

Complication of Stenting in Intracranial Arterial Stenosis

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Abstract

Introduction: To evaluate the perioperative complications and long-term restenosis rates following percutaneous transluminal angioplasty and stenting (PTAS) in patients with intracranial atherosclerotic stenosis (ICAS).

Methods: A retrospective analysis was performed on the clinical data of 102 ICAS patients (103 cases of stenosis) who underwent PTAS. The perioperative complications and long-term restenosis rates were analyzed.

Results: The success rate of PTAS was 100%. Six patients (5.83%, 6/103) had perioperative complications. Six cases (6.52%, 6/92) of restenosis occurred and one patient (1.09%) died. Five of the 6 restenosis cases (5.43%) occurred in the blood-supplying region and were associated with ischemic symptoms and one patient (1.09%) had no ischemic symptom. The postoperative restenosis rates at 6, 6 – 12, and 12 – 74 months were 3.26%, 2.56%, and 2.38%, respectively. The postoperative restenosis rates had a significant difference between the residual stenosis rate $\geq 20\%$ and $< 20\%$ ($P < 0.05$), and between postoperative regular medication and non-regular medication ($P < 0.05$). The postoperative restenosis risk in patients with age ≥ 60 years was 13.481 times to that in patients with age < 60 years. The postoperative restenosis risk in patients with residual stenosis rate $< 20\%$ was 31.25 times to that in patients with residual stenosis rate $\geq 20\%$. The postoperative restenosis risk in patients with regular medication was 12.65 times to that in patients without regular medication.

Conclusions: The vasospasm, arterial dissection, arterial occlusion and acute thrombosis are common perioperative complications following PTAS in patients with ICAS. The medium- and long-term postoperative restenosis rate is low. Age is the risk factor for postoperative restenosis.

Keywords: Complication, intracranial arterial stenosis, percutaneous transluminal angioplasty, stenting,

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Introduction

Stroke has become a major economic burden in China, where it has a high incidence resulting in morbidity and mortality.¹ In Chinese patients, Intracranial atherosclerotic stenosis (ICAS) accounts for about 30% – 50% of ischemic stroke.²⁻⁴ ICAS has a high rate of progression toward transient cerebral ischemia and ischemic stroke.^{5,6} There are no studies showing the benefits of drug treatment in reducing the risk of stroke.⁷ In recent years, with the extensive application of percutaneous transluminal angioplasty and stenting (PTAS) in intracranial arteries,⁸ the occurrence and recurrence rates of ischemic stroke have significantly decreased⁹ and PTAS plays an important role in the field of neurology. This study retrospectively analyzed the clinical data of 102 patients who underwent PTAS for ICAS. In addition, a brief summary of perioperative complications and long-term restenosis, as well as prevention measures have been presented in this study. Our objective was to provide evidence-based medical support for the prevention and treatment of ischemic stroke.

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Patients and Methods

General materials

A total of 102 patients (88 men and 14 women, with 103 stenoses) with moderate to severe ICAS, who underwent PTAS between August 2007 and April 2013, were reviewed. Ages ranged from 44 – 80 years, with a mean age of 64 ± 10 years. Ninety-one patients had corresponding symptoms, while 11 patients were asymptomatic. The general data for all patients are shown in Table 1. All patients received a routine urine test, a routine blood test, blood biochemistry and blood coagulation tests, as well as the head and neck computed tomography angiography (CTA) examination. This study was conducted with approval from the Ethics Committee of Chifeng Municipal Hospital. Written informed consent was obtained from all participants.

Inclusion and exclusion criteria

The inclusion criteria were as follows: aged 40 to 80 years; CTA and digital subtraction angiography (DSA) showed that stenosis of the responsible intracranial vessels was more than 70% in symptomatic patients with cerebral infarction and TIA, or more than 90% in asymptomatic patients with no cerebral infarction or TIA. CTA results were verified by two chief physicians in the imaging department, and DSA results were verified by two chief physicians in the neurology intervention department. Finally DSA results were used as the standard. Patients received the dual anti-platelet drug treatment (Aspirin 100 mg/day + clopidogrel 75 mg/day) and atherosclerosis risk factors-controlling treat-

Table 1. General data of patients.

