

Establishment of Prediction Models for venous thromboembolism in non-oncological urological inpatients—a single center experience

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Abstract

Background

To establish prediction models for venous thromboembolism (VTE) in non-oncological urological inpatients.

Methods

A retrospective analysis of 1453 inpatients was carried out and the risk factors for VTE had been clarified our previous studies.

Results

Risk factors included the following 5 factors: presence of previous VTE (X_1), presence of anticoagulants or anti-platelet agents treatment before admission (X_2), D-dimer value ($\geq 0.89 \mu\text{g/ml}$, X_3), presence of lower extremity swelling (X_4), presence of chest symptoms (X_5). The logistic regression model is Logit (P) = $-5.970 + 2.882 * X_1 + 2.588 * X_2 + 3.141 * X_3 + 1.794 * X_4 + 3.553 * X_5$. When widened the p value to not exceeding 0.1 in multivariate logistic regression model, two addition risk factors were enrolled: Caprini score (≥ 5 , X_6), presence of complications (X_7). The prediction model turns into Logit (P) = $-6.433 + 2.696 * X_1 + 2.507 * X_2 + 2.817 * X_3 + 1.597 * X_4 + 3.524 * X_5 + 0.886 * X_6 + 0.963 * X_7$. Internal verification results suggest both two models have a good predictive ability, but the prediction accuracy turns to be both only 43.0% when taking the additional 291 inpatients' data in the two models.

Conclusion

We built two similar novel prediction models to predict VTE in non-oncological urological inpatients.

Trial registration:

This trial was retrospectively registered at <http://www.chictr.org.cn/index.aspx> under the public title "The incidence, risk factors and establishment of prediction model for VTE n urological inpatients" with a code ChiCTR1900027180 on November 3, 2019. (Specific URL to the registration web page: <http://www.chictr.org.cn/showproj.aspx?proj=44677>).

Background

Venous thromboembolism (VTE) includes deep venous thrombosis (DVT) and pulmonary embolism (PE), and it can cause preventable morbidity and mortality in patients undergoing pelvic surgery which

increases the burden of care for patients and society[1]. The risk of VTE is especially high in hospitalized patients as most of them have multiple risk factors for developing VTE, and the incidence of VTE for inpatients is considered to be as high as 34.7% (15–40% for major urological surgery) with fatal pulmonary embolism in 9.4% by autopsy researches[2].

Recent years, many urologists pay more attention to the development of VTE, especially to the patients undergoing urological oncological surgeries because the occurrence of VTE is thought to be related to cancers[1, 3–5]. According to current online literatures, there is not enough attention to non-oncological surgeries received from urologists. Although there is not enough high-quality evidence, the incidence of VTE in non-tumor surgery in urology is not as low as we think. For the major urological surgeries, the incidence of VTE varies from 0.3–10.8%, especially high in open recipient nephrectomy and open simple prostatectomy whose incidence is 1.3–5.3% and 2.7–10.8%, respectively[6]. Therefore, more attention should be paid to non-oncological patients in surgical departments.

This study aims to build prediction models for VTE according to our previous research about risk factors (*Wang Z, 2020, unpublished data*) and help urological clinicians better identify patients with VTE and make opportune clinical choices for non-oncological urological inpatients because VTE is an occult disease without specific symptoms and can be easily overlooked in urological clinics. In this paper, we made use of statistic methods to build prediction models for VTE. As far as we are concerned, no similar prediction model has been proposed to predict the VTE in urological inpatients undergoing non-oncological surgeries at present. In addition, we verified the accuracy of these two prediction models using internal and external data in the present study.

Methods

This retrospective, single center study gathered a total of 1453 consecutive inpatients who were admitted to the non-oncological urological ward in Xiangya Hospital, Central South University from January 1, 2018 to December 31, 2018. All data was collected from Electronic Medical Record System (EMRS) with the approval of the Ethics Committee of Xiangya Hospital (2019030078). In-hospital VTE events were defined as any DVT or PE appeared at all times from the patient's admission to discharge and determined by appropriate imaging procedures (ultrasounds and computed tomography pulmonary angiography)[3]. Patients with the following situations were excluded: (a) age is under 18 years old; (b) admission for surgery to remove malignant tumors; (c) postoperative pathological findings showed as malignant tumors; (d) incomplete case records.

