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Predictors of Long-term Major Adverse Cardiac Events Following Percutaneous Coronary Intervention in the Elderly

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Abstract

Background: We aimed to recognize the predictors of long-term major adverse cardiac events (MACE) in the elderly candidates for elective percutaneous coronary intervention (PCI) at our center.

Methods: In this retrospective cohort study, we reviewed the data of the elderly (age ≥65 years) candidates for elective PCI who met our study criteria, at Tehran heart center between 2004 and 2013. Demographic, anthropometric, clinical, angiographic, procedural and follow-up data of the enrolled patients were retrieved from the angiography/PCI databank of our center. The study characteristics of the patients with or without MACE were compared in a univariable Cox-regression analysis. A multivariable Cox-regression model was applied using variables selected from the univariable model to determine the predictors of MACE.

Results: We reviewed the data of 2772 patients (mean age=70.8±4.7 years, male sex=1726 patients [62.3%]) from which 393 patients (14.4%) developed MACE. In the multivariable regression model, female sex was a protective factor for MACE (hazard ratio [HR]=0.701; *P*=0.001), while presence of diabetes mellitus (HR=1.333; *P*=0.007), family history of coronary artery disease (CAD) (HR=1.489; *P*=0.003) and plain balloon angioplasty (HR=1.810; *P*=0.010) were independent risk factors for MACE.

Conclusion: PCI is a safe and effective method of revascularization in the elderly patients, and some clinical and procedural factors can predict MACE in this group of patients.

Keywords: Cohort study, Elderly, Major adverse cardiac events, Percutaneous coronary intervention

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Introduction

Improvements in the life expectancy have resulted in the increase of prevalence of non-communicable diseases, particularly cardiovascular diseases and to be exact, coronary artery disease (CAD). Therefore, the number of elderly people who are referred for coronary revascularization, either by coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) has increased in the past years. However, less invasive methods, i.e. PCI, are preferred in the elderly, and the number of elderly candidates for such procedures is on the rise. As the elderly people are not usually in a healthy condition and most of them have several comorbidities, it is important to acknowledge their risk factors for mortality and morbidity following coronary revascularization.

Several studies have discussed the risk factors for mortality and outcome of CABG in the elderly,[1,2] but the number of studies on the predictors for major adverse cardiac events (MACE) following PCI is limited. Until now, higher age, female gender, urgent or primary PCI, multivessel disease, hemodynamic instability, renal insufficiency and some other clinical, angiographic and procedural factors have been described as predictors for MACE in the elderly in some studies.[3-5] However, the results of these studies are inconsistent, and due to the differences in the clinical settings and health care systems as well as ethnic and genetic factors, more studies are required to reach a consensus. Moreover, most studies have shown the in-hospital and short-term MACE, but not the long-term outcomes. In the present study, we aimed to recognize the predictors of long-term MACE in the elderly candidates for elective PCI at a university tertiary center for cardiovascular diseases.

Materials and Methods

In this retrospective cohort study, we reviewed the data of elderly patients (age ≥65 years) who were candidates for elective PCI at our center between 2004 and 2013. Inclusion criteria were age ≥65 years and complete follow-up data unless the study endpoint occurred. Incomplete clinical and angiographic data was the main exclusion criteria. A written informed consent was obtained from

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the participants before admission stating that their clinical data would be used anonymously for research purposes.

Demographic, anthropometric, clinical, angiographic and procedural data of the selected patients based on the study criteria were retrieved from the angiography/PCI databank of our center. Demographic data included age and sex, and anthropometric data consisted of weight and height at the time of admission for calculating body mass index (BMI). The clinical data comprised the history of classical cardiovascular risk factors including diabetes mellitus, hypertension, dyslipidemia, smoking and family history of CAD. Definition of the cardiovascular risk factors in our databank has been described elsewhere.[6] Other collected data included previous CABG or PCI, presence of peripheral vascular disease or cerebrovascular accidents, ejection fraction based on the latest echocardiography before the intervention, as well as the angiographic and angioplastic data. The PCI procedures were performed based on the standard techniques with the femoral approach. Based on our routine, all patients received 300–600 mg loading dose of clopidogrel plus 325 mg aspirin before the procedure and 70–100 IU/kg intravenous unfractionated heparin during PCI. Additionally, clopidogrel (75 mg/d) and aspirin (325 mg/d) were maintained for a minimum of 1-month. Afterwards, aspirin was tapered to 80 mg for lifelong use while clopidogrel was prescribed for at least 1-month in BMS and 12 months in DES.

