RESEARCH ARTICLE

Factors affecting the prognosis of patients with lower extremity arteriosclerosis obliterans undergoing interventional treatment

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As society develops and the population ages, the incidence of lower extremity arteriosclerosis continues to rise. Interventional therapy has gradually become the preferred treatment method. However, patients still face the risks of vascular restenosis, amputation, and even death, and the prognosis is affected by multiple factors. This research built a logistic regression model (LRM) and examined its predictive efficacy to explore the variables influencing the prognosis of patients with arteriosclerosis obliterans after receiving treatments. The direct random sampling method was employed in the study with 222 hospitalized lower extremity arteriosclerosis obliterans patients from March 2020 to December 2022 being involved. According to the prognosis, patients were divided into the good prognosis group and the poor prognosis group. The factors influencing arteriosclerosis obliterans and patient prognosis in lower extremity after treatment were examined using univariate analysis (UA) and binary logistic regression analysis (BLRA), respectively. The results showed that 70 patients were in the poor prognosis group and 152 patients were in the good prognosis group. The effective recovery rate was 96.52%. BLRA results demonstrated that fibrinogen, smoking history, combined hypertension, combined diabetes mellitus, and combined hyperlipidemia were all independent risk factors for a poor prognosis of arteriosclerosis obliterans ($P < 0.05$). The analysis of receiver operating characteristics (ROC) curve showed that the area under curve (AUC) was 0.878 ($P < 0.05$). The results suggested that the proposed model enabled real-time understanding of patient prognosis. Hyperlipidemia, diabetes, fibrinogen levels, smoking, and hypertension might all increase the risk of a poor outcome in patients with arteriosclerosis obliterans in lower extremity after intervention. Clinical attention should be given to patients with high fibrinogen levels and smoking history, as well as comorbidities of hypertension, diabetes, and hyperlipidemia. Emphasis should be placed on disease control to reduce the risk of a poor prognosis in patients with arteriosclerosis obliterans of the lower extremities.

Keywords: lower limb; arteriosclerosis obliterans; influencing factors; logistic model construction.

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Introduction

Arteriosclerosis obliterans is a common clinical condition that causes chronic ischemia in the limbs. It is characterized by the narrowing and occlusion of arteries in the lower extremities due to the formation of atherosclerotic plaque. The incidence of arteriosclerosis obliterans in the lower extremities is on the rise with the increase in the overall level of society and the ageing of

the population [1]. For the treatment of arteriosclerosis obliterans, in the early stage, systemic treatment and drug therapy are the main approaches. The progression of the disease is mainly delayed by improving blood circulation and controlling risk factors. However, the therapeutic effect is limited for patients in the middle and advanced stages. Although surgical treatment can restore blood circulation to a certain extent, it involves significant trauma, numerous complications, a lengthy recovery period, and low patient acceptance.

In recent years, interventional techniques have developed rapidly. Due to its advantages such as being minimally invasive, simple to perform, and allowing for a quick recovery, it has gradually become the preferred treatment option for lower extremity arteriosclerosis obliterans [2, 3]. Although interventional therapy has significantly improved the therapeutic effect, patients with arteriosclerosis obliterans still face adverse prognostic risks such as intravascular restenosis, amputation, and even death after surgery. Meanwhile, previous studies have shown that various factors such as age, underlying diseases, and lifestyle habits may affect the prognosis of patients with lower extremity arteriosclerosis obliterans undergoing interventional therapy. However, all key influencing factors have not been clearly identified yet, and there is also a lack of precise and effective prognosis prediction models [4, 5].

This research examined and analyzed the factors influencing the prognosis of patients with arteriosclerosis obliterans of the lower extremities to identify additional factors that might affect the prognosis. Further, this study proposed a logistic regression model (LRM) to predict the prognosis of patients using the logistic model and to lower the risk of a poor prognosis by effectively and early controlling the corresponding influencing factors. The results of this study would promote the development and management of arteriosclerosis obliterans patient's prognosis by providing more individualized and precise treatment plans for patients with lower extremity arteriosclerosis obliterans, which would improve the overall medical quality and service level and has important clinical significance.

