorter than other studies with a minimum of 1 year follow up period.

Conclusion and Recommendations

1. We found that a large part of Palestinian patients (78.9%) who have ischemic heart diseases are not on statin medications despite the increasing evidence about the effect of statin use in decreasing mortality [15, 35, 36]. Further research about statin intake and patients' adherence in Palestine is recommended.

2. We recommend the use of radial access instead of femoral access since less morbidities are associated with the radial access; lower risk of infection, less bleeding risk and earlier ambulation [40]. Further control and randomized research is recommended.

3. We recommend improving the hypertension screening in Palestine since most of the patients were non-hypertensive which is inconsistent with other studies and this could indicate that hypertension is under-diagnosis. However, further investigation about the prevalence of hypertension in Palestine is needed.

List of Abbreviations and Acronyms

ACS	Acute Coronary Syndrome
CI	Confidence Interval
CK	Creatine Kinase
CABG	Coronary Artery Bypass Graft
DM	Diabetes Mellitus
HTN	Hypertension
IRB	Institutional Review Board
LAD	Left Anterior Descending
N (n)	Number
PCI	Percutaneous Coronary Intervention
SPSS	Statistical Package for the Social Sciences
STEMI	ST elevation myocardial infarction
WBC	White Blood Cells Count

ACKNOWLEDGEMENTS

The authors declare that this research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

We would like to acknowledge An-Najah National University (ANNU), the participants, and the hospitals directors for their cooperation.

CONFLICT OF INTERESTS

The authors report no conflicts of interest in this manuscript.

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