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Outcomes of tailored angioplasty and/or stenting for symptomatic intracranial atherosclerosis: a prospective cohort study after SAMMPRIS

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Abstract

Background and purpose—High periprocedural complication rate is a key limitation of endovascular treatment of intracranial atherosclerotic disease (ICAD), despite potential risk reduction of recurrent stroke. Taking lessons from the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Arterial Stenosis (SAMMPRIS) trial, targeting a selected patient population, we prospectively evaluated the feasibility and safety of tailored angioplasty and/or stenting for patients with ICAD.

Methods—From November 2011 to October 2012, 158 patients with symptomatic ICAD caused by hypoperfusion combined with poor collateral flow were consecutively recruited into a prospective single center study. Patients were divided into three groups based on arterial access and lesion morphology: balloon mounted stent group (group BS) for smooth access and Mori A lesion, angioplasty plus self-expanding stent group (group AS) for tortuous access and Mori B or C lesion, and angioplasty group (group AG) for tortuous access and Mori A lesion. The primary endpoints were successful procedure rate and any vascular event within 30 days.

Contributors All authors met the criteria for authorship and, more specifically, for contributorship. ZM and LS analyzed and interpreted the data, and wrote the article, and thereby take responsibility for this work. ZM, LS, DSL, LL, NM, YW, DM, FG, XZ, KD, DZ, and PG conceived the study and participated in its design and coordination. NM, YW, DM, FG, and LS collected and supplied the data. All authors agreed to publish this work and critically reviewed the article. Conception and design of this work were discussed with all of the authors.

Competing interests None.

Ethics approval The study was approved by the institutional ethics committee at Beijing Tiantan Hospital.

Provenance and peer review Not commissioned; externally peer reviewed.

Results—Overall technical success rate was 96.3% (154/158). There were significant differences in the technical success rate: 89.7% (35/39) in group AG compared with 97.5% (79/81) in group BS and 100% (38/38) in group AS (p=0.042). The 30 day composite stroke, myocardial infarction, or death rate was 4.4% (7/158). Stroke within 30 days occurred in four patients in group BS and in three patients in group AS.

Conclusions—Individualized treatment of ICAD using tailored devices according to arterial access and lesion morphology was feasible and safe in symptomatic patients caused by hypoperfusion with poor collateral flow.

Patients with intracranial atherosclerotic disease (ICAD) have a risk of recurrent stroke as high as 20% within the first years, despite standard medical therapy.[1] Although the Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Arterial Stenosis (SAMMPRIS) trial showed a lower stroke rate of 12.2% with aggressive medical therapy, whether the therapeutic goals of the medical arm of SAMMPRIS can be achieved consistently in the real world remains questionable. Subsets of patients, such as those with hypoperfusion symptoms, may not benefit from standard or aggressive medical therapy. They may be pressure dependent and develop more frequent transient ischemic attacks or permanent infarcts with antihypertensive therapy.

Although intracranial angioplasty and stenting showed initial promise for the treatment of ICAD, the SAMMPRIS trial yielded negative and disappointing results for the endovascular approach, revealing an unexpected higher rate of stroke and death within 30 days among patients treated with the Gateway and Wingspan system (Boston Scientific, Natick, Massachusetts, USA) than those treated with aggressive medical therapy alone (14.7% vs 5.8%, p=0.002).[2] The high periprocedural complications rate in the SAMMPRIS trial was largely due to perforator territory stroke and reperfusion hemorrhage, which could be avoidable with careful patient selection and perhaps technical improvement. Taking away these two types of complications, the periprocedural risks of intracranial angioplasty and stenting would be similar to that of previous registries and the medical arm of SAMMPRIS.

The Gateway and Wingspan system was the first device approved by the Food and Drug Administration for the treatment of ICAD. The SAMMPRIS trial took place before this device became widely used and operators gained extensive experience. Many types of flexible coronary stents were applied in the treatment of ICAD, with favorable results, especially in Asia.[3456789] The Apollo balloon mounted stent (MicroPort, Shanghai, China) received approval from State Food and Drug Administration in China in 2008 for the treatment of ICAD. Deployment of balloon mounted stents is simpler than the Gateway and Wingspan system and may imply a lower periprocedural complication rate. Angioplasty alone is another endovascular technique for the treatment of ICAD. Some case series have demonstrated the safety and good outcome of these techniques.[1011] Whether these techniques compare favorable with the Gateway and Wingspan system and medical therapy remains unknown.

