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Safety and Efficacy Analyses of Angioplasty and Stenting for Severe Intracranial Arterial Stenosis: A Single-Center Retrospective Study in China

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Background: The value of percutaneous transluminal angioplasty and stenting (PTAS) in the context of aggressive medical treatment for severe intracranial artery stenosis (ICAS) is under debate. This study compared the effects of PTAS and aggressive medical treatment in patients with severe ICAS and transient ischemic attack or stroke.

Material/Methods: A retrospective cohort study was performed. Patients with severe ICAS were assigned to a PTAS group or aggressive medical treatment group, according to the angiographic features of the stenotic lesions. The primary outcome was defined as stroke or death within 30 days or cerebral ischemia occurring ipsilaterally to the qualifying artery beyond 30 days.

Results: We included 220 patients: 48 in the PTAS group and 172 in the medical group. The median follow-up was 32 months. PTAS was not associated with an increased incidence of the primary outcomes (10/42 vs. 39/172, $p=0.96$) or increased risks of the secondary outcomes of stroke, cardiovascular events, major bleeding, or mortality. The results of log-rank tests did not support a significant difference in event-free survival as a primary outcome between the 2 groups ($\chi^2=0.07$, $p=0.79$). Moreover, although not significantly greater, the mean survival of patients in the PTAS group appeared to be better than that among patients in the medical group, as indicated by the curve for cumulative survival.

Conclusions: A suitable PTAS procedure is safe for patients with severe ICAS, and no significant differences in incidence of recurrent stroke or death were found between PTAS and aggressive medication treatment.

MeSH Keywords: **Arterial Pressure • Brain Stem Infarctions • Stents**

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Background

It is well documented that intracranial artery stenosis (ICAS) has become the most frequent cause of stroke worldwide [1,2]. Indeed, in Asian countries, ICAS has been found to be the cause for up to half of all stroke cases [3]. Similarly, previous studies in the United States also indicate that ICAS contributes to a substantial proportion of newly diagnosed stroke cases [4,5]. Moreover, atherosclerosis has been recognized as a key pathophysiological feature of ICAS [6]. Accordingly, pharmacological interventions for the process of atherosclerosis, including antiplatelets and statins, have been extensively recommended for patients with severe ICAS, according to the recent international guidelines for the diagnosis and treatment of stroke [7]. Although advances have been achieved during the past decades regarding the pharmacological treatment of ICAS, the recurrence of the cerebral vascular events in patients with severe stenosis of the cerebral arteries remains high, particularly in high-risk cases complicated by other cardiovascular risk factors [8,9]. The previously published Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) trial indicated that, despite aggressive medication treatment, the rate of recurrence of stroke in patients with severe ICAS was 18% within the first year [10]. In addition, the recently published Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial also indicated a 1-year incidence of stroke and death of 12% for patients in the aggressive medical management group [11]. Therefore, novel treatment strategies are still needed to improve the outcomes of patients with severe ICAS and stroke.

Some cohort studies have suggested a potential therapeutic role of percutaneous transluminal angioplasty and stenting (PTAS) for patients with severe ICAS [12,13]. However, the first and only published randomized controlled trial – the SAMMPRIS Study – challenged the benefits of Wingspan self-expanding stents in these patients by showing that, in comparison with patients who received aggressive medication therapy only, patients treated with PTAS not only had a significantly higher risk of stroke or death within 30 days, but also were significantly more likely to experience composite primary adverse outcomes [11,14]. Therefore, in this study we aimed to evaluate the safety and efficacy of PTAS for severe ICAS by retrospectively analyzing the data of 220 patients treated in our center, in comparison to data from patients who received aggressive medication treatment only.

Material and Methods

Study design

This study was designed as a single-center retrospective cohort study and was performed at the Department of Neurology,

General Hospital of Lanzhou Military Command in Gansu Province of China. Patients who were admitted due to the diagnosis of transient ischemic attack (TIA) or stroke with a severe stenosis of a major intracranial artery between July 2006 and July 2012 were included in the current study. The study protocol was approved by the local ethics committee before performance, and all of the included patients provided written consent before enrollment.

