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Analysis of the survival of patients with cardiac conditions after angioplasty operation and factors affecting it

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ABSTRACT

Cardiovascular conditions have been known to be the most important causes of mortality and disability in most countries. Official statistics show that mortality rate from such a phenomenon is on the rise in Iran. The present study was aimed to measure survival rate and factors affecting it in patients with heart conditions after angioplasty operation. This study focused on medical histories of 1188 patients who experienced angioplasty operation in Imam Ali medical-educational cardiovascular-condition-based institute in Kermanshah, from 2006 to 2013. Patients were monitored till the end of 2013 in order to incorporate main conditions (death, myocardial infarction, and brain stroke). In order to analyze the survival of these patients, non-parametric method (Kaplan Meier) and semi-parametric method (Cox regression) were used. All calculations were done using STATA software – version 12 – and significance of 0.05 was obtained. In this study, from the 1188 patients who received angioplasty surgery, 819 patients were male and 369 patients were female. 98 patients had major clinical conditions (MACE), 6 patients died, one patient had a brain stroke, and 91 patents had myocardial infarction. Using Kaplan Meier method, one, three, five, and seven-year survival levels of patients after angioplasty operation were calculated to be 99/8, 97, 91/8, 69/7, respectively. In addition, average survival period was 82.253 ± 1.283 months, and mean survival period was 82.5 months. Factors influencing survival period, based on Cox regression model are: dyslipidemia, angioplasty history, and number of embedded stents. Over time, the likelihood of vascular blockage rises in patients with angioplasty, and their survival period decreases after 52 months. Additionally, hazard rate for these patients is very high after the 52 months.

Keywords: survival, patients with heart conditions, angioplasty, Cox regression.

INTRODUCTION

Today, cardiovascular diseases are the most common causes of mortality in developed countries as well as the entire world. According to predictions made by WHO, the main cause of death across the world will be in 2020 [1]. In 2020, world's population will reach 7.8 billion, and 32 percent of deaths will happen due to cardiovascular conditions. In addition, according to another prediction made by WHO, in 2030, cardiovascular diseases will cause 24 deaths across the world [2, 3]. In developing countries, especially in Iran, because there is not enough awareness of factors causing cardiovascular conditions, and because no measures are taken in order to prevent them, mortality

rate is on the rise. In addition, considering the fact that the age range of patients with cardiovascular conditions is decreasing, the society has to pay higher costs [4]. Epidemiologic examinations report the most important risk factors of cardiovascular diseases to be: improper diet, obesity, little physical activity, smoking, high blood pressure, high cholesterol, other blood lipids, family history, age, gender, alcoholism, environmental factors, air and sound pollution, and mental stresses. Some factors such as smoking, foods, and physical activity are modifiable [5]. Currently, there are several methods for treating cardiovascular conditions, such as: bypass coronary vascular implant surgery (CABG), coronary vascular angioplasty through skin (PCI), and other corresponding techniques [6]. Angioplasty medical method is an inexpensive method compared to coronary bypass vascular surgery. Today, because angioplasty is not very risky and because it is highly successful, in the USA, 400000 patients receive angioplasty annually [7]. Before 1977, bypass surgery was the only way to treat vascular diseases, but currently angioplasty id the main method for treatment [2]. It must be noted that in this type of treatment, deterioration necessitates further treatment [7]' if 6 months after angioplasty, angiography is done, in 40 to 50 percent of cases, stenosis is again reported. But this is seen in less than one-third of clinical cases [7]. Restenosis is a phenomenon that is caused by many factors. Among factors causing restenosis, we can refer to factors such as sweet diabetes, low-diameter vessels, incomplete stenosis, vascular elasticity, left frontal descending coronary vascular blockage, and stenosis containing flocculation [8]. Studies in this field focus more on the identification of risk factors for these patients, while this study was done aiming to predict the time of further angioplasty-related clinical problems, and to measure the effect of variables corresponding to this factor, based on the analysis of survival data, using Cox model.