Baseline demographics and clinical data of all the 1453 patients have been collected and the risk factors for VTE have been clarified during our previous research which had been submitted (*Wang Z, 2020, unpublished data*).

Every risk factor would be given a specific score by regression coefficient of the equation (B), respectively, then rounding. A prediction model was established for predicting VTE of non-oncological surgeries in urology by calculating a comprehensive score of every single patient.

To verify the accuracy of the models, another 291 inpatients who were admitted to the non-oncological urological ward and accepted imaging examinations for VTE from January 1, 2019 to June 30, 2019 were enrolled in this study and their related data had been collected. These data were used for the verification of these novel prediction models.

All statistics analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA). When the p -value was under 0.05 in the univariate analyses, the related factors would be enrolled in the multivariate logistic regression model. A stepwise regression method was used to screen the relevant influencing factors for VTE and construct a logistic regression prediction model. The receiver operator characteristic curve (ROC) was carried out to evaluate the accuracy and efficiency of the prediction model. Statistical tests were declared significant for a two-tailed p value not exceeding 0.05, but the other prediction model was created by widening the p value to not exceeding 0.1 in multivariate logistic regression model.

Results

A total of 1453 inpatients were enrolled in this study, and the incidence of VTE in non-oncological urological inpatients was 2.3%. We found that patients with older age, previous VTE, history of varicose veins in the lower extremities, history of surgery within one month, anticoagulants or anti-platelet agents before admission, preoperative bleeding, preoperative sepsis, greater D-dimer value, greater Caprini score, complications, lower extremity swelling, lower extremity pain, chest symptoms were more susceptible to VTE (Wang Z, 2020, unpublished data).

In order to establish a prediction model, we incorporated the above-mentioned risk factors into a multivariate logistic regression model with p value not exceeding 0.05, and used a stepwise regression method to screen the relevant influencing factors for VTE. As shown in Table 1, presence of previous VTE (X_1), presence of anticoagulants or anti-platelet agents treatment before admission (X_2), D-dimer value ($\geq 0.89 \mu\text{g/ml}$, X_3), presence of lower extremity swelling (X_4), presence of chest symptoms (X_5) were considered as independent risk factors for VTE. The cutoff of D-dimer is derived from our previous research (Zi-Qiang Wu, 2020, unpublished data). And the logistic regression model is built as Logit (P) = $-5.970 + 2.882 * X_1 + 2.588 * X_2 + 3.141 * X_3 + 1.794 * X_4 + 3.553 * X_5$. The probability model for predicting VTE is $P = 1 / 1 + \exp (5.970 - 2.882 * X_1 - 2.588 * X_2 - 3.141 * X_3 - 1.794 * X_4 - 3.553 * X_5)$.

Table 1
Logistic regression prediction model for influencing factors of VTE

Risk factors	B	S.E,	Wals	df	Sig.	OR	95% CI for EXP(B)	
							lower	upper
Previous VTE(X1)	2.882	.606	22.639	1	.000	17.854	5.446	58.526
Anticoagulants or anti-platelet agents before admission(X2)	2.588	.650	15.839	1	.000	13.301	3.719	47.575
D-dimer(X3)	3.141	.530	35.067	1	.000	23.135	8.180	65.437
Lower extremity swelling(X4)	1.794	.794	5.113	1	.024	6.016	1.270	28.500
Chest symptoms(X5)	3.553	1.038	11.726	1	.001	34.907	4.569	266.709
Constant	-5.970	.506	139.416	1	.000	.003		
B = regression coefficient; S.E = Standard Error; Wals = wald chi-square; df = degrees freedom; Sig. = significance; OR = odds ratios; CI = confidence interval; VTE = venous thromboembolism.								

Next, we brought the 1453 patients into this equation to evaluate the accuracy of this prediction model, which is shown in Table 2. Among all the 1453 patients, 32 patients were predicted to have VTE and they actually did, and 1158 patients were predicted to have no VTE and they actually didn't. Furmore, sensitivity of this prediction model is 94.1%; specificity is 82.0%; misdiagnosis rate is 18.0%; missed diagnosis rate is 5.9%; positive predictive value is 11.1%; negative predictive value is 99.8%; correct rate is 82.3%; Youden Index is 76.1%; consistency test shows statistical significance (Kappa value = 0.164, $P=0.000$), which indicates that internal verification results suggest the model has a good predictive ability.

