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Predictive factors of poor outcome and mortality among anterior ischaemic stroke patients despite successful recanalisation in China: a secondary analysis of the CAPTURE trial

Guangwen Li ,[1] Yujie Sun,[1] Tonghui Liu,[1] Pengfei Yang,[2] Ya Peng,[3] Wenhuo Chen,[4] Liyong Zhang,[5] Jianfeng Chu,[6] Dong Kuai,[7] Zibo Wang,[8] Wei Wu,[9] Yun Xu,[10] Bin Zhou,[11] Yu Geng,[12] Congguo Yin,[13] Jiang Li,[14] Ming Wang,[15] Xiaoxiang Peng,[16] Yaping Xiao,[17] Minghua Li,[18] Xianjun Zhang,[1] Peng Liu,[1] Naidong Wang,[1] Yong Zhang[1]

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For numbered affiliations see end of article.

Correspondence to
Professor Yong Zhang;
bravezhang@126.com

ABSTRACT

Objectives This work aimed to analyse the risk factors for poor outcomes and mortality among patients with anterior large vessel occlusion (LVO) ischaemic stroke, despite successful recanalisation.

Setting and participants This study conducted a secondary analysis among patients who underwent successful recanalisation in the CAPTURE trial. The trial took place between March 2018 and September 2020 at 21 sites in China. The CAPTURE trial enrolled patients who had an acute ischaemic stroke aged 18–80 years with LVO in anterior circulation.

Interventions Thrombectomy was immediately performed using Neurohawk or the Solitaire FR after randomisation in CAPTURE trial. Rescue treatment was available for patients with severe residual stenosis caused by atherosclerosis.

Primary and secondary outcome measures The primary goal was to predict poor 90-day survival or mortality within 90 days post-thrombectomy. Univariate analysis, using the χ^2 test or Fisher's exact test, was conducted for each selected factor. Subsequently, a multivariable analysis was performed on significant factors ($p \leq 0.10$) identified through univariate analysis using the backward selection logistic regression approach.

Results Among the 207 recruited patients, 79 (38.2%) exhibited poor clinical outcomes, and 26 (12.6%) died within 90 days post-thrombectomy. Multivariate analysis revealed that the following factors were significantly associated with poor 90-day survival: age ≥67 years, internal carotid artery (ICA) occlusion (compared with middle cerebral artery (MCA) occlusion), initial National Institutes of Health Stroke Scale (NIHSS) score ≥17 and final modified Thrombolysis in Cerebral Infarction (mTICI) score 2b (compared with mTICI 3). Additionally, the following factors were significantly associated with mortality 90 days post-thrombectomy: initial NIHSS score ≥17, ICA occlusion (compared with MCA occlusion) and recanalisation with more than one pass.

Conclusions Age, NIHSS score, occlusion site, mTICI score and the number of passes can be independently used to predict poor 90-day survival or mortality within 90 days post-thrombectomy.

Trial registration number NCT04995757.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ For identifying the risk factors of poor outcomes and mortality among patients with successful recanalisation, this study used logistic regression to eliminate the effect of confounding variables.

⇒ The data for this study were derived from a prospective multicentre randomised controlled trial, ensuring relatively high data quality.

⇒ This study had a small sample size and exclusively recruited Chinese patients, which may introduce bias when analysing clinical outcomes.

INTRODUCTION

Acute ischaemic stroke (AIS) resulting from the occlusion of large arteries is often associated with poor outcomes and high mortality.[1] Mechanical thrombectomy is a critical component of the primary interventions used for acute anterior circulation occlusion patients.[2] A previous study suggested that successful occlusion recanalisation positively impacts the survival of individuals suffering from ischaemic stroke due to great artery occlusion.[3] However, three randomised clinical trials [DAWN (Diffusion-Weighted Imaging or Computed Tomography Perfusion Assessment With Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention With Trevo), DEFUSE 3 (Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3), DIRECT-MT(Direct Intraarterial