Inclusion and exclusion criteria

All of the included patients were diagnosed with TIA or stroke within 30 days before enrollment. The diagnoses of TIA and stroke were based on the standards of the World Health Organization [15], and possible brain hemorrhage was excluded by head computed tomography (CT) scanning. Patients were included if they also fulfilled all of the following criteria: (1) the TIA or stroke was attributed to a digital subtraction angiography (DSA)-confirmed severe atherosclerotic stenosis of a major intracranial artery ($\geq 70\%$ of the diameter, according to the Warfarin-Aspirin Symptomatic Intracranial Disease trial [WASID] standards [10]); (2) the patient was stabilized with a modified Ranking Scale (mRs) of ≤ 3 [16] or a National Health Institute Stroke Score of < 9 [17]; (3) the patient had at least 1 of the following cardiovascular risk factors, including age over 65 years, current smoking, hypertension, type 2 diabetes mellitus (T2DM), and dyslipidemia; (4) the patient agreed to be followed during the study period. Patients who met any of the following criteria were excluded from the current study: (1) the patient had a complication, such as atrial fibrillation, that could increase the risk of cardiogenic embolization of the brain; (2) the patient had non-atherosclerotic stenosis of the intracranial arteries; (3) the patient had brain hemorrhage or hemorrhagic stroke as detected by CT scanning; (4) the patient experienced severe stroke with a large infarction area (diameter > 5 cm) or were unstable with an mRs > 3 or NIHSS ≥ 9 ; (5) the patient had a restenosis lesion and had undergone a previous PTAS procedure; (6) the patient had angiographically-confirmed sequential stenosis (intracranial or extracranial, $> 50\%$ of the arterial diameter) distal or proximal to the original arterial stenosis; or (7) the patient was lost to follow-up.

Treatment strategies

Because there is currently no consensus regarding the determination of treatment strategies in patients with severe ICAS, the patients were assigned to the PTAS group based on the following considerations: (1) the stenotic lesions as observed by DSA were confirmed to be suitable for PTAS by an attending physician with expertise in the PTAS procedure. These lesions were often located in arteries with diameters of > 2 mm, with no significant circuitry, which may prevent access of the wires and stents, and the lengths of the lesions were < 15 mm; (2)

the patients were in a generally stable state, without any of the contraindications for the PTAS procedure, such as severe renal dysfunction or recent incidence of major hemorrhage; (3) the patients agreed to the PTAS procedure and provided written consent; and (4) the patients and their families could afford the medical expenses of the PTAS procedure. Otherwise, the patients were assigned to the aggressive medical treatment group. All of the included patients received aggressive treatment to control potential risk factors for ICAS, including aggressive medications for the treatment of comorbidities such as hypertension, T2DM, and dyslipidemia, as well as patient education and exercise prescriptions for smoking cessation, reduced alcohol consumption, and weight loss. Antiplatelet drugs (100–300 mg/d aspirin and/or 75 mg/d clopidogrel, as dual-antiplatelets for at least 6 months in the medical treatment group, then either one was selected for lifetime use), statins (20–80 mg/d atorvastatin), in addition to antihypertensives and anti-diabetic medications that were administered as indicated by the recent guidelines, targeting a systolic blood pressure of <140 mmHg (<130 mmHg in patients with T2DM), a low-density lipoprotein cholesterol level of <1.8 mmol/L, and glycosylated hemoglobin level of <6.5%.

PTAS procedures

The PTAS procedure was performed by physicians who were trained for neurointerventional therapies 2–4 weeks after the diagnosis of TIA of stroke to ensure the patients were in a stable condition. The mean number of procedures that these physicians performed annually was more than 20. For patients scheduled to receive the PTAS procedure, 75 mg/d clopidogrel and 100 mg/d aspirin were prescribed at least 5 days before the procedure. The PTAS procedure was performed as previously described [18]. Briefly, the procedure was performed under general anesthesia with a continuous heparin infusion to maintain an activated prothrombin time (APTT) of 250–300 s. After paracentesis of the right femoral artery, a 6-F arterial sheath was placed for the transfer of a 0.014 micro-guidewire through the stenotic lesion of the intracranial artery. Then, a balloon or a stent was chosen according to the physician's decision for subsequent interventional treatment. Generally, the interventional treatment strategies included balloon-dilation only, balloon dilation and stenting, and implantation of a self-expanding Wingspan stenting system [19]. Selection of the strategy was generally based on the angiographic characteristics of the stenotic lesions and the previous experience of the physician. If the arterial diameter was 2–2.5 mm and the stenosis was relieved without the formation of dissection, stenting was generally not required. However, for patients with arterial dissection after balloon-dilation, a Wingspan stenting system was released. The Wingspan stenting system was also used in cases with a difference between the distal and proximal arterial diameter of >0.5 mm and for cases in which the stenotic

