Predicting the Risk of Stroke in Chinese Internal Carotid Artery Stenosis Patients Underwent Carotid Artery Stenting: Validation and Improvement of Siena Carotid Artery Stenting Risk Score

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Background: Siena carotid artery stenting (CAS) risk score is developed based on Chinese internal carotid artery (ICA) stenosis patients recruited in Italy, whether it is equally applicable in Chinese remains unknown. We aimed to investigate Siena CAS risk score value for predicting stroke risk in ICA stenosis patients underwent CAS and explore additional factors for improving accuracy of scoring system. *Methods:* Totally 401 patients with ICA stenosis who underwent CAS were enrolled. The clinical data (including patient characteristics, lesion features, and procedure-related features) were collected and the Siena CAS score was calculated. Stroke incidence with 30 days was documented. *Results:* The incidence of stroke was 4.5%, and the Siena CAS score in stroke patients was higher compared with nonstroke patients, further receiver operating characteristic (ROC) curve illustrated that Siena CAS score was acceptable at predicting stroke risk with area under curve (AUC) of .743 (95%CI: .638-.848). Multivariate logistic regression model revealed that Siena CAS score and current fasting-blood glucose (FBG) greater than 7.1 mmol/l independently predicted higher stroke risk; followed ROC curve disclosed that Siena CAS score combined with current FBG greater than 7.1 mmol/l was of good value in predicting stroke risk (AUC: .770 (95%CI: .677-.863)), which was numerically increased compared with Siena CAS score alone. *Conclusions:* Siena CAS risk scoring system exhibits to be a useful tool to predict stroke risk, and the combination of Siena CAS score and current increased FBG might be a more accurate stratification for stroke risk in Chinese ICA stenosis patients after CAS.

Key Words: Siena CAS risk score—carotid artery stenting—stroke—fasting blood glucose

Background

Carotid arteries, the principle blood supply to the brain via neck, are especially susceptible for atherosclerosis due to position profile and hemodynamic changes, whose occlusive injuries are responsible for around 20% of all stroke cases.[1] At the present, the gold standard surgical solution for carotid artery stenosis is carotid endarterectomy (CEA), whereas benefiting from the advances in interventional devices and techniques, the less invasive carotid artery stenting (CAS) is preferably used as an alternative to carotid endarterectomy in some cases.[2] Although CAS is shown to result in less patients' discomfort and hospitalization, studies observe that the benefits of CAS could be neutralized or even reduced by the increased risk of in-stent restenosis.[3,4] Moreover, the stenting-induced intraoperative complications and perioperative complications (such as transient cerebral ischemia, infarction, and stent thrombosis) contribute to relatively high risk of stroke after CAS.[4] Therefore, in patients with carotid artery stenosis, it is essential to know the risk factors predicting stroke after CAS, so that the corresponding treatment strategies could be taken in advance.

The existing studies have demonstrated several common risk factors for stroke in internal carotid artery (ICA) stenosis patients underwent CAS. For instance, female gender and lesion at bifurcation have been described as risk factors for

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restenosis and stroke after CAS.[5] And other factors such as disease history and procedures in surgery are also associated with neurological complications including stroke in ICA stenosis patients underwent CAS.[6,7] Known that there are a considerable number of individual risk factors for stroke after CAS, 1 previous study has proposed a preoperative scoring system (Siena CAS risk score) that integrated multiple factors, including patient-related, lesion-related, procedure-related, and operator-related variables, to independently stratify the risk of stroke (CAS I: low risk, CAS II: moderate risk, CAS III: high risk) in 30 days after CAS.[8] However, Siena CAS risk score is developed based on ICA stenosis patients recruited in Italy, and whether it is equally applicable in Chinese population remains unknown. Therefore, we conducted this study to investigate the value of Siena CAS risk score for predicting stroke risk in Chinese ICA stenosis patients underwent CAS and explore additional factors that could help improve the accuracy of the scoring system.

Methods

Patients

A total of 417 patients with ICA stenosis who underwent CAS at Xinqiao Hospital between January 2010 and December 2017 were screened in this study. The screening criteria were as follows: (1) presenting with ICA stenosis verified by digital subtraction angiography; (2) underwent CAS successfully; (3) clinical and follow-up data were complete. Finally, 401 patients were included in the analysis, and 16 patients were excluded: 10 patients without complete clinical or follow-up data, and 6 patients underwent CAS unsuccessful. This study was approved by Ethics Committee of Xinqiao Hospital, and the written informed consents or verbal agreements (with tape recording) were collected from the patients or their guardians included the analysis.