Materials and methods

Patient selection

For research including surveys, the sample size should be five to ten times more than the number of indicators. This study applied 10 times more sample size than 19 survey indicators to reduce the impact of outside variables on the results. A total of 230 patients with arteriosclerosis obliterans of the lower extremities who were hospitalized in Shandong Provincial Hospital (Jinan, Shandong, China) between March 2020 and March 2022 were initially included in this research using a straightforward random sample technique. Among them, 132 were male patients with an age range from 41 to 83 years old and the average age of 70.23 ± 6.89 years old. There were 98 female patients with an age range from 42 to 85 years old and an average age of 73.15 ± 6.21 years old. The Clinical Practice Series-Interventional Manual's pertinent protocols were followed when treating each patient [6]. The patient inclusion criteria included meeting the diagnostic criteria related to lower extremity arteriosclerosis obliterans in the Guidelines for the Diagnosis and Treatment of Lower Extremity Atherosclerosis [7], aging over 40 years old. The exclusion criteria included combining malignant tumor, serious dysfunction of heart, liver, kidney, and other organs, coagulation dysfunction, depression, anxiety disorder, schizophrenia, and other psychiatric disorders. The procedures of this research were approved by the Medical Ethics Committee of Shandong Provincial Hospital (Jinan, Shandong, China). All participants signed an informed consent form after being briefed about the study's purpose.

Data collection and laboratory tests

The clinical database of Shandong Provincial Hospital (Jinan, Shandong, China) was employed

as the data resource of this study. The data were extracted from the structured electronic medical record system, which included gender, age, duration of illness, duration of hospitalization, smoking history, and drinking history. The patient's systolic blood pressures of bilateral brachial and ankle arteries at rest condition were obtained using a Hadeco ES-100VX Doppler ultrasound instrument (Hadeco, Kawasaki, Japan). The ratio of ankle systolic blood pressure to brachial artery systolic blood pressure was calculated. The systolic pressure of each limb was measured twice, and the average value was taken to obtain the ankle-brachial index (ABI). Three medical doctors with more than five years of experience in vascular surgery evaluated the Rutherford classification (RC) of the patients based on their clinical symptoms and signs. When there were different assessments, the physicians discussed together and reached an agreement. Fasting venous blood was collected in the early morning of the second day after the patient's hospital admission and was processed using the Sysmex CS-5100 fully automatic coagulation analyzer (Siemens Healthcare Diagnostics, Erlangen, Germany) to determine the blood fibrinogen (Fbg) level and white blood cell (WBC) number. The patients' comorbidities including hypertension, heart disease, diabetes, chronic obstructive pulmonary disease (COPD), cerebrovascular disease (CVD), chronic renal insufficiency, hyperlipidemia, hypoproteinemia, and anemia were confirmed by reviewing their medical records, laboratory test results, and imaging reports. The patients were then divided into two groups based on prognosis. All patients received a one-year follow-up and returned to the hospital for a reexamination every six months during that time. The patients were divided into two groups with poor prognosis group being classified as the arterial stenosis more than 50%, amputation, or death, while the others as good prognosis group.

Construction of predictive model

Binary logistic regression analysis (BLRA) was used to conduct multivariate screening for age, disease duration, duration of hospitalization, ankle-brachial index, blood fibrinogen level, smoking history, combined hypertension, diabetes, and hyperlipidemia in the univariate analysis. The screened variables were taken as independent variables, and the prognosis of patients after interventional therapy was taken as the dependent variable with poor prognosis as 1 and good prognosis as 0. The enter method was used to include all independent variables in the model, and the regression coefficients and constant terms were iteratively calculated using maximum likelihood estimation method below.

$$log(\frac{p}{1-p}) = B_0 + \sum_{i=1}^{n} B_i X_i$$

where *P* was the probability of poor prognosis. X_i was the value of each variable. The final model equation was then obtained as below.

$$Y = B_0 + B_1 \times A + B_2 \times B + B_3 \times C + B_4 \times D + B_5 \times E$$

The proposed logistic regression model was then constructed based on the relevant formulae.

Statistical analysis

SPSS 26.0 (IBM, Armonk, New York, USA) was employed to process and analyze the data. The normal distribution data was expressed as mean ± standard deviation (SD) and was examined using Kolmogorov-Smirnov test. Independent t-tests were conducted to examine the difference between groups. The median and quartiles M (P25, P75) were used to express the data that were not normally distributed, and the Mann-Whitney U test was used to compare the results between groups. Counting data were expressed as number of cases and percentages n (%) and were subjected to the χ^2 test. Hierarchical data were subjected to Wilcoxon rank sum test. Independent variables with *P* values less than 0.05 in univariate analysis were subjected to BLRA. The receiver operation characteristic (ROC) curve analysis was performed on the prognostic value of patients with arteriosclerosis obliterans in the lower extremities treated by intervention using the proposed model. *P* value less than 0.05 was defined as statistically significant difference.

