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Original Article

A Decision Support Model for the Necessity of Cardio-Angiography, A Result of Generalized Additive and logistic Regression Model

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ABSTRACT

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Introduction: Angiography is used as the gold standard for diagnosis of coronary artery disease (CAD). It is an invasive procedure and has several complications. Also, some patients refuse angiograms for reasons such as fear, high cost, and loss of trust in physician diagnosis. The negative results of this test is more than a third. Therefore, having a statistical predictive model for estimating the risk of CAD, as an evidence-based support system, can help the physician and patient decide on the necessity of angiography.

Aims: In this study we aimed to find an evidence-based supportive model for decision making on the necessity of angiography in people who were candidates for angiography by the physician after initial tests.

Methods: In this study, 1187 patients who had been referred to Ghaem Hospital of Mashhad University of Medical Sciences and diagnosed with physicians after initial tests were enrolled. Demographic data, lipid and blood sugar levels, and the history of underlying disorders were variables that were studied in the statistical model fitting. Initially, generalized additive models were used singularly for quantitative predictors, then by applying right transformations on the predictor variables we entered them simultaneously in logistic and count regression models. These two models were fitted to the data using R software and then compared in terms of predictive accuracy.

Findings: Generalized additive models showed that the relationship between CAD with the hs-CRP level was not monotone. Exploratory analyzes showed that 62% of people with hs-CRP level <3 and 50% of people with hs-CRP levels between 3 and 6 were suffered from the CAD. The highest rate of CAD was seen in the range of 6-8 (93%) but with increasing the hs-CRP level to above 8 it decreased to 70%. The relationship between age and the risk of CAD was S-shaped. Risk of CAD in diabetic subjects with normal FBS was equal to that of non-diabetic subjects with normal fasting blood sugar. The age, gender, diabetes, FBS, and hs-CRP were significant in both models ($p < 0.05$). The area under the ROC curve was upgraded to 81 for the logistic model.

Conclusion: The most important finding of this exploratory study was that out of 232 patients with hs-CRP level between 6 to 8, 217 (93%) had coronary artery occlusion, for these subjects the probability of occluding a coronary artery was 0.93. The present study also showed that if the blood sugar is controlled in patients with diabetes, then this disease will not be a risk factor for patients with coronary artery occlusion. The logistic regression model presented in this study is recommended as the final model to support decision-making about the necessity of angiography.

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Introduction:

Heart disease has been one of the most prominent problems in recent years that have caused many economic and side problems which forcing health authorities in various countries to make a comprehensive plan for education, prevention and treatment in this field(1). According to the Centers for Disease Control and Prevention (CDC), 1.5 million people have diagnosed with the cardiovascular disease annually, which 15 to 65 percent of them dying (2). According to the American Heart Association, by 2020 about 25 million people will die because of heart disease and this disease will be known as the main factor of death and disability in the world(3). Cardiovascular disease is also the main cause of mortality in Iran which over 39.3% of deaths in Iran related to ischemic heart disease (2). Coronary artery disease (CAD) is caused by atherosclerosis which is a buildup of plaque inside the artery walls. This plaque increases over time, causing disease and a decrease in myocardial tissue blood flow(4). There are different diagnostic methods for evaluating patients with cardiovascular disease which angiography is the most reliable one(5). However, this method is expensive and invasive, and it is associated with risks such as death, myocardial infarction and stroke(6). Therefore, it is important to find people with negative angiograms and the factors that influence angiographic results. Doing so requires appropriate statistical methods. The main purpose of classification and modeling in statistics is to predict based on evidence and variables and data from a particular subject. This is done by statistical methods such as linear regression, logistic regression, audit analysis, time series, tree regression, neural network and other methods. Considering a default distribution such as the normal distribution for the response variable, the linear relationship between the predictor variables with the response variable, and equality of error variances are some of the classical methods that practical use of them is not possible or may result in a significant error if the actual data do not meet the assumed conditions (7). Meanwhile, the logistic regression method is widely used in medical studies because it does not need a lot of assumptions, and due to the easing of use and offering the odds ratio, and expressing the effect of each independent variable in the model. Many scientific studies prefer to categorize and analyze count variables in two ways. The purpose of this study was to model the risk factors of heart disease using logistic and zero inflated negative binomial regression models to predict the negative results of angiography. For this reason, we first fitted each of the two models to the data and compared the results with each other.