Clinical Data Collection

According to the medical records, following clinical data were collected: (1) patient characteristics: age, gender, smoke status, drink status, coronary artery disease, hypertension, diabetes, peripheral arterial disease, symptomatic status, serum creatinine, low-density lipoprotein cholesterol, uric acid, homocysteine, glycated hemoglobin, and fasting blood-glucose (FBG); (2) lesion features: severe stenosis, plaque ulceration, plaque calcification, side of the lesion, ostial lesion, lesion length, and ICA tortuosity; (3) procedure-related features: use of protection, type of protection, predilatation, postdilatation, type of stent, type of arch, bovine arch, arch calcification, duration of procedure, contralateral stenosis, contralateral occlusion, common carotid artery tortuosity, general anesthesia, and operator's experience (CAS procedures). For plaque characteristics evaluation, the plaque components (such as lipid-rich plaque, fibrous cap, in-plaque hemorrhage) were not evaluated, which was partly due to that there was no plaque component in the items of Siena scoring system, and it meant that plaque component would not affect the score of Siena scoring system. Considering that the plaque characteristics of plaque ulceration and plaque calcification were included in the items of Siena scoring system, which might affect the score of Siena scoring system, the plaque characteristics of plaque ulceration and plaque calcification were determined through computed tomography (CT) angiography of head and neck. If the results of CT angiography of head and neck showed high-density shadows, it was determined as plaque calcification; if the results of CT angiography of head and neck showed low-density shadows and there was ulcer cavity, it was determined as plaque ulceration.

Siena CAS Score Assessment

The Siena CAS score of each patient was scored according to the Siena CAS risk scoring system developed by Carlo Setacci et al,[8] which was based on patient-related, lesion-related, procedure-related, and operator-related variables as shown in the Table 1. Total Siena CAS score was the sum of the score of each variable. According to the Siena CAS score, stroke risk within 30 days after CAS was classified as follows: (1) CAS I (low risk): Siena CAS score less than 8; (2) CAS II (moderate risk): Siena CAS score 8-15; (3) CAS III (high risk): Siena CAS score greater than 15.

Follow-Up Data Collection

All included patients were closely followed up within 30 days after CAS, during which, the occurrence of stroke events that were identified by cerebral CT/magnetic resonance scan was documented. The stroke events encompassed transient ischemic attacks, minor stroke, major stroke, and fatal stroke. A transient ischemic attack was defined as a focal, retinal, or hemispheric event from which the patient made a complete recovery within 24 hours.[8] Minor stroke was defined as any new neurological deficit that persisted for more than 24 hours, associated with a modified Rankin score of less than 3 (i.e., at most only slight disability from the index stroke, without the need for assistance in daily affairs).[9] A major stroke was defined as a new neurological deficit that persisted more than 30 days and increased on the National Institutes of Health Stroke Scale by more than or equal to 4.[8] A fatal stroke was defined as death attributed to an ischemic stroke or intracerebral hemorrhagic stroke.[8] All patients enrolled in this study received anti-platelet therapy at least 3-5 days before the surgery with the following drugs: acetylsalicylic acid (100 mg/time, 1 time/day); Clopidogrel (75 mg/time, 1 time/day); Atorvastatin calcium tablets (40 mg/time, 1 time/night). After the surgery, all patients continued to receive antiplatelet therapy until 1 month

Table 1. *Siena CAS risk scoring system*

Variables	Scoring
Patient-related	
Age	0 (any)
Gender	0
Cardiac disease	+1.5
Renal insufficiency	0
Presence of neurological symptoms	+3
Smoker	0
Hypertension	0
Diabetes	+2
Peripheral arterial disease	0
Hypercholesterolemia	0
Lesion-related	
Calcified lesion	+2.5
Ulcerated lesion	+4
Native/recurrent stenosis	+3
Length of the lesion	+6 (if ≥15 mm)
Ostial lesion	+4.5
Plaque composition	0 (any case)
Side of lesion	0
Internal carotid tortuosity	0
Procedure-related	
Arch type	+2.5 (if type III)
Bovine arch	+3
Arch calcification	+4
Common carotid tortuosity	0
Need for pre-dilatation	+6
Type of embolic protection device	0 (any)
Type of stent	0 (any)
Contrast use >100 mL	0
Contralateral stenosis or occlusion	0
Procedure duration	+2 (if ≥30 min)
Operator-related	
Operator's experience	+4.5 (if <50 CAS procedures) −1 (if >100 CAS procedures)
CAS risk classification	
CAS I (low risk)	<8
CAS II (moderate risk)	8-15
CAS III (high risk)	>15