lesions were located in the circuitry region of the arteries. For cases with similar arterial diameters (both >2.5 mm) across the stenotic lesion, an Apollo or a Wingspan stenting system were both acceptable (Figures 1, 2). After the procedure, patients in the PTAS group were required to take dual-antiplatelet medications (100 mg/d aspirin and 75 mg/d clopidogrel) for at least 6–12 months and then continued with either antiplatelet drug for their lifetime.

Follow-up and outcomes

Patients were evaluated at 1 and 12 months after admission and at the end of the observation period (July 31, 2013). The first 2 evaluations were made by in-person interviews with physicians in outpatient clinics, and the final evaluation was made by a telephone interview with the patient or their relative. The primary outcome of the study was defined as stroke (ischemic or hemorrhagic, within or out of the territory of the qualifying artery) or death within 30 days after enrollment or cerebral ischemia ipsilaterally to the qualifying artery between day 31 and the end of the follow-up period. The secondary outcomes were defined as a composite outcome of stroke events (ischemic or hemorrhagic), cardiovascular events, major hemorrhage (including gastrointestinal [GI] bleeding, ocular bleeding, and large subcutaneous ecchymosis), and all-cause deaths.

Statistical analysis

The statistical analyses were performed with the SPSS analytic software. The continuous variables are presented as means (X) ± standard deviations (S) if they were normally distributed, and median (M) and interquartile ranges (Q₂₅, Q₇₅) are presented if the data were not normally distributed. The differences between the continuous variables were evaluated with t tests or Mann-Whitney U tests. The category variables were presented as numbers (N) and frequencies, and the differences between the category variables were evaluated with the chi-square test or the Fisher's exact test. We used the Kaplan-Meier method to estimate the cumulative event-free survival during the follow-up, and the incidences of primary or secondary outcomes in patients in the 2 groups were compared using a 2-sided log-rank test. A p value of <0.05 was considered indicative of a statistically significant difference.

Results

Baseline characteristics of the included patients

Overall, 220 TIA or stroke patients with angiographically-confirmed severe ICAS were included in our cohort study. Among them, 48 patients were treated with PTAS and aggressive medical management (PTAS group), whereas the other 172 patients

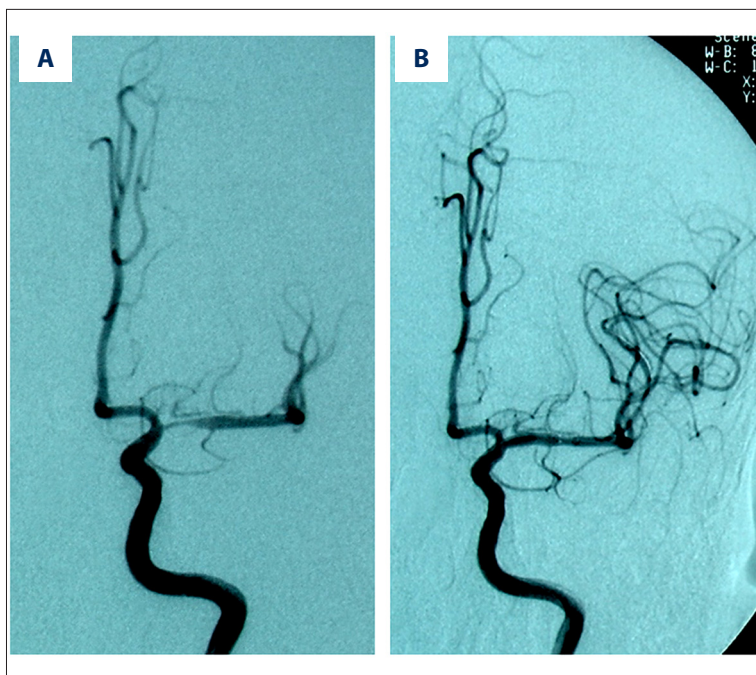


Figure 1. Representative angiographic images of a case with left middle cerebral artery stenosis before (A) and after (B) the PTAS process with a self-expansion Wingspan stenting system. PTAS, percutaneous transluminal angioplasty and stenting.