Table 2
Comparison of actual VTE and predicted VTE

Predicted VTE	Observed VTE		overall
	No	Yes	
NO	1164	2	1166
Yes	255	32	287
overall	1419	34	1453
VTE = venous thromboembolism.			

To futher evaluate this model for discriminating VTE, a ROC curve was conducted and the area under the correlation curve (AUCs) was calculated and the cut-off point was determined, which were show in Fig. 1. After calculation, the area under the ROC curve is 0.915 (95% CI: 0.864–0.967). As for the cut-off point,

the analysis found that when the sensitivity is 0.941 and specificity is 0.820, the maximum value of the two is 1.761, and the corresponding cut-off value is 0.03824, which means if a patient's predicted value is greater than or equal to 0.03824, he or she will be considered to be more susceptible to VTE.

ROC = Receiver operating characteristic (ROC) curve.

Futhermore, 291 additional inpatients who were admitted to the non-oncological urological ward during January 1, 2019 to June 30, 2019 were enrolled in this study to verify the accuracy and efficiency of the prediction model in Table 3. Sensitivity, specificity, and accuracy of the prediction model in the validation database were 96.43%, 37.2%, and 43.0%, respectively.

Table 3
Comparison of actual VTE and predicted VTE
using additional data

Predicted VTE	Observed VTE		overall
	No	Yes	
NO	98	1	99
Yes	165	27	192
overall	263	28	291
VTE = venous thromboembolism.			

In order to assess more potential risk factors for VTE, we widened the p value to not exceeding 0.1 and built a new prediction model. Compared with the first prediction model, the new model included two novel variables: Caprini score (≥ 5 , X_6), presence of complications (X_7) (Table 4). The cutoff of Caprini score is derived from our previous research (*Zi-Qiang Wu, 2020, unpublished data*). The new model turned into $\text{Logit}(P) = -6.433 + 2.696 * X_1 + 2.507 * X_2 + 2.817 * X_3 + 1.597 * X_4 + 3.524 * X_5 + 0.886 * X_6 + 0.963 * X_7$, and the probability model for predicting VTE is $P = 1 / 1 + \exp(6.433 - 2.696 * X_1 - 2.507 * X_2 - 2.817 * X_3 - 1.597 * X_4 - 3.524 * X_5 - 0.886 * X_6 - 0.963 * X_7)$.

Table 4
Logistic regression prediction model for influencing factors of VTE

Risk factors	B	S.E,	Wals	df	Sig.	OR	95% CI for EXP(B)	
							lower	upper
Previous VTE(X1)	2.696	.607	19.722	1	.000	14.828	4.511	48.743
Anticoagulants or anti-platelet agents before admission(X2)	2.507	.651	14.811	1	.000	12.266	3.422	43.972
D-dimer(X3)	2.817	.542	26.973	1	.000	16.729	5.778	48.437
Lower extremity swelling(X4)	1.597	.775	4.247	1	.039	4.936	1.081	22.532
Chest symptoms(X5)	3.524	1.031	11.672	1	.001	33.911	4.492	256.028
Caprini score(X6)	.886	.491	3.256	1	.071	2.426	.926	6.353
Complications(X7)	.963	.544	3.133	1	.077	2.621	.902	7.617
Constant	-6.433	.598	115.731	1	.000	.002		
B = regression coefficient; S.E = Standard Error; Wals = wald chi-square; df = degrees freedom; Sig. = significance; OR = odds ratios; CI = confidence interval; VTE = venous thromboembolism.								

We used similar internal verification and ROC curve to evaluate the new this prediction model. As shown in Table 5, the sensitivity of this new prediction model is 94.1%; specificity is 81.6%; misdiagnosis rate is 18.4%; missed diagnosis rate is 5.9%; positive predictive value is 10.9%; negative predictive value is 99.8%; correct rate is 81.9%; Youden Index is 75.7%; consistency test also showed statistical significance (Kappa value = 0.161, $P = 0.000$). Also, a ROC curve was conducted to evaluate the new model, as shown in Fig. 2. The AUCs is 0.941 (95% CI: 0.910–0.972) and when the sensitivity is 0.941 and specificity is 0.816, the maximum value of the two is 1.757 and the corresponding cut-off value is 0.02474.