Taking the lessons from the SAMMPRIS trial and combining our experience of using various techniques in the treatment of ICAD, we designed this prospective study to evaluate

the safety and short term outcomes in a selected group of patients with ICAD treated with a tailored endovascular approach in a single high volume center in China.

METHODS

Overall design

The protocol for this prospective single center study was approved by the institutional ethics committee at Beijing Tiantan Hospital before screening any patients. The primary aim of the study was to assess the safety and short term outcome of different endovascular techniques, including balloon mounted stent (Apollo), angioplasty alone (Gateway), and angioplasty plus self-expanding stent (Gateway and Wingspan system). All patients received standard medical therapy of critical control of risk factors, antiplatelets, and statins. All reported endpoints were evaluated and confirmed by a central adjudication committee composed of specialists in neurology, neurosurgery, and radiology, all blinded to the clinical data.

Enrollment of patients

Inclusion and exclusion criteria were established by the executive committee. Patients with symptomatic ICAD caused by hypoperfusion combined with poor collateral flow who met the following inclusion criteria were eligible: (1) stenosis of >70% measured by digital subtraction angiography,[1] and lesion length ≤15 mm and vessel diameter ≥2.0 mm; (2) hypoperfusion with poor collaterals was determined by the following three methods: American Society of Interventional and Therapeutic Neuroradiology/Society of Interventional Radiology Collateral Flow Grading System score <3, confirmed by digital subtraction angiography[12]; ≥40% decrease in cerebral blood flow in the territory distal to the target lesion by CT perfusion (the reference area for CT perfusion is the contralateral hemisphere for anterior circulation lesions and anterior circulation territory for posterior circulation lesions)[13]; and hemodynamic ischemic lesion by MRI or CT.

Patients were excluded if they had acute infarcts within 3 weeks or they presented with perforator territory strokes, severe vessel tortuosity precluding the deployment of endovascular devices by the executive committee, non-atherosclerotic lesion confirmed by high resolution MRI, embolic or perforator stroke based on MRI or CT, or a baseline modified Rankin Scale (mRS) score of >3.

Final enrollment of patients was decided by an executive committee composed of three neurologists (XZ, KD, LL), two neurosurgeons (DZ, ZM), and one neuroradiologist (PG).

Between November 2011 and October 2012, 158 patients were consecutively recruited. Before enrollment, medical management of the patients consisted of aspirin 100 mg/day and clopidogrel 75 mg/day for at least 4 days. Written informed consent was obtained from all patients or their legal proxy.

Devices selection

Device selection depended on arterial access and lesion morphology. For patients with smooth arterial access and Mori A lesion,[14] or mid-basilar artery and distal M1 segment lesions, the Apollo balloon mounted stent was selected (group BS). For patients with

tortuous arterial access and Mori B or C lesions, or lesions with a significant mismatch in the diameter between the proximal and distal segment, angioplasty plus self-expanding stent (Gateway balloon plus Wingspan stent system) was preferred (group AS). For patients with tortuous arterial access with a Mori A lesion, or small target vessel diameter (<2.5 mm), direct dilation with a Gateway balloon was selected (group AG). If severe dissection or elastic recoil occurred after angioplasty, a balloon mounted stent (for patients with less tortuous access) or Wingspan (for patients with severe tortuous access or small target vessel) stent could be implanted.

Periprocedural management and stenting procedure

The procedure was performed by experienced neurointerventionists, who had each done at least 100 endovascular procedures for ICAD. Intravenous heparin was administered after placement of a 6 F sheath or a 5 F sheath by the transfemoral artery or transradial artery (only for the posterior circulation and tortuous arch) as a bolus (75 U/kg) followed by half the dose 1 h later; if the procedure lasted longer than 2 h, a quarter of the initial dose was given every hour thereafter. The guiding catheter was advanced into the cervical vertebral or internal carotid artery as high as the vessel tortuosity allowed.

