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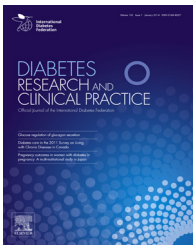

Modeling of in hospital mortality determinants in myocardial infarction patients, with and without type 2 diabetes, undergoing pharmaco-invasive strategy: the first national report using two approaches in Iran

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ABSTRACT

This study was conducted to compare the characteristics of patients, with and without diabetes mellitus, presenting with myocardial infarction (MI) and treated with coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), or thrombolytic therapy. Factors related to mortality due to MI in Iran were also determined. This study was a prospective analysis. To analyze the data, Stata software (chi square, *t* test, Cox and logistic regression) was used. Participants were patients hospitalized for MI for the first time in 540 hospitals from April, 2012 to March, 2013. Out of 20,750 patients with MI, 461 2 (22.3%) had type 2 diabetes. MI case fatality rate was 13.22% (95%CI: 12.24–14.19) and 11.78% (95%CI: 11.28–12.27) in patients with and without diabetes, respectively. The rates of CABG, PCI, and thrombolytic therapy use were 4.2%, 8%, and 58% in patients with diabetes, and 2.1%, 6.5%, and 55% in patients without diabetes. The odds ratio of mortality for ST segment elevation myocardial infarction (STEMI) and chest pain resistant to treatment was, respectively, 6.3 and 2.8 in those with diabetes, and 3.9 and 3.7 in patients without diabetes. The hazard ratio of mortality for gender, education, smoking, left bundle branch block, PCI, and type of MI was different between the two groups ($P < 0.05$). Characteristics of patients dying post MI were different in those with or without diabetes mellitus. Although use of CABG, PCI, and thrombolytic therapy was more frequent in patients with diabetes than without, mortality was higher in diabetes patients.

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1. Introduction

Despite decreases in morbidity and mortality rates due to cardiovascular diseases in most developed countries, these diseases have become the most important health challenge and cause of mortality in many developing countries worldwide, including the Islamic Republic of Iran. Myocardial Infarction (MI) is the leading reason for mortality in this country [1–3]. Type 2 diabetes has an important role in mortality from MI [3–5]. A study in Japan showed that, among patients with MI, diabetes was not an independent predictor of hospital mortality [6]. Type 2 diabetes is one of the most common metabolic disorders in the world. Most people with type 2 diabetes live in low- and middle-income countries and these will experience the greatest increase in cases of diabetes over the next 22 years. [7]. In Iran, type 2 diabetes prevalence varies between 4.2% and 15.9% in general population [8–10]. Diabetes is the 9th and 16th leading reason for death in women and men, respectively in Iran [11,12]. Use of treatments such as coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI), and thrombolytic therapy has lowered mortality from ischemic heart disease, but these procedures do not lead to similar outputs for all patients [13–15]. In Iran, no study has been yet conducted to compare the characteristics of new MI cases in those with and without diabetes undergoing pharmaco-invasive therapy nor to establish the factors related to mortality from MI. Therefore, the contribution of type 2 diabetes to the risk and outcome of MI remain unspecified in this country and relevant healthcare decisions in Iran's health system are made based on research conducted in other countries [16]. This study was conducted to determine and compare the characteristics of patients with or without diabetes who underwent pharmaco-invasive therapy post MI, and to determine the factors contributing to mortality.