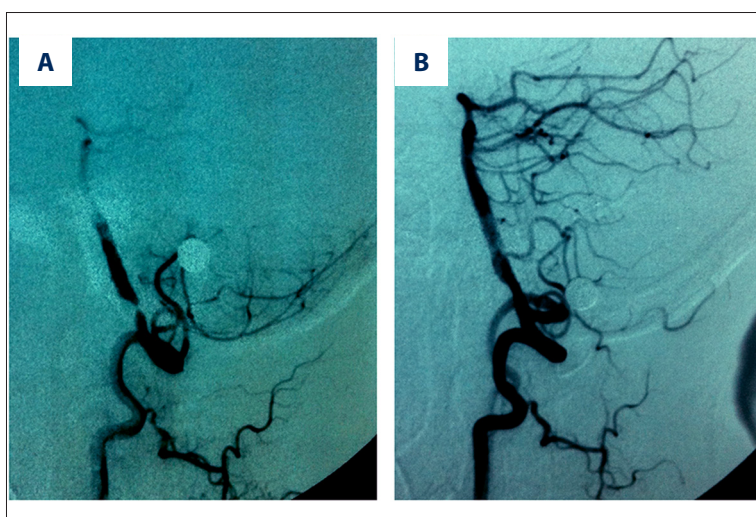


Figure 2. Representative angiographic images of a case with vertebral artery stenosis before (A) and after (B) the PTAS process with a self-expansion Wingspan stenting system. PTAS, percutaneous transluminal angioplasty and stenting.

received aggressive medical management only (medical group). The baseline characteristics of patients in both groups are given in Table 1. Patients from the 2 groups were well matched for demographic characteristics (e.g., age and sex), cardiovascular risk factors (e.g., current smoking, prevalence of hypertension, T2DM, and dyslipidemia), and concurrent medications (e.g., antiplatelets and statins). Moreover, these 2 groups were also well balanced for the degree of stenosis of the qualifying arteries, the distributions of the qualifying arteries, the clinical manifestations of cerebral ischemia (TIA or stroke), and the severity of brain ischemia (mRS and NIHSS scores). The mean follow-up durations for the patients in the 2 groups also were not significantly different ($p < 0.05$).

Effects of PTAS on the risks of primary outcomes

The incidences of primary outcomes among patients in the PTAS and medical groups are listed in Table 2. No significant difference was detected regarding the total incidence of primary outcomes in patients in the PTAS group compared with those of the medical group (10/42 vs. 39/172, $p = 0.96$) during the follow-up period. Similarly, no significant differences were detected in the incidence of ischemic stroke within 30 days (2/42 vs. 4/172, $p = 0.85$), hemorrhagic stroke within 30 days (2/42 vs. 3/172, $p = 0.65$), or ipsilateral ischemic stroke of the qualifying artery after day 30 (6/42 vs. 25/172, $p = 0.90$) between patients in PTAS and medical groups. We also found that 7 patients died within 30 days after enrollment in the medical group, whereas no

Table 1. Baseline characteristics of patients in the PTAS and medical groups.