The clinical follow-up data were collected by scheduled clinic evaluations or direct telephone interviews. All events were recorded from the time of intervention. MACE was defined as the occurrence of one or more of the following items within at least 5 years after PCI: (1) cardiac death; (2) myocardial infarction; (3) CABG; (4) rehospitalization due to unstable angina; (5) target vessel revascularization (TVR) or target lesion revascularization (TLR). Then the predictors of 5-year survival were searched for.

Statistical Analysis

Categorical variables were expressed as frequency with percentages, and continuous variables were described as mean with standard deviation (SD) or median with interquartile range (IQR) boundaries for normally or non-normally distributed data, respectively. Distribution of continuous data was evaluated using descriptive aforementioned parameters as well as histogram charts. The univariate effect of covariates on MACE was assessed using Cox regression model and was reported through hazards ratio (HR) with 95% CIs. Covariates with *P* values less than 0.1 in the univariate Cox regression analyses were candidate for the multivariable model. A multivariable Cox regression model with backward elimination method (considering entry and removal probabilities equal to 0.05 and 0.1, respectively) was applied to find the multiple predictors of MACE. Proportional hazards (PH) assumption was evaluated through the chi-square test of correlation coefficient between transformed survival time and the scaled Schoenfeld residuals. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 24.0 (Armonk, NY: IBM Corp.).

Results

Based on our databank, 2907 patients were older than 65 years. A total of 135 patients were lost to follow up and finally, we reviewed the data of 2772 patients (mean age=70.8±4.7 years, male sex = 1726 patients [62.3%]) from which 393 patients (14.4%) developed MACE. In the MACE group, there were more males, with a higher frequency of diabetes mellitus, family history of CAD, previous cardiac revascularization (either PCI or CABG), low levels of ejection fraction and higher fasting blood sugar levels (Table 1).

As described in Table 2, none of the angiographic/procedural characteristics was associated with MACE, except for plain balloon angioplasty (POBA) (P=0.018) which was more frequent in patients without MACE.

In the multivariable Cox regression model, female sex was a protective factor for MACE while presence of diabetes mellitus, family history of CAD and POBA were independent risk factors for MACE in our elderly population (P = 0.007, P = 0.003, and P = 0.010, respectively) (Table 3).

Discussion

In the present study, we aimed to determine the predictors for 5-year MACE in elderly patients who underwent PCI in our center. We found that male sex, presence of diabetes mellitus, family history of CAD and POBA were risk factors for MACE. The incidence of MACE in our population was 14.4%.

Research on the elderly, particularly those struggling with their survival, is nowadays an important issue in clinical research as the number of elderly people is increasing globally.[7] On the other hand, cardiovascular disease is the major cause of death all over the world, and every day many individuals undergo revascularization procedures to survive.[8] PCI is currently a well-accepted treatment modality for revascularization in the elderly.[9] Therefore, recognition of the predictors of mortality in the elderly patients undergoing PCI is an important issue because they are known to have a higher rate of MACE as compared with the younger patients.[10–12]

Several researches have been performed to evaluate the short-term predictors of adverse outcomes in the

Table 1. Demographic and Clinical Characteristics of the Study Group and Their Unadjusted Predictive Effect

