

Validation of Predictive Value of Patterns of Nonadherence to Antiplatelet Regimen in Stented Patients Thrombotic Risk Score in Chinese Population Undergoing Percutaneous Coronary Intervention: A Prospective Observational Study

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Abstract

Background: The patterns of nonadherence to antiplatelet regimen in stented patients (PARIS) thrombotic risk score are a novel score for predicting the risk of coronary thrombotic events (CTEs) after percutaneous coronary intervention (PCI) with drug-eluting stents. However, the prognostic value of this score has not been fully evaluated in non-Euro-American PCI populations.

Methods: We performed a prospective, observational study of 10,724 patients who underwent PCI in Fuwai hospital, China and evaluated the PARIS thrombotic risk score's predictive value of CTEs in the PCI population. The area under the receiver operating characteristic curve (AUROC) was used to assess the predictive value of the PARIS score for CTE.

Results: Among 9782 patients without in-hospital events, a total of 95 CTEs occurred during the 2-year follow-up. The PARIS score was significantly higher in patients with CTEs (3.38 ± 2.04) compared with patients without events (2.53 ± 1.70 , $P < 0.001$). According to the risk stratification of the PARIS thrombotic score, the risk of CTEs in the high-risk group was 3.14 times higher than that in the low-risk group (hazard ratio [HR], 3.14; 95% confidence interval [CI], 1.92–5.13; $P < 0.001$). However, the risk of CTEs in the intermediate-risk and low-risk groups was not significant (HR, 1.39; 95% CI, [0.86–2.24]; $P = 0.184$). The PARIS score showed prognostic value in evaluating CTEs in the overall population (AUROC, 0.621; 95% CI, 0.561–0.681), the acute coronary syndrome (ACS) population (AUROC, 0.617; 95% CI, 0.534–0.700; $P = 0.003$), and the non-ACS population (AUROC, 0.647; 95% CI, 0.558–0.736; $P = 0.001$).

Conclusions: In a real-world Chinese population, the PARIS thrombotic risk score shows a modest prognostic value for CTEs in patients after PCI. This score also has a predictive value for CTEs in the ACS and non-ACS subgroup populations.

Key words: Coronary Thrombosis; Percutaneous Coronary Intervention; Prognosis; Risk Assessment

INTRODUCTION

Percutaneous coronary intervention (PCI) has good efficacy and safety in the treatment of patients with coronary heart disease and coronary stenosis and evidence of myocardial ischemia. With advances in coronary heart disease in recent years, using new-generation drug-eluting stents (DESs) and dual-antiplatelet therapy (DAPT) have further reduced the risk of coronary thrombotic events (CTEs).^[1-3] However, stent thrombosis and myocardial infarction still occur in

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some patients, which lead to a poor prognosis in patients with PCI and an increased risk of death. Therefore, identifying patients with a high risk of thrombosis DAPT undergoing PCI is important.

The patterns of nonadherence to the antiplatelet regimen in stented patients (PARIS) thrombotic risk score^[4] are a novel score for predicting risks for long-term out-of-hospital CTEs. The PARIS thrombotic risk score is derived from the United States and European populations. However, Asian patients have a different risk of thrombotic events from European and American populations, which is called the “East Asia paradox.”^[5] Therefore, validating the PARIS thrombotic risk score in Asian populations is important. There is one study^[6] that showed the value of PARIS scores in Asian populations; however, this study did not strictly follow the PARIS study entry criteria,^[4] and only patients with acute coronary syndrome (ACS) were included. However, the original PARIS study included the entire PCI population. Therefore, in this study, we aimed to validate the PARIS thrombotic risk score in the real-world Chinese population with the entire PCI population.

METHODS

Ethical approval

The study was conducted in accordance with the *Declaration of Helsinki* and was approved by the local Ethics Committee of the Fuwai hospital’s Research Ethics Committee (No. 2013-449). The Institutional Review Board approved the study protocol, and all of the patients provided written informed consent.