Abbreviations: CAS, carotid artery stenting.

with the following drugs: acetylsalicylic acid (100 mg/time, 1 time/day); Clopidogrel (75 mg/time, 1 time/day); Atorvastatin calcium tablets (20 mg/time, 1 time/per night). The mentioned drugs were taken orally.

Statistical Analysis

All statistical analyses were performed in SPSS software version 22.0 (IBM Corporation, Armonk, NY), and all graphs were made in the GraphPad Prism software version 7.02 (GraphPad Software Inc., San Diego, CA). Data were displayed as mean and standard deviation or as absolute frequencies and percentages (no. (%)). Comparison was determined by the t test or Chi-square test. The predictive performance of variable in the occurrence of stroke within 30 days after CAS was analyzed by receiver operating characteristic (ROC) curve and the area under the curve (AUC). Variables related to the occurrence of stroke within 30 days after CAS were determined by univariate logistic regression analysis, and the independent variables affecting the occurrence of stroke within 30 days after CAS were screened by the stepwise forward multivariable logistic regression analysis, and $P < .05$ was considered as significant.

Results

Patients' Characteristics

The mean age of 401 patients was 65.9 ± 9.4 years, and 340 (84.8%) of them were males (Table 2). The mean Siena score was 13.4 ± 6.7, and the number of patients classified as CAS I (Siena CAS score <8, low risk), CAS II (Siena CAS score 8-15, moderate risk), and CAS III (Siena CAS score >15, high risk) was 89 (22.2%), 167 (41.6%) and 145 (36.2%) respectively. The detailed information about other patients' characteristics, lesion features, procedure-related features that were included or not included in Siena score were shown in Table 2.

Incidence of Stroke and Predictive Value of Siena CAS Score on Stroke Risk

The incidence of stroke was 4.5% in this study (Fig 1A), and the mean Siena CAS score in patients with (N = 18) stroke was 19.08 ± 6.24, which was higher than that of patients without (N = 383) stroke (mean Siena score: 13.13 ± 6.61) ($P < .001$) (Fig 1B). Based on stroke risk classification by Siena CAS score, the incidence of stroke in patients classified as CAS I, CAS II, and CAS III was .0%, 3.0%, and 9.0%, respectively, which was different among the three groups of patients ($P = .003$) (Fig 1C). Patients at CAS I had the lowest incidence of stroke, followed by patients at CAS II and then patients at CAS III. Furthermore, ROC curve illustrated that Siena CAS score was good at distinguishing patients with stroke from those without stroke with AUC of .743 (95%CI: .638-.848) (Fig 1D). The sensitivity and specificity at the cut-off value by the median value of Siena CAS score (13) was 83.3% and 53.3%, respectively.

Factors for Stroke Risk After CAS

Univariate logistic regression model analysis revealed that Siena CAS score predicted increased risk of stroke after CAS ($P < .001$, OR = 1.140) (Table 3). As for variables uninvolved in the Siena CAS score, FBG more than 7.1 mmol/l was correlated with higher stroke risk ($P = .014$, OR = 4.472), whereas other variables including drinking, low-density lipoprotein cholesterol more than

Table 2. *Patients' characteristics, lesion features, and details of the CAS procedure*