Thrombectomy in Order to Revascularize Acute Ischemic Stroke Patients with Large Vessel Occlusion Efficiently in Chinese Tertiary Hospitals: a Multicenter Randomized Clinical Trial)] reported successful reperfusion on final angiography in approximately 80% of anterior circulation occlusion patients who underwent thrombectomy, with only about 40% of patients achieving a modified Rankin score (mRS) of 0–2 on day 90 post-thrombectomy.[3–5] These findings indicate that despite artery occlusion recanalisation and ischaemia reperfusion, around 50% of patients experience unfavourable survival. Efforts to improve post-thrombectomy outcomes for acute intracranial arterial occlusion patients rely in part on identifying risk factors associated with poor outcomes. However, despite recanalisation, the specific risk factors related to poor clinical outcomes in patients who had an AIS post-thrombectomy remain unknown.

Therefore, in this study, we analysed baseline characteristics and risk factors related to poor survival in patients who had an AIS who achieved successful recanalisation of large arteries through thrombectomy.

METHODS

Study design and oversight

This study represents a subgroup analysis of ProspeCtive, RAndomized, Controlled, OPen Label, Single Blinded, All China, Multi-Center, Registration Trial of the Thrombectomy System for the Treatment of AcUte Ischemic StRokE (CAPTURE)[6] conducted following Good Clinical Practice guidelines and registered at ClinicalTrials.gov (NCT04995757). Blood flow restoration in recruited patients was achieved using either the Neurohawk (MicroPort NeuroTech, Shanghai, China) or the Solitaire FR Recanalisation Device (Medtronic, California, USA). All angiographic endpoints were independently evaluated by a Core Laboratory, and serious adverse events were adjudicated by a clinical event committee. Members of the Core-Lab and clinical event committee were unaware of the treatment group assignment.

Patient population and participating centres

This subgroup analysis focused on patients who achieved successful recanalisation and finishing 90-day follow-up (including patients who died within 90 days) in the CAPTURE trial. The trial was conducted from March 2018 to September 2020 at 21 academic tertiary care centres in China capable of providing endovascular therapy. These sites were required to have performed at least 30 mechanical thrombectomy procedures in the previous year. An executive committee established the inclusion and exclusion criteria.

Inclusion criteria: Age 18–80 years, acute stroke due to the occlusion of the internal carotid artery (ICA) and the middle cerebral artery (MCA) at M1/M2 segment treatable within 6 hours of symptom onset prestroke functional ability equivalent to ≤1 on the mRS.

Exclusion criteria: Intracranial haemorrhage or a large ischaemic core on baseline imaging (Alberta Stroke Program Early CT Score, ASPECTS, <6), concomitant use of oral anticoagulation drugs and an international normalised ratio >3.0 or a platelet count $<30\times10^9$/L, severe concomitant diseases with an anticipated life expectancy of less than 1 year.

Intervention

As part of routine stroke care, brain CT images were collected and analysed before the thrombectomy procedures. The choice between general anaesthesia and local anaesthesia depended on the operators' experience and the patients' status. The Seldinger approach was employed for femoral artery puncture. Access to the ICA could be achieved with an 8-F sheath and an intermediate catheter. A microcatheter equipped with a microwire was positioned at the distal end of the occlusion site. Subsequently, either the Neurohawk or the Solitaire FR was deployed for 5 min to securely bind the thrombus. This was followed by the gradual retraction of the microcatheter and stent. Angiography immediately followed thrombectomy. In cases of severe residual stenosis caused by atherosclerosis, rescue treatment involving balloon and stent angioplasty was an option. A brain CT examination was performed immediately after the procedure. Tirofiban (Crand Pharma, China) could be administered through the microcatheter or through continuous intravenous infusion, depending on the angiography findings after thrombectomy or angioplasty.