Vessels diameter and stenosis were recalibrated using the guide catheter as reference. If the stenosis appeared <70%, much improved, or occluded asymptomatically, the procedure was aborted. A single wire technique similar to percutaneous transluminal coronary angioplasty was used for all procedures without microcatheter exchange. Under roadmap guidance, a 300 cm microwire was carefully steered through the target lesion to the distal segment and baseline angiography was acquired. The Gateway balloon was advanced over the microwire, centered across the lesion, and inflated slowly to 6–8 atm. Angiography was repeated before removal of the balloon. The Wingspan stent delivery system was advanced over the microwire across the target lesion followed by deployment of the stent and removal of the delivery catheter. The Gateway balloon was also used as primary angioplasty for those with very short lesions (<5 mm). Repeat angiography was obtained 20 min later to identify dissection or elastic recoil. A stent (Apollo balloon mounted or Wingspan) was implanted if obvious dissection or elastic recoil was detected. As per the original design, the balloon mounted stent was done without predilation. Technical success rate of angioplasty was defined as complete coverage of the target lesion with residual stent stenosis <50%, and with Thrombolysis in Cerebral Ischemia grade 3.[15]

Systolic blood pressure was kept between 100 and 120 mm Hg with intravenous nimodipine or urapidil hydrochloride (Altana Pharma AG) to prevent potential hyperperfusion after the procedure. Non-contrast head CT was obtained to evaluate potential hemorrhage.

Postprocedure treatment and medication

All patients were given a weight based dose of 0.4–0.6 mL Fraxiparine (Sanofi Winthrop Industry) every 12 h subcutaneously for 3 days and monitored closely until discharge. After enrollment, medical management consisted of aspirin at a dose of 100 or 300 mg/day; clopidogrel 75 mg/day for 90 days; and management of atherosclerotic risk factors,

including elevated systolic blood pressure and elevated low density lipoprotein cholesterol levels, diabetes, smoking, excess weight, and insufficient exercise.

Data collection and follow-up

The following data were collected consecutively: baseline demographics, vascular risk factors, stroke severity, imaging studies, stroke management, complications, and diagnosis and discharge status. Follow-up information on clinical outcomes were reviewed and collected by trained personnel who were blinded to treatment group assignment 30 days after the procedure via face to face interview. If necessary, brain imaging studies, including MR angiography or CT angiography, were obtained in patients with symptoms.

Outcome assessment

Patients were evaluated by study neurologists at the time of enrollment and at 30 days. The primary endpoints were technique success rate and any clinical vascular event within 30 days (ischemic stroke, hemorrhagic stroke, myocardial infarction, vascular death), analyzed as a composite, and also individually. Ischemic stroke was defined as a new focal neurologic deficit of sudden onset, lasting at least 24 h, unassociated with hemorrhage on CT or MRI. Symptomatic brain hemorrhage refers to parenchymal, subarachnoid, or intraventricular hemorrhage that was associated with a seizure or with symptoms or signs lasting 24 h or longer. The second endpoints were functional outcomes, and other severe adverse events, including vessel dissection, stent migration, new vascular events during the procedure, or gastrointestinal hemorrhage. Functional outcome at 30 days was evaluated using mRS.

Statistical analysis

We compared baseline demographic and clinical features of patients among treatment groups. Continuous variables were expressed as means (SD) or medians (IQR), as appropriate. Categorical data were presented as proportions. The differences between groups were tested for continuous variables with normal distribution using one way analysis of variance and continuous variables with skewed distribution using the Kruskal–Wallis test. The χ^2 or Fisher exact test was used for categorical variables. All patients were divided into three groups based on treatment manner and devices used: balloon mounted stent group (BS group), angioplasty group (AG group), and angioplasty+self-expanding stent group (AS group).

All statistics were two sided with $p<0.05$ considered significant. All statistical analyses were performed with SPSS software.

RESULTS

Patient enrollment and characteristics

Between November 2011 and October 2012, 158 consecutive patients with symptomatic intracranial stenosis of 70–99% were screened for potential enrollment. The procedure was performed under local (n=5) or general anesthesia (n=153). Catheter access included the transfemoral artery (n=134) or transradial artery (n=24) (table 1).