Most scholars in medication are more interested in using semi-parametric models such as Cox; because these models need fewer pre-hypotheses, compared to parametric models [9, 10]. In order to use Cox model, the hypothesis of the suitability of risks (PH) must hold for all independent variables available in the final model. This means that the ratio of risks must be fixed over time. If this hypothesis holds, the interpretation of the obtained model will be easier than parametric models. If the hypothesis does not hold, stratified Cox model is used; and risk ratio is not calculated for variables of the hypothesis that does not hold. On the one hand, considering hypotheses and selecting probability distribution for survival period makes statistical inference more accurate, estimating standard deviation of calculations to be small when such hypotheses are not available [11]. Cox model which was used in this study has special features because it enters other variables in the model. And it estimates risk function as well as introducing significant variables [11]. Considering the fact that so far, no comprehensive study has focused on the survival of cardiovascular conditions receiving angioplasty surgery, the present study was aimed to measure survival level in any period, and to examine factors affecting survival in patients with cardiac conditions in Kermanshah.

MATERIALS AND METHODS

This study was done in a historical cohort method, including 1188 patients who received angioplasty surgery and stents in Imam Ali medical-educational institute in Kermanshah, from 20006 to 2013. Data were obtained from patients' cases, and were approved by research ethics committee. The data were confidential and were not reported. Criterion for entering the study was the experience of angioplasty in the above-mentioned time period. Patients were monitored for one to even years; those who experienced other treatments than coronary vascular angioplasty or were impossible to be monitored after angioplasty were removed from the study. In this study, the spread of main risk factors was examined, using the cases of patients who received coronary vascular angioplasty and stent implants, i.e. those patients who were diagnosed with MACE or clinical restenosis. It was used in order to incorporate information needed from information bank and cases of patients. All the information related to patients, including demographic properties (age, gender, height, weight), presence of all types of risk factors (diabetes, high blood pressure, hyperlipidemia, smoking, coronary vascular condition family history, angioplasty history, cardiac infarction history, coronary bypass surgery history, brain stroke history, left ventricle ejection fraction) were recorded in an information form for each patient. This information has been collected through talks with patients and diagnosing signs of restenosis within continual monitoring done by doctors and the results of angioplasty and its reports by cardiologist international fellowship in an information bank.

MCAE has been defined as death, cardiac infarction, and brain stroke. In this study, the starting point of the first angioplasty has been considered as initial event, and time of death, heart attack, and brain stroke have been considered as final event, which shows vascular restenosis. When monitoring patients, if cardiac infarction is seen, activity-based angina, ventricle ejection fraction drop, positive work-out test have been put under angiography, controlled by doctors; and based on the result and the interpretation presented by international cardiologists, they received re-angioplasty, or they received cardiovascular bypass surgery. By collecting required data and calling in order to gain awareness, patients' current status was asked about. In order to analyze the survival of these patients, Cox semi-parametric and Kaplan Meier non-parametric methods were used. Base group (reference) was used for calculations of group risk ratio, which was least risky. Data analysis was done using statistical STATA v.12 software, and significance was 0.05.

RESULTS

In this study, there were 1188 patients: 819 men (68.9 percent), 369 women (39.1 percent). Patients' age average in angioplasty was 56.26 ± 9.97 years (55.36 ± 10.16 years for men, and 58.24 ± 9.25 years for women). The age of the youngest patient was 26, and the age of the oldest patient was 98.

From 98 patients with MACE, 6 patients died, 1 patient had brain stroke, and 91 patients had myocardial infarction. Among patients with MACE, 68 patients were men, and 30 patients were women. They had histories of high blood pressure (38.7 percent) hyperlipidemia (32.6 percent), smoking (34.6 percent), myocardial infarction (36.7 percent), coronary conditions (23.4 percent), cardiac angioplasty (6 percent), and diabetes (14.2 percent). From these patients, 1729 cases received angioplasty; when monitoring 128 cases, 91 patients were diagnosed with stenosis and restenosis.