2. Materials and methods

This study was a prospective analysis of data obtained from the Myocardial Infarction Registry of Iran's Cardiovascular Diseases Surveillance System. 20,750 patients hospitalized with a new presentation with MI (across 540 hospitals) between April 2012 to March 2013 were included. The study protocol was approved by the Management Center of Non-Communicable Diseases and Office of Cardiovascular Diseases Prevention of Iran Ministry of Health and Medical Education (approval no. 305/837). Inclusion criteria were based on the World Health Organization (WHO) and World Heart Federation definition of myocardial infarction diagnosis as per the International Classification of Diseases (ICD10) codes I21, I22 [17]. Patients with prior myocardial infarction history or no definite diagnosis by a cardiologist were excluded from the study. Data on age, gender, education, ischemic heart disease symptoms, duration of hospital stay, smoking, dyslipidemia, hypertension, heart failure, and family history of cardiovascular diseases were collected. Confirmation of presence of type 2 diabetes was by fasting blood glucose test and levels of glycosylated hemoglobin (HbA1C) obtained from the patients' medical records. Diabetes was confirmed when fasting plasma glucose (FPG) $\geq$7 mmol/L or when a participant self reported having been diagnosed by a physician and was on medication for type 2 diabetes [9,10,18]. After definite diagnosis of MI by a cardiologist, data on left bundle branch block (LBBB), right bundle branch block (RBBB), atrial fibrillation, ventricular and atrial tachycardia, type and location of MI, and use of therapeutic regimens like CABG, PCI, and thrombolytic therapy were gathered. Hospital mortality from MI was determined as a dependent variable. To analyze the data, chi-square, *t* test, and two regression models were conducted. Odds ratio (OR) and hazard ratio (HR) of death for clinical and demographic risk factors were calculated by logistic regression and Cox regression, respectively. The cohort of patients was defined by the date at MI diagnosis, hospital stay, and follow-up till discharge or death (disease outcome). HR of death was calculated and reported as crude and adjusted rates for those with and without diabetes by seven Cox proportional hazards models. First, univariate analysis was used. To control for confounders, we entered the variables which were significant or approximately significant into a multiple regression model. Stata software (Stata Corp. 2011. Stata Statistical Software: Release 12. College Station, TX: Stata Corp LP) was used and $P < 0.05$ was considered significant.

3. Results

Of 20,750 new MI patients, 4612 had type 2 diabetes. The prevalence of diabetes was thus 22.3% and 58.5% were men. Mean $\pm$ standard deviation of age at the time of MI was 61.9 ± 11.7 and 60.9 ± 13.8 years for those with or without diabetes mellitus, respectively. The mean duration of hospitalization was 6.5 days for all patients and similar for those with or without diabetes ($P > 0.05$). Data on age groups, education, gender, and medical history are shown in Table 1. Out of 2834 type 2 diabetes patients presenting with STEMI, 224 (7.9%) died within a year. MI case fatality rate (CFR) was 13.22% (95%CI: 12.29–14.19) and 11.78% (95%CI: 11.28–12.27), respectively, in those with or without diabetes ($P = 0.008$). 58.4% of patients with type 2 diabetes were between 30 and 64 years old. The prevalence of hypertension was 52.8% and 30.6% in those with or without diabetes, respectively. The prevalence of heart failure was 28.2% in those with type 2 diabetes patients. The prevalence of respiratory distress and vomiting was 6% and 3.3% in those with diabetes and 5.2% and 2.6% in those without diabetes, ($P < 0.05$). No significant difference was seen for other complaints and symptoms prior to MI including sweating, nausea, and jaw pain in those with or without diabetes ($P > 0.05$). The proportion of CABG, PCI, and thrombolytic therapy use was, respectively, 4.2%, 8%, and 58% in those with diabetes and 2.1%, 6.5%, and 55% in those without diabetes. Mortality following PCI and CABG was 7.28% and 15.74% in those with diabetes and 4.72% and 11.4% in those without diabetes. Mortality following the above therapies was significantly higher in those with diabetes without ($P < 0.001$). Mortality following thrombolytic therapy in patients with diabetes was significantly less than in those without (13.23% vs. 15.57%, $P < 0.05$). Comparison of clinical characteristics between the two groups of patients is shown in Table 2. Determinants of mortality were different in multiple

Table 1 – Demographic details for patients presenting with new MI.