	PTAS Group (n=48)	Medical Group (n=172)	P value
Age (years, x±s)	59.2±10.7	59.9±11.4	0.70
Age subgroup [n, (%)]			0.11
≥65 years	14 (29.2)	72 (41.9)	
<65 years	34 (70.8)	100 (58.1)	
Male [n, (%)]	36 (75.0)	112 (65.1)	0.20
Current smoking [n, (%)]	22 (45.8)	68 (39.5)	0.43
Comorbidities			
Hypertension [n, (%)]	35 (72.9)	132 (76.7)	0.58
T2DM [n, (%)]	18 (37.5)	55 (32.0)	0.40
Dyslipidemia [n, (%)]	11 (22.9)	30 (17.4)	0.39
CAD [n, (%)]	4 (8.3)	22 (12.8)	0.29
PAD [n, (%)]	7 (14.6)	34 (19.8)	0.42
Stroke [n, (%)]	11 (22.9)	39 (22.7)	0.97
Arrhythmia [n, (%)]	6 (12.5)	27 (15.7)	0.58
Current smoking [n, (%)]	22 (45.8)	68 (39.5)	0.43
Numbers of CVD risk factors			0.20
0~1 [n, (%)]	16 (33.3)	75 (43.6)	
≥2 [n, (%)]	32 (66.7)	97 (56.4)	
Concurrent medications			
Aspirin [n, (%)]	48 (100.0)	172 (100.0)	
Clopidogrel [n, (%)]	48 (100.0)	172 (100.0)	
Statins [n, (%)]	48 (100.0)	172 (100.0)	
Anticoagulation medications [n, (%)]	14 (29.2)	47 (27.3)	0.80
Culprit artery stenosis (% x±s)	81.0±8.0	78.0±9.0	0.16
Qualified events			0.62
Stroke	32 (66.7)	121 (70.4)	
TIA	16 (33.3)	51 (29.7)	
Symptomatic qualifying artery – no. (%)			0.96
Internal carotid artery	8 (16.7)	28 (16.3)	
Middle cerebral artery	27 (56.3)	90 (52.3)	
Vertebral artery	9 (18.6)	33 (19.2)	
Basilar artery	3 (6.3)	13 (7.6)	
Anterior cerebral artery	1 (2.1)	6 (3.5)	
Posterior cerebral artery	0	2 (1.2)	
Follow-up duration [months, M (Q ₂₅ , Q ₇₅)]	32.5 (24.3, 47.8)	35.0 (24.0, 56.5)	0.47

Table 1 continued. Baseline characteristics of patients in the PTAS and medical groups.

	PTAS Group (n=48)	Medical Group (n=172)	P value
mRS Score [n, (%)]			0.81
0	11 (22.9)	47 (27.3)	
1	22 (45.8)	82 (47.7)	
2	11 (22.9)	31 (18.0)	
3	4 (8.3)	12 (7.0)	
NIHSS Score [M (Q ₂₅ , Q ₇₅)]	3 (1, 5)	3 (1, 5)	0.90

Cardiovascular disease risk factors including age over 65 years, current smoking, hypertension, T2DM and dyslipidemia. PTAS – percutaneous transluminal angioplasty and stenting; T2DM – type 2 diabetes mellitus; CAD – coronary artery disease; PAD – peripheral arterial disease; CVD – cardiovascular diseases; TIA – transient ischemic attack; mRS – modified Rankin Scale; NIHSS – NIH Stroke Scale.

Table 2. Incidence of primary and secondary outcomes in patients of the PTAS and medical groups.

	PTAS group (n=48)	Medical group (n=172)	P value
Primary outcomes			
Ischemic stroke within 30 days	2	4	0.85
Hemorrhagic stroke within 30 days	2	3	0.65
Death within 30 days	0	7	–
Ipsilateral ischemic stroke of the qualifying artery after day 30	6	25	0.90
Total	10	39	0.96
Secondary outcomes			
Any stroke or death	12	43	0.85
Any stroke	11	37	0.98
Death	1	10	0.61
Any CV events	1	5	0.74
Major hemorrhage	2	1	0.18
GI bleeding	1	1	0.85
Ocular bleeding	1	0	–
Subcutaneous ecchymosis	0	0	–
Total	15	50	0.34

PTAS – percutaneous transluminal angioplasty and stenting; CV – cardiovascular; GI – gastrointestinal.

patients died in the PTAS group during this period. The results of Kaplan–Meier analysis of the primary outcomes showed that the estimated median event-free survival period for patients in the PTAS group was 54.2 months (95% confidence interval [CI]: 46.5–61.8 months), whereas for patients in the medical group it was 62.0 months (95% CI: 56.7–67.3 months, Figure 3). The results of a log-rank test did not support a significant difference in

event-free survival between the patients in the PTAS and medical groups (chi-square=0.07, p=0.79, Figure 3).