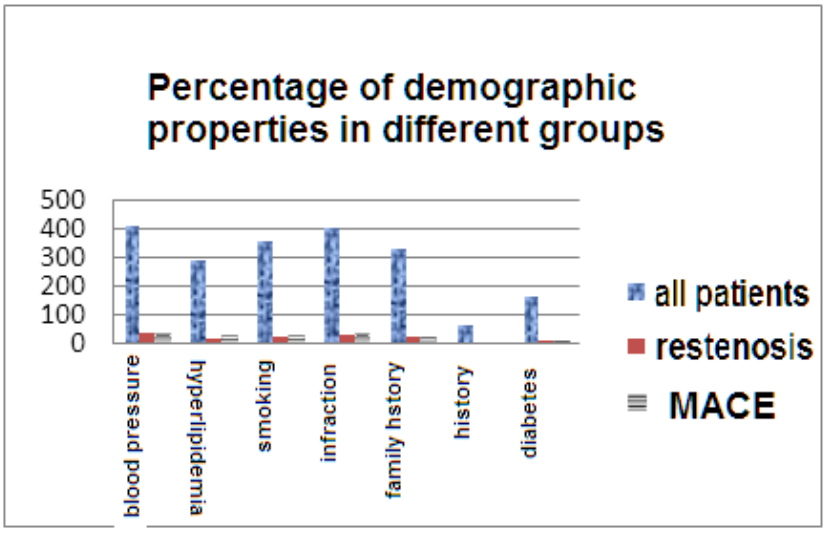
Table 1: Major Events when monitoring

Major Events when monitoring	All cases	
	number	percentage
death	6	6.1
Brain vascular events	1	1
Myocardial infarction	91	91

In total, 6.1 percent of all patients died within the period of monitoring. 1 percent of the patients experienced brain vascular events, and 92.8 percent of the patients had myocardial infarction. The present study showed that MACE in these patients was most related to restenosis and stenosis (P=0.001). In this study, 92 patients (7.7 percent) experienced restenosis, 90 patients needed revascularization due to restenosis. Revascularization was done within two methods: PCI and CABG. In addition, among the 6 patients who died, 1 died in the first six months after interventions, 1 died in the 2nd six-month period after interventions, 3 died in the 2nd year after interventions, and 1 died in the third year after interventions. Among them, 2 had an FE lower than 30 percent, one had an FE between 30 percent and 40 percent, one had an FE between 40 percent and 50 percent, and two had an FE higher than 50 percent.

Table 2: Demographic properties of groups with restenosis and MACE, and of all patients

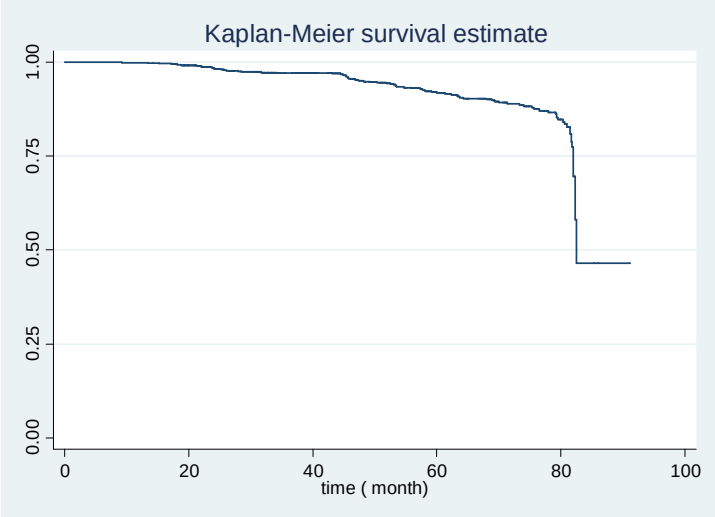
Demographic variables	Number of all cases	MACE		restenosis	
	number	number	percentage	number	percentage
Man	819	68	8.3	61	7.4
Woman	369	30	8.1	30	8.1
Blood pressure history	411	38	9.2	35	8.5
Hyperlipidemia history	291	32	11	20	6.8
Smoking history	357	34	9.5	21	5.9
infarction history	407	36	8.9	31	7.6
Coronary condition family history	62	26	6.9	26	7.8
Angioplasty history	165	6	9.7	7	11.2
Diabetes history		14		13	7.9
total	1188	68	8.5	91	



Graph 1: Percentage of blood pressure, hyperlipidemia, smoking, cardiac infarction, coronary family history, and diabetes in other groups having stenosis and MACE, and all patients