Characteristic	Total (%)	With type 2 diabetes	Without type 2 diabetes	P value
Sample size	20,750	4612 (22.2%)	16,138 (77.8%)	–
Age (mean ± SD) (years)	61.2 ± 13.4	61.9 ± 11.7	60.9 ± 13.8	<0.05*
Hospital stay (days)	6.5 ± 14.6	6.6 ± 14.7	6.5 ± 14.5	0.814
Gender				
Men	15,033 (72.4)	2701 (58.5)	12,332 (76.4)	<0.05*
Women	5717 (27.6)	1911 (41.5)	3806 (23.6)	
Education				
Illiteracy	9611 (46.3)	2243 (48.6)	736 8(45.6)	<0.05*
Primary	4941 (23.8)	1144 (24.8)	3797 (23.5)	
Guidance	1940 (9.3)	370 (8.1)	1570 (9.7)	
High school	2992 (14.4)	613 (13.3)	2379 (14.7)	
University	1266 (6.1)	242 (5.2)	1024 (6.3)	
Smoker	5443 (26.2)	1107 (24)	4336 (26.8)	<0.05*
Family history of MI	4293 (20.6)	1290 (27.9)	3003 (18.6)	<0.05*
Hypertension	7376 (35.5)	2435 (52.8)	4941 (30.6)	<0.05*
High cholesterol	3710 (17.8)	1572 (34)	2138 (13.2)	<0.05*
Heart failure	1682 (8.1)	474 (28.2)	1208 (71.8)	<0.05*

* P value less than 0.05 to be assumed significant.

logistic regression model. The OR of mortality for gender, education, smoking, hypertension, and PCI use was significant in patients without diabetes and non significant for those with diabetes. The OR (95% CI) for the above variables is shown in Table 3. Chest pain resistant to treatment amongst patients with diabetes mellitus gave the highest OR of mortality (6.3) followed by ventricular tachycardia (3.4), lack of thrombolytic therapy (3.1), and heart failure (2.2). Correspondingly, the highest OR of mortality amongst patients without diabetes patients was chest pain resistant to treatment (3.7) followed by lack of thrombolytic therapy (2.9), and MI in the family history (2.1). The HR for mortality was different between those with or without diabetes. Amongst diabetes patients, the highest HR of death was for STEMI (3.01) followed by chest pain resistant to treatment (2.9), ventricular tachycardia (2.6), lack of thrombolytic therapy (2.5), family history of MI (1.6), and LBBB (1.5) (Table 4). HR of death by gender, education, smoking, high cholesterol, LBBB, and PCI treatment was different in those with or without diabetes. The HR of death after adjusting for variables is shown in Table 5.

4. Discussion

In the present study, the characteristics of new MI patients with and without type 2 diabetes, undergoing conventional therapies were determined and compared. After controlling for confounders, we found that, the HR of mortality for MI was significantly higher in type 2 diabetes patients than in patients without diabetes. Additionally, the determinants of mortality from MI were different in those with or without diabetes. Use of PCI and CABG among diabetes patients appears considerably lower in Iran than in some other countries [19,20]. The study of Gnavi et al. showed that, mortality from MI in those

Table 2 – Clinical characteristics of MI presentation.

Characteristic	Total (%)	With type 2 diabetes	Without type 2 diabetes	P value
AF	511 (2.5)	143 (3.1)	545 (3.3)	>0.05
VT	1198 (5.8)	205 (4.5)	993 (6.2)	<0.05*
RBBB	289 (1.4)	82 (1.7)	207 (1.2)	<0.05*
LBBB	383 (1.8)	97 (2.1)	286 (1.7)	>0.05
Lateral MI	990 (4.8)	186 (4)	804 (5)	<0.05*
Anterior MI	4332 (20.9)	892 (19.3)	3440 (21.3)	<0.05*
Inferior MI	7179 (34.6)	1578 (34.2)	5601 (34.7)	>0.05
Posterior MI	853 (4.2)	175 (3.8)	678 (4.2)	>0.05
STEMI	15,729 (75.8)	2834 (61.4)	10,271 (63.6)	<0.05*
Death	2511 (12.1)	610 (13.2)	1901 (11.7)	<0.05*
PCI	1431 (6.9)	371 (8)	1060 (6.5)	<0.05*
CABG	539 (2.6)	197 (4.2)	342 (2.1)	<0.05*
Lack of thrombolytic Therapy	9222 (44.5)	1939 (42)	7283 (45)	<0.05*
Chest pain	2229 (10.7)	505 (10.9)	1724 (10.6)	>0.05

AF—atrial fibrillation; VT—ventricular tachycardia; RBBB—right bundle branch block; LBBB—left bundle branch block; MI—myocardial infarction; STEMI—ST-segment elevation myocardial infarction; NSTEMI—non ST-segment elevation myocardial infarction; PCI— percutaneous coronary intervention; CABG—coronary artery bypass grafting.