Table 5
Comparison of actual VTE and predicted VTE

Predicted VTE	Observed VTE		overall
	No	Yes	
NO	1158	2	1160
Yes	261	32	293
overall	1419	34	1453
VTE = venous thromboembolism.			

ROC = Receiver operating characteristic (ROC) curve.

We found that not only the internal verification and ROC curve results of the two models were similar, but also the external verification results were similar, too. The same 291 inpatients were included to verify the accuracy and efficiency of the new prediction model (Table 6). Sensitivity, specificity, and accuracy of the prediction model in the validation database were 100.0%, 36.9%, and 43.0%, respectively.

Table 6
Comparison of actual VTE and predicted VTE using additional data

Predicted VTE	Observed VTE		overall
	No	Yes	
NO	97	0	97
Yes	166	28	194
overall	263	28	291
VTE = venous thromboembolism.			

Discussion

Although VTE is a rare event, it can be life-threatening and cause a series of social health problems. Patients with VTE have a greater mortality rate than those without VTE based on previous studies[7]. And hospitalization is a major risk factor for VTE[8]. In the 1990s, when anticoagulation treatment for inpatients was not mature, some studies showed the incidence of VTE was in the range of 10–30% for hospitalized patients and interestingly the non-surgical inpatients suffering more deaths than surgical inpatients[9, 10]. Recently, our previous research and other literatures have demonstrated that VTE event is not rare in non-oncological urology which can be associated with significant higher rate of intensive care hospital transfer, longer inpatient recover, more medical costs, and more mortality[6, 11]. So early diagnosis of VTE can prevent a lot of troubles for human and society because VTE is a preventable disease. The risk of development of VTE should be distinguished by a reliable scoring system to avoid the threat of health issues and financial burden caused by VTE.

There are a variety of risk assessment models (RAMs) of stratify risk degree in Western countries, such as Rogers RAM[12], Padua RAM[13], Khorana RAM[14], and Caprini RAM[15]. Due to the heterogeneity of the population, RAMs for VTE in Western countries may not be suitable for the Asian population unless they have been verified by large-scale, multi-center population. And more efforts should be required to focus on building a preferable and validated Asian model even if Caprini RAM may be suitable for Chinese proved by some researches[16, 17]. In addition, the current RAMs for VTE show limited ability to predict the development of VTE in many common cancers[18].

Prediction models are commonly used to predict the diagnosis of a disease, which can quickly and effectively find the high-risk group from a large group of patients, and perform appropriate medical

treatment. But at present, there are only a few prediction model of VTE in urology. Shi et al found that D-dimer lever $\geq 1 \mu\text{g/ml}$ on postoperative day 1 and Charlson comorbidity index ≥ 2 were independently associated with VTE in patients who underwent urologic tumor surgery. And the level of plasma D-dimer on postoperative day 1 can predict the development of VTE[19]. Angelika Bezan et al established a stratification model for VTE for patients with testicular germ cell tumors. They used clinical stage (cS) and retroperitoneal lymphadenopathy (RPLN) to divide the patients into 4 groups: cS IA-B, cS IS-IIB, cS IIC and cS IIIA-C, each group corresponded to a related specific incidence of VTE and this model was externally validated well with another cohort[20]. There is no prediction model for VTE of non-oncological urological patients when searching the commonly used databases (Pubmed, EMBASE, CNKI (China National Knowledge Infrastructure), Wanfang database, OVID, Springer, until March 14, 2020), which indicates that VTE attention for non-oncological surgery in urology is indeed not enough.

Although the current consensus guidelines for VTE in urology have been updated and taking risk into stratification, they are still not fully developed and underutilized. More appropriate guidelines should be taken seriously[21]. European Association of Urology (EAU) and Canadian Urological Association have published guidelines to urology perioperative thrombosis and thromboprophylaxis recent years, which provide thromboprophylaxis guidelines for oncological and non-oncological surgeries. However, the proof of recommendations are weak[22, 23]. To reduce potential waste of medical resources and to identify VTE inpatients in non-oncological urology, we establish two similar prediction models. These models can help doctors to distinguish VTE inpatients initially and formulate appropriate strategies.