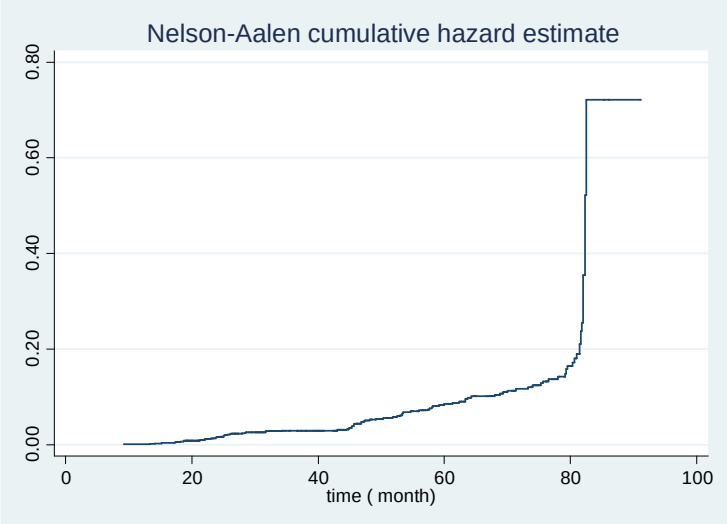
The results of the analysis showed that demographic properties in patients, despite the obvious effect on coronary problems, do not make a significant difference in clinical results after angioplasty. In this study, survival period has been considered as the period from angioplasty operation to major cardiac events. One-year, two-year, three-year, four-year, five-year, six-year, and seven-year survival of patients after angioplasty was 99.8, 98.3, 97, 94.9, 91.8, 88.6, 69.7 percent, respectively. In addition, the average of survival period was 82.253 ± 1.283 months, and mean of survival period was 82.5 months.

Graph 2 shows patients' survival function after angioplasty, with redundancy of slack variable. As it can be inferred from this graph, patients' survival significantly decreases after 52 months.



Graph 2: Patients' survival after angioplasty, with the redundancy of slack variables

Graph 3 shows patients' hazard rate after angioplasty, using Cox proportional hazard model. As it can be inferred from this graph, patients' hazard rate decreased significantly after 52 months.



Graph 3: Patients' cumulative hazard rate after angioplasty, using Cox hazard model

In order to fit the model for survival data, first we identify variables affecting patients' survival period, using Ranked Logarithm Test. Then, all variables that became significant in the test above, and those variables whose p-value was lower than 0.25 entered Cox model. In this model, factors affecting patients' survival were identified and final model was formed, using step-by-step method eliminating the effect of confounders. Based on values of log-rank statistics, dyslipidemia variables, angioplasty history, left ventricle ejection fraction, coronary blockage intensity were examined, and patients' survival was significant for all variables (p-value < 0.05) (table 3). Such that mean of survival period for patients who did not have dyslipidemia was 84 months, and it was 76 months for those patients who had dyslipidemia. Mean of survival period for patients with an ejection fraction greater than 50 percent, 40 to 49 percent, 30 to 39 percent, and lower than 30 percent was 84, 78, 74, and 70 months, respectively. Mean of

survival period for patients with blockage in one vessel, two vessels, and three vessels was 82, 79, and 73 months, respectively. Mean of survival period for patients with one, two, and three stents was 83, 78, and 74, respectively.

Table 3: Results of Log-Rank test

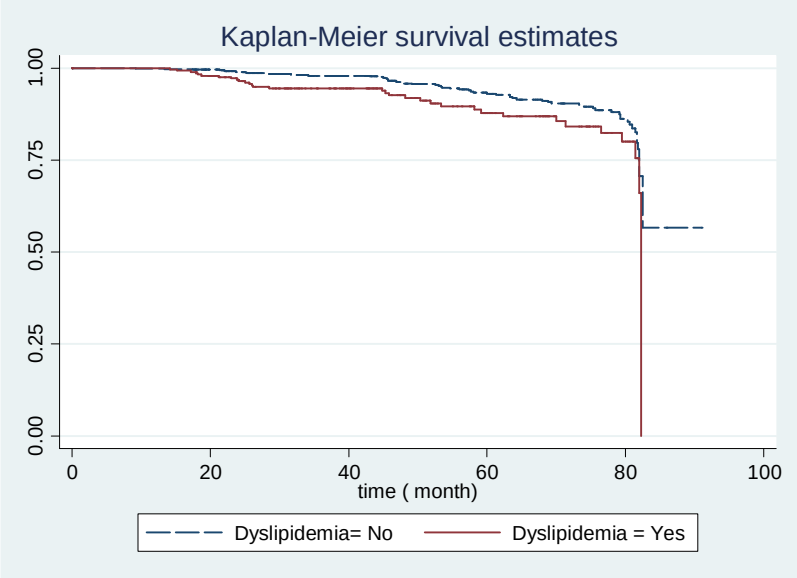
variable	Degree of freedom	Chi-2 statistic	P-value
dyslipidemia	3.306	1	0.012
PCI history	4.464	1	0.035
Left ventricle ejection fraction	12.308	3	0.006
Coronary stenosis intensity	7.185	2	0.028