Table 1. Univariate analysis of prognosis of patients with arteriosclerosis obliterans in the lower extremity treated with intervention.

Projects		GPG (n = 152)	PPG (*n* = 70)	$\chi^2/t/Z$	*P*
Female		48 (31.58%)	22 (31.43%)	0.001	0.982
Male		104 (68.42%)	48 (68.57%)		
Duration of disease (years)		6.00 (4.00 - 7.00)	12.00 (6.00 - 9.00)	-5.612	<0.001
Fbg (g/L)		3.61 ± 0.26	4.00 ± 0.46	-8.029	<0.001
Duration of hospitalization (days)		14.00 (14.00-15.00)	16.00 (14.00-17.00)	-4.704	<0.001
Ankle-brachial index		0.90 (0.70, 1.00)	0.70 (0.60, 0.80)	4.836	<0.001
WBC ($\times10^9$/L)		6.10 ± 1.01	5.90 ± 1.02	1.407	0.161
Age (years)		69.45 ± 6.75	74.93 ± 6.07	-5.788	<0.001
Drinking history	No	104 (68.42%)	45 (64.29%)	0.371	0.542
	Yes	48 (31.58%)	25 (35.71%)		
Smoking history	No	81 (53.29%)	15 (21.43%)	19.823	<0.001
	Yes	71 (46.71%)	55 (78.57%)		
Rutherford classification	1～2	65 (42.76%)	32 (45.71%)	-0.096	0.923
	3～4	63 (41.45%)	23 (32.86%)		
	5～6	24 (15.79%)	15 (21.43%)		
Combined hypertension	No	60 (39.47%)	7 (10.00%)	19.759	<0.001
	Yes	92 (60.53%)	63 (90.00%)		
Combined anemia	No	110 (72.37%)	54 (77.14%)	0.566	0.452
	Yes	42 (27.63%)	16 (22.86%)		
Combined diabetes	No	117 (76.97%)	32 (45.71%)	21.220	<0.001
	Yes	35 (23.03%)	38 (54.29%)		
Combined COPD	No	147 (96.71%)	67 (95.71%)	0.000	1.000
	Yes	5 (3.29%)	3 (4.29%)		
Combined hyperlipidemia	No	99 (65.13%)	26 (37.14%)	15.261	<0.001
	Yes	53 (34.87%)	44 (62.86%)		
Combined cerebrovascular disease	No	126 (82.89%)	54 (77.14%)	1.034	0.309
	Yes	26 (17.11%)	16 (22.86%)		
Combined chronic renal insufficiency	No	111 (21.15%)	55 (78.57%)	0.781	0.377
	Yes	41 (78.85%)	15 (21.43%)		
Combined hypoproteinemia	No	65 (42.76%)	30 (42.86%)	0.000	0.990
	Yes	87 (57.24%)	40 (57.14%)		
Combined heart disease	No	51 (33.55%)	22 (31.43%)	0.098	0.754
	Yes	101 (66.45%)	48 (68.57%)		

Results

Single factor analysis of prognosis of patients with arteriosclerosis obliterans in the lower extremity treated with intervention

A total of 222 out of 230 patients with valid data was eventually recovered, yielding a 96.52% valid recovery rate. Based on the prognosis, 152 patients were assigned as good prognosis group (GPG), while 70 patients were in poor prognosis group (PPG). Univariate analysis (UA) showed that age, duration of disease, duration of hospitalization, ABI, Fbg, smoking history (SH), combined hypertension (CH), combined diabetes

mellitus (DM) and combined hyperlipidemia (CHL) were all influential factors contributing to poor prognosis of patients with arteriosclerosis obliterans of the lower extremity treated with intervention ($P < 0.05$). The average age of the PPG group was higher than that of the GPG group ($P < 0.001$), suggesting a worse prognosis for older patients. The Fbg level in the PPG group was higher than that in the GPG group ($P < 0.001$), indicating that a higher Fbg level might increase the risk of poor prognosis. The incidence of hyperlipidemia in the PPG group was significantly higher than that in the GPG group ($P < 0.001$), which indicated that dyslipidemia had a significant impact on the prognosis of arteriosclerosis obliterans (Table 1).