Outcome measures

The initial and final intracranial flow was assessed using the modified Thrombolysis in Cerebral Infarction (mTICI) scale. Effective vascular recanalisation was defined by an mTICI score ≥2b immediately after thrombectomy. Potential preoperative and intraoperative risk factors for poor survival and mortality were picked up and analysed, such as baseline population data and medical history, severity of stroke, the cause of artery occlusion, occlusion site of artery, the number of passes, the duration between stroke onset to recanalisation and the use of rescue therapy. The modified Rankin scale (mRS) was used to evaluate patient outcomes at 90 days post-thrombectomy, with scores of 0–2 indicating favourable outcomes and scores of 3–6 indicating poor outcomes.

Statistical analysis

Among patients who underwent successful recanalisation, continuous variables were analysed using mean±SD or median with IQR, while categorical variables were represented as counts and proportions.

Subsequently, we picked up risk factors and transformed continuous variables into dichotomous ones according to the medians, and a χ^2 test or Fisher's exact test was conducted to identify potential risk factors for predicting poor 90-day outcomes and mortality post-thrombectomy in univariate analysis. Using the backward selection logistic regression approach, multivariable analysis was performed on significant factors (p≤0.10) identified in univariate analysis. The retention criterion for variables in multivariable analysis was set at p≤0.05. ORs, R-value, and 95% CIs were calculated for all risk factors associated with 90-day patient survival as determined through univariate and multivariate analyses. Statistical analysis was performed by using SPSS V.17.0 (SPSS).

Patient and public involvement

Patients and public were not involved in the development of the research question or in the design of the study. Patients received oral and written information about this trial, however, they were not involved in the recruitment and conduct of the study. The general results (no personal data) were communicated to patients who expressed an interest during clinical visits.

RESULTS

In this study, a total of 207 patients who had an AIS were included. The median age of all patients was 67 years (IQR 58–72), with 36.7% (76/207) being female. The median National Institutes of Health Stroke Scale (NIHSS) score was 17 (IQR 13–21). Occlusion sites included ICA in 37.7% (78/207) of patients, M1 in 51.7% (107/207) and M2 in 10.6% (22/207). The median time between symptom onset and groin puncture was 258 min (IQR 196–318), while the median time between groin puncture and eventual recanalisation was 55.8 min (IQR 38.4–85.2). Among the 207 patients, recanalisation with a single pass was achieved in 91 patients (44.0%). Final mTICI scores were 2b for 39.1% (81/207) of patients and 3 for 60.9% (126/207). Symptomatic intracranial haemorrhage (sICH) occurred in 8.8% (18/204) of patients within 30 hours postprocedure. During the 90-day follow-up period, we observed poor prognosis for 38.2% (79/207) patients. Additionally, 12.6% (26/207) of patients died during the follow-up period.

Table 1 presents the results of univariate analysis for factors potentially associated with poor 90-day patient survival. These potential risk factors included age ≥67 years, diagnosis of atrial fibrillation, initial NIHSS score ≥17, longer duration between onset and procedure initiation (≥258 min), ICA occlusion, final mTICI score 2b, recanalisation with more than one pass, and longer duration between procedure initiation and recanalisation (≥55.8 min). Additionally, stent retrieval alone and the absence of contact aspiration were closely associated with poor patient survival (p=0.054). Conversely, sex, smoking history, alcohol use, hypertension, diabetes mellitus, hyperlipidaemia, ASPECT score, anaesthesia methods, TOAST classification, intravenous tissue plasminogen activator, balloon-guided catheter use, tirofiban use and rescue therapy were not associated with patient outcomes. Furthermore, multivariate logistic regression analysis (table 2) revealed age ≥67 years, initial NIHSS score ≥17, ICA occlusion and final mTICI score 2b as independent factors predicting poor 90-day patient survival.

Regarding 90-day mortality, the results of the univariate analysis showed that potential risk factors included age ≥67 years, a diagnosis of atrial fibrillation, an initial NIHSS score ≥17, ICA occlusion, recanalisation with more than one pass, and the use of tirofiban (p<0.05). Additionally, multivariate regression analysis demonstrated that an initial NIHSS score ≥17, ICA occlusion and recanalisation with more than one pass independently predicted 90-day mortality (as shown in table 3).

