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External Validation of Pooled Cohort Risk Equations to Predict 1-Year Clinical Outcome in Ischemic Stroke Patients

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Background: The present study aimed to validate the pooled cohort risk (PCR) equations in a Chinese ischemic stroke population and to explore its prognostic value in predicting stroke recurrence, coronary heart disease, and vascular death.

Material/Method: Patients were selected from the China National Stroke Registry. The C statistic was used to examine the clinical prediction of the scores. To analyze the relevant risk factors, univariate and multivariate logistic regressions were performed.

Results: Out of a total of 22 216 patients, 8287 patients (including 7652 acute ischemic stroke [AIS] and 635 transient ischemic attack [TIA] patients) were selected and enrolled in the study. At 1-year follow-up, for stroke recurrence rate, the C statistic value was 0.584 in AIS patients and 0.573 in all patients. For non-fatal myocardial infarction, the C statistic value was 0.533 in AIS patients and 0.493 in all patients. For vascular death, the C statistic value was 0.592 in AIS patients and 0.592 in all patients. For all events, the C statistic value was 0.582 in AIS patients and 0.575 in all patients. For AIS patients, the 12-month cumulative rates for recurrent stroke, vascular death, and combined vascular events were higher in the high-PCR group (PCR ≥20%).

Conclusions: Pooled cohort risk equations may serve as potential tools to predict and stratify the 1-year risk of recurrent stroke and combined vascular events in AIS/TIA patients in China.

MeSH Keywords: Acute Ischemic Stroke • Pooled Cohort Risk Equations • Recurrence • Transient Ischemic Attack

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Background

Stroke is the leading cause of disability and mortality worldwide, resulting in an enormous socioeconomic burden. There has been a greater that 100% increase in stroke incidence rates in low-to-middle income countries over the past 4 decades [1]. Readmissions were reported to be 31–53% in the first year after stroke, frequently from recurrent stroke or cardiovascular diseases [2–4]. About half of the patients experienced readmission or death during the first year after stroke and carried substantial risk and burden [5]. The ability to accurately estimate the 1-year clinical outcome of stroke is very important and may help healthcare providers and family make decisions on a treatment plan, discharge arrangement, and resource use. The risk assessment would aid practitioners in identifying high-risk patients and developing a targeted and cost-effective preventive strategy.

In 2013, the American College of Cardiology/American Heart Association (ACC/AHA) task force developed the Guideline on the Assessment of Cardiovascular Risk and introduced the pooled cohort risk (PCR) equations, which were designed to predict 10-year risk for a first atherosclerotic cardiovascular disease (ASCVD) event [6]. The ASCVD event includes non-fatal myocardial infarction (MI), coronary heart disease (CHD) death, as well as non-fatal and fatal stroke. The PCR equations were derived from 4 major population-based cohort studies in the United States involving white and black Americans. The inclusion of stroke as an endpoint is a major strength. It is recommended as a guide to make decision on initiating statin therapy for primary prevention in adults without clinical ASCVD. When the PCR score is ≥7.5%, statin use is recommended for non-diabetic patients. The PCR equations have been further validated by different external cohorts [7,8].

The present study aimed to validate the performance of the PCR equations in acute ischemic stroke (AIS) and transient ischemic attack (TIA) patients in China. We investigated whether the PCR equations can predict the clinical outcomes, including stroke recurrence, CHD, and vascular death, during 1-year follow-up. We also compared the predictive validity between the PCR equations and the ESSEN score, which has been widely validated internally and externally [9–11].