Cox test was done in a single-variable format for variables such as gender, age (classified), body mass index, diabetes, high blood pressure, smoking, angioplasty history, coronary vascular bypass surgery history, coronary stenosis intensity, number of embedded stents, coronary stenosis positive family history, myocardial infarction history, and left ventricle ejection fraction. Using Cox regression, it is possible to control and calculate the effect of important confounding variables and variables affecting patients' survival period. Cox regression model considered the variables such as dyslipidemia, angioplasty history, coronary stenosis intensity, and number of stents to be significant. Table 4 presents data related to these variables.

Table 4: Variables predicting survival based on single-variable Cox regression method

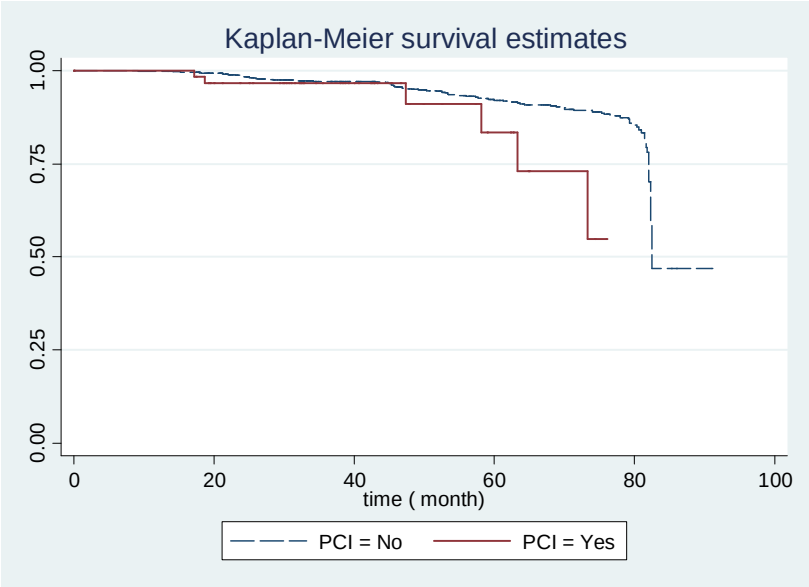
Variable	Variable elements	β	Hazard Rate (HR)	95-percent certainty for HR	P-value
gender	Male	-	Reference	-	-
	female	- 0.080	0.922	0.598 – 1.421	0.715
Age range	26 to 35 years	-	Reference	-	-
	36 to 45 years	0.057	1.059	0.128 – 8.711	0.957
	46 to 55 years	0.699	2.013	0.270 – 14.960	0.494
	56 to 65 years	0.249	1.283	0.169 – 9.699	0.809
	66 to 75 years	0.784	2.191	0.284 – 16.868	0.451
	76 years	0.098	1.145	0.067 – 18.054	0.924
Body mass index	< 18.5	-	Reference	-	-
	18.5 – 24.9	- 0.314	0.729	0.097 – 5.394	0.758
	25 – 29.9	- 0.450	0.637	0.087 – 4.647	0.657
	30 to 34.9	- 0.544	0.580	0.077 – 4.350	0.597
	35 to 39.9	- 0.104	0.900	0.108 – 7.502	0.923
Diabetes	-	-	Reference	-	-
	Without insulin	0.158	1.171	- 0.473 – 0.789	0.624
	With insulin	0.600	1.823	0.554 – 1.755	0.308
High blood pressure	-	-	Reference	-	-
	+	0.341	1.406	0.926 – 2.136	0.109
smoking	-	-	Reference	-	-
	+	0.341	1.406	0.926 – 2.136	0.109
dyslipidemia	-	-	Reference	-	-
	+	0.536	1.711	1.118 – 2.616	0.013
PCI history	-	-	Reference	-	-
	+	0.876	2.402	1.037 – 5.562	0.041
CABG history	-	-	Reference	-	-
	+	- 0.068	0.933	0.229 – 3.797	0.923
Coronary stenosis intensity	1 vessel	-	Reference 9	-	-
	2 vessels	0.400	1.492	0.934 – 2.386	0.094
	3 vessels	0.860	2.364	1.127 – 4.958	0.023
Number of embedded stents	1	-	Reference	-	-
	2	0.286	1.331	0.835 – 2.122	0.228
	> 3-5	0.774	2.169	1.101 – 4.274	0.025

Cox model, focusing on the effect of dyslipidemia on patients' HR showed that the chance of MACE in patients with dyslipidemia was 1.711 times more than the chance of MACE in patients without dyslipidemia, and this significant (P-value < 0.05, 95 percent, CI=1.118 – 2.616, HR = 1.711). As it can be seen in graph 4, the survival of patients with dyslipidemia was lower than the survival of patients without dyslipidemia.