* $P < 0.05$ to be assumed significant.

Table 3 – Adjusted odds ratio and mortality.

Characteristics	With type 2 diabetes			Without type 2 diabetes		
	OR	CI	P-value	OR	CI	P-value
Standardized age (year)	1.32	1.1–1.4	0.001	1.5	1.4–1.6	0.001
Women	1.09	0.8–1.3	0.424	1.2	1.1–1.4	0.001
Education						
Illiterate	1.1	0.6–1.8	0.61	0.93	0.1	0.555
Primary	0.96	0.5–1.5	0.877	0.81	0.08	0.068
Guidance	1.1	0.6–2	0.001	0.64	0.08	0.001
High-school	1	0.6–1.7	0.855	0.69	0.08	0.002
University	Ref.	–	–	–	–	–
Smoking	1.05	0.8–1.3	0.637	1.2	1.08–1.3	0.001
Family history	2.07	1.67–2.56	0.001	2.1	1.9–2.4	0.001
Hypertension	0.85	0.6–1.06	0.159	0.8	0.7–0.91	0.001
High cholesterol	0.80	0.64–0.99	0.046	0.91	0.7–1.07	0.285
Chest pain	6.3	4.9–8	0.001	3.7	3.3–4.3	0.001
Lack of thrombolytic therapy	3.1	2.5–3.9	0.001	2.9	2.6–3.3	0.001
RBBB	2.07	1.1–3.7	0.017	1.7	1.1–2.5	0.004
VT	3.4	2.4–4.9	0.001	1.8	1.5–2.2	0.001
STEMI	2.8	2.3–3.6	0.001	3.9	3.5–4.4	0.001
PCI	0.81	0.5–1.2	0.364	0.62	0.4–0.85	0.003
CABG	0.96	06–1.5	0.881	0.88	0.6–1.2	0.495
Heart failure	2.26	1.7–2.9	0.001	1.4	1.1–1.67	0.001
Lateral MI	2.05	1.3–3.1	0.001	2.03	1.64–2.5	0.001

OR—odds ratio; SE—standard error; RBBB—right bundle branch block; VT—ventricular tachycardia; STEMI—ST-segment elevation myocardial infarction; PCI—percutaneous coronary intervention; CABG—coronary artery bypass grafting; MI—myocardial infarction.

with or without diabetes was 3.7% and 0.7%, respectively [21], suggesting lower mortality rate than in Iran. Higher mortality from MI in Iran than in other countries could be explained by less frequent use of PCI, CABG, and thrombolytic therapy. Juutilainen et al. conducted a study on diabetes patients and found that, HR of mortality was 0.9 (95% CI: 0.6–1.5) and was not significant in diabetes patients with MI history compared to non-diabetes patients without the history of MI [22]. In our

Table 4 – Hazard ratio of various factors* and mortality.