Material and Methods

The cohort was derived from the China National Stroke Registry (CNSR) [12], which is the largest, nationwide, multicenter, and prospective registry of consecutive patients with acute cerebrovascular diseases corresponding to World Health Organization diagnostic standards [13]. The study of CNSR was approved by the Central Institutional Review Board at Beijing Tiantan Hospital. All patients or their designated relatives signed the informed consent forms and their data were kept confidential and protected. The cohort, comprising AIS and TIA patients, was followed up for 1 year. The inclusion criteria according to the PCR equations were: age: 40–79 years; total cholesterol: 130–320 mg/L; HDL: 20–100 mg/L; and BP: 90–200 mmHg. Patients diagnosed with hemorrhagic strokes, or missing baseline characteristics, or without follow-up outcomes, or did not meet the PCR standards were excluded. Among the 22 216 acute stroke patients who were hospitalized from 132 participating hospitals in the CNSR, a total of 8287 patients, including 7652 AIS and 635 TIA patients, fulfilled the inclusion criteria, finished the follow-up, and were thus enrolled in the study (Figure 1).

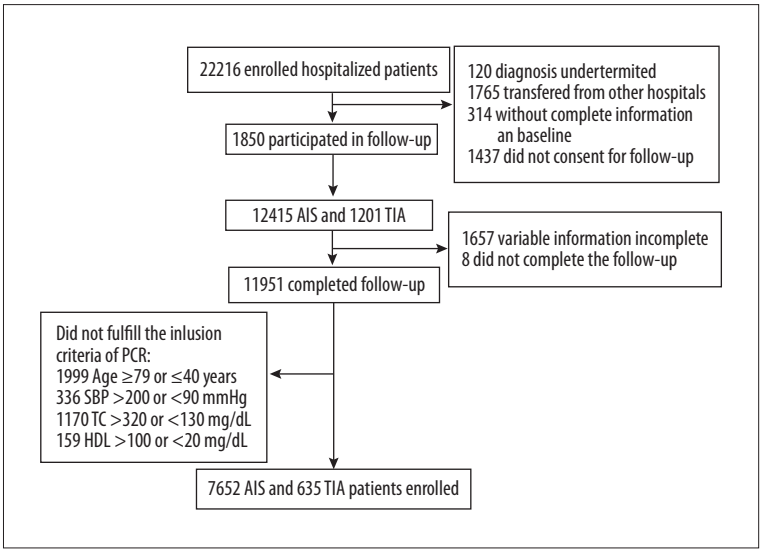

Figure 1. Schematic illustration of study population. AIS – acute ischemic stroke; TIA – transient ischemic attack; SBP – systolic blood pressure; TC – triglyceride; HDL – high-density lipoprotein.

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For the present study, the following baseline variables were analyzed: (1) demographics (age and gender); (2) stroke risk factors: body mass index (BMI), current smoking, and heavy alcohol consumption (≥2 standard alcohol beverages per day), hypertension, diabetes mellitus, dyslipidemia, heart failure, atrial fibrillation, coronary heart disease, peripheral artery disease, and history of stroke/TIA; (3) admission stroke severity based on the National Institutes of Health Stroke Scale score (NIHSS); and (4) pre-admission medications: antihypertensive treatment, hypoglycemic treatment, statins usage, and antiplatelet treatment.

The primary endpoint was stroke recurrence during 1-year follow-up, referring to a new or worsened neurological deficit (defined as NIHSS worsened ≥4), or readmission due to cerebrovascular diseases including ischemic stroke, intracerebral hemorrhage, or subarachnoid hemorrhage. The secondary endpoints were CHD (including MI, coronary revascularization, and cardiac resuscitation) and all-cause vascular death during 1-year follow-up. Blinded trained interviewers obtained the outcome data by using standardized questionnaires via phone calls.

Statistical analysis

Data were summarized as mean values and SD for continuous parameters, or absolute count and percentage for categorical endpoints. Comparisons across the groups were examined using the chi-square test for categorical variables. Student's t-test was used for continuous/score variables. To analyze relationship between the risk factors and the outcomes, univariate and multivariate logistic regression were utilized. To validate the discrimination of the PCR equations and the ESSEN score, the area under the receiver operating curve (AUC) by C statistic was assessed. All tests were 2-tailed, and $P<0.05$ was considered statistically significant. Statistical analysis was performed using SAS software version 9.3 (SAS Institute Inc, Cary, NC).