Multifactorial analysis of prognosis of patients with arteriosclerosis obliterans in the lower extremity treated with intervention

In this study, BLRA was performed using prognosis as the dependent variable and age, duration of illness, duration of hospitalization, ABI, Fbg, smoking history, combined hypertension, combined diabetes mellitus, and combined hyperlipidemia as the independent variables. The results showed that Fbg, smoking history, combined hypertension, combined diabetes mellitus, and combined hyperlipidemia were all independent risk factors for the prognosis of patients with poor arteriosclerosis obliterans undergoing interventional treatment for lower extremity ($P < 0.05$). The B value of Fbg was 4.056, indicating that the risk of poor prognosis for patients increased exponentially, while Wald $\chi^2 = 23.764$, $P < 0.001$, and the OR value was as high as 57.765 (95% CI: 11.308 - 295.094), indicating that Fbg had a significant impact on prognosis. The B of the patients with smoking history was 1.228, Wald $\chi^2 = 7.236$, $P = 0.007$, OR = 3.415 (95% CI: 1.396 - 8.359), indicating that the risk of poor prognosis in patients with a smoking history was significantly higher than that in patients without a smoking history. In addition, the B value of combined hypertension was 1.959, Wald χ^2 was 10.002, P value was 0.002, OR was 7.091 (95% CI: 2.106 - 23.872), while the B value of combined diabetes mellitus was 1.086, Wald $\chi^2 = 6.452$, $P = 0.011$, OR = 2.963 (95% CI: 1.282 - 6.852), and the B value of combined hyperlipidemia was 1.045, Wald $\chi^2 = 5.735$, $P = 0.017$, OR = 2.843 (95% CI: 1.209 - 6.685). The results indicated that the risk of poor prognosis significantly increased in patients with hypertension, diabetes, and hyperlipidemia (Table 2).

Logistic regression model construction and predictive performance analysis

A binary logistic regression model was constructed as follows with none as 0 and presence as 1.

$$Y = -23.267 + 4.056 \times Fbg + 1.228 \times SH + 1.959 \times CH + 1.086 \times DM + 1.045 \times CHL$$

The model was well fitted and reflected the data results with its results of Cox & Snell ($R^2 = 0.445$), Nagelkerke ($R^2 = 0.625$), and Hosmer-Lemeshow test (HLT) ($\chi^2 = 4.144$) ($P > 0.05$). The ROC curve analysis results showed that the model ROC curve AUC = 0.878 (95% CI = 0.827 to 0.918, $P < 0.05$), Youden J = 0.623, best cut-off value ≥ -5.28, sensitivity = 88.57%, specificity = 73.68% (Figure 1).

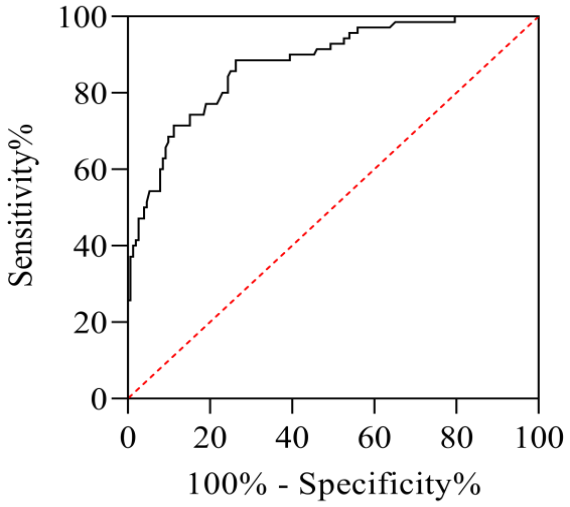

Figure 1. ROC curves for predicting prognosis of patients with arteriosclerosis obliterans in the lower extremity treated by binary logistic regression model.

Table 2. Binary logistic regression analysis of the prognosis of patients with arteriosclerosis obliterans in the lower extremity treated with intervention.