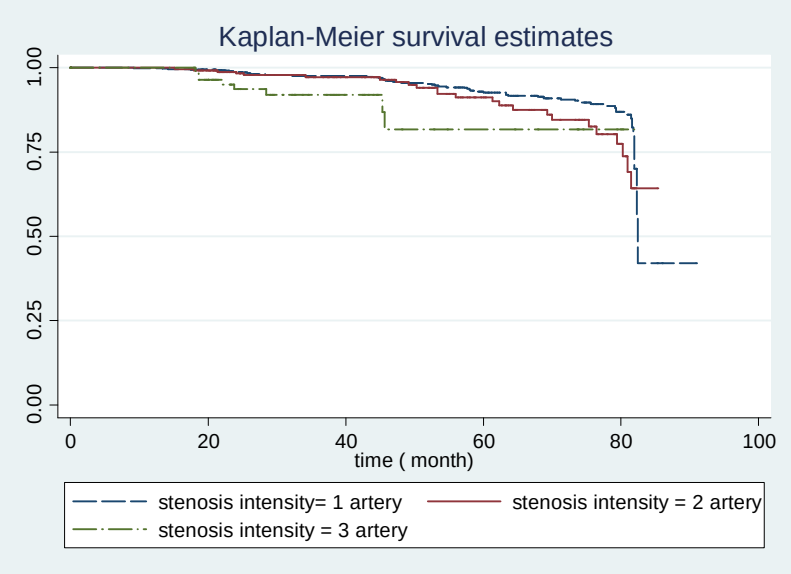
Graph 4: Kaplan Meier survival calculation at the presence of dyslipidemia

Cox model, focusing on angioplasty history, showed that the chance of MACE in patients with angioplasty history was 2.402 times more than the chance of MACE in patients without angioplasty history; and this ratio was significant (P-value < 0.05, 95 percent, CI=1.037 – 5.562, HR=2.402). As it can be seen in graph 5, the survival of patients with angioplasty history was lower than patients without angioplasty history.



Graph 5: Kaplan Meier survival calculation at the presence of angioplasty history

Cox model, focusing on the effect of coronary stenosis intensity on hazard rate, showed that the chance of MACE in patients with three blocked vessels was 2.364 times more than the chance of MACE in patients with one blocked vessel; and this ratio was significant (P-value < 0.05, 65 percent, CI=1.127 – 4.958, HR=2.364). As it can be seen in graph 6, the survival curve for patients with three blocked vessels is lower than that for patients with one blocked vessel; and the survival of patients with two blocked vessels was lower than that of patients with one blocked vessel.



Graph 6: Kaplan Meier survival calculation at the presence of coronary stenosis intensity

Cox model, focusing on the effect of the number of embedded stents on hazard rate, showed that the chance of MACE in patients with 3 to 5 stents was 2.169 times more than the chance of MACE in patients with 1 stent (P-value < 0.05, 95 percent, CI=1.101 – 4.274, HR=2.169). As you can see in graph 7, the survival curve for patients with 3 to 5 stents was lower than that for patients with one stent; and the survival of patients with two stents was lower than that of patients with one stent.