Index	Data
Age (year, mean \pm SD)	64 \pm 10
Male [n (%)]	88 (86.27%)
With symptom [n (%)]	91 (89.22%)
Posterior circulation [n (%)]	78 (75.73%)
Hypertension [n (%)]	70 (68.63%)
Diabetes [n (%)]	58 (56.86%)
Smoking history [n (%)]	26 (25.49%)
High LDL-C [n (%)]	58 (56.86%)

LDL- C: Low density lipoprotein-cholesterol.

ment for three months, but symptoms including dizziness were not relieved. The stricture lesion length was less than 15 mm (the length of stent used in this study was less than 18 mm), and at least one risk factor for artery atherosclerosis (hypertension, diabetes, smoking, etc.) was present. Exclusion criteria were as follows: ischemic stroke within 2 weeks; bleeding in the blood supplying region of responsible vessels within 6 weeks; potential cardiac source of embolism; lesion vessels were with non-artery atherosclerotic stenosis (e.g., arterial inflammation, dissection, etc.).

Surgical procedures

Patients were orally administered aspirin (100 mg/d) and clopidogrel (75 mg/d) for 3 – 7 days before the surgery. For all patients, surgery was performed by the same regularly trained physician in the neurology intervention department. All patients were under general anesthesia and the Seldinger technique was used for the percutaneous puncture into the right femoral artery. A 6F sheath was then implanted for systemic heparinization. Then, a guiding catheter was set and a 0.014-inch micro guidewire was passed through the stenotic segment. An appropriate balloon-expansion stent was then implanted into the stenotic segment along the guide wire and slowly filled. After angiography confirmed the accuracy of the stent placement with no vascular rupture, the stent was slowly released. Therefore, the stent-releasing pressure did not exceed its specified pressure. In the case of severe stenosis, one 2-mm coronary balloon was implanted along with the guidewire for 2 to 3 rounds of pre-dilation. When a self-expanding stent was used, a Gateway balloon was sent into the stenotic segment along with the guidewire and after accurate positioning, gradually expanded to 6 atm for approximately 10 sec. The balloon catheter was removed after angiographic confirmation and the self-expanding stent was then delivered along with the guidewire to cover the stenosis. The stent was then released and withdrawn along with the guidewire following the review. When a simple balloon was used for expansion, an appropriate balloon was sent along with the guidewire into the proper position and expanded to a pressure of 8 atm for 3 sec to dilate the balloon. The guidewire was then withdrawn after the review. Postoperative conventional ECG was monitored. Conventional anticoagulation treatment, with oral administration of aspirin (100 mg/d) and clopidogrel (75 mg/d), was performed for 1 year. This was followed by using single antiplatelet drugs.

Postoperative follow-up

Patients were asked to be re-examined at the 1st, 3rd, 6th, and 12th postoperative month, followed by an annual review. Examination contents included checking clinical symptoms, blood biochemistry, and imaging examination. The telephone follow up was per-

formed monthly, and the adverse events were recorded.

Statistical analysis

SPSS 13.0 software (SPSS Inc., IL, USA) was used for statistical analysis. The enumeration data were analyzed using corrected Chi-square test and Fisher exact probability test. The postoperative restenosis was analyzed using Kaplan-Meier curve, and the risk factors for restenosis were analyzed by multiple COX regression analysis. $P < 0.05$ was considered as statistically significant.