Projects	*B*	*S.E.*	*Wald* χ^2	*P*	*OR*	95% *CI*	
						Lower limit	Upper limit
Smoking history	1.228	0.457	7.236	0.007	3.415	1.396	8.359
Combined hyperlipidemia	1.045	0.436	5.735	0.017	2.843	1.209	6.685
Duration of disease	0.685	0.559	1.505	0.220	1.984	0.664	5.931
Combined diabetes	1.086	0.428	6.452	0.011	2.963	1.282	6.852
Ankle-brachial index	1.417	1.315	1.162	0.281	4.125	0.314	54.258
Fbg	4.056	0.832	23.764	<0.001	57.765	11.308	295.094
Duration of hospitalization	0.266	0.178	2.250	0.134	1.305	0.922	1.849
Combined hypertension	1.959	0.619	10.002	0.002	7.091	2.106	23.872
Age	-0.076	0.176	0.188	0.665	0.926	0.656	1.309
Upper limit	-23.267	9.998	5.416	0.020	0.000	—	—

Discussion

Fbg is one of the key coagulation factors in the coagulation response. Thrombin cleaves it to form fibrin monomers, which can polymerize to form thrombi. This process significantly impacts coagulation, platelet aggregation, and vascular endothelial cells. The results revealed that Fbg was a separate risk factor for the outcome of patients receiving treatments for arteriosclerosis obliterans in the lower extremities [8]. Since Fbg and its breakdown products are present in high concentrations in atheromatous plaques and can promote the migration and proliferation of smooth muscle cells, as well as vascular smooth muscle, the cleavage of Fbg into fibrin monomers is an important factor in atherosclerosis and thrombosis [9]. Previous studies concluded that high levels of Fbg increased plasma viscosity, mediated platelet adhesion and aggregation, and raised the risk of thrombosis. It also found that fibrin encouraged lipoprotein adsorption to the intima and increased lipid aggregation in fibrous plaques [10, 11]. This research found that hypertension, diabetes mellitus, hyperlipidemia, and smoking history were all separate risk factors for prognosis of patients with arteriosclerosis obliterans of the lower extremity that received treatments. Smoking had a considerable risk of developing restenosis, which increased the chance of severe lower extremity ischemia and amputation. The possible mechanisms included that the nerve endings and adrenal glands might be stimulated by long time smoking and caused them to release more adrenaline and norepinephrine, which could lead to arteriosclerosis obliterans spasm and, in turn, promote luminal constriction and decrease blood flow, ultimately resulting in thrombosis. In addition, long smoking history could increase the levels of lipids and fibrin in the blood and increase blood viscosity. Nicotine widened the gaps between the endothelial cells of the blood vessels, leading to endothelial damage and then to narrow the blood vessels in the lower extremities. Further, the endothelium could absorb platelets, leukocytes, and low-density lipoproteins (LDL) that penetrated the inner layers of blood vessels in the lower extremities, leading to vascular aging and plaque formation. Chiang *et al*. found that the amount of smoking showed a positive correlation with the severity of the disease. Therefore, patients should quit smoking immediately after the diagnosis of the disease and exclude smoking as an influencing factor whenever possible [12]. Taneja *et al*. reported that hypertension was more closely related to lower extremity arteriosclerosis obliterans. In particular, the higher the patient's systolic blood pressure level, the worse the

prognosis of patients with lower extremity arteriosclerosis obliterans [13]. In the patients with diabetes, although most patients were able to control their blood glucose levels through glucose lowering therapy and dietary modification, their blood glucose levels were still at a higher level than that in healthy people. Hyperglycemia could cause abnormal hormone secretion and lead to vascular endothelial cells and platelet dysfunctions, thus increasing the risk of atherosclerosis [14]. In hyperlipidemia patients, elevated LDL cholesterol might cause atherosclerosis. Gary *et al*. demonstrated that Apo B could positively influence relapses in patients after intervention [15]. Therefore, in arteriosclerosis obliterans patients with hypertension, diabetes, and hyperlipidemia, measures should be taken to control the conditions as much as possible to reduce the risk of disease recurrence. Previous studies also indicated that age, hypoproteinemia, and anemia were also major factors influencing poor prognosis of patients with arteriosclerosis obliterans of the lower extremities treated with interventions. However, the absence of notable variations in the incidence of anemia and hypoproteinemia might be because of the inclusion of geographically significant factors in the research population. To forecast the prognosis of patients with lower extremity arteriosclerosis obliterans, a logistic regression model was constructed utilizing the separate risk factors. The results suggested that the model was a good fit and reflected the data well. The results also discovered that the model was a good predictor for the prognosis of patients with arteriosclerosis obliterans in the lower extremities. Poor prognosis of patients with arteriosclerosis obliterans of the lower extremity treated with treatments were caused by many independent risk factors. The proposed logistic regression model could be used to predict poor prognosis and effectively control the relevant risk factors to reduce the risk of poor prognosis.

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