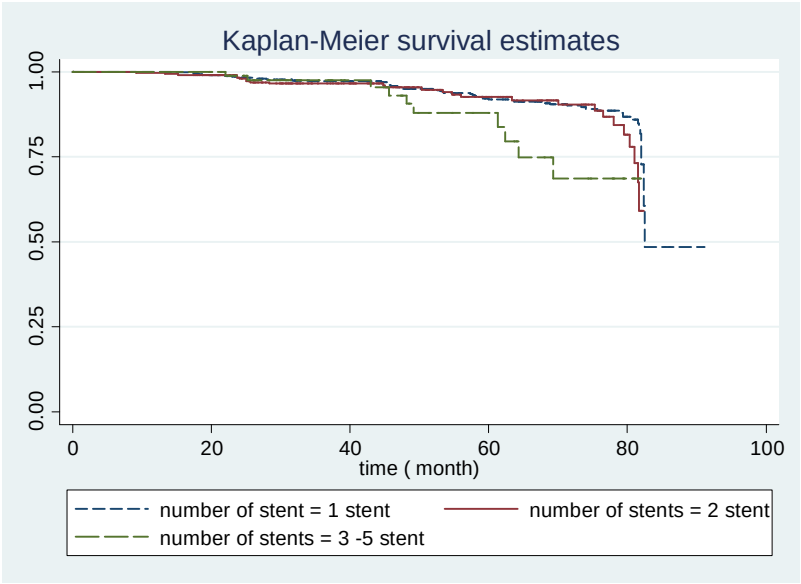


Table 7: Kaplan Meier survival calculation at the presence of the number of stents

Multivariate Cox regression model was used after confounding effect moderator of other variables in order to examine factors affecting MACE. In this case, those variables which had a p-value lower than 0.25 in the single-variant analysis entered the multivariate analysis in order for us to be able to identify effective variables if it is ignored due to confounders. In addition, variables, for which there were not Cox hazards model hypotheses that fit, were classified. Like in single-variant Cox model, variables such as dyslipidemia, angioplasty history, and number of stents became significant. In the single-variant case, stenosis intensity was significant when patients had three blocked vessels. But in the moderated case, after other variables were added to the model, corresponding hazard rate was significant. The chance of MACE in patients with dyslipidemia was 1.675 times more than the chance of MACE in patients without dyslipidemia, and this ratio was significant (P-value < 0.05, 95 percent, CI=1.093 – 2.566, HR=1.711). the chance of MACE in patients with angioplasty history was 2.338 times more than the chance of MACE in patients without angioplasty history; and this ratio was significant (P-value < 0.05, 95 percent,

CI=1.002 – 5.455, HR=2.338). The chance of MACE in patients with 3 to 5 stents was 2.215 times more than the chance of MACE in patients with 1 stent (P-value < 0.05, 95 percent, CI=1.124 – 4.365, HR=2.215).

Table 5: Variables predicting survival based on multivariate Cox regression method

variable	Variable elements	β coefficient	hazard rate (HR)	95-percent certainty for HR	P-Value
High blood pressure	-	-	Reference	-	-
	+	0.034	1.035	0.640 – 1.673	0.888
Smoking	-	-	Reference	-	-
	+	0.205	1.278	0.838 – 1.950	0.254
dyslipidemia	-	-	Reference	-	-
	+	0.515	1.675	1.093 – 2.566	0.018
PCI history	-	-	-	-	-
	+	0.849	2.338	1.002 – 5.455	0.040
Coronary stenosis intensity	1 vessel	-	-	-	-
	2 vessels	0.310	1.141	0.668 – 1.949	0.629
	3 vessels	0.795	1.872	0.872 – 4.019	0.107
Number of embedded stents	1	-	-	-	-
	2	0.231	1.364	0.855 – 2.177	0.192
	3 to 5	0.708	2.215	1.124 – 4.365	0.022
Moderated using left ventricle ejection fraction and myocardial infarction history and coronary stenosis family history					

The data presented in the table shows that dyslipidemia with a coefficient of β=0.515 and p < 0.05 increases risk rate to 1.675, leading to an increase in hazard function and a decrease in patients' survival function.

PCI history with a coefficient of β=0.877 and P< 0.05 increased risk rate to 2.338, leading to an increase in hazard function and a decrease in patients' survival function.

The number of stents with a coefficient of β=0.708 and P< 0.05 increased risk rate to 2.215, leading to an increase in hazard function and a decrease in patients" survival function.
Remaining variables in the final model include dyslipidemia, angioplasty history and number of stents embedded in vessels, for which hazard rate (HR) and 95-percent certainty were calculated. Table 5 shows data connected to these variables.