Results

Perioperative complications

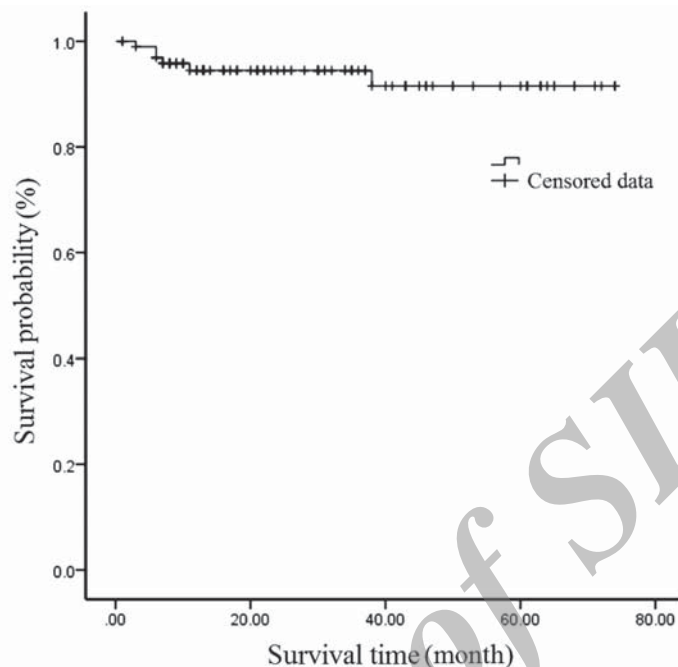
There were 103 vessel lesions in 102 patients and the success rate of PTAS was 100%. Perioperative complications occurred in 6 patients (5.83%), including 2 cases (1.94%) of vasospasm (1 case thereafter had paroxysmal right limb paralysis, and 1 case had paroxysmal speech disorder; the symptom disappeared after drug treatment), 1 case (0.97%) of arterial dissection (no neurologic impairment occurred; the dissection disappeared after implantation of the stent), 2 cases (1.94%) of side branch occlusion (1 case thereafter had right central facial paralysis, with mild neurological impairment after drug treatment; 1 case had right limb paralysis, with moderate neurological impairment after drug treatment), and 1 case (0.97%) of acute thrombosis (the patient who had recovered from coma, had slurred speech and limbs paralysis; after drug treatment, the consciousness restored to normal, but the moderate neurologic impairment was remained) (Table 2).

Results of postoperative long-term follow-up

Out of 102 patients, 92 were followed up for 6 – 74 months, while 10 cases were lost due to change of contact information. Among 92 patients with stenosis who were followed up, 6 cases of restenosis were observed (6/92, 6.52%), and 1 patient died (1/92, 1.09%). The 6, 6 – 12, and 12 – 74 month postoperative restenosis rates were 3.26%, 2.56%, and 2.38%, respectively. One case (1/20, 5.00%) of restenosis occurred in the anterior circulation with symptoms of transient ischemic attack (TIA). Five cases (5/72, 6.94%) of restenosis occurred in the posterior circulation. Among these five cases, one case was confirmed by postoperative follow-up (the stenosis rate was 90%). After implanting one drug-eluting stent, restenosis did not appear within the 30-month follow-up period. Four patients had an ischemic stroke in the blood-supplying region of the treated vessel, which was mitigated after treatment. One case suffered from the sudden death at postoperative 6 months. Remaining patients had no adverse event in the blood-supplying region of the treated vessel. The Kaplan-Meier curve analysis of postoperative restenosis showed with prolong-

Table 2. Perioperative complications in six cases and the causes.

Complication	N (%)	Vascular tortuosity	Improper stent selection	Aspirin resistance
Vasospasm	2 (1.94)	1	1	---
Artery dissection	1 (0.97)	1	---	---
Lateral branch artery occlusion	2 (1.94)	---	2	---
Acute thrombosis	1 (0.97)	---	---	1

**Figure 1.** Kaplan-Meier curve for postoperative restenosis.

ing the time after PTAS, the survival rate of patients was high. The survival time for postoperative restenosis was 69.232 ± 1.904 months, and the 95% confidence interval was (65.499, 72.965) (Figure 1).

Impacts of different factors on occurrence of restenosis

Chi-square test and the Fisher exact probability test showed postoperative restenosis rates had a significant difference between cases with residual stenosis rate $\geq 20\%$ and $< 20\%$ ($P < 0.05$), and between cases with postoperative regular medication and non-regular medication ($P < 0.05$). However, age, sex, lesion site, preoperative stenosis rate, hypertension, diabetes, history of

smoking, and high LDL-C had no significant difference in the occurrence of restenosis ($P > 0.05$) (Table 3). Multiple COX regression analysis showed the screened model with three variables, including age, residual stenosis rate and non-regular medication. The postoperative restenosis risk in patients with age ≥ 60 years was 13.481 times to that in patients with age < 60 years. The postoperative restenosis risk in patients with residual stenosis rate $< 20\%$ was 31.25 times to that in patients with residual stenosis rate $\geq 20\%$. The postoperative restenosis risk in patients with regular medication was 12.65 times to that in patients without regular medication (Table 4 and 5).

