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Original Article

The short- and long-term efficacy of intravascular stenting in the treatment of intracranial artery stenosis

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Abstract: Objective: To investigate the short- and long-term efficacy of intravascular stenting in the treatment of intracranial artery stenosis. Methods: This prospective study was conducted in 132 patients who underwent intravascular stenting for intracranial artery stenosis. In the perioperative period, complications were recorded. During a 2-year follow-up, postoperative stenosis rate, collateral circulation, changes in peak blood flow velocity, National Institute of Health stroke scale score, modified Rankin scale score, and restenosis were recorded. Factors influencing postoperative restenosis were analyzed using univariate analysis and multivariate logistic regression analysis. Results: In the perioperative period, 4 patients had complications, while 1 patient died. Compared with before operation, peak stenosis rate, blood flow velocity, National Institute of Health stroke scale score, and modified Rankin scale score at 1 year and 2 years after operation were significantly decreased, while the classification of collateral circulation was increased (all $P<0.05$). However, there were no statistical differences in the above indicators between 1-year and 2-year postoperative patients (all $P>0.05$). Two years after surgery, a total of 8 patients suffered from restenosis. There were statistical differences concerning age (≥70 years), the history of hypertension, diabetes, and coronary heart disease between the restenosis group and the non-restenosis group (all $P<0.05$). The results of multivariate analysis showed that the history of coronary heart disease and advanced age (≥70 years) were independent risk factors that affect the occurrence of postoperative restenosis. Conclusion: The short- and long-term efficacy of intravascular stenting in the treatment of intracranial artery stenosis is significant. What's more, a history of coronary heart disease and advanced age (≥70 years) are independent risk factors contributing to postoperative restenosis.

Keywords: Intravascular stenting, intracranial artery stenosis, efficacy

Introduction

Previous epidemiological data has revealed that intracranial artery stenosis is the leading cause of ischemic stroke in the Asian population [1, 2]. After onset, the cerebral artery narrows and cerebral blood flow decreases. Furthermore, cerebral infarction occurs. What's worse, the patient's life is endangered in severe cases [3-5]. At present, drug therapy, surgical bypass surgery and vascular interventional therapy are the essential clinical treatments for intracranial artery stenosis [6]. In patients with more than 70% stenosis, the annual recurrence rate of stroke in the ipsilateral blood supply area is still over 20% after taking oral antiplatelet drugs regularly. As for surgical bypass surgery, there are drawbacks including a high incidence of complications, high risk of death, and so on [7, 8]. The primary purpose of vascular stenting is to broaden patients' narrowed vessels. Accordingly, blood supply in the distal end of blood vessel is resupplied [9, 10]. A study published in the New England Journal of Medicine, a well-known international journal, shows that the clinical efficacy of intravascular stenting in treating intracranial artery stenosis is controversial and insignificant. What's more, there are certain risks [11]. Some studies have revealed that there are certain limitations in the design of surgical indications and other conditions in previous reports, resulting in negligible effects [12]. On the basis of previous research, we analyzed the baseline data and results of intervention in enrolled patients, aiming to provide clinical evidence for the treat-

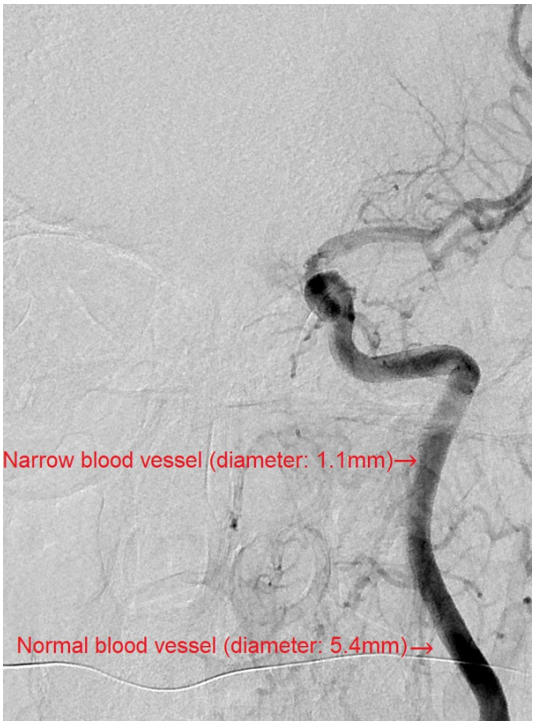

Figure 1. The result of Angiography before surgery (with a stenosis rate of 83%).

ment of intracranial artery stenosis in clinical practice.