Methods

The data of this study were obtained from a cross-sectional study in Mashhad between 2011 and 2013. Patients referred to Ghaem Hospital of Mashhad for angiography were the target population. The minimum required sample size with a 95% confidence level and 90% power of the test was 964. Considering a 20% dropout rate to avoid the loss of power of study facing possible missing data, the final sample size of 1187 was considered. The tools used to measure the variables of this study were two checklists (patient medical records and laboratory results) which were completed by the patients and included demographic information, Body Mass Index, fasting blood sugar level, blood pressure, lipid profile, C-reactive protein, angiography results, the number of artery occlusion, cigarette smoking level, diabetes, and family history. After completing the checklists and entering the data into the software, the analysis was performed using R software.

Statistical Methods

In recent decades, with the development of evidence-based care, especially in the medical field, using various statistical methods and models has also made great progress, so that evidence-based supportive models can be used to make optimal care decisions and interventions. In this study, an exploratory pre-analysis was performed based on a generalized linear model in order to find the relationship between variables and variable of coronary artery occlusion response were analyzed using two methods of logistic regression and count regression.

Generalized Linear Model (GLM): GLM was used to investigate the relationship between the response variable and the study quantitative variables, which is very helpful in exploring the relationship between the quantitative variables with the response variable and selecting transformations to fit the conditions of the logistic model (8, 9)

Generalized Additive Model (GAM): GAMs are kind of non-parametric regression that are generalized smoothing methods such as Spline, LOESS, Kernel, etc. which are used for non-normal response variables such as binary responses and are defined as follows:

$$g\big(E(y|x)\big) = \alpha + \sum_{i=1}^{p} S(x_i)$$

Where y is the response variable and the random component, x_i represents the i^{th} covariate variable, S is the smoothing function, and g is the link function. In the present study, we used the identity link function to explore the relationship between quantitative variables and the binary response: if the smooth curve obtained as S indicates that the variable is fit to the logistic model without any conversion, otherwise the required conversions for smoothing the relationship and the relative compliance with model conditions should be considered and then the variable should be applied to the model(8-14).

Logistic Regression Model:

In this approach, the response variable was considered as binary: with/without artery occlusion. Therefore, on the condition that there is a logistic relationship between the response variable and the quantitative independent variables, the logistic regression model is the appropriate model for this approach. In the medical sciences, the outcome variable is usually the presence or absence of a condition or disease. The basic mathematical concept, which is the basis of logistic regression, is logit i.e. the logarithm of the odds. Since the predicted probability must be between 0 and 1, simple linear regression techniques are not enough to obtain it. Because they have allowed the dependent variable to exceed these constraints and produce inconsistent results. The general form of the logistic regression model is as follows:

$$\log\left(\frac{\pi}{1-\pi}\right) = \alpha + \sum \beta x$$

Where x is the predictor variable indicator, β is the estimated coefficient for the relevant predictor variable, which is estimated using the maximum likelihood estimation, and α is the y-intercept. π indicates the probability of disease or no disease. One of the benefits of using a logistic regression model is the ability to predict the probability of belonging to which level of the dependent variable and to calculate the odds ratio directly using model coefficients. Therefore, the results of this model can be used to estimate the probability of artery involvement before angiography.