Results

Baseline characteristics of the selected 8287 patients are shown in Table 1. The clinical features, including demographic characteristics, risk factors, and drug treatments, were compared between the patients with and without recurrences. The cumulative 1-year stroke recurrence was 11.27%. Older patients and patients with smoking, heavy drinking, hypertension, diabetes mellitus, dyslipidemia, heart failure, coronary heart disease, atrial fibrillation, history of stroke/TIA, and high admission NIHSS score were more likely to be recurrent ($P<0.05$). On the other hand, patients with lipid-lowering agents, antihypertensive agents, hypoglycemic agents, and antiplatelet agents were less likely to be recurrent ($P<0.05$).

Table 2 shows the univariate logistic regression analysis results of the risk factors. Older patients (OR 1.250, 95% CI: 1.130–1382), continual smoking (OR 1.296, 95% CI: 1.112–1.510), heart failure (OR 1.947, 95% CI: 1.215–3.119), coronary heart disease (OR 2.004, 95% CI: 1.689–2.378), hypertension (OR 1.514, 95% CI: 1.303–1.759), diabetes mellitus (OR 1.193, 95% CI: 1.018–1.400), dyslipidemia (OR 1.404, 95% CI: 1.162–1.696), history of stroke/TIA (OR 2.046, 95% CI: 1.782–2.350), and high admission NIHSS score (OR 1.017, 95% CI: 1.006–1.028), were associated with higher risk of stroke recurrence. The multivariate logistic regression analysis (Table 3) found that stoke recurrence was higher in patients with atrial fibrillation and history of stroke/TIA. The adjusted odds ratio was 1.958 (95% CI: 1.508–2.542) and 1.736 (95% CI: 1.496–2.014), respectively.

At 1-year follow-up, the C statistic values were as follows: (1) For the stroke recurrence rate, 0.584 for PCR equations and 0.565 for ESSEN score in AIS patients and 0.573 for PCR equations and 0.558 for ESSEN score in all patients. (2) For non-fatal MI, 0.533 for PCR equations and 0.512 for ESSEN score in AIS patients and 0.493 for PCR equations and 0.520 for ESSEN score in all patients. (3) For vascular death, 0.592 for PCR equations and 0.612 for ESSEN score in AIS patients and 0.592 for PCR equations and 0.609 for ESSEN score in all patients. (4) For all events, 0.582 for PCR equations and 0.579 for ESSEN score in AIS patients and 0.575 for PCR equations and 0.572 for ESSEN score in all patients (Table 4).

The study subjects were categorized into 2 groups: a low-PCR group (PCR<20%) and a high-PCR group (PCR ≥20%). For AIS patients, the 12-month cumulative rates of recurrent stroke, vascular death, and combined vascular events were higher in the high-PCR group ($P<0.001$); however, the rates for non-fatal MI did not differ between the 2 groups (Table 5). For TIA patients, there were no significant differences in the 12-month cumulative rates for recurrent stroke, non-fatal MI, vascular death, and combined vascular events between the 2 groups (Table 6).

Discussion

The present study was primarily conducted to determine whether the PCR equations could predict the 1-year clinical outcome in AIS/TIA patients in China. A previous study showed that the ESSEN score can predict and stratify the risk of recurrent stroke and combined vascular events in Chinese AIS/TIA patients [14]. The present results showed that the PCR equations and the ESSEN score had similar predictive validity for either recurrent stroke or cumulative vascular events. In our study results, the C statistic values were approximately 0.6, indicating a moderate predictive value of the 2 scores in stroke/TIA patients in China. We also found that the AUC values of the PCR equations were

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Table 1. Baseline characteristics of patients with and without recurrence.