Of these 158 patients, 81(51.3%) were assigned to the Apollo stent (BS group), 38 (24.1%) to the Gateway balloon and Wingspan stent (AS group), and 39 (24.7%) to Gateway balloon angioplasty alone (AG group). In the AG group, 21 patients required additional stenting (53.8%): 20 with the Apollo stent (51.3%) and one with the Wingspan stent (2.6%) (table 1).

Demographic and clinical characteristics of the patients are shown in table 1. Of the 158 patients, 126 (79.7%) were men. Median age at enrollment was 58 years. Regarding lesion location, 63 (39.9%) lesions were located in the intradural segment of the vertebral artery, 58 (36.7%) in the basilar artery, 22 (13.9%) in the middle cerebral artery, and 15 (9.5%) in the intracranial internal carotid artery. The degree of mean preprocedure stenosis was 82.01%. There were no significant differences between the three groups with respect to any of the baseline characteristics, including vascular risk factors, with the exception of mean length of target lesion (table 1).

Primary endpoints

The overall technical success rate was 96.2% (154/158). There were significant differences in technical success rates: 89.7% (35/39) in group AG compared with 97.5% (79/81) in group BS and 100% (38/38) in group AS (p=0.042). Excluding bail out stenting, angioplasty alone had a significantly lower success rate of 83.3% (p=0.005) (table 2).

The 30 day composite stroke, myocardial infarction, or death rate was only 4.4% (7/158). Stroke occurred in four patients in group AG and in three patients in group AS. Of these, six patients were ischemic, and one was hemorrhagic (subarachnoid hemorrhage in group AS). The subarachnoid hemorrhage was caused by the guidewire passing through the top of the basilar artery (case No 4, see online supplementary table S1).

Secondary endpoints

Regarding functional outcome at the 30 day visit, 154 (97.5%) patients had no neurological deficit or mild stroke disability (mRS score 0–2), four (1.9%) patients had moderate or severe stroke disability (mRS score 3–5), and no patient had died. Of these patients, no one suffered with vessel dissection or stent migration, but one patient in group AS had gastrointestinal hemorrhage (table 2 and see online supplementary table S1).

DISCUSSION

This prospective study demonstrated the feasibility and safety of tailored angioplasty and/or stenting in symptomatic ICAD patients caused by hypoperfusion with poor collateral flow. Using this approach, a 30 day stroke and death rate that is lower than the medical arm of the SAMMPRIS trial can be achieved.

The patient population in this study was stricter than that in the SAMMPRIS trial. We selected patients with hypoperfusion symptoms and poor collaterals who are most likely to fail medical therapy and benefit from revascularization. Antihypertensive therapy may worsen perfusion and aggravate symptoms in these patients. Angioplasty and stenting can remedy hypoperfusion immediately. Even if restenosis develops in the next few months, patients would have gained time to develop new collaterals and allowed medical therapy to

stabilize their plaques. Although reperfusion hemorrhage was a concern in this patient population, we did not observe any symptomatic intraparenchymal hemorrhage in this study, suggesting that the risk of reperfusion hemorrhage can be minimized with increased vigilance and tight blood pressure control in the postoperative period.

The patient selection criteria in this study excluded patients with perforator strokes. Patients with symptoms related to local disease of ICAD, such as those with mid-basilar stenosis and pontine infarct, or distal middle cerebral artery stenosis and basal ganglia infarcts, are at high risks of periprocedural complications. Their symptoms are related to extension of the atherosclerotic plaque or thrombus into the origin of these perforators. Crushing the atherosclerotic plaque with angioplasty and stenting may send debris or thrombus into these perforators or cause mechanical obstruction of these perforators via dissection, device placement, straightening of the parent vessel, and kinking of the perforator, etc. These patients are better treated with medical therapy to stabilize the atherosclerotic plaque and to prevent further progression of local disease. On the other hand, patients with distal symptoms and hypoperfusion may not have perforators in the diseased vessel segments or have local collaterals to these perforators, making them more tolerant to angioplasty and stenting.

