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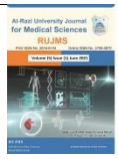

Predictors of Major Adverse Cardiac Events After Percutaneous Coronary Intervention in Sana'a City-Yemen (Single Center Study)

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Abstract:

Background: Recently, many hospitals in Yemen have been started using Percutaneous Coronary Intervention (PCI) procedure for treatment coronary artery disease (CAD), including Dr. Hashim Eraqi hospital. However, there is no systematic research has so far been conducted to predict mortality and morbidity following PCI in Yemen. **Aims**: To estimate the incidence of PCI complications, and identify independent predictors of major adverse cardiac events (MACE) after PCI procedure. **Patients and Methods**: This is retrospective observational study included 202 patients who underwent PCI at Dr. Hashim Iraqi hospital, Sana'a City, Yemen from January 2020 till February 2021. **Results**: Median age was 58.5 (range = 28- 82) years. Out of our study subjects, 100 (49.5%) patients were ≥ 60 years. Majority were males 177 (87.6%). The most prevalent pre procedural risk factors were smoking in 136 (67.3%), sedentary life style in 129 (63.4%), hypertension (HTN) in 101 (50%) and ischemic heart disease (IHD) in 96 (47.5%) patients. In general, the incidence of PCI complications was nearly 28% observed in 56 patients. In hospital mortality occurred in only one patient (0.5%). Renal insufficiency and hypotension were the most common PCI complications observed in 28 (13.9%) and 19 (9.5%) patients respectively. MACE occurred in a total of 39 (19.3%) patients. We have found chronic kidney disease (CKD), pre-PCI left ventricular ejection fraction (LV EF) < 30%, developed cardiogenic shock, underwent multiple stents PCI, post PCI hemoglobin (Hb) < 11, and post PCI serum creatinine (S.Cr) > 2 to be significantly associated with increased MACE likely in hospital. **Conclusion**: The incidence of PCI complications was high in our study. CKD, pre-PCI LV EF < 30%, cardiogenic shock, post PCI Hb < 11, post PCI S.Cr > 2, and multiple stents PCI were independent predictors of MACE.

Keywords: Percutaneous coronary intervention, Major Adverse Cardiac Events, Coronary artery disease, Sana'a, Yemen.

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Introduction

Coronary artery disease (CAD) is the main cause of morbidity and mortality, posing a significant health and economic burden on the majority of developed countries, accounting for about 7.2 million deaths each year[1]. It is predicted that it causes 790,000 heart attacks in the United States each year[2], at a cost of $89 billion in 2016 and expected to rise to $215 billion by 2035 [3].

Improved medicines have reduced CAD-related mortality while boosting survival after a myocardial infarction over the last decades[1]. Percutaneous coronary intervention (PCI), which has achieved tremendous progress in the therapy of obstructive CAD during the last three decades is one of the improved therapies[4]. In addition, for ST-elevation myocardial infarction, PCI is the primary therapeutic option[5].

Stent placement is now the preferred treatment option in a considerable proportion of patients with atherosclerotic coronary stenosis who have had PCI[6].

Over the last decades, advances in technology and personal experience, as well as the use of stents and intensive antiplatelet medication, have dramatically reduced the incidence of serious periprocedural complications of PCI[7].

Recently, many hospitals in Yemen have been started using PCI procedure for treatment CAD, including Dr. Hashim Eraqi hospital. Despite the need to estimate the incidence of PCI complications, as well as find out effectiveness and safety of PCI procedure itself, no systematic research has so far been conducted to identify predictors that may estimates risks associated with PCI procedure, or even estimate the incidence of PCI complications in Yemen. So, our study is the first, and encouraging further future researches. In addition, information drawn from our study allows us to estimate the risk of PCI complications according to patient and lesion characteristics; therefore, every physician needs to consider if the risk to benefit ratio of the planned procedure is appropriate on the basis of these data before performing any intervention.