***Count Regression Model*:**

In this approach, we consider the number of arteries involved as response variables that take values of 0,1,2,3. This count variable was examined at the beginning of the Poisson distribution curve. Since the number of cases without involved arteries was more than expected in the Poisson distribution, we faced the problem of zero-inflated. This problem cannot be ignored because, in addition to the loss of important information, it will lead to erroneous estimation of parameters and misleading results; so it is important to assume that the surveyed individuals may be heterogeneous, then in this study, zero-inflated models, which dividing the study population into two hidden subpopulations, were used. Another challenge we encountered in these data was the problem of over-dispersion over the Poisson distribution, so the log-linear regression model or the count regression with zero-inflated negative binomial distribution was considered for the response variable. The average and variance of this distribution are defined as follows:

$$E(y_i) = \mu_i(1 - q_i)$$

$$Var(y_i) = (1 - q_i)\left(\mu_i + \frac{\mu_i^2}{k}\right) + \mu_i^2(q_i^2 + q_i)$$

Using a latent variable approach, this model considers the zero in the data as the result of two processes and modeled as follows:

$$p(Y = y) = \begin{cases} q_i + p(Y = 0|\mu) & if \quad Y = 0 \\ (1 - q_i)p(Y > 0|\mu) & if \; Y > 0 \end{cases}$$

$$\log(\mu) = \alpha + \beta_1\alpha_1 + \cdots .. + \beta_p\alpha_p$$

Where μ is the mean of Poisson distribution or negative binomial distribution. If we consider the data as the result of two hidden processes, μ is the probability of being in a process that produces only zero. This means that some people are not exposed to coronary artery occlusion and with a probability of 1, their angiography result is negative. These zeros are called structural zeros. The probability being in another process that produces other values for the response variable including zero number of occluded arteries is -1. In this process, although zero values are likely for angiography results, people are at risk of artery occlusion, and as a result, the number of artery occlusion may be greater than zero in the future. In zero inflated regression, logistic regression can be used for modeling the artery occlusion (-1). Thus, in interpreting the counting coefficients (Poisson or negative binomial), the reader should be informed that the inference is related to the people exposed to the artery occlusion and not all samples(15, 16).

First, logistic and zero inflated binomial negative models were used to identify the determinants and evaluate the accuracy of the model in detecting negative angiographic outcome. Comparison of the fitted models was performed using the results obtained from the ROC curve (sensitivity, specificity, accuracy and area under the ROC curve). Data analysis was performed using R 3.6.1 software and the reported results were around 0.05 level.

For compatibility of the results of this model with the logistic regression we used the same categories as in the logistic model. The results of this model can be used to estimate the number of involved arteries before angiography.

Results

Of the 1187 samples, 404 (0.34) patients with negative angiography result, 783 (0.66) patients with positive angiography result, 211 (17.8) patients had one involved artery, 216 (18.2) patients had two involved arteries, and 356 (30) patients had three involved arteries. A total of 577 (48.6) women and 610 (51.4) men were included in the study. The average age of the subjects was 11.15±57.11. The relative frequency of men and women with positive angiography result (negative angiography result) was 38.3 (68.6) and 61.7 (31.4), respectively. In those with positive angiography result (negative angiography result), the relative frequency of history of diabetes, history of hypertension, history of heart disease and family history of heart disease were 54.6 (38.6), 47 (43.3), 44.7 (48.3) and 67.9 (32.1) percent, respectively. Age, sex, and history of diabetes were significantly different for people with different results of angiography (at the significant level 0.05). Table 1 describes and compares the variables by person angiography results.

In this study, two regression models for data were compared. Due to the initial fitting of all the variables with logistic and zero-inflated binomial regression models it was found that only variables of age, sex, diabetes, and C reactive protein were significant in these two models.

Table1 . Characteristics of Patients Based on Angiography Results

Variable		Positive Angiography Result	Negative Angiography Result	p- value
Age (mean(SD))		53.60(11.39)	58.93(10.58)	<0.001
Gender (n(%))	Male	483(79.1)	127(20.8)	0.001
	Female	300(51.99)	277(48.01)	
Diabetes (n(%))	Yes	424(73.10)	156(26.90)	0.001
	No	352(58.67)	248(41.33)	
Blood Pressure History (n(%))	Yes	368(67.77)	175(32.23)	0.228
	No	415(64.44)	229(35.56)	
Family Heart Diseases History (n(%))	Yes	390(67.94)	184(32.06)	0.164
	No	393(64.11)	220(35.89)	
Heart Diseases History (n(%))	Yes	350(64.22)	195(35.78)	0.234
	No	433(67.45)	209(32.55)	
hsCRP (n(%))	0-3	221(62.3)	134(37.7)	<0.001
	3-6	213(51.7)	199(48.3)	
	6-8	217(93.5)	15(6.5)	
	>8	132(70.2)	56(29.8)	