DISCUSSION

Currently, mechanical thrombectomy is the primary treatment for AIS caused by large artery occlusion.[7 8] Several studies indicate that successful recanalisation strongly predicts a favourable prognosis for patients who had an AIS.[3 9] However, previous research has revealed that among individuals with intracranial artery occlusion who underwent mechanical thrombectomy, only 40% exhibited favourable 90-day outcomes, with a mortality rate ranging from 16% to 44.2%, regardless of achieving a recanalisation rate of over 80%.[3 4]

Identifying the risk factors for a poor prognosis post-thrombectomy is crucial for improving patient survival. In our trial, among patients who achieved successful recanalisation, approximately 39.1% (81 out of 207) achieved mTICI 2b, while 60.9% (126 out of 207) achieved mTICI 3. During our follow-up analysis, 38.2% (79 out of 207) of patients who achieved successful recanalisation exhibited poor survival, with an overall death rate of 12.6% (26 out of 207). Our results indicate that individuals with acute anterior circulation large artery occlusion who underwent thrombectomy had a poor 90-day prognosis if they aged ≥67 years or older, had an initial NIHSS score of ≥17 or higher, had ICA occlusion (as opposed to MCA occlusion) or achieved a final mTICI score of 2b (as opposed to mTICI score 3). Additionally, we found that an initial NIHSS score of ≥17 or higher, ICA occlusion (vs MCA occlusion) and recanalisation requiring more than one pass independently predicted mortality within 90 days post-thrombectomy. These findings can assist physicians in making critical clinical decisions for such patients.

Our results indicate that older age is associated with an unfavourable prognosis for patients treated with thrombectomy,[10] which corroborates Singer *et al*'s report. They reported that about 60% of patients in the lowest age quartile (18–56 years) exhibited a favourable prognosis. This percentage decreased progressively with increasing age, with 47% for patients aged 57–68 years, 37% for patients aged 69–76 years and 17% for patients aged 77–94 years.[11] Similarly, our trial showed that older age may lead to decreased functional independence, with 71.6% of patients aged 67 years or younger achieving functional independence compared with 50.1% for those aged over 67 years. Generally, age is commonly considered an indicator of brain reserve.[12 13] Therefore, our

Table 1 Univariate analysis for each selected factor

Variables	No of patients	No of mRS>2	P value	No of death	P value
Age, years					
≥67	98	48 (49.0%)	0.002	17 (17.3%)	0.049
<67	109	31 (28.4%)		9 (8.3%)	
Gender					
Male	131	49 (37.4%)	0.768	16 (12.2%)	0.843
Female	76	30 (39.5%)		10 (13.2%)	
Smoking history					
Yes	57	17 (29.8%)	0.128	5 (8.8%)	0.311
No	150	62 (41.3%)		21 (14.0%)	
Alcohol use					
Yes	37	10 (27.0%)	0.124	3 (8.1%)	0.583*
No	170	69 (40.6%)		23 (13.5%)	
Hypertension					
Yes	133	56 (42.1%)	0.143	19 (14.3%)	0.516
No	64	20 (31.3%)		7 (10.9%)	
Diabetes mellitus					
Yes	35	16 (45.7%)	0.339	6 (17.1%)	0.419*
No	162	60 (37.0%)		20 (12.3%)	
Hyperlipidaemia					
Yes	10	4 (40.0%)	1.00	0 (0)	0.365*
No	187	72 (38.5%)		26 (13.9%)	
Atrial fibrillation					
Yes	84	43 (51.2%)	0.002	16 (19.0%)	0.036
No	113	33 (29.2%)		10 (7.5%)	
Admission glucose					
≥7	106	43(40.6%)	0.36	17(16.0%) 0.055	
<7	96	33(34.4%)		7(7.3%)	
Initial NIHSS Score					
≥17	107	54 (50.5%)	0.000	21 (19.6%)	0.002
<17	100	25 (25.0%)		5 (5%)	
ASPECT Score					
≥8	143	53 (37.1%)	0.721	11 (7.7%)	0.120
<8	63	25 (39.7%)		14 (22.2%)	
Time from onset to procedure start (min)					
≥258	105	47 (44.8%)	0.047	12 (11.4%)	0.618
<258	102	32 (31.4%)		14 (13.7%)	
Location of occlusion					
ICA	78	42 (53.8%)	0.001	18 (23.1%)	0.002*
M1	107	31 (29.0%)		8 (7.5%)	
M2	22	6 (27.3%)		0 (0%)	
TOAST classification					
Large artery atherosclerosis	54	18 (33.3%)	0.092	3 (5.6%)	0.126
Cardioembolism	101	46 (45.5%)		17 (16.8%)	
Stroke of undetermined cause	52	15 (28.8%)		6 (11.5%)	
Anaesthesia					
General anaesthesia	72	32 (44.4%)	0.174	13 (18.1%)	0.081
Local anaesthesia	135	47 (34.8%)		13 (9.6%)	