Characteristics[a]	MACE - (n=2379)	MACE + (n=393)	HR	95.0% CI for HR		*P* Value[b]
				Lower	Upper	
Age, year	70.8 ± 4.6	71.0 ± 4.9	1.010	0.989	1.031	0.362
Female sex, n (%)	919 (87.9)	127 (12.1)	0.766	0.620	0.947	0.014
BMI, kg/m^2	27.31±4.23	27.2±4.3	0.992	0.968	1.016	0.504
Diabetes mellitus, n (%)	706(83.6)	139(16.4)	1.278	1.040	1.572	0.020
Hypertension, n (%)	1444(85.6)	242(14.4)	1.031	0.842	1.264	0.767
Dyslipidemia, n (%)	1500(85.9)	247(14.00)	0.975	0.795	1.196	0.808
Family history of CAD, n (%)	285(81.0)	67(19.0)	1.432	1.101	1.862	0.007
Smoking, n (%)	651(84.8)	117(15.2)	1.116	0.899	1.385	0.321
Opium, n (%)	138(83.1)	28(16.9)	1.272	0.865	1.870	0.222
Previous PCI, n (%)	194 (8.1)	61 (15.5)	1.977	1.504	2.599	<0.001
Previous CABG, n (%)	146 (3.2)	45 (11.4)	1.842	1.350	2.514	<0.001
Previous CAG, n (%)	599 (25.1)	134 (34.0)	1.484	1.204	1.829	<0.001
History of ACS, n (%)	1613(85.2)	281(14.8)	1.189	0.955	1.480	0.122
Stable angina, n (%)	940 (39.5)	155 (39.4)	0.989	0.808	1.211	0.918
Unstable angina, n (%)	927 (38.9)	97 (24.6)	1.072	0.876	1.312	0.498
NSTEMI, n (%)	295 (12.4)	66 (16.7)	1.383	1.061	1.080	0.016
STEMI, n (%)	573 (41.5)	97 (24.6)	1.051	0.835	1.322	0.673
Ejection fraction (%)	51±10.1	49.9±10.8	0.989	0.979	0.999	0.028
Serum creatinine, mg/dL	1.1 [1.3, 0.9]	1.1 [1.3,0.9]	1.183	0.990	1.415	0.065
FBS, mg/dL	101 [89, 122]	102 [90, 129]	1.003	1.001	1.005	0.007
LDL, mg/dL	97 [124,73]	95 [126,75]	1.001	0.998	1.003	0.720
HDL, mg/dL	41 [49,35]	41 [47.7,36]	1.003	0.993	1.014	0.497
Total cholesterol, mg/dL	168 [201,140]	166 [139.7,201]	1.000	0.997	1.002	0.878
Triglyceride, mg/dL	141 [196,104]	135 [182,103]	1.000	0.999	1.001	0.924

ACS: Acute coronary syndrome; BMI: Body mass index; CABG: Coronary artery bypass graft; CAD; Coronary artery disease; CAG: Coronary angiography; CI: Confidence interval; FBS: Fasting blood sugar; HDL: High density lipoprotein; HR: Hazard ratio; LDL: Low density lipoprotein; MACE: Major adverse cardiac events; NSTEMI: Non-St elevation myocardial infarction; PCI: Percutaneous coronary intervention; STEMI: ST elevation myocardial infarction;
[a] Variables are shown as median [interquartile range], mean ± standard deviation or frequency (percentage) where appropriate.
[b] A *P* value less than 0.05 was considered as significant.

Table 2. Angiographic and Procedural Characteristics of the Study Group and Their Unadjusted Predictive Effect

Characteristic[a]	MACE - (n=2379)	MACE + (n=393)	HR	95% CI for HR		*P* Value[b]
				Lower	Upper	
Multi-vessel disease, n(%)	1866 (78.4)	313 (79.6)	1.068	0.836	1.365	0.599
LCX territory, n (%)	433(84.9)	77(15.1)	1.087	0.847	1.394	0.513
RCA territory, n (%)	522(84.5)	96(15.5)	1.151	0.914	1.448	0.232
LAD territory, n (%)	1419(86.7)	218(13.3)	0.845	0.693	1.031	0.098
Left main artery, n (%)	5(71.4)	2(28.6)	2.837	0.707	11.386	0.141
Bare metal stent, n (%)	851 (87.2)	125 (12.8)	1.000	-	-	0.051
Drug eluting stent, n (%)	1448 (85.4)	246 (14.6)	1.152	0.929	1.429	0.198
POBA, n (%)	85 (79.4)	22 (20.6)	1.730	1.099	2.721	0.018
Diameter of stent, mm	3.4±0.46	3.02±0.47	0.939	0.758	1.162	0.562
Length of stent, mm	23.02±7.62	23.11±7.16	1.002	0.989	1.015	0.786

CI: Confidence interval; HR: Hazard ratio; LAD: Left anterior descending artery; LCX: Left circumflex artery; MACE: Major adverse cardiac events; POBA: Plain old balloon angioplasty; RCA: Right coronary artery
[a] Variables are shown as mean ± standard deviation or frequency (percentage) where appropriate.
[b] A *P* value less than 0.05 was considered as significant.