Patients and Methods

A retrospective observational study included all patients over the age of 18 and under the age of 85 who underwent therapeutic PCI at Dr. Hashim Iraqi hospital in Sana'a City, Yemen from January 2020 to February 2021. Patients who underwent only diagnostic coronary angiogram procedure, and who referred to coronary artery bypass grafting (CABG), as well as those with sepsis, active cancer, and COVID-19 were excluded from analysis. Procedures were performed either electively or primary by experienced operators. The attending physician made the decisions on the interventional procedures and devices employed, as well as whether or not to use glycoprotein IIb/IIIa receptor inhibitors and intra-aortic counter pulsation balloons. In all cases, transfemoral catheterization was the access route of choice, and the arteriotomy site was the femoral artery. Due to a scarcity of bare metal stents in the hospital's lab, only second generation drug eluting stents were attempted to be implanted in all cases. Full doses of aspirin (325 mg) and Clopidogrel 300-600 mg orally as single loading doses were given on the day of procedure. If patients had had prior allergic reactions to contrast, prednisone was generally given for at least three doses beforehand. Patients with food allergies and asthma were premedicated with hydrocortisone, and Chlorphenamine injection, as well as Ondansetron injection was given to all patients to control possible nausea, and vomiting. Coronary intervention was performed with full sterile technique. Lidocaine 2% was used as the local anesthetic agent. All in the hospital PCI complications were collected, as well as major adverse cardiovascular event (MACE) which including procedural mortality, myocardial infraction (MI), renal insufficiency, hematoma, stent thrombosis and stent restenosis, stroke, and ischemic target vessel revascularization. The hospital's institutional review boards gave its approval to this study. Data collection was based on retrospective chart review, hence informed consent was not required.

Statistical analysis

The collected data was entered into the statistical package for the social sciences (SPSS) version 25.0 for analysis (SPSS, Inc., Chicago, Illinois, USA). A Shapiro–Wilk test confirmed that all continuous variables were not normally distributed. Therefore, quantitative data were stated as the median associated with the 25th to 75th percentile interquartile range (IQR), and Wilcoxon Signed rank test was used to compare differences between pre and post PCI procedure. Chi square test was employed to differentiate the incidence of different indicators. Fisher's exact test was used when Chi square test was violated. For ordinal variables, the Kruskal-Wallis test was used. Linear regression analysis was used to assess multicollinearity. Univariate logistic regression was used to examine the association between MACE after PCI and all potential variables

with a p-value less than or equal to 0.2. A step-wise logistic regression model was used for the multivariate analysis, and variables were retained if the final p-value was less than or equal 0.05.

Results

Two hundred and two patients were included in our study analysis. The majority of the patients were males (87.6%) and male to female ratio was 7:1. The median age was 58.5 (IRQ= 50- 65) years with the range (28-82) years. Also, the majority of our patients were non-educated (72.3%). The most prevalent pre-procedural risk factors were smoking, sedentary life style, HTN, IHD, DM and dyslipidemia. The majority of our patients underwent to PCI procedure electively (82.3%), while multiple stents were implanted to 47 patients (23.3%).

Table 1: Characteristics of all patients included in the analysis

Characteristics	Frequency (F)	Percentage (%)
Male	177	87.6
Non-educated	146	72.3
Sedentary life style	129	63.9
Dyslipidemia	63	31.2
IHD	96	47.5
Peripheral Vascular Disease (PVD)	3	1.5
CKD	4	2
DM	72	35.6
HTN	101	50
Underwent primary PCI	36	17.8
Multiple stents	47	23.3
Smoking status		
Current smokers	65	32.2
Ex-smokers	66	32.7
Never-smokers	71	35.1
Median age = 58.5 (50-65) years		
Median Body Mass Index (BMI) = 27 (23.6-30.7) kg/m²		
Median pre PCI Hb = 14.5 (13-15.2) gm/dl		
Median pre PCI white blood cells (WBC) = 7 (6-8.8) per mcL of blood		
Median pre PCI platelets = 270 (220-321.2) mcL		
Median pre PCI S.Cr = 0.9 (0.8-1.2) mg/dL		

The Incidence of PCI complications

In general, the incidence of PCI complications was nearly 28% observed in 56 patients. MACE was observed in 39 (19.3%) patients.