Study design

This was a prospective, observational, single-center study in Beijing, China. All data were collected from consecutive patients who underwent PCI between January 2013 and December 2013. As described previously,^[7] a total of 10,724 patients were enrolled. Using the PARIS inclusion and exclusion criteria,^[4] we excluded the following patients: those who were not discharged with DAPT; those who did not successfully receive DESs; those with only balloon dilatation without stents; those with in-hospital major bleeding, stent thrombosis, myocardial infarction, or death; and those who were lost to follow-up. After PCI, aspirin 100 mg daily was prescribed indefinitely, and clopidogrel 75 mg daily or ticagrelor 90 mg twice daily was advised for at least 1 year.

Definitions and endpoints

The PARIS score for thrombotic risk in this study was based on the risk score for CTEs from PARIS.^[4] The PARIS registry was derived from the United States and European populations with DES implantation to assess associations between different modes of DAPT cessation and cardiovascular risk.^[8] The PARIS thrombotic risk score for CTEs takes into account six factors including current smoking, creatinine clearance lower than 60 ml/min, diabetes, ACS, previously received PCI, and previously received coronary artery

bypass grafting. CTEs were defined as the occurrence of stent thrombosis or spontaneous myocardial infarction. Stent thrombosis was defined according to the Academic Research Consortium^[9] including definite, probable, and possible in the analysis. Myocardial infarction was defined as the presence of electrocardiographic changes or clinical symptoms consistent with myocardial ischemia in the setting of increased cardiac biomarkers greater than the upper limit of normal, in accordance with the universal definition.^[10] Creatinine clearance was calculated using the Cockcroft–Gault formula.

Follow-up

All of the patients were assessed on their scheduled visits to the clinic, by phone, letter, or messages at 30 days, and at 6, 12, and 24 months. This was performed by the Fuwai Hospital Follow-up Center. Of the 10,724 PCI patients, 10,665 patients (99.4%) had completed 2 years of follow-up. The follow-up was carried out by phone in the PARIS study. Patients were suggested to return for coronary angiography if clinically indicated by symptoms of myocardial ischemia. All of the events were evaluated and adjudicated centrally by two independent cardiologists. In any case of disagreement, the consensus was sought.

Statistical analysis

The mean \pm standard deviation (SD) was used to reflect continuous variables, while frequency (percentage) was used for categorical variables. The Student’s *t*-test was used to compare the mean levels of continuous variables, and the Pearson Chi-square test or Fisher’s exact test was used for categorical variables. The area under the receiver operating characteristic curve (AUROC) was used to assess the predictive value of the PARIS score for CTE. All statistical analyses were performed at a two-sided significance level of 0.05. SAS 9.2 software (SAS Institute, Cary, NC, USA) was used for statistical analysis. A $P < 0.05$ was considered statistically significant.

RESULTS

Patients’ characteristics

After excluding patients who failed to satisfy the inclusion criteria, a total of 9782 patients were included in the present study [Figure 1] (mean age: 58.2 ± 10.2 years, women: 22.9%). Baseline profiles are shown in Table 1. There were 5867 (60%) patients with ACS (including unstable angina pectoris and acute myocardial infarction). The majority (99.87%) of patients took clopidogrel, and only 13 (0.13%) patients took ticagrelor. The mean treatment period for DAPT was 551.0 ± 162.9 days.

At the 2-year follow-up, CTEs occurred in 95 (0.97%) patients. In patients with CTEs, a previous history of myocardial infarction, previous PCI, previous coronary artery bypass grafting, previous stroke, and peripheral vessel disease were observed more frequently than in those without CTEs. Creatinine clearance rates of <60 ml/min and left main disease were observed more frequently in patients with CTEs than in those without CTEs [Table 1].

Table 1: Baseline clinical characteristics of patients with and those without 2-year CTEs