Table 3. Risk factors for postoperative restenosis.

	n	Restenosis [n (%)]	χ^2 (corrected)	P (χ^2)	P (Fisher bilateral)
Age ≥ 60 years	44	5 (11.36)	1.899	0.168	0.1
Male	81	5 (6.17)	---	---	0.545
Posterior circulation	72	5 (6.94)	0.000	1.000	1.000
Stenosis rate $\geq 90\%$	52	3 (5.77)	0.000	1.000	1.000
Residual stenosis rate $\geq 20\%$	4	2 (50.00)	---	---	0.020
Hypertension	65	5 (7.69)	0.059	0.809	0.667
Diabetes	55	3 (5.45)	0.006	0.94	0.681
Smoking history	24	2 (8.33)	0.000	1.000	0.649
Non-regular medication	20	4 (20.00)	5.052	0.025	0.019
High LDL-C	54	4 (7.41)	0.000	1.000	1.000

LDL- C: Low density lipoprotein-cholesterol.

Table 4. Quantity and encoding of risk factors.

Variable	Risk factor	Quantity and encoding	
x1	Age	0, < 60 years	1, ≥ 60 years
x2	Gender	0, Female	1, Male
x3	Position	0, Anterior Circulation	1, Posterior Circulation
x4	Stenosis rate	0, 50%–90%	1, ≥ 90%
x5	Residual stenosis rate	0, < 20%	1, ≥ 20%
x6	Hypertension	0, No	1, Yes
x7	Diabetes	0, No	1, Yes
x8	Smoking history	0, No	1, Yes
x9	Non-regular medication	0, No	1, Yes
x10	High LDL-C	0, No	1, Yes
y	Outcome	0, No Restenosis	1, Restenosis

LDL- C: Low density lipoprotein-cholesterol.

Table 5. Multiple COX regression analysis of risk factors for postoperative restenosis.

	Partial regression coefficient	Standard error	Wald	Degrees of freedom	Sig.	RR	95.0% CI for HR	
							Lower	Upper
x1	-2.601	1.277	4.149	1	0.042	13.481	1.103	164.711
x5	-3.451	1.106	9.741	1	0.002	0.032	0.004	0.277
x9	-2.532	0.964	6.894	1	0.009	0.079	0.012	0.526

x1: Age; x5: Residual stenosis rate; x9: Non-regular medication.

Discussion

ICAS is an important cause of ischemic stroke. Surgical methods (extracranial/intracranial artery bypass grafting or sticking technique), drugs, and PTAS are often used for treating this disease.¹⁰ In surgical treatment, the intracranial/intracranial arterial anastomosis is often used for ICAS, but the indications of this method are relatively limited. It cannot be applied to the stenosis, which exists in the posterior circulation.^{10,11} Drug treatments, include antiplatelet/anticoagulant therapy and controlling risk factors, but the rate of stroke occurrence is still high (10% – 24%).¹² The American Society of Interventional and Therapeutic Neuro-radiology recommend PTAS for symptomatic ICAS patients who are refractory to medical therapy.¹³ Recently, a number of scholars have reported the short-term efficacy of PTAS in the treatment of ICAS. Results indicate the overall 30-day death or stroke rate after surgery is 1.9% – 6.3%.¹⁴

PTAS provide a positive treatment method for patients at high risk for stroke. Similar to results seen with stenosis vessel reconstruction done in extracranial carotid artery bypass,¹⁵ the benefit of reestablishing the blood supply in symptomatic ICAS patients was strictly dependent on the lower incidence rate of perioperative stroke or death. In this study, the cause of stenosis in enrolled patients was atherosclerosis. Subjects were asymptomatic patients with > 90% stenosis, and symptomatic patients with > 70% stenosis and ischemic symptoms, including cerebral infarction and TIA. Asymptomatic patients had no cerebral infarction or TIA, but they experienced dizziness or headaches, which may be related to global cerebral ischemia. In all patients, treatment with dual antiplatelet drugs (oral aspirin combined with clopidogrel) was ineffective. Therefore, surgical treatment was performed and the symptoms disappeared or were mitigated after surgery. The incidence of perioperative complications and postoperative restenosis was lower than those reported in other studies.^{16–19}

Common perioperative complications of PTAS, include vascular spasms, dissection, lateral branch artery occlusion, acute thrombosis, vascular rupture, and embolic loss. In this study, there were 6 cases (5.83%) of perioperative complication. Two patients (1.94%) had vascular spasms, possibly related to stent shift due to vascular tortuosity and the small stent. One case (0.97%) had an arterial dissection and the symptom disappeared after implantation of the stent. Two patients (1.94%) had side branch occlusion due to the small stent and the symptom was mitigated after drug treatment. One patient (0.97%) had acute thrombosis due to aspirin resistance and the symptom was mitigated after drug treatment.