Sixteen different complications were observed in our study patients and only one patient was referred to dialysis. An in hospital mortality was in only one patient (0.5%). One patient (0.5%) with perforation of coronary artery (PCA), two patients (1%) with retroperitoneal bleeding, two patients (1%) with MI, two patients (1%) with stent thrombosis, two patients (1%) with pericardial effusion, three patients (1.5%) with cerebrovascular accident (CVA), three patients (1.5%) with stent re-stenosis, three patients (1.5%) with contrast allergy, four patients (2%) with arrhythmia, five patients (2.5%) with coronary dissection, five patients (2.5%) with cardiogenic shock, eleven patients (5.5%) with hematoma, nineteen patients (9.5%) with hypotension and 28 (13.9%) with renal insufficiency. Table 2.

Investigations differences between pre and post PCI procedure

Table 3 represents differences in investigations between pre and post PCI among our patients. Regarding Hb, there was statistically significant decrease in post PCI Hb (p-value = 0.000), but in respect to WBC counts, there was no statistically significant differences in WBC counts between pre and post PCI (p-value = 0.524). When platelets were compared as pre and post PCI procedure, there was no statistically significant difference between pre and post PCI platelets (p-value = 0.867). In contrast, there was statistically significant increase in post PCI S.Cr (p-value = 0.000).

Table 2: Incidence of different PCI complications among patients

PCI Complications	F	%
Mortality in hospital	1	0.5
New Dialysis	1	0.5
PCA	1	0.5
Retroperitoneal Bleeding	2	1
New MI	2	1
Pericardial Effusion	2	1
Stent Thrombosis	2	1
Stent Re-stenosis	3	1
Contrast Allergy	3	1.5
CVA	3	1.5
Coronary Dissection	5	2.5
Arrhythmia	4	2
Cardiogenic Shock	5	2.5
Hematoma	11	5.5
Hypotension	19	9.5
Renal Insufficiency	28	13.9
MACE	39	19.3
Total PCI complications	56	27.7

Table 3: Investigations differences between pre and post PCI procedure

Investigations	Mean Ranks	Z	P-value
Hb			
Pre PCI Hb	100.67	- 3.6	0.000*
Post PCI Hb	84.78		
WBC			
Pre PCI WBC	98.41	0.137	0.524
Post PCI WBC	97.64		
Platelets			
Pre PCI Platelets	90.95	0.192	0.867
Post PCI Platelets	91.11		
Serum creatinine			
Pre PCI S.Cr	83.66	3.8	0.000*
Post PCI S.Cr	103.06		