Characteristics	With type 2 diabetes			Without type 2 diabetes		
	HR	CI	P-value	HR	CI	P-value
Age (year)	1.21	1.09–1.34	0.001	1.3	1.2–1.38	0.001
men	0.84	0.7–1.01	0.073	0.76	0.68–0.85	0.001
Education						
Illiterate	0.95	0.63–1.4	0.61	0.86	0.7–1.06	0.555
Primary	0.84	0.55–1.2	0.877	0.81	0.6–1	0.068
Guidance	0.94	0.58–1.5	0.001	0.68	0.52–0.89	0.001
High-school	0.84	0.54–1.3	0.855	0.74	0.58–0.94	0.002
university	Ref.	–	–	–	–	–
Smoking	0.97	0.8–1.17	0.797	1.16	1.05–1.28	0.003
Family history	1.62	1.36–1.93	0.001	1.71	1.5–1.8	0.001
Hypertension	0.84	0.7–1.01	0.065	0.84	0.75–0.93	0.001
High Cholesterol	0.78	0.65–0.94	0.01	0.92	0.8–1.06	0.270
Chest pain	2.91	2.3–3.5	0.001	2.5	2.2–2.7	0.001
Lack of thrombolytic therapy	2.58	2.1–3	0.001	2.2	2–2.4	0.001
RBBB	1.52	0.97–2.3	0.06	2.2	1.6–3	0.001
VT	2.6	1.9–3.4	0.001	1.5	1.35–1.8	0.001
STEMI	3.01	2.7–3.3	0.001	2.3	1.92–2.8	0.001
PCI	0.79	0.53–1.1	0.264	0.70	0.52–0.93	0.015
CABG	1.1	0.75–1.6	0.607	0.78	0.56–1.08	0.138
Heart failure	1.4	1.1–1.8	0.001	1.2	1.03–1.4	0.017
LBBB	1.55	1–2.3	0.048	0.79	0.6–1	0.114

VT—ventricular tachycardia; STEMI—ST-segment elevation myocardial infarction; RBBB—right bundle branch block; TT—thrombolytic therapy; PCI—percutaneous coronary intervention.

* The variables were entered as dichotomous (0 & 1) and 0 was set as reference.

Table 5 – Modeling of hazard ratio (95% confidence interval) for mortality in patients with type 2 diabetes in comparison to patients without type 2 diabetes.

Models		Type 2 diabetes
0	Unadjusted HR	1.1:1–1.2 $P < 0.039$
1	Adjusted for age and gender	1.06:0.97–1.1 $P = 0.176$
2	Above + adjusted for education and interaction of gender with education	1.06:0.97–1.16 $P = 0.173$
3	Above + past medical history	1.07:0.97–1.18 $P = 0.151$
4	Above + treatment regime	1.13:1.03–1.24 $P = 0.01$
5	Above + ischemic pattern pain	1.15:1.04–1.26 $P = 0.004$
6	Above + complication of MI	1.12:1.01–1.23 $P = 0.022$
7	Above + MI type	1.13:1.02–1.24 $P = 0.013$

Model 2: age + gender + interaction of gender with education. *Model 3:* smoking + type 2 diabetes mellitus + hypertension + hyperlipidaemia. *Model 4:* percutaneous coronary intervention + coronary artery bypass grafting + thrombolytic therapy. *Model 5:* chest pain + pain left arm + dyspnea + sweating + vomiting + nausea + jaw pain. *Model 6:* right bundle branch block + left bundle branch block + atrial fibrillation + -ventricular tachycardia. *Model 7:* ST-segment elevation myocardial infarction + non-ST-segment elevation myocardial infarction + myocardial infarction status.