We found out the variables which showed statistical difference between VTE inpatients and non-VTE inpatients in non-oncological urology (*Wang Z, 2020, unpublished data*). And then we incorporated these variables to multivariate logistic regression models to build a prediction model for VTE. The variables which were eventually screened out included presence of previous VTE (X_1), presence of anticoagulants or anti-platelet agents treatment before admission (X_2), D-dimer value ($\geq 0.89 \mu\text{g/ml}$, X_3), presence of lower extremity swelling (X_4), presence of chest symptoms (X_5). Most of the variables have been proved to be independent risk factors for VTE such as previous VTE[24], higher D-dimer value[19], and chest symptoms[25]. And the prediction model is $\text{Logit}(P) = -5.970 + 2.882 * X_1 + 2.588 * X_2 + 3.141 * X_3 + 1.794 * X_4 + 3.553 * X_5$. Unlike other prediction models, we first tried to use logistic regression to build a VTE prediction model, which makes the risk of VTE directly calculated by a simple formula. It is simpler and could be automated.

We created the ROC curve in order to evaluate the accuracy and efficiency of our prediction model for predicting VTE events in non-oncological urological inpatients. And we found that the cut-off point of this model was 0.03824, with the AUC of 0.915, a sensitivity of 0.941 and a specificity of 0.820, respectively. This model is considered to have a high degree of accuracy of predicting VTE in non-oncological urological inpatients according to the statistical data above. The comprehensive score is positively correlated with the risk of VTE which means the higher the score, the greater the risk of VTE. Furthermore, 291 additional inpatients' data were used to verify this prediction model and the accuracy of it was only

43.0%, which means this prediction model's clinical application value was not good enough. However, the sensitivity and specificity are 96.43%, 37.2%, respectively, which means that this model could be used in VTE screening. Despite the possible limited clinical application value of this model, we still found that this prediction model has a good VTE exclusion capability and it can greatly help the screening of VTE in non-oncological urological inpatients.

A new prediction model was created by widening the p value to not exceeding 0.1 in multivariate logistic regression model. The reasons why we widen the p -value are as follows: (a) the sample size is not big enough and some potential risk factors will be eliminated, so we want to evaluate more potential risk factors for VTE; (b): the new variables proved to be important independent risk factors, especially the Caprini score[17, 26]; (c): provide clues for our follow-up studies of VTE. As for results, the new prediction model turns into Logit (P) = $-6.433 + 2.696 * X_1 + 2.507 * X_2 + 2.817 * X_3 + 1.597 * X_4 + 3.524 * X_5 + 0.886 * X_6 + 0.963 * X_7$. The results of the internal verification, external verification and ROC evaluation are all similar but we can still find that the new prediction model has a larger AUCs (0.941 vs 0.915) in the ROC analysis and a higher sensitivity (100% vs 96.43%), which indicates that the new prediction model might be a little bit better.

Our research does have limitations as following. The models we built were only based on the whole year cases data of 2018 in a tertiary hospital, which is a relatively small sample size. So, we will further expand the number of clinical cases to optimize the model in the future. In addition, some patients with VTE were missed due to the unclear screening methods, which resulted in statistical bias. And the data we used to validate the model came from the patients who have completed the diagnostic images, so there may be some limitations and biases. Moreover, this study may be restricted by retrospective bias because it's a single center, retrospective analysis. Multi-center, large-scale studies are needed to establish more accurate models. Despite these limitations, we suppose that the data integrity is excellent. And as far as we are concerned, these are the first two prediction models of VTE for urological non-oncological inpatients and they will surely provide an intuitive assessment of the development of VTE during the perioperative periods in urological non-oncological surgeries.

Conclusions

Based on the analysis of our previous studies of risk factors, we firstly establish two similar prediction models for assessing the development and risk of VTE for non-oncological urological inpatients. These prediction models exhibited excellent accuracy during internal verification, but related poor application value during external verification was found. However they can still be used as a screening tool and give preliminary suggestion for urologists.