Characteristics	CTE (n=95)	No CTE (n=9687)	Statistics	P
Age, years	60.68 ± 12.30	58.20 ± 10.18	-1.96*	0.053
Female	14 (14.74)	2222 (22.94)	3.59†	0.058
BMI, kg/m ²	26.03 ± 2.99	25.94 ± 3.18	-0.28*	0.783
PARIS thrombotic risk score	3.38 ± 2.04	2.53 ± 1.70	-4.01*	0.000
Clinical presentation				
Stale coronary heart disease	42 (44.21)	3873 (39.98)	0.73†	0.695
Tropin-negative ACS	37 (38.95)	4121 (42.54)		
Troponin-positive ACS	16 (16.84)	1693 (17.48)		
Hypertension	70 (73.68)	6204 (64.04)	3.80†	0.051
Diabetes mellitus				
Nondiabetes mellitus	61 (64.21)	6801 (70.21)	3.29†	0.193
Noninsulin-treated	19 (20.00)	1893 (19.54)		
Insulin-treated	15 (15.79)	993 (10.25)		
Current smoking	60 (63.16)	5531 (57.10)	1.41†	0.235
Dyslipidemia	71 (74.74)	6508 (67.18)	2.44†	0.118
Previous MI	38 (40.00)	1802 (18.60)	28.21†	0.000
Previous PCI	38 (40.00)	2276 (23.50)	14.19†	0.000
Previous CABG	8 (8.42)	380 (3.92)	5.00†	0.025
Previous stroke	17 (17.89)	1025 (10.58)	5.29†	0.021
Previous vascular disease	24 (25.26)	1198 (12.37)	14.31†	0.000
Anemia	6 (6.32)	329 (3.40)	2.42†	0.120
CrCl <60 ml/min	19 (20.65)	1064 (11.41)	7.64†	0.006
Heart rate >100 beat/min	2 (2.11)	92 (0.95)	1.32†	0.251
Systolic BP <90 mmHg	0 (0.00)	22 (0.23)	0.22†	0.643
ST deviation	23 (24.21)	2083 (21.50)	0.41†	0.523
Congestive heart failure	4 (4.35)	181 (1.91)	2.86†	0.091
Abnormal myocardial enzyme	18 (18.95)	2083 (21.50)	0.36†	0.546
Coronary artery anatomy				
LM	7 (7.37)	244 (2.52)	7.02†	0.008
1-vessel disease	71 (74.74)	7295 (75.31)	0.02†	0.898
2-vessel disease	14 (14.74)	1959 (20.22)	1.76†	0.185
3-vessel disease	3 (3.16)	172 (1.78)	0.39†	0.534
Bridge vascular lesions	0	17 (0.18)	<0.001†	1.000
Baseline SYNTAX score	12.25 ± 7.41	11.95 ± 7.78	-0.36*	0.717
IABP use, %	2 (2.11)	101 (1.04)	0.26†	0.614
Number of stents per patient	2.02 ± 1.06	1.91 ± 1.05	-1.07*	0.286
Femoral artery puncture	10 (10.53)	702 (7.25)	1.50†	0.221
IVUS use	8 (8.42)	504 (5.20)	1.37†	0.242

Values are presented as mean ± SD or n (%). **t* values; † χ^2 values. CTE: Coronary thrombotic event; PARIS: Patterns of nonadherence to antiplatelet regimen in stented patients; BMI: Body mass index; MI: Myocardial infarction; ACS: Acute coronary syndrome; CABG: Coronary artery bypass grafting; PCI: Percutaneous coronary intervention; CrCl: Creatinine clearance; LM: Left main; SYNTAX: Synergy between percutaneous coronary intervention with taxus and cardiac surgery; IABP: Intra-aortic balloon pump; IVUS: Intravascular ultrasound; SD: Standard deviation; BP: Blood pressure.

Patterns of nonadherence to antiplatelet regimen in stented patients thrombotic risk score in CTE and non-CTE groups

The mean PARIS score in the CTE group was significantly higher than that in the non-CTE group (3.38 ± 2.04 vs. 2.53 ± 1.70 , $P < 0.001$).

Risk stratifications of patterns of nonadherence to antiplatelet regimen in stented patient thrombotic risk score

The PARIS thrombotic risk score was categorized as low risk (0–2), intermediate risk (3–4), and high risk (≥ 5). We

found that the risk of CTEs using the PARIS thrombotic risk score in the high-risk group was 3.14 times higher than that in the low-risk group (hazard ratio [HR], 3.14; 95% confidence interval [CI], 1.92–5.13; $P < 0.001$). However, the risk of CTEs in the intermediate-risk and low-risk groups was not significant (HR, 1.39; 95% CI, 0.86–2.24; $P = 0.184$) [Table 2].