In examining the relationship between the quantitative variables with the artery occlusion variable, a non-monotonic relationship was observed between the artery occlusion and hs-CRP level (Fig. 1), and the relationship between age and the artery occlusion was also S-shaped (Fig. 2). Given that the relationship between the artery occlusion risk and hs-CRP was non-monotonic, it was not possible to interpret it quantitatively, so subsequent exploratory analyzes were carried out to obtain new categories. The exploration method used was based on a thoroughly intuitive approach based on fine grading, comparing results, and merging similar categories, and the results were very surprising.

The analysis showed that 62% of those with hs-CRP level <3 and 50% of those with hs-CRP levels between 3 and 6 had arterial occlusion. The highest rate of arterial occlusion was seen in the range of 6-8 (93%) but with an increase of hs-CRP level above 8 is decreased to 70%. The likelihood of arterial occlusion in diabetic subjects with normal fasting blood sugar was equal to that of non-diabetic subjects with normal fasting blood sugar.

Tables 2 and 3 show the results of the final fit of logistic regression and zero-inflated negative binomial regression models as well as p-values of these coefficients.

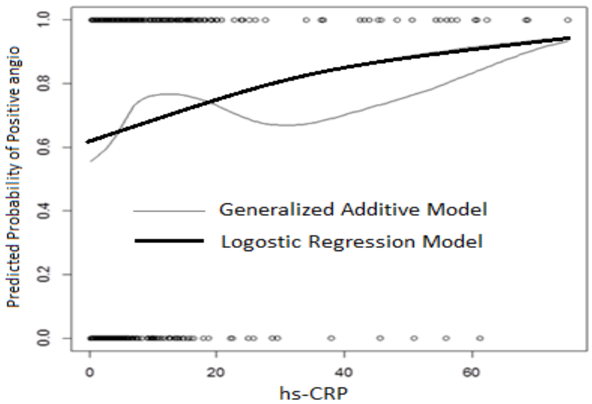

Figure 1.Comparing the predicted probability of positive angiography according to the level of hs-CRP between Generalized additive model and Logistic regression model

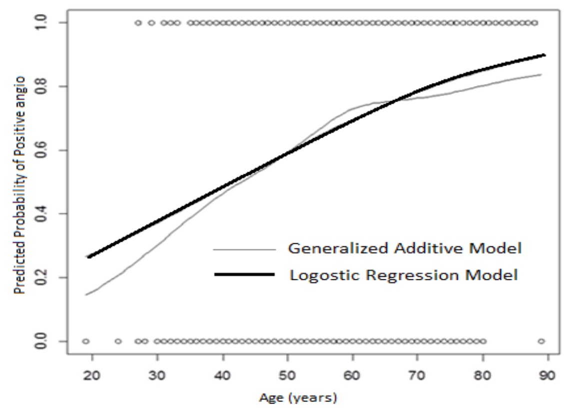

Figure 2. Comparing the predicted probability of positive angiography according to the age of patients between Generalized additive model and Logistic regression model

Table2 . The results of logistic regression to predict the risk of CAD by diabetes, hs-CRP, age and sex

Variable	Levels	Estimation (standard deviation)	Wald Test	Odds ratio (Confidenceinterval)	p- value
Constant		-3.22(0.41)	-7.78	0.03(0.01,0.08)	<0.001
Age		0.04(0.006)	7.15	1.04(1.03,1.06)	<0.001
Gender	Male	1.53(0.14)	10.29	4.63(3.47,6.22)	<0.001
	Female	-	-	-	-
Diabetes	FBS<120 (Yes/No)	-	-	-	-
	No & FBS>120	0.79(0.22)	3.59	2.20(1.44,3.42)	<0.001
	Yes & FBS>120	1.04(0.18)	5.61	2.84(1.98,4.12)	<0.001
C-reactive Protein	0-3	-	-	-	-
	3-6	-0.48(0.16)	-2.92	0.61(0.44,0.85)	<0.001
	6-8	2.20(0.30)	7.19	9.07(5.11,17.13)	<0.001
	8<	0.26(0.21)	1.23	1.30(0.85,1.98)	0.21