study, HR of mortality from MI in diabetes patients was higher than in those without diabetes. Based on a study on diabetes patients with multi-vessel coronary disease, CABG was more effective in reducing mortality and led to fewer repeated revascularizations than PCI [23]. The result of this study is not consistent with our study finding of the ratio of mortality following CABG being higher than mortality following PCI. The reason may be technique used, the frequency of use and level of professionals' skill, and the different characteristics and risk factors in the studied patients. Lee et al. assessed the efficacy and safety of CABG compared to drug-eluting stenting (DES) in patients with diabetes mellitus and multivessel coronary artery disease (CAD) and found that, PCI with DES was safe and could represent a viable alternative to CABG for selected patients with diabetes and multivessel CAD [24]. Our study showed that in diabetes patients, mortality following CABG was higher than that following thrombolytic therapy. In our study on a group of Iranian patients, use of PCI in diabetes patients was associated with lower mortality compared to CABG and treatment with thrombolytic therapy. In the study of Juutilainen et al., the HR of mortality from cardiovascular diseases was 1.9 (1.4–2.6). Juutilainen et al. used the patients' self-report to classify diabetes and MI [22] and hence bias is probable, which could explain the inconsistency between the present investigation and Juutilainen et al. findings. To answer the question whether the risk of cardiovascular disease is the same in diabetes patients without MI history and non-diabetes patients with MI history, Bulugahapitiya et al. established that diabetes patients without MI history were at lower (by 43%) risk of all cardiovascular diseases compared to non-diabetes patients with MI history. In this study, HR was detected 0.56 [4]. Moreover, Haffner et al. showed that, non-diabetes patients with MI history and diabetes patients without MI history were at equal risk of coronary heart disease (CHD) incidence, which is not consistent with our study. A meta-analysis reviewed 13 seminal studies and reported no support for the hypothesis that diabetes is a coronary heart disease equivalent. However, diabetes was reported as an important risk factor for cardiovascular diseases [4]. Kanaya et al. reported gender-based disparity in mortality from CHD concurrent with type 2 diabetes, and found that, OR of mortality from CHD was higher in women with diabetes than in men with diabetes. OR of death for diabetes was 2.3 and 2.9 in men and women, respectively, and HR of death for gender was not significant when other variables were adjusted [25]. In our study, although the adjusted OR of mortality for diabetes was higher in women than in men, the difference was not significant, which is consistent with the result of the study of Kanaya et al. [25]. In the present study, OR of mortality was significantly higher in women than in men and the mortality from MI was significantly higher in diabetes patients than in non diabetes patients, consistent with the studies of Cho et al. and Zuanetti et al. which investigated the diabetes contribution in post-MI patients receiving fibrinolytic therapy [26,27]. Although use of PCI, CABG, and thrombolytic therapy in our study was higher in those with or without diabetes, mortality was higher in those with diabetes when these therapies were controlled for in analysis. The higher mortality in diabetes patients in the present study could be explained through comorbidities such as hypertension, age, gender, cholesterolemia, RBBB, and LBBB. In the meta-analysis conducted by Lee et al., the relative risk of death from CHD for diabetes was higher in women (2.58) than in men (1.85) [24]. Our study confirms the findings of Lee et al. Lee et al. reported that mortality from MI was higher in women with diabetes than in men without diabetes. They also showed that, the risk of death was insignificantly higher in women with diabetes than in men with diabetes, which was not consistent with our findings. Cho et al. found that 2.5% of men had diabetes and they smoked more frequently than those without [27]. Similarly, the study of Pyorala et al. found that, use of Simvastatin in diabetes patients, as compared to non diabetes

patients, reduced total mortality and the mortality from CHD [28]. In contrast, use of PCI, CABG, and thrombolytic therapy in our study did not decrease the risk of death in patients with diabetes compared to those without. In our study, use of PCI could be considered a protective factor against death for non diabetes patients, but it was not significant for diabetes patients. Our findings are consistent with a study reporting that diabetes and variables such as age, gender, and hypertension were the main determinants of acute coronary heart syndromes [29]. In the studies conducted by Hu et al., Merry et al., and Zaliunas et al., age, Killip class, hypertension, and STEMI were predictors of hospital mortality from coronary heart syndrome, which is in agreement with the present study [30–32]. However, our findings are not consistent with Zaliunas et al. study, which showed that interventional therapies were a cause of decreased mortality in diabetes patients [30]. This inconsistency was explored in our study by enrolling a large sample size including patients with or without diabetes and investigating the association between treatment strategy and hospital mortality, using MI and definite diabetes diagnosis, and avoiding use of self-reporting. Failure to include diabetes duration in the model was one of the limitations of the present study, which should be considered in future studies.

5. Conclusions

The hospital mortality from MI following use of PCI, thrombolytic therapy, and CABG was, respectively, 7.28%, 13.23%, and 15.74% in diabetes patients and 4.72%, 15.57%, and 11.4% in non diabetes patients. OR and HR of death from MI following these treatments was significantly higher in diabetes patients than in patients without diabetes. The mortality from MI in patients with and without diabetes was higher in Iran than reported from some other countries. Also, use of the above therapies appeared considerably lower in Iran than in other countries. The mortality from MI in diabetes patients following PCI was lower than the mortality following CABG.

Conflict of interest statement

None.

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