Materials and methods

Inclusion and exclusion criteria

This study was performed in patients with intracranial artery stenosis who were admitted to our hospital from January 2017 to December 2019. The study was approved by the Ethics Committee of our hospital.

Inclusion criteria: Patients aged between 18 and 75 years; patients were preliminarily diagnosed by imaging examinations like magnetic resonance angiography (MRA), transcranial Doppler (TCD), and computed tomography angiography (CTA), and further confirmed with intracranial artery stenosis using digital subtraction angiography (DSA); patients had unilateral stenosis, with above 70% stenosis in the diseased blood vessels [13]; patients met the standards for endovascular stent implantation, which were defined by the cerebrovascular disease sub-branch of Neurology Branch of Chinese Medical Association in 2015 [14]; patients and their family members were aware of the research content and signed the informed consent.

Exclusion criteria: Patients had non-atherosclerotic stenosis, such as vasculitis and cardiogenic embolism; patients suffered from severe diseases of other organs and tissues; patients were allergic to drugs like aspirin, heparin, and contrast agents; patients had severe ischemic stroke within the past 6 months.

According to the inclusion and exclusion criteria, 132 patients were recruited. Among them, 90 were males while 42 were females, with an average age of 59.4±13.2 years. There were 45 patients who suffered from transient ischemic attack while 87 had stroke. The number of patients with stenosis on the left side was 59, while 73 had it on the right side. As for underlying disease, 102 patients had hypertension; 38 patients had diabetes, 29 patients had coronary heart disease. In addition, there were 78 patients who had a history of smoking. The collateral circulation assessment system, which was proposed by the American Society of Interventional and Therapeutic Neuroradiology/Society of Interventional Radiology in 2003, was applied to evaluate patients' collateral circulation [15]. To be specific, no patient was allocated to grades 0-1; 78 patients were allocated to grade 2; 54 patients were allocated to grades 3-4. Diseased blood vessels were classified by 2 chief physicians based on Mori classification criteria [16]. In this study, 94 patients were classified into type A, while 38 patients were classified into type B. The result of preoperative angiography was illustrated in **Figure 1**. The baseline data of patients was shown in **Table 1**.

Methods

Two types of stents were implemented in this study. Specifically, the Wingspan stent was placed in 40 patients, while the Apollo stent was placed in 92 patients. All patients recruited underwent preoperative routine examinations, including electrocardiogram (ECG), chest radiograph, routine blood work, anticoagulation, and antiplatelet care. They also took oral aspirin (100 mg/d, Bayer HealthCare Co., Ltd., Germany), clopidogrel (75 mg/d, Lepu Pharmaceutical Co., Ltd., China), and atorvastatin (20 mg/d, Sandoz Pharmaceutical Co., Ltd., China) for 3 days before operation. In addition, they

Table 1. Baseline data

Items	Patients with intracranial artery stenosis (n = 132)
Average age (years)	59.4±13.2
Age (n)	
≥70 years	31
<70 years	101
Gender (n)	
Male	90
Female	42
Preoperative stenosis rate (%)	82.17±12.24
Preoperative MRS score (scores)	2.1±0.8
Preoperative NIHSS score (scores)	4.2±1.7
The type of stent (n)	
Wingspan stent	40
Apollo stent	92
Preoperative collateral circulation (n)	
Grade 2	78
Grades 3-4	54
Circulation site (n)	
Anterior circulation	35
Posterior circulation	97
The Type of arterial stenosis (n)	
Transient ischemic attack	45
Stroke	87
Stenosis site (n)	
Left site	59
Right site	73
History of hypertension (n)	102
History of diabetes (n)	38
History of smoking (n)	78
History of coronary heart disease (n)	29
Mori classification (n)	
Type A	94
Type B	38
Combined with other underlying disease (n)	48

Note: NIHSS: National Institute of Health stroke scale; MRS: modified Rankin scale.

were fasted and water-deprived for 8 h before surgery. After general anesthesia, a 6F guiding catheter was horizontally placed at a carotid petrosity or vertebral artery in the C2 vertebra. The stent was released according to the methods for different stent placement. Patients were subcutaneously injected with low-molecular-weight heparin calcium on 3 to 7 days after surgery. After taking oral clopidogrel and aspirin for 3 to 6 months, they were insturcted to take aspirin for a long time.