Characteristics	Overall	With recurrence	Without recurrence	P-value
Sample size	8287	934	7353	
Sex (male), n,%				
Female	3054/8287 (36.9%)	349 (37.4%)	2705 (36.8%)	
Male	5233/8287 (63.1%)	585/934 (62.6%)	4648/7353 (63.2%)	0.7299
Age, y (mean±SD)	63.24±9.65	64.86±9.05	63.03±9.71	0
Age, median (Q1–3), y	64 (56–72)	66 (58–73)	64 (55–71)	0
BMI (kg/m^2) (mean ±SD)	24.62±3.83	24.68±3.38	24.61±3.88	0.6594
BMI (kg/m^2) median (Q1–Q3)	24.34 (22.49–26.45)	24.46 (22.49–26.67)	24.3 (22.48–26.42)	0.1786
BMI <25	4442/7534 (59%)	483/838 (57.6%)	3959/6696 (59.1%)	0.5463
BMI 25–30	2698/7534 (35.8%)	314/838 (37.5%)	2384/6696 (35.6%)	
BMI ≥30	394/7534 (5.2%)	41 (4.9%)	353 (5.3%)	
Vascular risk factor, n,%				
Smoking	5664/8287 (68.3%)	683/934 (73.1%)	4981/7353 (67.7%)	0.0009
Heavy drinking	2395/8287 (28.9%)	237/934 (25.4%)	2158/7353 (29.3%)	0.0116
Hypertension	5285/8287 (63.8%)	671/934 (71.8%)	4614/7353 (62.7%)	0
Diabetes mellitus	1794/8287 (21.6%)	228/934 (24.4%)	1566/7353 (21.3%)	0.0295
Dyslipidemia	1018/8287 (12.3%)	148/934 (15.8%)	870/7353 (11.8%)	0.0004
Heart failure	112/8287 (1.4%)	22/934 (2.4%)	90/7353 (1.2%)	0.0048
Coronary heart disease	1086/8287 (13.1%)	201/934 (21.5%)	885/7353 (12.0%)	0
Peripheral artery disease	40/8287 (0.5%)	4/934 (0.4%)	36/7353 (0.5%)	0.7989
Atrial fibrillation	434/8287 (5.2%)	97/934 (10.4%)	337/7353 (4.6%)	0
History of stroke/TIA	2586/8287 (31.2%)	429/934 (45.9%)	2157/7353 (29.3%)	0
Admission NIHSS score	5.53+5.93 (8287)	6.09+6.69 (934)	5.46+5.83 (7353)	0.0021
NIHSS, median (Q1–Q3)	4 (2–8) (8287)	4 (1–8) (934)	4 (2–7) (7353)	0.247
Drugs				
Lipid-lowering agents	223/8218 (2.7%)	44/919 (4.8%)	179/7299 (2.5%)	0
Antihypertensive agents	3887/8287 (46.9%)	507/934 (54.3%)	3380/7353 (46.0%)	0
Hypoglycemic agents	1983/8287 (23.9%)	269/934 (28.8%)	1714/7353 (23.3%)	0.0002
Antiplatelet agents	1359/8287 (16.4%)	223/934 (23.9%)	1136/7353 (15.4%)	0

BMI – body mass index; NIHSS – the National Institutes of Health Stroke Scale. Heavy drinking indicates ≥2 standard alcohol intake/day.

analogous to those of a recent study wherein the patients were included from the Vitamin Intervention for Stroke Prevention (VISP) trial [15]. In the VISP cohort, comprising 3680 patients with an average of 20 months of follow-up, the C statistics of the PCR were 0.56 for stroke and 0.62 for major vascular events.

In the REGARDS study [7], the PCR model yielded better discrimination, with the C value 0.72 (95% CI, 0.70–0.75). Although the participants have not been followed up for 10 years, Muntner et al. modified the PCR model into 5-year risk version and the participants were not taking statins at baseline, for

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Table 2. Risk factors for stroke recurrence by univariate logistic regression.