Abbreviations

VTE

Venous thromboembolism

DVT
Deep venous thrombosis
EMRS
Electronic Medical Record System
ROC
Receiver operator characteristic curve
AUCs
Area under the correlation curve
RAMs
Risk assessment models
cS
Clinical stage
RPLN
Retroperitoneal lymphadenopathy
CNKI
China National Knowledge Infrastructure
EAU
European Association of Urology

Declarations

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Author Contributions:

KL: data collection, manuscript writing, and data analysis; QZ: data collection; HL: data collection; ZW:data collection; ZT: project development and administration; ZW: project development and administration. All authors read and approved the final manuscript.

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The data analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate:

The study was approved by the Ethics Committee of Xiangya Hospital (2019030078). Consent to participate: Not Applicable.

Consent for publication:

Not Applicable.

Competing interests:

The authors declare no conflict of interest.

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Figures

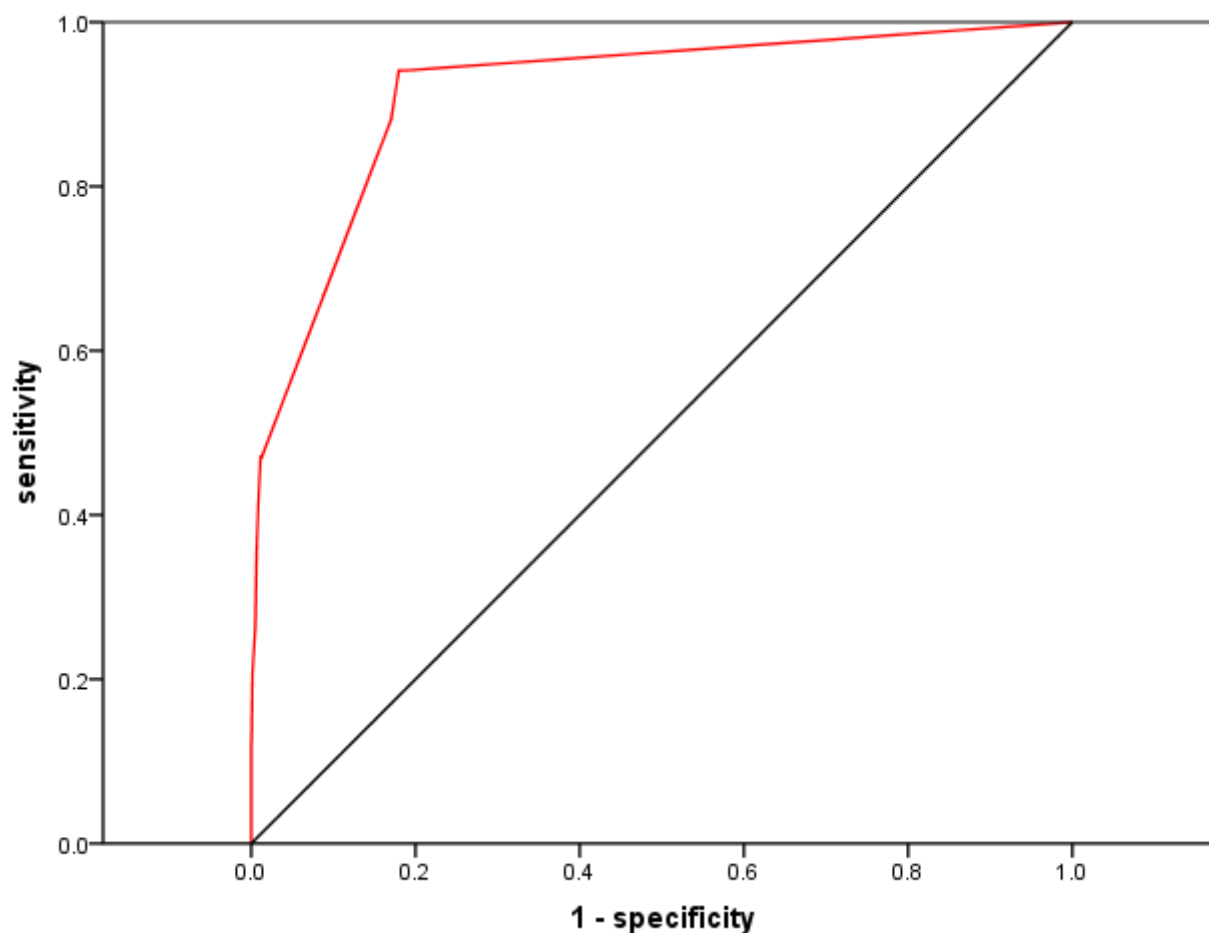


Figure 1

ROC curve of multivariate logistic regression prediction model ROC = Receiver operating characteristic (ROC) curve.