Outcome measures

Main outcome measures: Patients were followed-up for 2 years after operation. Changes of the National Institute of Health stroke scale (NIHSS) and modified Rankin scale (MRS) scores were obtained before operation, 1 year and 2 years after operation and were analyzed. The higher the NIHSS score, the worse the neurological function [17]. Similarly, the higher the MRS score, the worse the prognosis [18].

Vascular stenosis rate and collateral circulation were recorded by angiography before operation, 1 year and 2 years after operation. During the vasoconstriction of the diseased middle cerebral artery, basilar artery, and vertebral artery, peak blood flow velocity was examined by transcranial Doppler ultrasound.

After a follow-up of 2 years, in-stent restenosis was observed by angiography. Restenosis was defined as: (1) there was no obvious residual stenosis after surgery, while more than 50% stenosis shown in follow-up results; (2) postoperative residual stenosis was 30%-50%; (3) the degree of lumen stenosis increased by over 20% [19]. Restenosis rate = the number of restenosis cases/the total number of patients followed-up × 100%.

Secondary outcome measures: During the perioperative period, the incidence of complications such as vasospasms, acute thrombosis, vascular rupture, cerebral infarction, cerebral, and parenchymal hemorrhage, and the success rate of surgical implantation were recorded. The success rate of surgical implantation = the number of successful surgical implantation cases/the total number of patients received surgical implantation × 100%.

The differences in age, gender, the history of hypertension, diabetes, smoking, and coronary heart disease, Mori classification, and the history of other underlying diseases were compared between patients with restenosis and without stenosis. Logistic regression analysis

Table 2. Stent implantation

The number of cases (n)	Basilar artery	Middle cerebral artery	Intracranial segment of vertebral artery
Wingspan stent	12	19	9
Apollo stent	57	16	19

Table 3. Collateral circulation

Time	Grades 0-1	Grade 2	Grades 3-4
Before operation	0	78	54
One year after operation	0	5	116
Two years after operation	0	1	97
Before operation vs. One years after operation (Z)	9.281		
Before operation vs. One years after operation (P)	<0.001		
Before operation vs. Two years after operation (Z)	9.150		
Before operation vs. Two years after operation (P)	<0.001		
One year vs. Two years after operation (Z)	1.401		
One year vs. Two years after operation (P)	0.163		

Table 4. Vascular stenosis rate

Time	The number of cases (n)	Stenosis rate (%)
Before operation	132	82.17±12.24
One year after operation	121	8.09±2.21[a]
Two years after operation	98	7.25±1.38[a]
F	3895.202	
P	<0.001	

Note: *P* value refers to the statistical significance of satisfaction with each dimension and overall satisfaction. Compared with before operation, [a]P<0.05.

was further performed on the indicators with statistical differences with univariate analysis.

Statistical methods

All data were analyzed using SPSS statistical software version 22.0. The enumeration data were expressed as number/percentage (n/%); comparison was conducted with chi-square test. The measurement data were calculated as mean ± standard deviation ($\bar{x}$ ± sd); pairwise test including repeated measures analysis of variance combined with post-hoc Bonferroni test was applied for comparison among multiple groups. The classification data were compared using rank sum test. Logistic regression analysis was further performed on the indicators (like age and the history of hypertension, diabetes, and coronary heart disease) with statistical differences using univariate analysis. The difference was statistically significant when *P* value was less than 0.05.

Results

The success rate of surgical implantation and perioperative complications

All patients enrolled were successfully implanted with stents, with a total of 132 stents. As shown in **Table 2**, 35 stents were placed in the anterior circulation (35 stents in the middle cerebral artery), while 97 stents were placed in the posterior circulation (28 stents in the intracranial segment of vertebral artery and 69 stents in the basilar artery). During the perioperative period, 2 patients had symptomatic cerebral infarction; 2 patients had intraparenchymal hemorrhage; and 1 patient died (0.8%).