Effects of PTAS on the risk of secondary outcomes

The incidences of secondary outcomes in patients in the PTAS and medical groups also are listed in Table 2. We did

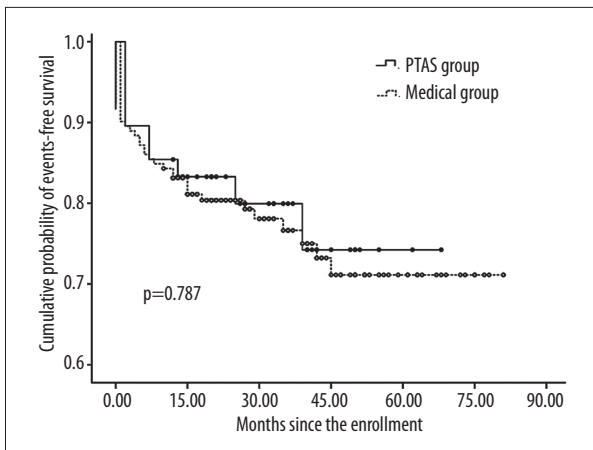


Figure 3. The cumulative event-free survival for the primary outcomes of patients in the PTAS and aggressive medical treatment groups: results of the Kaplan-Meier analysis. PTAS, percutaneous transluminal angioplasty and stenting.

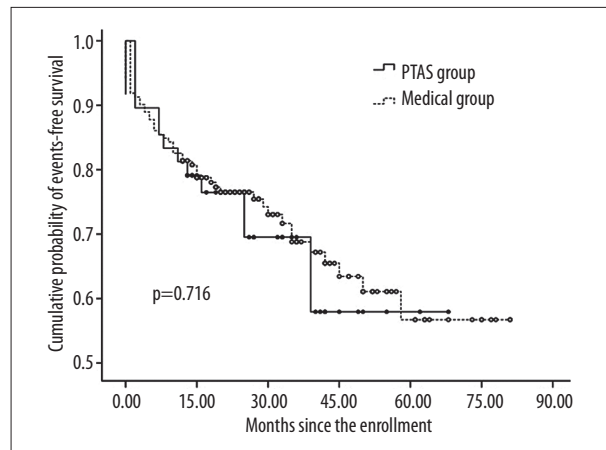


Figure 4. The cumulative event-free survival for the secondary outcomes of patients in the PTAS and aggressive medical management groups: results of the Kaplan-Meier analysis. PTAS, percutaneous transluminal angioplasty and stenting.

not detect a significant difference in the incidence of secondary outcomes during the follow-up period between patients from the PTAS group and those from the medical group (16/42 vs. 50/172, $p=0.34$). Similarly, no significant differences were detected for the incidences of stroke events, cardiovascular events, major bleeding, or all-cause mortality between patients in the 2 groups. Interestingly, we noticed that no stroke-related death occurred among the patients of the PTAS group (Table 2). However, 4 deaths in patients in the medical group were considered to be stroke-related. Consistently, the results of Kaplan-Meier analysis of the secondary outcomes showed that the estimated median event-free survival period for patients in the PTAS group was 47.1 months (95% CI: 38.5–55.7 months), whereas for patients in the medical group the event-free survival was 55.9 months (95% CI: 50.1–61.7 months, Figure 4). The results of log-rank tests did not support a significant difference in event-free survival between the patients in the PTAS and medical groups ($\chi^2=0.13$, $p=0.72$, Figure 4). However, the curve of cumulative survival for patients in the PTAS group was generally above the curve for those in the medical group (Figure 5), indicating that PTAS may be superior to aggressive medical treatment alone with respect to the survival endpoints for patients with symptomatic severe ICAS.

Discussion

The results of our retrospective cohort study indicate that, for patients with severe ICAS, use of appropriate treatment strategies of PTAS is safe, and no significant differences were found between PTAS and aggressive medication treatment with respect to stroke recurrence or death. Moreover, cumulative

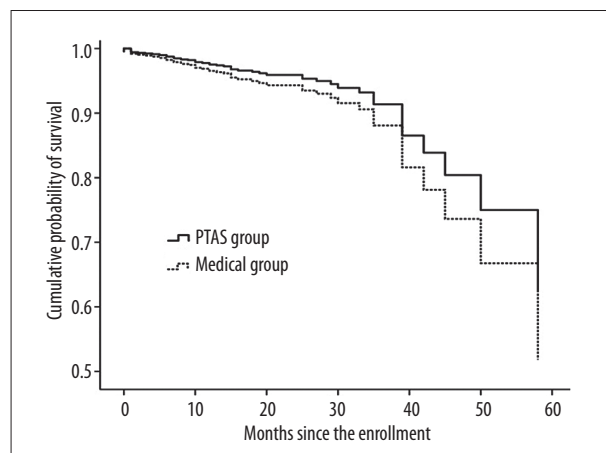


Figure 5. Cumulative survival curves for patients in the PTAS and aggressive medical treatment groups. PTAS, percutaneous transluminal angioplasty and stenting.

survival analyses indicated that PTAS may be superior to aggressive medical therapy in our study.