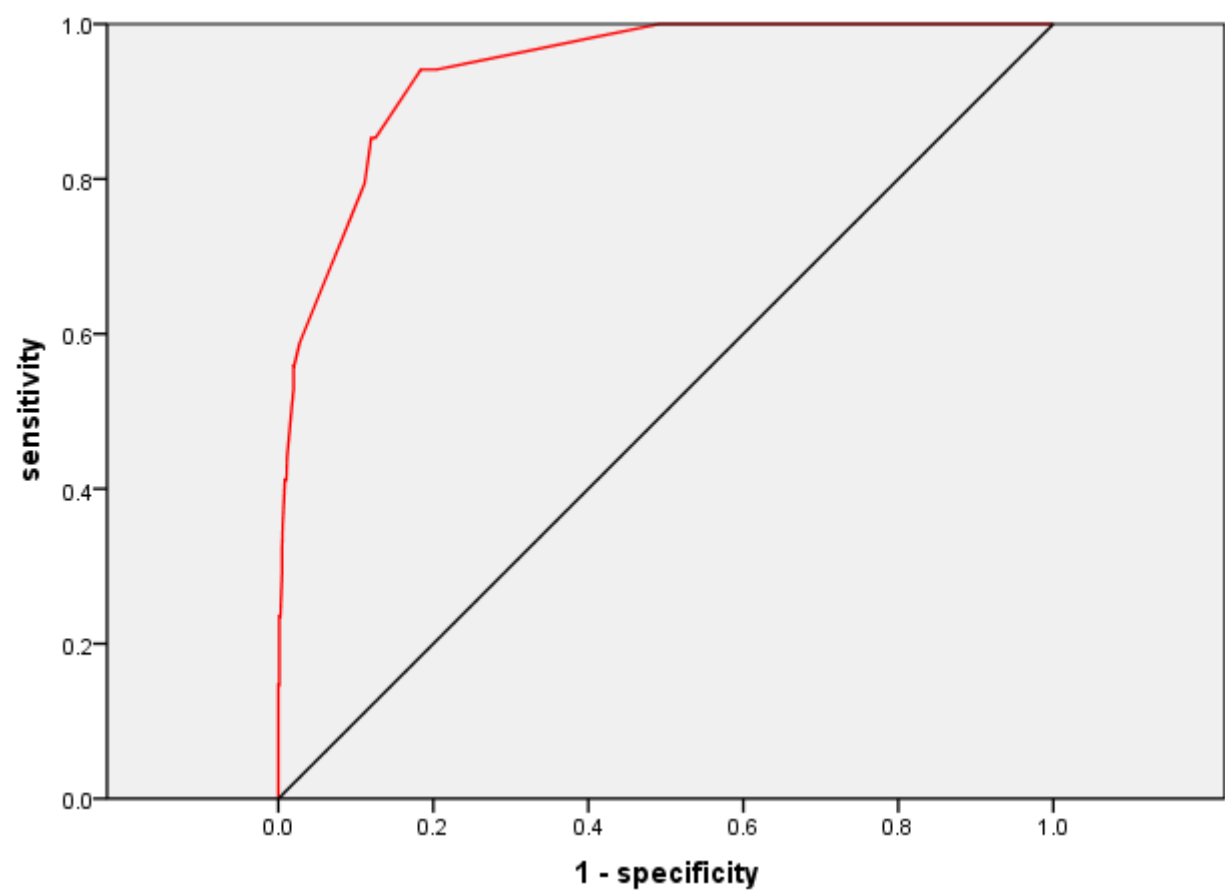


Figure 2

ROC curve of multivariate logistic regression prediction model ROC = Receiver operating characteristic (ROC) curve.