The Gateway/Wingpsan system tested in the SAMMPRIS trial is but one of several endovascular techniques utilized in the treatment of ICAD, particularly in Asia, where ICAD is far more prevalent than in the USA. To simulate the real world situation and to test endovascular treatment rather than device, we developed a set of criteria based on access vessel tortuosity, Mori type, and target vessel diameter to assign patients to balloon mounted stents, angioplasty alone, and angioplasty and stenting with self-expanding stent. These criteria summarized our previous experience and were intended to minimize the periprocedural risks of vessel perforation and perforator occlusion. For patients with smooth arterial access and Mori A lesions, balloon mounted stents were considered the primary option because they did not require exchange and less procedural time was needed. For particular sites, such as the mid-basilar artery and distal M1 segment, Apollo stenting was preferred because the longer tip of the Wingspan system could lead to distal vessel rupture. For patients with tortuous arterial access and Mori B or C lesions, or lesions with a significant mismatch in the diameter between the proximal and distal segments, the Gateway balloon plus Wingspan stent system was preferred because of its flexibility. For patients with tortuous arterial access and Mori A lesions, or small target vessel diameter (<2.5 mm), direct dilation with the Gateway balloon had the advantage of smallest profile and most flexibility amount of devices. Additionally, angioplasty was simpler and easier than stent implantation.

The technical success rates of the various devices were similar or better than published data. The procedural technical success rate with the Apollo stent was 97.5% (79/81), with a 30 day complication rate of 0.0% (0/81), better than the previously published technical success rate of 91.7% (44/48) and complication rate of 6.5% (3/46),[16] and also superior to the results of a study using a balloon mounted coronary stent.[6] Our results confirmed that direct Apollo balloon stenting was suitable for patients with easy arterial access and short and straight lesions. The procedural success rate of the Gateway/Wingspan system was 100% (38/38),

and the complication rate within 30 days was 5.3% (2/38), which are similar to the technical success rate of 95.2–100% and periprocedural complication rate within 30 days of 4.5–9.6% in previous studies,[17,18,19] and lower than that in the SAMMPRIS study.[2] The results indicated that the Gateway plus Wingspan could be safely applied to patients with long and angle lesions and tortuous arterial access, or lesions with a significant mismatch in the diameter between the proximal and distal segments.

The technical success rate of angioplasty was 89.7%. However, 53.8% of patients required additional stenting because of the elastic recoil and dissection. Despite the preprocedural anticipation of the difficulty of stenting, the Apollo stent was successfully deployed in 20 patients and only one patient received the Wingspan stent due to the small caliber of the target vessel and mismatch of vessel size. The rate of elastic recoil and dissection was higher than two retrospective studies using balloon angioplasty in which the dissection rate was 18.8% (6/33 without an ischemic event),[19] which may be related to older ages in the AS group (60 years, range 38–78 vs 50 years, range 37–61 years).

Apart from patient selection and tailored angioplasty and/or the stenting approach, other factors may have contributed to the lower complication rate in this study. Firstly, the procedures were performed by operators with vast experience of intracranial angioplasty and stenting, who have long since passed the steep portion of the learning curve. The senior interventionist in the group, who supervised or performed all of the procedures, had performed >1000 intracranial stenting procedures prior to this study. Secondly, the principles of ‘one person manipulation’ and ‘single wire technique’ were used during the procedure, reducing communication and human error during the procedure. Thirdly, the time from the last episodic event to the procedure was 30 days (7–30 days), which is substantially longer than the 7 days (7–19 days) in the SAMMPRIS trial. The longer waiting time may have allowed the plaque to stabilize and thrombus to dissolve, and probably also reduced the risk of hemorrhagic transformation.

Our study has some limitations. The results from this high volume highly experienced center may not be generalizable to other centers. The study sample was not large enough for subgroup analysis, particularly for anterior circulation lesions. The medical treatment was not as vigorous as in the SAMMPRIS trial and there was no control medical arm in this study. Finally, the follow-up period was relatively short for outcomes in patients with percutaneous transluminal angioplasty and stenting. The long term risks and benefits of endovascular treatment of ICAD remain to be seen.