Early observational studies have suggested possible beneficial effects of PTAS for the treatment of patients with severe ICAS [1,20–22]. Indeed, the procedure is easily accepted by patients because it is minimally invasive. More importantly, if properly performed, the blood flow of the specific cerebral artery can be recovered and the blood supply to the brain tissue may be improved, thereby reducing the vulnerability to subsequent ischemic events [23,24]. However, the recently published SAMMPRIS study challenged the potential therapeutic role of PTAS for patients with severe ICAS. The mid-term results of the SAMMPRIS study with a follow-up duration of 11.9 months demonstrated that aggressive medical management

was superior to PTAS with the use of the Wingspan self-expanding stent system to prevent recurrent stroke [11]. Consistently, the final results of the SAMMPRIS study with a median follow-up duration of 32.4 months further confirmed that the early benefits of aggressive medical management on the prevention of recurrent stroke over stenting with the Wingspan system persists over the extended follow-up [14]. Moreover, PTAS with the Wingspan system was associated with a higher risk for major bleeding. The poor performance of PTAS in the SAMMPRIS study has been indicated to be mostly due to the high incidence of perioperative complications in the PTAS procedure, as indicated by a post-hoc analysis of the SAMMPRIS data [25]. However, others have argued that the disappointing results of the SAMMPRIS study may be related to the possibility of inappropriate selection of the PTAS patients, imperfect determination of interventional strategies and timing of the procedure, and, more importantly, inexperience of the operators in some study centers [1,24].

The differences in the results of our study compared to those of the SAMMPRIS trial may be explained by the differences in study characteristics regarding the features of patients, the lesions, the procedures, and the operators. First, we included patients with stable stroke, as confirmed by an mRs ≤ 3 or NIHSS < 9 , since patients with high-risk unstable stroke may be at risk for adverse events in the PTAS procedure. Moreover, we chose to perform the procedure 2–4 weeks after the onset of cerebral ischemia to avoid the high incidence of perioperative complications of PTAS within the first few days of stroke onset. In addition, the interventional treatment strategies were more individualized according to the features of the stenotic lesions, including not only the Wingspan stent system, but also angioplasty only and angioplasty and stenting. Indeed, there have been reports that simple angioplasty [15,26] or angioplasty and stenting [27] also may be effective and safe for some patients with severe ICAS. Finally, our operators had extensive experience in the PTAS procedure. We believe that these factors reduced the incidence of perioperative complications in our study as compared to that of the SAMMPRIS study.

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The limitations of the current study should be considered when interpreting the results. First, this study was a retrospective cohort study with a non-randomized design. Although we have balanced the baseline characteristics of the patients in the 2 groups, there might be imbalanced factors that affect the results of the study. In addition, another limitation is that the primary outcome of our study showing the superiority of PTAS to medical therapy was not supported by statistical significance. However, unlike the results of the SAMMPRIS study, which showed that PTAS resulted in a higher incidence of stroke, death, and adverse events, our study at least indicated that PTAS is not inferior to medical therapy. Possible explanations for the insignificant results may include that the sample sizes were limited in our study, which make the statistics under-powered. Another possible explanation is that the patient population included in our study was heterogeneous in that it included patients with both TIA and stroke, and multiple candidate PTAS strategies were applied. PTAS procedures may be particularly beneficial to a subgroup of patients, but with the limited number of patients in our study, we were unable to perform subgroup analyses to explore the possible characteristics of these patients. Indeed, the study was a hypothesis-generating pilot study, and the results need to be further confirmed in large randomized controlled trials.

Conclusions

The results of our single-center experience indicated that PTAS may be effective and safe in certain ICAS patients if performed by an experienced physician with qualified strategies. The identification of subgroups that may benefit more from PTAS and optimization of PTAS procedures warrant further investigation.

Conflict of interest

The authors declare that they have no potential conflicts of interest.

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