Continued

Table 1 Continued

Variables	No of patients	No of mRS>2	P value	No of death	P value
Balloon-guided catheter					
Yes	31	11 (35.5%)	0.739	3 (9.7%)	0.773*
No	176	68 (38.6%)		23 (13.1%)	
Stent retrieval and contact aspiration					
Yes	147	50 (34.0%)	0.054	15 (10.2%)	0.109
No	60	29 (48.3%)		11 (18.3%)	
Intravenous t-PA					
Yes	78	25 (32.1%)	0.159	7 (9.0%)	0.226
No	129	54 (41.9%)		19 (14.7%)	
Final mTICI					
2b	81	38 (46.9%)	0.038	14 (17.3%)	0.100
3	126	41 (32.5%)		12 (9.5%)	
Recanalisation with a single pass					
Yes	91	27 (29.7%)	0.026	5 (5.2%)	0.007
No	116	52 (44.8%)		21 (18.1%)	
Time from procedure start to recanalisation (min)					
≥55.8	103	48 (46.6%)	0.013	14 (13.6%)	0.656
<55.8	104	31 (29.8%)		12 (11.5%)	
Rescue therapy					
None	162	63 (38.9%)	0.527	23 (14.2%)	0.674
Stent placement	13	4 (30.8%)		1 (7.7%)	
Balloon alone	13	3 (23.1%)		0 (0%)	
Balloon+stent placement	19	9 (47.4%)		2 (10.5%)	
Tirofiban use					
Yes	94	32 (34.0%)	0.266	7 (7.4%)	0.043
No	113	47 (41.6%)		19 (16.8%)	

TOAST
*Fisher's exact test.
ASPECT, Alberta Stroke Program Early CT Score; ICA, internal carotid artery; mRS, modified Rankin score; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale; TOAST, Trial of Org 10172 in acute stroke treatment; t-PA, tissue plasminogen activator.

findings may be explained by poor neuronal reserve, limited rehabilitation potential and higher comorbidities among elderly patients who had a stroke. However, acute endovascular intervention should be considered for elderly patients due to the poor prognosis in patients not receiving thrombectomy.[14]

Table 2 Multivariate analyses of the factors associated with poor 90-days outcomes (mRS>2)

	Multivariable analysis	
Variable	OR (95%CI)	P value
Age, years (≥67/<67)	2.05 (1.10 to 3.81)	0.024
Initial NIHSS score (≥17/<17)	2.25 (1.20 to 4.23)	0.012
Location of occlusion (MCA/ICA)	0.40 (0.21 to 0.74)	0.004
Final mTICI (2b/3)	2.02 (1.08 to 3.77)	0.027

ICA, internal carotid artery; MCA, middle cerebral artery; mRS, modified Rankin score; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale.