DISCUSSION

Cardiovascular diseases are the most important factor of mortality in the world and in Iran. The increasing growth of these diseases is mostly seen in countries with low and medium income [12]. Survival is the main measurable consequence of cardiac diseases. This study was aimed to determine survival period and factors related to it in patients who received angioplasty. As it was mentioned before, Cox proportional hazard model is one of the most common ways of analyzing variables predicting survival in clinical researches. This might be because this model allows researcher make statistical inferences without any pre-hypotheses about the distribution of survival period. Using this model does not require proportional hazard hypothesis to hold over time; and in many studies, this hypothesis does not hold. In studies examining survival [13] it was known that only five percent of these studies have focused on testing pre-hypotheses needed in Cox model. If the proportional hazard pre-hypothesis does not hold, the results obtained from Cox model will not be trusted [14, 15]. Based on the results obtained from multivariate regression analysis and after modification the effect of other variables (by eliminating probable confounding effect), variables such as dyslipidemia, angioplasty history in patients with a coefficient of 0.849 showed that the an increase in hazard was 2.338 times more than that in patients with angioplasty history, which was in line with the study done by Yousef Nejad [16]. The number of embedded stents was another variable which increased hazard rate to 2.215.

From 1188 studied patients, 1091 patients (91.8 percent) received successful angioplasty. The percentage of success was 91.8 and the percentage of major events was 8.2 percent. The present study had a reasonable success percentage, compared to studies done by Hamon in France [17], Inguiz in Spain [18], and Finessi in Germany [19]. The percentage of major events in the end of monitoring period (8 years) done by Choussat in France, which included 232 cases, was 54.8 percent; the percentage of survival without any events was 45.2 percent [24]. And in the study done by Finessi in Germany, one year after PCI including 27 major events, was 17.3 percent; and event-free survival was 83 percent [19]. In the study done by Camsar in Turkey after a 6-month monitoring period and after two years, there were 13 events (8.78 percent) and 30 events (20 percent) [25].

In their study, Schneider et al showed that over time the chance of restenosis in patients receiving angioplasty increases; hence, it must be always monitored. The average age of patients in their study was 61 ± 11 [26], which

were in line with the study conducted by Etemadi Nejad et al [8], and in line with the present study in which patients' age average was 56.26 ± 9.97. This study also showed that MACE was mostly connected with restenosis in patients.

In another study conducted by Gambhir in India, patients receiving angioplasty were monitored within a 60-month period. Collected data were analyzed using Kaplan Meier model. In this study, 71.1 percent of patients received one stent, 21.2 percent of them received 2 stents, and 7.7 percent of them received 3 stents [27]. But in the present study, 64.5 percent of patients had 1 stent, 26.9 percent of them had 2 stents, and 8.7 percent of them had 3 or more stents. The survival of patients based on major events in the study done by Gambhir, was 72.5 percent in the third year, 68 percent in the fifth year, 61.8 percent in the seventh year, and 55.6 percent in the tenth year [27]. In the present study, 1-year, 2-year, 3-year, 4-year, 5-year, 6-year, and 7-year survival, using Kaplan Meier non-parametric method, was calculated to be 99.8, 98.3, 97, 94.9, 91.8, 88.6, 69.7 percent, respectively. But in a study done by Etemadi Nejad [8], survival of patients who have received angioplasty was 85 percent in the end of the sixth year [28], and in a study conducted by Mass, survival of patients after angioplasty was 91 percent, 80 percent, 64 percent, and 59 percent for 5, 10, 15, and 17 years, respectively [29].

Since in most survival studies, events happen on both sides of survival, data have skewness, hence it is not possible to accept normality hypothesis in most cases. That is why the calculation of mean value in such studies is very important. Mean value in these data is a point in time, after which 50 percent of the studied population are expected to stay alive. However, in the present study, the mean of survival period was 82 months, and the mean of hazard function was 0.10. This means that the chance of a patient facing risks during study is 0.10. In the study done by Etemadi Nejad [8], the mean of survival time was 44 months, and the mean of hazard was 0.12.

In another study done by Espinola-Klein within ten years on 313 patients with angioplasty history, 28 percent of them experienced major events till the end of the study [30]. The percentage of major events in the study done by Etemadi Nejad [8], was 25 percent, which was in line with Espinola-Klein's study, including death factors such as cardiac diseases, heart attack, PTCA, CABG. The percentage of MACE incidence was 8.2 percent in the present study. This difference can be referred to as the difference of study duration.

CONCLUSION

Based on the results obtained from this study and other studies, the likelihood of restenosis increases over time. Considering the intense effect of some variables, and the survival of these patients, it is advised that serious measures are taken in order to evaluate cardiovascular status and control diseases affecting these people.

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