Risk factors	OR (95% CI)	P-value
Age	1.020 (1.013–1.028)	<0.001
Age_c	1.250 (1.130–1.382)	<0.001
Gender	1.025 (0.891–1.180)	0.729
BMI	1.004 (0.986–1.023)	0.659
BMI-cat	1.032 (0.915–1.164)	0.608
Smoking	1.296 (1.112–1.510)	<0.001
Heavy drinking	0.819 (0.701–0.956)	0.011
Heart failure	1.947 (1.215–3.119)	0.005
Coronary heart disease	2.004 (1.689–2.378)	<0.001
Hypertension	1.514 (1.303–1.759)	<0.001
Diabetes mellitus	1.193 (1.018–1.400)	0.029
Dyslipidemia	1.404 (1.162–1.696)	<0.001
Peripheral artery disease	0.874 (0.310–2.462)	0.799
History of stroke/TIA	2.046 (1.782–2.350)	<0.001
Admission NIHSS score	1.017 (1.006–1.028)	0.002
Hypoglycemic agents	1.331 (1.144–1.549)	<0.001
Lipid-lowering agents	2.000 (1.428–2.802)	<0.001
Antihypertensive agents	1.396 (1.217–1.600)	<0.001
Antiplatelet agents	1.716 (1.458–2.021)	<0.001

OR – odds ratio; CI – confidence interval; BMI – body mass index; NIHSS – the National Institutes of Health Stroke Scale. Heavy drinking indicates the standard alcohol intake per day ≥2; OR represents the standard alcohol intake per day ≥2 *vs.* <2.

Table 3. Risk factors for stroke recurrence by multivariate logistic regression.

Risk factors	OR (95% CI)
Age	1.010 (1.002–1.018)
Admission NIHSS score	1.009 (0.997–1.020)
Gender	0.889 (0.746–1.060)
Smoking	0.960 (0.803–1.148)
Heavy drinking	0.925 (0.769–1.114)
Heart failure	1.026 (0.620–1.698)
Coronary heart disease	1.515 (1.258–1.826)
Hypertension	1.367 (1.107–1.689)
Diabetes mellitus	0.820 (0.659–1.021)
Dyslipidemia	1.060 (0.857–1.311)
Atrial fibrillation	1.958 (1.508–2.542)
History of stroke/TIA	1.736 (1.496–2.014)
Hypoglycemic agents	1.397 (1.135–1.720)
Lipid-lowering agents	1.351 (0.929–1.966)
Antihypertensive agents	0.923 (0.759–1.123)
Antiplatelet agents	1.159 (0.966–1.390)

OR – odds ratio; CI – confidence interval; NIHSS – the National Institutes of Health Stroke Scale. Reference for age was <65-years-old. Reference for NI-HSS score was 3. Reference for female sex was male sex. Adjusted for gender, ethnicity, educational background, smoking, heavy drinking, adiposity, and history of disease including heart failure, hypertension, diabetes mellitus, hyperlipidemia, vascular disease, and drug intervention such as antihypertensive agents use, hypoglycemic agents use, lipid-lowering agents use, antiplatelet agents and anticoagulants use.

which the PCR model was specifically designed to be used. In our study, the PCR model was modified to 1-year and 46.2% had vascular comorbidities, including known-ASCVD and heart failure. Furthermore, in our cohort, there was 2.7% lipid modifier use and the secondary preventions included antithrombotic medication (16.4%), antihypertensive medication (46.9%), and hypoglycemic medication (23.9%). All these may have attenuated the discrimination power of vascular outcome events. Another potential factor was racial difference.

We used 20% as the threshold value to discriminate low and high risk, since a score of ≥20% in 10 years is known to predict increased CVD risk that requires the modification of driving risk factors [16]. Our study confirmed that the AIS patients with PCR score ≥20% faced a higher risk of recurrent stroke and combined vascular events, which could not be applied to TIA patients. Other studies also found that high PCR (PCR score ≥20%) predicts a 1.8-fold increase in risk of stroke and a 2.1-fold increase in risk of stroke/CHD/vascular death over a 2-year period [15]. The PCR equations may be a potentially useful and easy-to-use risk stratification tool to aid clinicians in identifying patients at high risk of recurrent stroke and vascular events, thereby raising awareness of secondary prevention.

The strengths of this study are the prospective and multicenter design of the CNSR and the large sample size of consecutive stroke patients. Nevertheless, our study also has several limitations. First, selection bias cannot be excluded. All the participating hospitals involved in the CNSR were located in the urban regions because of the selection for intensive care and follow-up, although they represent nationwide areas. The urban areas have more resources and expertise than their rural counterparts. Thus, we might have underestimated the

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Table 4. Predictive accuracy of PCR equations and ESSEN Score.