Previous studies have also shown that the initial NIHSS score of patients was associated with their clinical outcomes 90 days post-thrombectomy,[15] and our study yielded similar results. This association may be explained by patients with large artery occlusion and high NIHSS scores typically having poor collateral circulation and a large infarct volume.[16 17] However, some studies have reported that patients who had a severe stroke with high initial NIHSS scores may benefit more from mechanical thrombectomy than medical therapy alone. Román *et al* reported that individuals with severe baseline conditions exhibited superior 90-day survival post-thrombectomy compared with patients using medical therapy alone.[18]

In this study, patients with acute ICA occlusion exhibited poorer 90-day survival compared with patients with MCA occlusion. Recent studies have shown that ICA occlusion is independently associated with neurological

Table 3 Multivariate analyses of the factors associated with death at 90 days

Variable	Multivariable analysis	
	OR (95%CI)	P value
Initial NIHSS score (≥17/<17)	3.24 (1.10 to 9.57)	0.033
Location of occlusion (MCA/ICA)	0.24 (0.09 to 0.65)	0.005
Recanisation with a single pass (yes/no)	0.26 (0.08 to 0.82)	0.022
Admission Glucose (≥7/<7)	2.65 (0.98 to 7.15)	0.054

ICA, internal carotid artery; MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale.

deterioration poststroke and poor outcomes after intravenous thrombolysis.[19] Moreover, Goebel *et al* examined stroke cases receiving endovascular treatment for ICA, M1 and M2 segment occlusions and compared angiography and clinical outcomes.[20] They found that patients with ICA occlusions exhibited higher post-therapeutic NIHSS scores than those with MCA occlusion within 14 days after thrombectomy.[20] This finding may be attributed to a larger initial infarct volume and poorer collateral vessels in ICA occlusion compared with MCA occlusion.

In this study, we found that patients with a final mTICI score of 2b exhibited a poorer 90-day functional outcome compared with those with a final mTICI score of 3. Goyal *et al* reported that smooth reperfusion with an mTICI score of 3 was associated with favourable neurological improvement during the hospital stay and a good 90-day survival rate compared with reperfusion with an mTICI score of 2b.[21] Another study by Dargazanli *et al* reported that 71.7% of patients with mTICI score 3 reperfusions exhibited favourable 90-day functional outcomes post-thrombectomy, significantly higher than the proportion of patients with mTICI score 2b (50.5%) displaying favourable outcomes.[22] This result could be explained by the reduction in larger infarct volumes in mTICI 3 patients, ultimately leading to a favourable survival rate. In a previous study, baseline angiograms of patients revealed that those who attained complete reperfusion exhibited superior collateral flow.[22]

Our analyses also demonstrated that recanalisation requiring more than one pass was associated with significantly higher mortality. Previously, Zaidat *et al* reported that patients with first-pass recanalisation exhibited better clinical outcomes and lower mortality,[23] which aligns with the results of our current study. Zaidat *et al* also reported that multiple passes increased the sICH rate and mortality rate to 5.6% and 16%, respectively.[23] Furthermore, multiple passes were associated with increased procedure duration, resulting in poor clinical outcomes. Finally, compared with a single device pass, multiple passes were associated with a risk of endothelial vascular injury.[24] In our study, we found that an increase in admission glucose may potentially predict death in patients who had a stroke, although the p value was 0.054, which was not statistically significant. Meanwhile, Merlino *et al* reported that stress hyperglycaemia was a modifiable predictor of futile recanalisation in patients undergoing mechanical thrombectomy for AIS.[25] Furthermore, Liu *et al* also showed that elevated blood glucose, as well as elevated triglycerides, predicted death in patients who had a stroke.[26] Considering the limited sample size of this study, future research will focus on the metabolic status of patients who had an ischaemic stroke to better understand the correlation with prognosis.