Items	Patients (N = 401)
Patient characteristics	
Age,* years, M ± SD	65.9 ± 9.4
Male,* no. (%)	340 (84.8)
Smoker,* no. (%)	191 (47.6)
Drinker, no. (%)	123 (30.7)
CAD,* no. (%)	61 (15.2)
Hypertension,* no. (%)	278 (69.3)
Diabetes,* no. (%)	103 (25.7)
Peripheral arterial disease,* no. (%)	259 (64.6)
Symptomatic status,* no. (%)	187 (46.6)
Renal insufficiency (Scr > 1.5 mg/dl),* no. (%)	9 (2.2)
LDL-C > 3.38 mmol/L, no. (%)	63 (15.7)
UA > 420 umol/L, no. (%)	29 (7.2)
HCY > 15 umol/L, no. (%)	71 (17.7)
GHb > 7%, no. (%)	75 (18.7)
FBG > 7.1 mmol/l, no. (%)	27 (6.7)
Lesion features	
Severe stenosis, no. (%)	361 (90.0)
Plaque ulceration,* no. (%)	82 (20.4)
Plaque calcification,* no. (%)	149 (37.2)
Side of the lesion (right).* no. (%)	178 (44.4)
Ostial lesion,* no. (%)	230 (57.4)
Lesion ≥ 15 mm,* no. (%)	122 (30.4)
ICA tortuosity,* no. (%)	33 (8.2)
Procedure-related features	
No use of protection, no. (%)	2 (.5)
Type of protection,* no. (%)	
FilterWire	94 (23.4)
Spider	148 (36.9)
NAV6	103 (25.7)
Angioguard	53 (13.2)
MOMA	1 (.2)
Predilatation,* no. (%)	141 (35.2)
Postdilatation, no. (%)	115 (28.7)
Type of stent,* no. (%)	
Precise	130 (32.4)
Acculink	118 (29.4)
Cristallo	52 (13.0)
Protégé	64 (16.0)
Wallstent	30 (7.5)
SPD2	7 (1.7)
Closed stent,* no. (%)	313 (78.1)
Open cell stent,* no. (%)	36 (9.0)
Hybrid stent,* no. (%)	52 (13.0)
Type of arch,* no. (%)	
I	238 (59.4)
II	107 (26.7)
III	56 (14.0)
Bovine arch,* no. (%)	16 (4.0)
Arch calcification,* no. (%)	71 (17.7)
Duration of procedure,* no. (%)	
<15 min	156 (38.9)
15-30 min	111 (27.7)
30-45 min	70 (17.5)
>45 min	64 (16.0)
Contralateral stenosis > 50%,* no. (%)	64 (16.0)
Contralateral occlusion,* no. (%)	27 (6.7)
CCA tortuosity,* no. (%)	20 (5.0)
General anesthesia, no. (%)	100 (24.9)
Operator's experience (CAS procedures),* no. (%)	
<50	90 (22.4)
50-100	56 (14.0)
100-150	120 (29.9)
Siena CAS score	13.4 ± 6.7
CAS risk classification	
CAS I (Siena CAS score <8, low risk)	89 (22.2)
CAS II (Siena CAS score 8-15, moderate risk)	167 (41.6)
CAS III (Siena CAS score >15, high risk)	145 (36.2)

Abbreviations: CAD, coronary artery disease; CAS, carotid artery stenting; CCA, common carotid artery; FBG, fasting blood-glucose; GHb, glycated hemoglobin; HCY, homocysteine; ICA, internal carotid artery; LDL-C, low-density lipoprotein cholesterol; M ± SD, mean ± standard deviation; Scr, serum creatinine; UA, uric acid.

*The variable was involved in the assessment of Siena CAS score.

3.38 mmol/L, uric acid more than 420 umol/L, homocysteine more than 15 umol/L, glycated hemoglobin more than 7%, severe stenosis, no use of protection, postdilatation, and general anesthesia were not correlated with stroke risk (all $P > .05$). In addition, stepwise forward multivariate logistic regression analysis further displayed that Siena CAS score ($P = .001$, OR = 1.136) and FBG >7.1 mmol/l ($P = .048$, OR = 3.433) independently predicted increased risk of stroke after CAS (Table 3).

The Predictive Value of Siena CAS Score Combined with FBG More Than 7.1 mmol/l on Stroke Risk

Among the variables uninvolved in the Siena CAS score, FBG more than 7.1 mmol/l was an independent predictive factor for increased stroke risk, thus, the predictive value of Siena CAS score combined with FBG more than 7.1 mmol/l on stroke was evaluated by ROC curve, which disclosed that Siena CAS score combined with FBG more than 7.1 mmol/l was of good value in differentiating patients with stroke from those without stroke with AUC of .770 (95%CI: .677-.863), which was relatively better compared with that of Siena CAS score alone (Fig 2).