	Recurrence stroke		Non-fatal MI		Vascular death		RS+MI+VD	
	AUC	95% CI	AUC	95% CI	AUC	95% CI	AUC	95% CI
PCR								
AIS	0.584	4.927 (83.302, 7.353)	0.533	0.825 (0.164, 4.138)	0.592	4.927 (3.221, 7.537)	0.582	4.725 (3.422, 6.525)
TIA	0.499	0.753 (0.206, 2.754)	0.490	0.776 (0.004, 140.407)	0.588	9.654 (1.023, 91.116)	0.499	0.872 (0.267, 2.856)
AIS and TIA patients	0.573	3.945 (2.697, 5.771)	0.493	0.811 (0.174, 3.776)	0.592	5.375 (3.547, 8.145)	0.575	4.174 (3.062, 5.690)
ESSEN								
AIS	0.565	1.095 (1.065, 1.125)	0.512	0.978 (0.881, 1.085)	0.612	1.173 (1.138, 1.210)	0.579	1.117 (1.093, 1.142)
TIA	0.495	0.998 (0.922, 1.080)	0.594	0.862 (0.605, 1.227)	0.526	1.028 (0.871, 1.213)	0.503	0.988 (0.918, 1.063)
AIS and TIA patients	0.558	1.083 (1.055, 1.112)	0.520	0.967 (0.875, 1.068)	0.609	1.169 (1.134, 1.204)	0.572	1.106 (1.083, 1.129)

Table 5. 12-month cumulative rates for recurrent stroke and combined vascular events stratified by PCR in AIS patients.

	Recurrence stroke			Non-fatal MI			Vascular death			RS+MI+VD		
	N	Percent (95% CI)	P	N	Percent (95% CI)	P	N	Percent (95% CI)	P	N	Percent (95% CI)	P
PCR <20%	259	8.38%		19	0.59%		218	6.83%		471	14.75%	
PCR ≥20%	564	12.72%		35	0.76%		478	10.37%		961	20.85%	
Total	823	10.94%	<0.001	54	0.69%	0.3891	696	8.92%	<0.001	1432	18.35%	<0.001

Table 6. 12-month cumulative rates for recurrent stroke and combined vascular events stratified by PCR in TIA patients.

	Recurrence stroke			Non-fatal MI			Vascular death			RS+MI+VD		
	N	Percent (95% CI)	P	N	Percent (95% CI)	P	N	Percent (95% CI)	P	N	Percent (95% CI)	P
PCR <20%	62	15.82%		3	0.74%		10	2.48%		74	18.36%	
PCR ≥20%	49	13.17%		3	0.79%		12	3.16%		60	15.79%	
Total	111	14.53%	0.2999	6	0.77%	0.9424	22	2.81%	0.5670	134	17.11%	0.3394

unfavorable events rate. Moreover, our study selected the hospitalized patients, and exclusion of non-hospitalized patients in a study of survival after stroke may introduce significant bias [17]. Second, our study did not classify the subtypes of acute ischemic stroke, which might influence the functional outcome, survival, and recurrence of patients [18,19]. Third, the PCR equations do not involve severity of stroke and information on imaging or laboratory studies, which may affect the outcomes of patients [20].

The present report provides the first external validation of the PCR equations in China. In Chinese patients with AIS or TIA, the PCR equations may be a potentially useful tool for predicting the risk of recurrent stroke and combined vascular events.

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Conclusions

The current study shows that the PCR equations and the ESSEN score have similar predictive validity for either recurrent stroke or cumulative vascular events. Our study confirms that AIS patients with PCR score ≥20% face a high risk of recurrent stroke and combined vascular events.

The pooled cohort risk equations may serve as potential tools to predict and stratify the 1-year risk of recurrent stroke and combined vascular events in AIS/TIA patients in China. The PCR equations may be a useful and easy-to-use risk tool which can raise awareness of secondary prevention.

Conflict of interests

The authors declare that they have no conflict of interests.

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