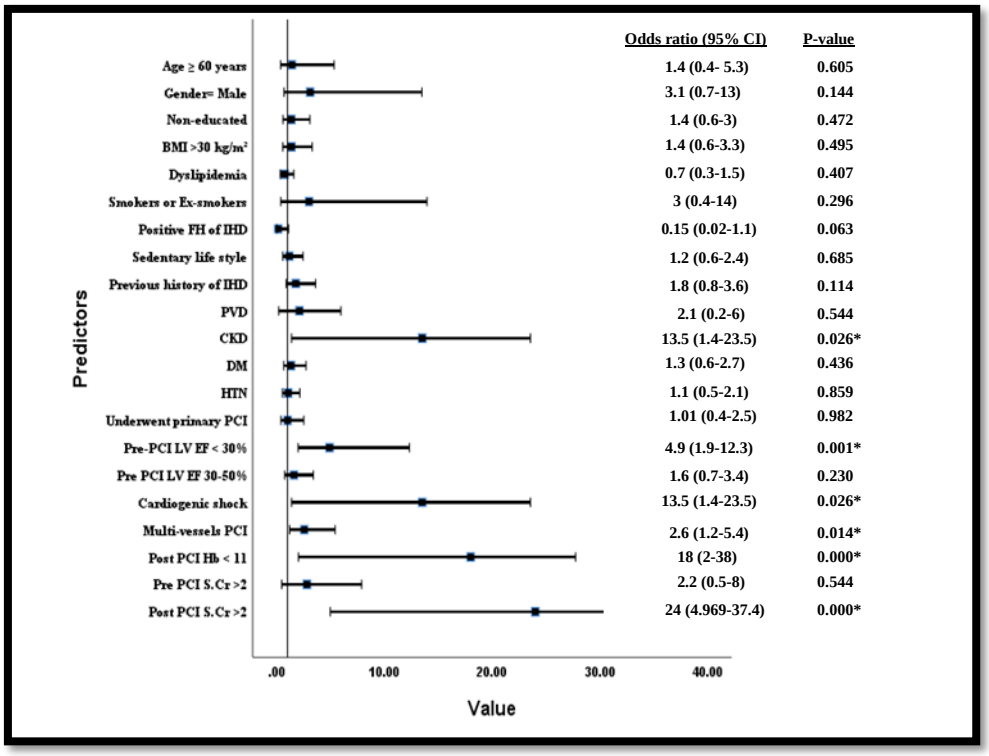
*Indicates significant result.

Table 4, and figure 1 show the relationship between MACE and the predicators from the previous tables. We have found CKD, pre-PCI LV EF < 30%, developed cardiogenic shock, underwent multiple stents PCI, post PCI Hb < 11, and post PCI S.Cr > 2 to be significantly associated with increased MACE in the hospital.

Table 4: Association Between Predictors and MACE

Predictors	MACE (N= 39)		P-value
	Yes % (N)	No % (N)	
Age ≥ 60 years	4.5 (9)	14.8 (30)	0.522
Gender= Male	18.3 (37)	69.3 (140)	0.127
Education=non-educated	14.8 (30)	57.4 (116)	0.472
BMI >30 kg/m²	3.9 (8)	12.9 (26)	0.495
Dyslipidemia	4.9 (10)	26.2 (53)	0.406
Smoking	18.8 (38)	74.7 (151)	0.296
Positive family history of IHD	0.5 (1)	12.4 (25)	0.033*
Sedentary life style	12.9 (26)	51 (103)	0.686
Previous history of IHD	11.4 (23)	36.1 (73)	0.112
PVD	0.5 (1)	1 (2)	0.536
CKD	1.5 (3)	0.5 (1)	0.005*
DM	7.9 (16)	27.7 (56)	0.436
HTN	9.9 (20)	40 (81)	0.859
Underwent primary PCI	3.5 (7)	14.3 (29)	0.982
Pre PCI LV EF 30-50%	6.4 (13)	19.3 (39)	0.229
Pre-PCI LV EF < 30%	5.4 (11)	5.9 (12)	0.000*
Cardiogenic shock	1.5 (10)	0.5 (1)	0.004*
Multiple stents (Multi-vessel) PCI	7.4 (15)	15.8 (32)	0.013*
Pre PCI Hb < 11	0.5 (1)	0.5 (1)	0.270
Post PCI Hb < 11	2 (4)	0.5 (1)	0.001*
Pre PCI S.Cr > 2 mg/Dl	0.5 (1)	0.5 (2)	0.536
Post PCI S.Cr > 2 mg/Dl	4.4 (9)	1 (2)	0.000*

*Indicates significant result.



*Indicates significant result.

Figure 1: Using logistic regression analysis, a forest plot represents the odds ratio.

Discussion

As our knowledge, our study is the first study that identify the incidence of PCI complications in Sana'a City, Yemen, which makes it difficult to compare at local level.