CONCLUSION

Tailored endovascular treatment of ICAD using balloon mounted stents, angioplasty alone, and plus self-expanding stents based on anatomical features and lesion morphology yielded a low complication rate in patients with hypoperfusion symptoms and poor collateral flow. Future clinical trials may be constructed in this patient population with this treatment approach.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Baseline demographic and clinical characteristics of the patients in the different groups

	BS group n=81	AG group n=39	AS group n=38	Total n=158	p Value
Age (year) (median (IQR))	59 (37–79)	60 (38–78)	56 (37–73)	58 (37–79)	0.195
Male (n (%))	63 (77.8)	30 (76.9)	33 (86.8)	126 (79.7)	0.456
Medical history (n (%))					
Hypertension	56 (69.1)	27 (69.2)	26 (68.4)	109 (69.0)	0.996
Hyperlipidemia	49 (60.5)	24 (61.5)	21 (55.3)	94 (59.5)	0.826
Diabetes mellitus	31 (38.3)	11 (28.2)	11 (28.9)	53 (33.5)	0.434
Myocardial infarction	17 (21.0)	6 (15.4)	3 (7.9)	26 (16.5)	0.195
Stroke history	25 (30.9)	11 (28.2)	8 (21.1)	44 (27.8)	0.695
Current or ex-smoker	46 (56.8)	22 (56.5)	26 (68.4)	94 (59.5)	0.558
Current or ex-alcoholism	32 (39.5)	21 (53.9)	17 (44.8)	70 (44.3)	0.346
Baseline NIHSS score (median (IQR))	0 (0–1)	0.5 (0–3)	0 (0–1)	0 (0–1)	0.342
Baseline mRS score (n (%))					0.489
0	17 (21.3)	4 (10.5)	8 (21.1)	29 (18.6)	
1	57 (71.3)	31 (81.6)	25 (65.8)	113 (72.4)	
2	6 (7.5)	3 (7.9)	5 (13.2)	14 (9.0)	
Vessel involved (n (%))					0.516
Intracranial ICA	7 (8.6)	5 (12.8)	3 (7.9)	15 (9.5)	
M1	9 (11.1)	8 (20.5)	5 (13.2)	22 (13.9)	
V4	36 (44.4)	10 (25.6)	17 (44.7)	63 (39.9)	
BA	29 (35.8)	16 (41.0)	13 (34.2)	58 (36.7)	
Mean stenosis preprocedure (%) (mean (SD))	81.02 (7.43)	83.95 (9.36)	82.11 (7.23)	82.01 (7.94)	0.167
Mean length of target lesion (mm) (mean (SD))	5.58 (2.19)	5.95 (1.77)	7.58 (3.05)	6.14 (2.45)	0.000
Last onset event preprocedure (%)					0.315
TIA	37 (45.7%)	11 (28.2)	19 (50.0)	67 (42.4)	
Minor stroke	38 (46.9%)	23 (59.0)	16 (42.1)	77 (48.7)	
Stroke	6 (7.4%)	5 (12.8)	3 (7.9)	14 (8.9)	

AG group, angioplasty group; AS group, angioplasty plus self-expanding stent group; BA, basilar artery; BS group, balloon mounted stent group; ICA, internal carotid artery; M1, the horizontal segment of the middle cerebral artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; TIA, transient ischemic attack; V4, the intradural segment of the vertebral artery.

Table 2

Efficacy endpoints of the different therapy groups

	BS group (n=81)	AG group (n=39)	AS group (n=38)	Total (n=158)	p Value
Primary endpoints					
Successful PTAS (n (%))	79 (97.5)	35 (89.7)	38 (100.0)	152 (96.2)	0.042
Secondary endpoints					
Any stroke or death	4 (4.9)	0 (0.0)	3 (7.9)	7 (4.4)	0.231
Any ischemic stroke	4 (4.9)	0 (0.0)	2 (5.3)	6 (3.8)	0.359
Any hemorrhagic stroke	0 (0.0)	0 (0.0)	1 (2.4)	1 (0.6)	0.204
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
MI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
SAE	0 (0.0)	0 (0.0)	1 (2.4)	0 (0.6)	0.204
mRS≥3	2 (2.5)	0 (0.0)	2 (5.3)	4 (2.5)	0.339

AG group, angioplasty group; AS group, angioplasty plus self-expanding stent group; BS group, balloon mounted stent group; MI, myocardial infarction; mRS, modified Rankin Scale; PTAS, percutaneous transluminal angioplasty and stenting; SAE, serious adverse event.