elderly following PCI, but the number of research on the long-term outcomes is limited. In one study, older age was a risk factor for MACE, and renal, neurological, and access-site complications were all more frequent in the very elderly (≥85 years) patients.[3] Based on the data of a large PCI registry,[4] hemodynamic instability and acute ST-elevation myocardial infarction were the strong predictors of in-hospital mortality in patients ≥75 years who underwent primary PCI. Procedural complications were the most powerful determinants of death in the elderly undergoing elective PCI. Another study that examined the influence of age on procedural success and long-term outcomes following primary or elective PCI in elderly patients, found that decreased ejection fraction (but not age) was the single strongest predictor of mortality at 1 year.[13]

To detect the long-term outcomes of PCI and their predictors in the elderly, a study with a follow-up of 51.3 months has shown that older age, LVEF <40%, high creatinine level, and prior carotid surgery or stroke

Table 3. Final Predictors of Major Adverse Cardiac Events in the Elderly After Adjustment

Characteristic	HR	95% CI		*P* value*
		Lower	Upper	
Female sex	0.701	0.565	0.870	0.001
Diabetes mellitus	1.333	1.080	1.646	0.007
Family history of CAD	1.489	1.141	1.942	0.003
LAD territory	0.828	0.674	1.017	0.071
Bare metal stent	1	Reference	Reference	0.029
Drug eluting stent	1.179	0.944	1.474	0.147
POBA	1.810	1.150	2.850	0.010

CAD: Coronary artery disease; CI: Confidence interval; HR: Hazard ratio; LAD: Left anterior descending artery; POBA: Plain old balloon angioplasty;
[a] A *P* value less than 0.05 was considered as significant.
PH assumption: $P=0.339$

were independent predictors of long-term mortality.[14] Elderly females had the most significant risk factors for MACE in a large cohort of patients, in a 3-year follow-up.[15] However, another study with a 5-year follow up on 201 cases, recognized incomplete revascularization as the only predictor of adverse outcomes following PCI in the elderly.[16] This can be comparable to the results of our study if we consider POBA as incomplete revascularization in comparison with stenting. Similarly, a study showed that procedural success and diabetes mellitus were the independent predictors of MACE in the patients aged ≥75 years.[17] It should be noted that in our study, we only selected patients with successful PCI; therefore, the effect of unsuccessful PCI on MACE could not be assessed. A study in Mexico detected heart failure, cardiogenic shock, diabetes mellitus, TIMI flow 0–2 before and after intervention, and A-V block or atrial fibrillation as the long-term predictors of MACE.[18] Hypertension was the only predictor of all cause mortality in patients ≥75 years in another study.[19] In a combined model of angiographic and clinical characteristics, patients with high Euroscore and high SYNTAX score were at higher risk for developing MACE within 3 years of follow-up.[20]In another study, use of BMS was accompanied with an increased risk of MACE compared with those treated with DES.[21]

Similar to our findings, diabetes mellitus has also been shown as an independent risk factor for mortality in the elderly with chronic total occlusion treated by PCI.[17,18,22] This highlights the devastating effects of diabetes mellitus on the cardiovascular systems. The future studies should focus on the effects of the type of antiglycemic treatment or the levels of glycosated hemoglobin or fasting blood sugar on the occurrence of MACE in the elderly candidates for PCI.

The strengths of our study consist of its large population, long-term follow-up period, and introducing new predictors of MACE in the elderly population for the first time (male gender and family history of CAD). However, our study has some limitations too. First, this was a single center study, performed at a tertiary university hospital. So, the socioeconomic factors of our patients may influence our results.

In conclusion, PCI is a safe and effective method of revascularization in the elderly patients. We found that male sex, diabetes mellitus, family history of CAD and POBA were independent predictors of MACE in the elderly. Based on the current literature, we suppose that the next step would be performing a systematic review on the predictors of MACE in the elderly following PCI.

Authors' Contribution

Study concept, Proposal and drafting: AS; Data analysis: AJ; Supervision: HA; Data gathering: PN, AN; Scientific consult and patient management: HA, HP, SEK, MS, AH, AA, MA, EN; Final approval; All authors.

Conflict of Interest Disclosures

The authors have no conflicts of interest.

Ethical Statement

The study protocol was approved by the local Institutional Committee of Medical Ethics and the Research Board of Tehran University of Medical Sciences. This study conforms to the principles outlined in the Declaration of Helsinki.

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