Discussion

Stroke is one of the leading causes of death and permanent disability in China. An epidemiological survey

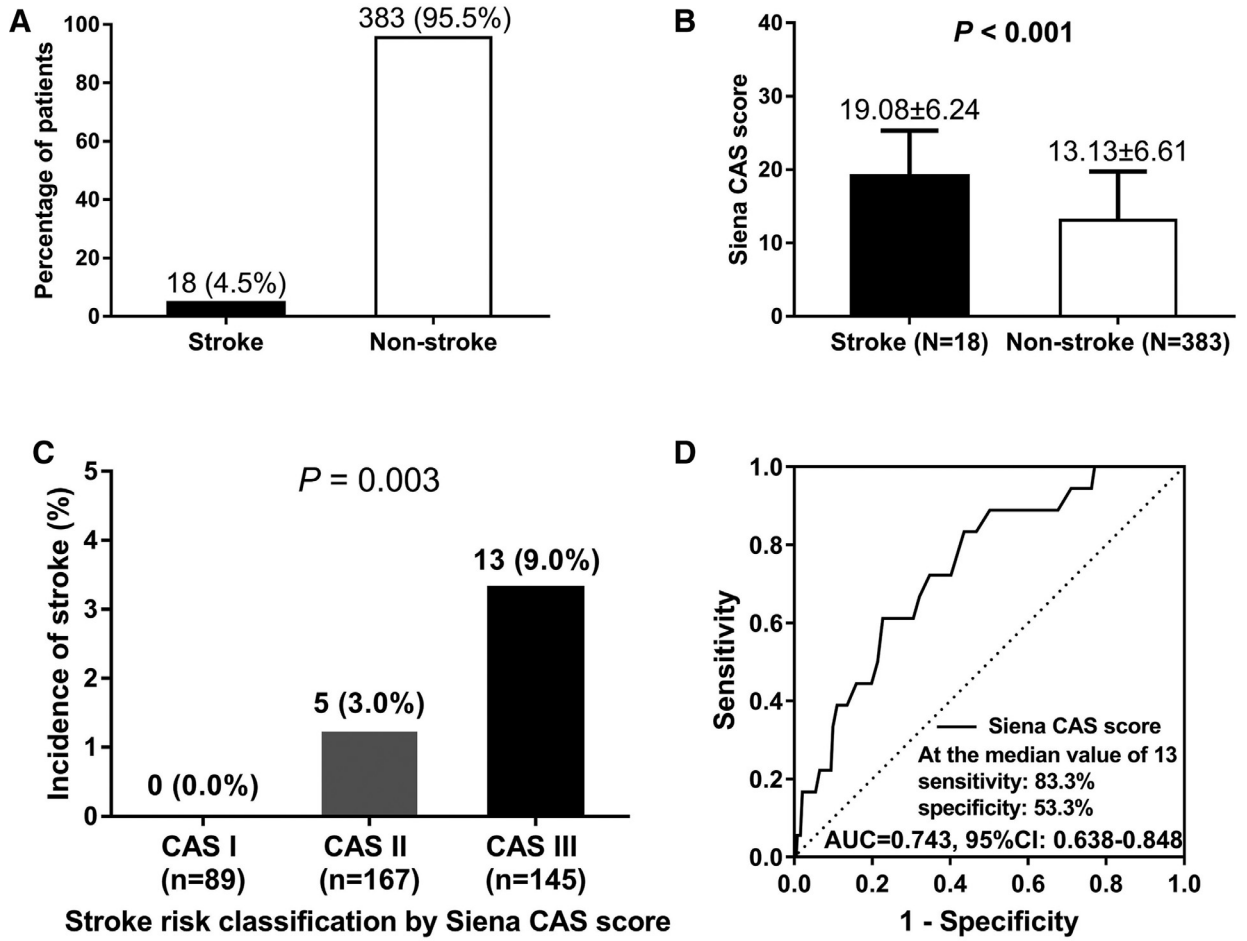

Figure 1. *Predictive value of Siena CAS score on stroke. The incidence of stroke (A), Siena CAS score of patients with and without stroke (B), incidence of stroke by Stroke risk stratification (C) and predictive value of Siena CAS score on stroke (D). Comparison was determined by the t test or Chi-square test.* P < .05 *was considered significant. The predictive performance of variable in the occurrence of stroke within 30 days after CAS was analyzed by ROC curve and the AUC. Abbreviations: AUC, area under curve; CAS, carotid artery stenting; ROC, receiver operating characteristic.*