Table3 . The results of zero inflated negative binomial model to predict the risk of CAD by diabetes, hs-CRP, age and sex

	Variable	Levels	Estimation (standard deviation)	Wald Test	Odds ratio (Confidence interval)	p- value
Binomial Model	Constant		0.104(0.16)	0.65	1.11(0.81,1.52)	0.515
	Age		0.008(0.002)	3.122	1.008(1.003,1.01)	0.001
	Gender	Male	-0.129(.057)	-2.262	0.87(0.78,0.98)	0.023
		Female	-	-	-	-
	Diabetes	FBS<120 (Yes/No)	-	-	-	-
		No & FBS>120	0.158(0.069)	2.281	1.17(1.02,1.34)	0.022
		Yes & FBS>120	0.241(0.059)	4.05	1.27(1.13,1.43)	<0.001
Logistic Model	Constant		3.98(0.72)	5.47	53.6(12.8,223.45)	<0.001
	Age		-0.075(0.012)	-5.92	0.92(0.91,0.95)	<0.001
	Gender	Male	-2.07(0.28)	-7.33	0.12(0.07,0.21)	<0.001
		Female	-	-	-	-
	C-reactive Protein	0-3	-	-	-	-
		3-6	0.474(0.242)	1.95	1.60(0.99,2.58)	0.050
		6-8	-13.05(127.38)	-.0103	0.000002~0(-)	0.91
		8<	-0.49(0.34)	-1.44	0.60(0.31,1.19)	0.148

According to the results of fitting the logistic regression model, it can be said that the probability of positive angiography results in men is 4 times higher than women. Also, the probability of positive angiography results in non-diabetic subjects with a fasting blood sugar over 120 is 2.2 times more than those with fasting blood sugar under 120, and the probability of positive angiography results in diabetic subjects with a fasting blood sugar over 120 is 2.84 times more than those with fasting blood sugar under 120. For a one-year increase in age, the probability of positive angiography results is increasing to 1.04 times. hs-CRP was applied to the model as a result of exploratory analysis and the subjects with hs-CRP between 0 and 3 were considered as a base group; It was found that the probability of positive angiography results in subjects with hs-CRP level between 3 and 6 is 0.61 times lower than a base group, in people with hs-CRP between 6 and 8 it is 9.07 times more than the base group and in those with hs-CRP level more than 8 it is 1.30 times more than the base group. The fit of the logit part of the zero-inflated negative binomial regression model showed similar results to the logistic regression. The findings of the study suggest that men with a fasting blood sugar over 120 and a C-reactive value between 6 and 8 have the highest risk of CAD.

Given the values of the area under the ROC curves plotted from the fitting of the two models (figures 3 & 4), two models have approximately equal power for predicting the angiography results.

Discussion

According to the importance of heart disease and the high prevalence of it in different communities, it is important to predict this disease and in this regard, selecting a suitable statistical model that can accurately predict angiography results based on observations is crucial. The aim of this study was to find a suitable model to predict angiography results based on easily measurable risk factors. According to the data structure, two statistical models of logistic regression and zero-inflated negative binomial regression seemed appropriate. Previous studies have shown that age, sex, high blood lipids, hypertension, fasting blood sugar, and hs-CRP are among the factors contributing to coronary artery disease.