Predictive value of patterns of nonadherence to antiplatelet regimen in stented patient thrombotic risk score on coronary thrombotic events

In the overall population, the PARIS thrombotic risk score (AUROC, 0.621; 95% CI, 0.561–0.681; $P < 0.001$) showed a moderate predictive value in CTEs [Figure 2].

We further grouped the study population into ACS and non-ACS populations. We found that in the ACS population, the PARIS thrombotic risk score showed predictive value (AUROC, 0.617; 95% CI, 0.534–0.700; $P = 0.003$). In the non-ACS population, a predictive value of the PARIS thrombotic risk score on CTEs was also observed (AUROC, 0.647; 95% CI, 0.558–0.736; $P = 0.001$) [Figure 2].

In the total population, when the PARIS score was 3 (best cutoff point), the specificity was 75.4%, the sensitivity

was 43.2%, the positive predictive value was 1.7%, and the negative predictive value was 99.3%.

DISCUSSION

The PARIS thrombotic risk score^[4] is a novel score, which was used to predict out-of-hospital CTEs in patients after PCI with DESs in our study. Due to the possible racial population difference, we comprehensively evaluated the PARIS thrombotic risk score's predictive value of CTEs in non-European and non-American populations including the total amount of patients with PCI and ACS and non-ACS subgroups. Our study showed that the PARIS thrombotic risk score had predictive value for CTEs in the Chinese PCI population.

Due to the different risks of thrombotic events in Asian PCI populations and European and American populations,^[5] the thrombotic risk score needs to be validated in different geographical and ethnic populations. The PARIS thrombotic risk score was derived from the United States and Europe populations. Therefore, we evaluated the predictive value of the PARIS thrombotic risk score for CTEs among the Chinese population in the real world (9782 patients). We found that the PARIS thrombotic risk score in patients with CTEs was significantly higher than that in those without CTEs. Our study showed that the PARIS thrombotic risk score had prognostic value for CTEs in the DAPT population after PCI, with an AUROC of 0.621. The AUROC in the

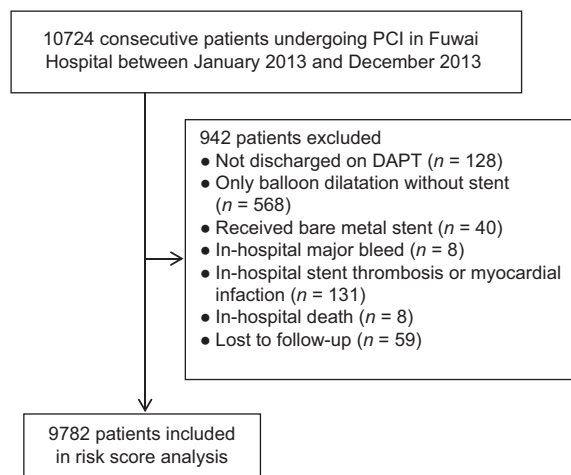


Figure 1: Flowchart of the study cohort. PCI: Percutaneous coronary intervention; DAPT: Dual-antiplatelet therapy.