shows that the incidence and mortality rate of stoke in China are 246.8 out of 100,000 and 114.8 out of 100,000, respectively.[10] As a common cause of stroke, carotid artery stenosis has the highest risk of early stroke occurrence after treatment compared with other causes such as cardioembolism and small artery occlusion.[11] In our study, the incidence of stroke was 4.8% among all the ICA stenosis patients underwent CAS, which was much higher than the overall stroke incidence in Chinese population (.247%) and increased compared with the previous study conducted in Italy (3.34%).[8] This might be attributable to that ICA stenosis was a cause of stroke, so patients with ICA stenosis were especially under high risk of stroke compared with the general population. Besides, according to the global statistics of stroke, population in east Asia presented higher incidence of stroke compared with the European, thus the incidence of stroke was higher in our study compared with the previous study in Italy.[12]

Siena CAS risk scoring system is a simple risk score model characterized by its easy operation and good performance in predicting stroke risk, which consists of several variables including patients' baseline characteristics, lesion features, procedure characteristics, and operator's experience.[8] Among these variables, lesion-related features appear to have a significant impact on the stroke risk as shown in several observational studies, and severe lesion (particularly in the presence of calcified lesion, ulcerated lesion, native/recurrent stenosis, long length of the lesion, and ostial lesion) may enhance the difficulties of operation and prolong operation time to cause a damage of the epithelium and enlarge area of carotid artery injury, thereby increases risk of carotid restenosis following stenting treatment and led to high risk of stroke after CAS.[8,13-15] As for procedure-related features, the rare periprocedural strokes correlates with the release of small emboli during arch manipulation (before catheter access into the common carotid artery or embolic protection device placement) with an increased risk in the case of arch calcification, a bovine arch, or a type III arch, thus, these procedure-related features (such as arch type, bovine arch, arch calcification, and need for predilatation) serve as potential critical predictors for increased stroke

Table 3. *Logistic regression model analysis of factors related to the occurrence of stroke within 30 days after CAS*

Parameters	Logistic regression model			
	P value	OR	95% CI	
			Lower	Higher
Univariate logistic regression				
Siena CAS score	<.001	1.140	1.059	1.226
Variables uninvolved in the Siena CAS score				
Drinker	.430	.634	.204	1.966
LDL-C > 3.38 mmol/L	.159	2.155	.740	6.274
UA > 420 umol/L	.998	.000	.000	-
HCY > 15 umol/L	.459	.569	.128	2.531
GHb > 7%	.405	.531	.119	2.360
FBG > 7.1 mmol/l	.014	4.472	1.363	14.677
Severe stenosis	.529	1.927	0.250	14.879
No use of protection	.999	.000	.000	-
Postdilatation	.931	.955	.332	2.741
General anesthesia	.412	.59	.167	2.081
Stepwise forward multivariate logistic regression				
Siena CAS score	.001	1.136	1.054	1.224
FBG>7.1 mmol/l	.048	3.433	1.011	11.661

Abbreviations: CAS, carotid artery stenting; CCA, common carotid artery; CI, confidence interval; FBG, fasting blood-glucose; GHb, glycated hemoglobin; HCY, homocysteine; LDL-C, low-density lipoprotein cholesterol; OR, odds ratio; UA, uric acid.

risk after CAS.[8,13] In addition, the highly significant correlation of patients' baseline characteristics (including cardiac disease, presence of neurological symptoms, as well as diabetes) with stroke risk after CAS has been reported in several previous studies, (1) for patients with history of cardiac disease, some types of cardiac diseases (including atrial fibrillation and valvular heart disease) are easy to form abnormal blood flow and condense into an unstable blood clot, and then falling off through cervical arteries into the cerebral blood vessels to block cerebral arteries, thereby leading to ischemic cerebral infarction and increasing risk of stroke after CAS.[16] (2) For patients with history of neurological symptoms, the presence of nervous system diseases (including stroke) might lead to high risk of stroke after CAS. (3) For patients with diabetes history, long duration of diabetes could not only cause aorta lesion and capillaries lesion (usually presenting smaller vessel dimensions and longer lesions) to increase the susceptibility to carotid restenosis, but also frequently accompany with limited glycemic control, dyslipidemia and poor immunologic function, thereby exposing to higher risk of stroke after CAS.[17] Furthermore, procedure duration and operator's experience could directly affect the outcomes of CAS as well as stroke risk. Siena CAS risk score has integrated these multiple risk factors to independently stratify the risk of stroke after CAS, whereas it is developed just focusing on patients recruited in Italy, and whether it is equally applicable in Chinese population is largely unknown.[8] In the current study, we included a total of 401 Chinese patients with ICA stenosis who underwent CAS, and validated the accuracy of Siena CAS risk score in these Chinese patients, and the results showed that the Siena CAS risk score was higher in stroke group compared with nonstroke group, and the incidence of stroke was increased with higher CAS risk classification, more importantly, Siena CAS risk score could predict stroke risk after CAS with AUC of .743 (95%CI: .638-.848) in these Chinese patients.