The middle wall of intracranial artery is thin, with less supporting tissue surrounding it. In addition, there is vascular tortuosity and accumulated lateral branch arteries are present. Therefore, surgery is difficult and requires a full preoperative evaluation of the surgical risks. In addition, the gentle operation, a graded stent (stent diameter less than arterial diameter), the slow and full expansion of stent, the application of a cerebral protection device, avoidance of stent shift, and the administration of complementary drugs (antiplatelet and anticoagulation drug, statins drug, nimodipine) will be required.^{20,21} To a certain extent, these steps reduce vascular spasms, dissection, acute thrombosis, embolic loss, as well as the “snow-plough effect”, due to the extrusion of plaques,²² and lateral branch artery occlusion. High perfusion syndrome is the main reason for bleeding from vascular rupture after intervention.²³ A high systolic blood pressure within 24 h after stroke occurrence is related to poor outcome at 10 days and at 6 months, but is not related to the vascular death rate and total mortality.²⁴ In addition, the Wingspan stent system has a balloon diameter 80% of the normal blood vessel diameter, and has a gradual longitudinal self-expanding force. It has obvious advantages in reducing the risk of intracranial vascular rupture and hemorrhage. In summary, a comprehensive understanding of indications and a full assessment of the surgical risk, the rational intraoperative application of

equipment and interventional techniques, postoperative attention to preoperative monitoring, and timely imaging examination provide the maximum possible reduction or avoidance of complications.

Postoperative in-stent restenosis, has long been a focus of research, significantly increase risks of early-onset and the recurrence of ischemic events in the responsible vessel's blood-supply region,¹⁹ thus seriously affecting the prognosis for intracranial stenting. In this study, there were 6 cases of in-stent restenosis (6.52%) with 1 death (1.09%). The restenosis rate and mortality rate were significantly lower than those found in similar studies (13.8% – 26.1%).^{18,19,25} This may be related to the correct postoperative management, good compliance of the subjects, regular postoperative long-term medication, and strict control of risk factors for atherosclerosis. According to the Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries, diabetes, small preoperative vascular diameter, and postoperative residual stenosis $\geq 30\%$ were high-risk factors for in-stent restenosis in the 6 months following the operation. In addition, hypertension, complex lesions, smoking, and irregular postoperative use of antiplatelet drugs may increase the risk of restenosis.²⁶

There was one death in this study. This patient had right vertebral artery occlusion, 90% stenosis of the left vertebral artery, and 50% stenosis of the basilar artery. After placing one Apollo stent in the left vertebral artery, the symptoms were obviously relieved and stenosis was immediately reduced to approximately 10%. The patient used anti-platelet drugs and other risk factors were intervened. At 1 and 3 month postoperative follow up, no obvious restenosis had occurred. Six months after the surgery, the patient was admitted to a hospital due to sudden loss of consciousness that lead to a deep coma and respiratory depression. Finally, the patient died without radiography. After a discussion by experts, it was assumed that the patient's death might have been related to an acute obstruction of the treated vessel caused by aspirin resistance.

In this study, PTAS was operated successfully by a regularly-trained physician. The incidence of perioperative complications was low. Main complications were vasospasm, arterial dissection, side branch occlusion, acute thrombosis, etc. The appropriate prevention and treatment can obtain a good outcome in reducing the perioperative complications. The 6 – 74 months of postoperative follow up finds the main middle- and long-term complication is the restenosis of treated vessels. The restenosis rate at postoperative 6 months is the highest (3.26%). With the prolonging the follow-up time, the restenosis rate is gradually lowered. The overall survival rate of patients is high, and their life quality is good. Multiple COX regression analysis shows that, age is the risk factor for postoperative restenosis. Patients with age ≥ 60 years are more susceptible than those with age < 60 years.

There are some limitations of this study, which may be related to race difference of samples, large number of lost cases, sample selection bias (too many selected samples have a better economic capacity), and other factors. In the future study, indications of surgery should be more strictly grasped to improve the representativeness of samples and reduce the bias.

Conflict of interest

All authors have no conflict of interest regarding this paper.

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