Limitations of the study

The study had several limitations that should be acknowledged. First, the sample size was relatively small, and the study exclusively recruited Chinese patients, which may introduce bias when extrapolating the clinical outcomes to other ethnic groups. Additionally, the impact of collateral status and the specific location of parenchymal defects within the left or right hemisphere on clinical outcomes was not considered in the analysis. Second, clinical outcomes were assessed solely based on the mRS. However, it would have been more comprehensive to incorporate additional assessment tools, such as cognitive scales, evaluations of stroke recurrence and depression scales, to provide a more holistic understanding of patient outcomes.

CONCLUSIONS

In conclusion, the study findings suggest that elder age, a high NIHSS score, ICA occlusion (as opposed to MCA occlusion), and a final mTICI score of 2b (compared with mTICI 3) can independently serve as predictive factors for poor 90-day survival despite successful recanalisation. Moreover, a high NIHSS score, ICA occlusion (vs MCA occlusion) and the need for multiple passes during recanalisation can independently predict mortality within 90 days following thrombectomy. These insights can aid healthcare professionals in assessing and managing patients who had a stroke more effectively.

Author affiliations
[1]Department of Neurology, The Affiliated Hospital of Qingdao University, Qingdao, China
[2]Neurovascular Center, Changhai Hospital, Naval Military Medical University, Shanghai, China
[3]Department of Neurosurgery, Changzhou First People's Hospital, Changzhou, Jiangsu, China
[4]Department of Neurology, Zhangzhou Hospital Affiliated to Fujian Medical University, Zhangzhou, China

[5]Department of Neurosurgery, Liaocheng People's Hospital Brain Hospital, Liaocheng, Shandong, China
[6]Department of Neurology, The First People's Hospital of Jining City, Jining, China
[7]Department of Neurosurgery, Shanxi Provincial Cardiovascular Hospital, Taiyuan, China
[8]Department of Neurointervention, The First Affiliated Hospital of Zhengzhou University, Zhengzhou, Henan, China
[9]Department of Neurology, Qilu Hospital of Shandong University, Jinan, Shandong, China
[10]Department of Neurology, Nanjing Gulou Hospital, Nanjing, China
[11]Department of Neurointervention, Cerebrovascular Disease Center, The Fifth Affiliated Hospital of Sun Yat-sen University, Zhuhai, Guangdong, China
[12]Department of Neurology, Zhejiang Provincial People's Hospital, Hangzhou, Zhejiang, China
[13]Department of Neurology, Hangzhou First People's Hospital, Hangzhou, Zhejiang, China
[14]Department of Neurosurgery, The Second Affiliated Hospital of Air Force Military Medical University, Xi'an, China
[15]Department of Neurointervention, Nanyang Second People's Hospital, Nanyang, China
[16]Department of Neurology, The Third People's Hospital of Hubei Province, Wuhan, China
[17]Department of Neurology, Shanghai Oriental Hospital, Shanghai, China
[18]Institute of Diagnostic and Interventional Neuroradiology, Shanghai Jiao Tong University Affiliated Sixth People's Hospital, Shanghai, China

Contributors GL analysed the data and drafted the article; PY aided in critical revision of manuscript, writing assistance and proofreading of the article; YZ designed and conducted this secondary analysis, analysed and interpreted the data. YS, TL, YP, WC, LZ, JC, DK, ZW, WW, YX, BZ, YG, CY, JL, MW, XP, YX, ML, XZ, PL and NW participated in patient enrolment or collection of data in CAPTURE trial. All authors critically reviewed the report and approved the final version. As guarantor, YZ accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval This study involves human participants and the study was reviewed and approved by the Ethics Committee of Changhai Hospital (ethical code: CHEC2017-078, 24 April 2017). Each participating site obtained institutional review board or ethics committee approval for data collection in accordance with the Health Insurance Portability and Accountability Privacy Act. Participants gave informed consent to participate in the study before taking part.

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ORCID iD
Guangwen Li http://orcid.org/0000-0003-3687-3682

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