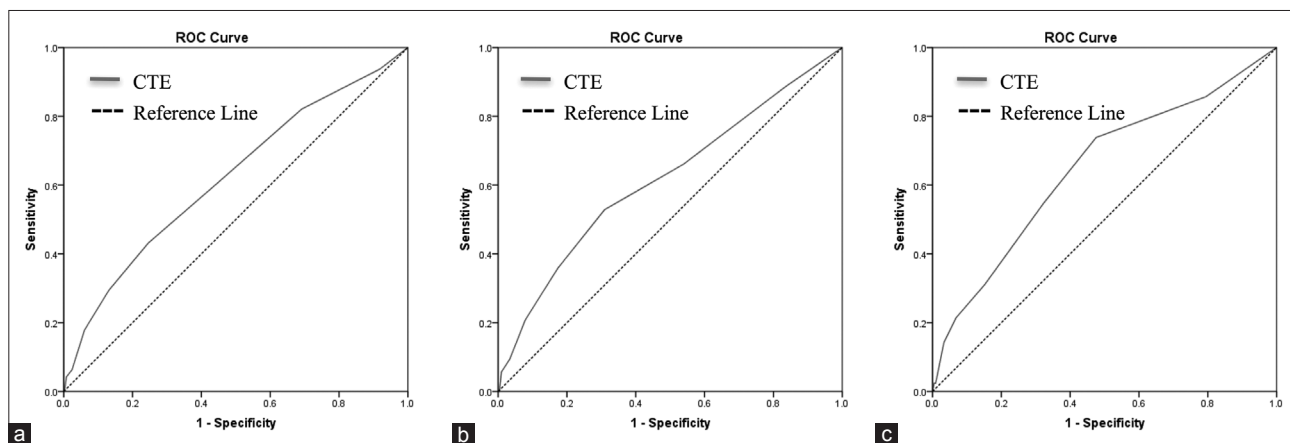


Figure 2: Predictive value of the PARIS thrombotic risk score for CTEs in the total population (a), the ACS population (b), and the non-ACS population (c). The PARIS thrombotic risk score showed predictive value for CTEs in the total population (AUROC, 0.621, 95% CI, 0.561–0.681; $P < 0.001$), the ACS population (AUROC, 0.617, 95% CI, 0.534–0.700; $P = 0.003$), and the non-ACS population (AUROC, 0.647, 95% CI, 0.558–0.736; $P < 0.001$). PARIS: Patterns of nonadherence to antiplatelet regimens in stented patients; AUROC: Area under the receiver operating characteristic curve; CTEs: Coronary thrombotic events; ACS: Acute coronary syndrome; CI: Confidence interval.

Table 2: HRs for CTEs according to risk stratifications of the PARIS thrombotic risk score

PARIS thrombotic score	All patients		Non-ACS patients		ACS patients	
	HR	P	HR	P	HR	P
Low (≤ 2)	Reference	–	Reference	–	Reference	–
Intermediate (3–4)	1.39 (0.86–2.24)	0.184	1.96 (0.98–3.91)	0.056	1.13 (0.57–2.21)	0.729
High (≥ 5)	3.14 (1.92–5.13)	0.000	4.64 (2.10–10.25)	0.000	2.80 (1.47–5.34)	0.002

CTE: Coronary thrombotic events; PARIS: Patterns of nonadherence to anti-platelet regimen in stented patients; HR: Hazard ratio; ACS: Acute coronary syndrome.

original PARIS study was 0.70,^[4] while that for the validation model in the PARIS study was 0.65.^[4] Our result is close to that of the validation model indicating that the PARIS thrombotic risk score has a modest predictive value for CTEs in the Chinese population.

The original PARIS study did not subdivide the population into ACS and non-ACS populations. Therefore, we assessed the value of the PARIS thrombotic risk score in predicting the risk for CTEs in non-ACS and ACS populations. We found that the PARIS thrombotic risk score for CTEs had predictive value in the ACS (AUROC, 0.617) and non-ACS populations (AUROC, 0.647). Recently, Song *et al.*^[6] analyzed the PARIS score. They found that the C statistic of the PARIS score in CTEs was 0.57, which is lower than our result of 0.617. The reason for this difference between studies may be attributed to the fact that Song *et al.* study^[6] did not strictly follow PARIS's criteria for inclusion and exclusion, such as not excluding patients who were not discharged on DAPT and excluding patients with failure of interventional treatment. However, the overall results of the two studies are similar. PARIS has a predictive effect on patients with ACS; however, this value is relatively limited. In a real-world population, our study showed that the PARIS thrombotic risk score could be helpful for predicting risks for CTEs not only in the overall population but also in the ACS and non-ACS populations.

In our study, based on the risk stratification of the PARIS thrombotic risk score for CTEs, the PARIS thrombotic risk scores in the high-risk group were significantly higher than those in the low-risk group. However, the intermediate- and low-risk populations did not show clear differentiation from the PARIS thrombotic risk score risk stratifications. A possible reason for this lack of finding could be that the CTE occurrence rate in our study was lower than that in the PARIS study.^[4] The CTE rate in the PARIS study was 3.60%^[4] compared with a significantly lower rate of only 0.97% in our study. East Asian patients appear to have a lower ischemic event rate after PCI than that in European and American populations,^[5,11,12] which has been described as the "East Asian paradox."^[5] In the Japanese population, Kimura *et al.*^[13] reported that the incidence of definite ST was only 0.77% at 2 years. In addition, in the Korean population, Park *et al.*^[14] reported that definite or probable ST of DESs was only 0.7% at 1–3 years after PCI. Kumar *et al.*^[15] reported that, when adjusting risk factors, the event rate of composite endpoints (death or myocardial infarction) after stent implantation in the Asian population was lower than that in Caucasians (*HR*, 0.89; 95% *CI*, 0.82–0.96). In our study, in patients with a relatively low risk of adverse cardiac events of the Asian population, risk stratification of the PARIS thrombotic risk score in the intermediate- and low-risk groups might need further adjustment and analysis.