Our study data showed high number of male patients presenting with CAD that requires PCI which was similar to what was reported by Bugami *et al.,* among Saudi patients[11]. Also, our study patients present 3 years younger than their Saudi counterparts[11]. We have observed an alarming raise in the prevalence of risk factors such as smoking, sedentary life style, HTN, IHD and DM. This is similar to what was reported in Saudi Arabia[8].

According to our study results and in light of other studies, the overall incidence of PCI complications was 28%. Our result is higher than findings of Bugami *et al.,* who estimated incidence of PCI complications was 4.5% among Saudi patients[8], also higher than findings of Ferreira *et al.,* which was 22.3% among Brazilian patients[9].

High incidence of PCI complications in our study might be relate to using of femoral access in our study compared to radial access in Saudi study. Also, hypotension was considered as a complication in our study, while Saudi study didn't consider hypotension as a complication. In addition, bad quality of iso-osmolar contrast was used in our study, but other studies used original iso-osmolar contrast, therefore this explains a high incidence of renal insufficiency in this study.

On the other hand, in-hospital mortality occurred in only one patient (0.5%), and this result is lower than findings of Bugami *et al.,* study in Saudi Arabia which was 1.2%[8]. Therefore, our study PCI is a safe and effective procedure.

According to our study results, there was statistically significant decrease in post PCI Hb. Our study findings may be exacerbated by the possible impact of bleeding, which itself also exacerbated by using femoral artery access. In contrast, there was statistically significant increase in post PCI S.Cr. This finding is consistent with what was reported by Brazilian study[9]. Our explanations could be relating to contract induced nephropathy (CIN).

There was a high prevalence of hypotension complication in our study data. Many issues can cause hypotension during or after PCI, but the most common causes are internal or external bleeding, cardiogenic shock from stent thrombosis, or a new MI with or without mechanical difficulties. Anaphylaxis and the use of specific drugs (for example, intracoronary nitroglycerin during coronary angiography) are further causes. Arrhythmias of any

kind, as well as pharmacological side effects, and vasovagal reaction are other causes[10].

Not surprisingly, CKD, pre-PCI LV EF < 30%, cardiogenic shock, post PCI Hb < 11, post PCI S.Cr > 2 were statistically at higher risk to develop MACE. These results are coherent to other studies that have also reported same results [8,11]. In addition, patients who underwent multiple stents PCI was statistically at higher risk to develop MACE. This result is coherent to other studies, that also reported similar findings [11-14].

In contrast, our study found no statistically relationship between type of PCI procedure (primary or elective) and MACE. While our finding is consistent to some studies[8,15,16], it is inconsistent to other studies[11,12,16,17]. Our result could be relate to that fact, due to poverty in Yemen, many patients who need PCI procedure still on the medicines for long time, therefore, their cardiac muscle might be more susceptible to myocardial necrosis.

Our study demonstrates the advantage in terms of outcome of the radial over the femoral approach in PCI procedure, and more preventive measures for the bleeding are recommended, as well as contrast media dose should be kept to the minimum, using good contrast media, and good hydration before and after PCI procedure. We are planning to conduct further large scale multicenter and prospective studies in the future.

Limitations

Our study, like any other, has limitations that must be acknowledged. Because of the observational nature of the study and the low number of in hospital events, it has an inherent selection bias. Furthermore, our study does not reflect what is happening in other hospitals in Sana'a City or other governorates in Yemen, nor does it allow for multicenter comparisons. Finally, this study is underpowered to generate a risk model, where the survival curve was not generated, due to extremely low events in hospital.

Conclusion

The incidence of PCI complications was high in our study, but mortality rate in hospital was low, therefore, according to our study PCI is a safe and effective procedure.

CKD, pre-PCI LV EF < 30%, cardiogenic shock, post PCI Hb < 11, post PCI S.Cr > 2, and multiple stents PCI were independent predictors of MACE after PCI procedure.

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