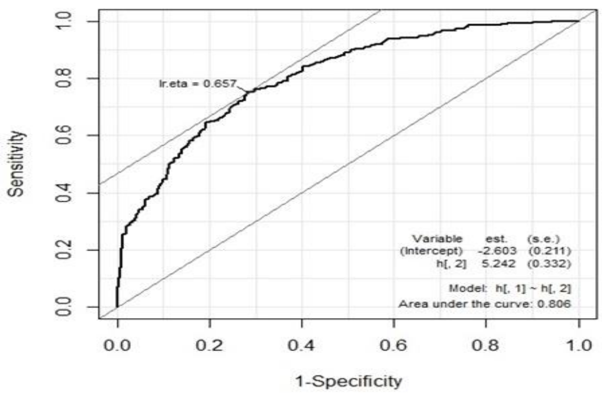

Figure 3. The ROC curve for predicting power of Logistic Regression Model

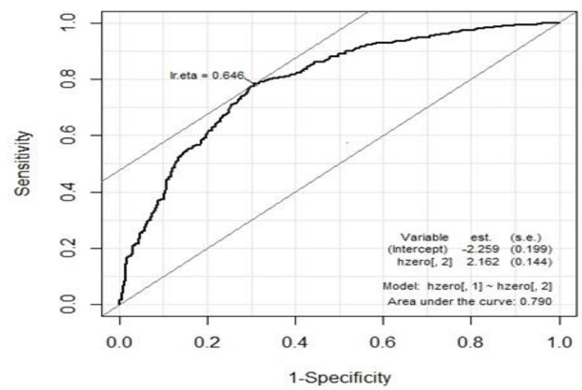

Figure 4. The ROC curve for predicting power of the Logit part of Zero Inflated Negative Binomial Model

In this study, the results of the fitting of the two models show that the variables of age, sex, fasting blood sugar over 120 and C-reactive proteins have a significant role in the incidence of artery occlusion. The results also showed that the incidence of coronary artery disease is greater in male than female. In the study of Chila et al., there was also a significant difference in the coronary arteries occlusion based on the gender, which is consistent with our study (17). In the study of Root et al., variables of age, gender, and diabetes were significant, in addition to these variables, the C-reactive protein variable was also significant in our study (18). In a study investigating the association of some risk factors with coronary artery occlusion, Bidel et al. identified age, sex, and smoking variables as risk factors associated with coronary artery occlusion (5), we identified age and sex as related factors on the response in our study but no significant relationship was found between the variables of smoking and response. This lack of relevance may be due to the approximately equal population of men and women under study. In another study by Hosseini et al., age, sex, diabetes, and hypertension were identified as risk factors associated with the number of coronary arteries involved(19), the predictive and significant variables in this study being similar to the Hosseini study, with this difference that blood pressure was not significant in this study. In the study of Mousavi Nasab et al., variables such as age, sex, cholesterol, triglyceride and fasting blood sugar were identified as contributing factors to coronary artery disease, but no relationship was found between blood pressure and arterial occlusion(20). There was also no relation between blood pressure and arterial occlusion in this study. The differences between the findings of different studies can be attributed to the cultural and geographical differences of the regions and communities under study. Studies investigating the relationship between hs-

CRP and coronary artery disease have reported different categories for hs-CRP(21-23). In this study, we classified the hs-CRP values into four groups, due to the non-monotonic relationship between hs-CRP and arterial occlusion. According to this classification, the study shows that values between 6 and 8 are the most influencing factors in arterial occlusion.

According to a literature search, many studies have been performed on the predictors of arterial occlusion using a logistic regression model(19, 20, 24, 25). But no study was found to compare the models examined in this study for angiography data. The only study that aimed at comparing count regression and logistic regression models was performed on side-effects data (26) and it has shown that count model had more predictive power than the logistic model, whereas in our study the two models had approximately the same power of prediction. This difference may be due to the different data sets used in these two studies. Using the rules obtained in this study, it is possible to determine the probability of a negative angiography result for a new person by having specific variables.

Conclusion

The most important finding of the present study is that hs-CRP levels between 6 and 8 can be a very strong index for CAD. A second important finding is that if blood sugar is controlled in diabetic patients, then diabetes would not be a risk factor for CAD. The logistic regression model presented in this study with 81% accuracy is recommended as the final model in support of decision-making regarding the necessity of angiography.

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