Our study indicates that the PARIS thrombotic risk score can contribute to identifying populations with a high risk of CTEs as defined in the PARIS study.^[4] In addition, this score has a predictive value for CTEs in the overall Chinese PCI

population and the ACS and non-ACS subgroup populations. This indicates good clinical practice values. For high-risk patients who are identified by the PARIS CTE risk score, strengthened monitoring and treatment should be conducted to decrease the incidence of adverse events after DESs. However, notably, the PARIS thrombotic risk score has a relatively limited predictive value for CTEs. In the future, new scores need to be established that are more suitable for Chinese people, or thrombotic biomarkers should be added to increase the predictive value of the PARIS score.

The present study has some limitations that need to be mentioned. First, our study was a single-center, observational study, which may have limited its generalizability. The second limitation is the relatively lower CTE rate in our study, which may have resulted in a relatively insufficient statistical performance. Third, predictors in the PARIS thrombotic risk score are clinical factors. Whether adding prognostic-related plasma biomarkers or genetic test indices can further improve the predictive value requires further study. Fourth, almost all of the patients in this study were taking clopidogrel, and only a small number of patients took ticagrelor. Therefore, the value of the PARIS thrombotic risk score for CTE assessment of novel P2Y₁₂ receptor inhibitors needs further study.

In conclusion, in this large cohort, real-world Chinese population who underwent PCI, the PARIS thrombotic risk score showed modest long-term out-of-hospital prognostic value for CTEs in the overall population, the ACS population, and the non-ACS population. In the future, we may need to improve the thrombotic risk score to be more suitable for the Chinese PCI population.

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Conflicts of interest

There are no conflicts of interest.

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PARIS血栓评分在中国经皮冠状动脉介入患者中的验证： 一项前瞻性队列研究

摘要

背景：支架术后抗血小板药物停药模式（PARIS）血栓风险评分是评估经皮冠状动脉介入治疗（PCI）并使用药物洗脱支架治疗的患者出现冠状动脉血栓事件（CTE）风险的新型评分工具。然而，该评分的预后价值尚未在非欧美PCI人群中得到充分的评估。

方法：我们对阜外医院接受PCI治疗的10,724例中国患者进行了一项前瞻、观察性研究，评估了PARIS血栓风险评分对PCI人群CTE的预测价值。使用操作特征曲线下面积（AUROC）用于评估PARIS评分对CTE的预测价值。

结果：入选未发生住院期间事件的9782例患者，经2年随访，共发生95例CTE。结果显示，发生CTE患者的PARIS评分（ 3.38 ± 2.04 ）显著高于无CTE事件的患者（ 2.53 ± 1.70 ）（ $P < 0.001$ ）。根据PARIS血栓评分的危险分层，高风险组患者的CTE风险是低风险组的3.14倍（风险比[HR]，3.14；95%置信区间[CI]，1.92-5.13； $P < 0.001$ ）。然而，中度风险组患者的CTE风险和低风险组之间并无显著性差异（HR，1.39；95%CI，[0.86-2.24]； $P = 0.184$ ）。PARIS评分显示出分别在总人群（AUROC，0.621；95%CI，0.561-0.681）；急性冠状动脉综合征（ACS）亚组人群中（AUROC，0.617；95%CI，0.534-0.700； $P = 0.003$ ）和非ACS人群亚组人群中（AUROC，0.647；95%CI，0.558-0.736； $P = 0.001$ ）均对CTE有预测价值。

结论：在现实世界的中国人群中，PARIS血栓风险评分显示出对PCI患者的CTE有一定的预测价值。同时，该评分还对ACS和非ACS亚组人群中的CTE具有预测价值。