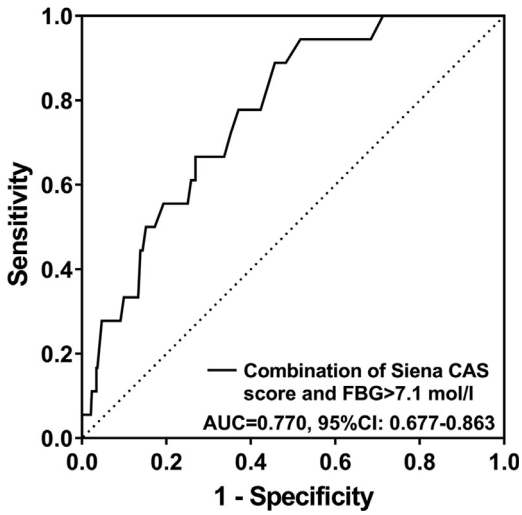

Figure 2. *ROC curve of Siena CAS score combined with FBG >7.1 mmol/l in predicting stroke risk. The predictive value of Siena CAS score combined with FBG >7.1 mmol/l in differentiating patients with stroke from those without stroke was shown by ROC curve and the AUC. Abbreviations: AUC, area under curve; CAS, carotid artery stenting; FBG, fasting blood-glucose; ROC, receiver operating characteristic.*

Although the good predictive value of Siena CAS risk score for stroke risk after CAS had been validated in the Chinese patients (mentioned above), exploring additional

risk factors is still necessary to help perfect the scoring and improve prognosis in patients with ICA stenosis who underwent CAS. In the present study, we further explored whether the additional stroke-related risk factors that were uninvolved in Siena CAS risk score affect stroke after CAS in these Chinese patients, and we discovered that FBG more than 7.1 mmol/l could independently predict high risk of stroke. The possible explanation was as follows: high FBG is presumably related to augmented blood viscosity, which might not only cause damages of cerebrovascular endothelial cells to result in the local thrombus formation, thereby directly increase stroke risk after CAS, but also destruct endothelial cells of carotid artery to generate local thrombus and carotid restenosis, which easily form falls off of thrombus to indirectly increase stroke risk after CAS. In order to investigate the predictive value of Siena CAS score combined with FBG more than 7.1 mmol/l for stroke risk in Chinese patients with ICA stenosis who underwent CAS, we subsequently performed ROC curve and found that Siena CAS score combined with FBG more than 7.1 mmol/l presented with a well predictive value for stroke risk in these Chinese patients with AUC of .770 (95%CI: .677-.863), which might be slightly more accurate compared with Siena CAS score alone. The results might provide a novel and convincing evidence for predicting stroke risk after CAS to improve prognosis in Chinese patients with ICA stenosis.

Some limitations still existed in this cohort study as follows: (1) this study was a single center study, thus, further study with more patients from multicenter is greatly needed. (2) Adding more stroke-related factors including patients' education and inflammation levels might enhance our findings in further study.

In summary, Siena CAS risk scoring system exhibits to be a useful tool to predict stroke risk, and the combination of Siena CAS score and current increased FBG might be a more accurate stratification for stroke risk in Chinese ICA stenosis patients after CAS.

Authors' Contributions

Huchuan Zhou and Jie Shuai designed the experiment, Huchuan Zhou, Lin Shen and Fei Wei performed the experiments, Lin Shen and Fei Wei analyzed the data. All authors wrote the manuscript and revised the manuscript.

Ethical Approval

This study was approved by Ethics Committee of Xinqiao Hospital, and the written informed consents or verbal agreements (with tape recording) were collected from the patients or their guardians included the analysis.

Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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