Collateral circulation

In total, 121 patients were followed up 1 year after surgery, while 98 patients were followed up 2 years after surgery. As shown in **Table 3**, the classification of collateral circulation at 1 year and 2 years after operation were increased when compared with before operation (both P<0.05); there was no statistical difference on the classification of collateral circulation between 1-year and 2-year postoperative patients (P>0.05).

Vascular stenosis rate

As displayed in **Table 4**, stenosis rates at 1 year and 2 years after operation were significantly decreased when compared with before operation (both P<0.05); there was no statistical difference concerning stenosis rates between 1-year and 2-year postoperative patients (P>0.05).

Peak blood flow velocity

As shown in **Table 5**, the peak blood flow velocities of the middle cerebral artery, basilar artery, and vertebral artery at 24 h, 1 year and 2 years

Table 5. Peak blood flow velocity

Time	The number of cases (n)	Middle cerebral artery (cm/s)	The number of cases (n)	Basilar artery (cm/s)	The number of cases (n)	Vertebral artery (cm/s)
Before operation	35	261.34±33.45	69	173.24±33.45	28	187.63±27.44
24 h after operation	35	148.97±22.38[a]	69	119.56±14.47[a]	28	128.61±21.35[a]
1 year after operation	32	146.45±21.85[a]	64	122.45±13.96[a]	25	130.88±23.26[a]
2 years after operation	26	145.78±24.21[a]	51	120.59±16.83[a]	21	127.33±24.71[a]
F	162.969		98.096		39.509	
P	<0.001		<0.001		<0.001	

Note: Compared with before operation, [a]P<0.05.

Table 6. NIHSS and MRS score

Time	The number of cases (n)	NIHSS score	MRS score
Before operation	132	4.2±1.7	2.1±0.8
1 year after operation	121	1.5±0.3[a]	0.5±0.3[a]
2 years after operation	98	1.3±0.3[a]	0.4±0.2[a]
F		281.037	394.447
P		<0.001	<0.001

Note: Compared with before operation, [a]P<0.05. NIHSS: National Institute of Health stroke scale; MRS: modified Rankin scale.

after operation were lower than those before operation (all P<0.05); there were no statistical differences on the peak blood flow velocities of the middle cerebral artery, basilar artery, and vertebral artery among 24-hour, 1-year, and 2-year postoperative patients (all P>0.05).

NIHSS and MRS score

As displayed in **Table 6**, NIHSS and MRS scores at 1 and 2 years after surgery were decreased when compared with before operation (all P<0.05); there were no statistical differences concerning NIHSS and MRS score between 1-year and 2-year postoperative patients (both P>0.05).

Recurrence of stenosis and univariate analysis

As shown in **Table 7**, 8 patients had restenosis during a 2-year follow-up, with a restenosis rate of 8.16%. There were statistical differences concerning age (≥70 years), the history of hypertension, diabetes, coronary heart disease between the restenosis group and the non-restenosis group (all P<0.05).

Logistic regression analysis

As displayed in **Table 8**, indicators with statistical differences (P<0.05) in univariate analysis results were included in the multivariate analysis, and these variables were assigned with values. Logistic regression analysis was performed using a stepwise forward logistic regression method. Our results showed that the history of coronary heart disease and advanced age (≥70 years) were independent risk factors contributing to postoperative restenosis (both P<0.05, **Table 9**).

Discussion

At present, intracranial stents including the self-expanding stent (Wingspan, Solitaire, and so on), the balloon expandable stent (Apollo), and the drug-coated stent (NOVA) are commonly observed in clinical practice [20, 21]. The Apollo stent is independently designed and developed by Chinese people. It has strong radial support, but also has insufficient flexibility. Therefore, stents with an inner diameter slightly smaller than the diameter of blood vessels are usually used in clinical practice to avoid the risk of vascular rupture [21]. The Wingspan stent, which is designed and developed by a foreign company, has high flexibility and strong compliance with blood vessels. In other words, it is more suitable for curved blood vessels, reducing blood vessels' damage and preventing vasospasms and rupture. The physician is supposed to select an appropriate stent based on patients' condition. In this study, we mainly applied the Wingspan stent and the Apollo stent for placement. In total, 132 patients were successfully implanted with stents. We believe that the following factors should be considered when patients are treated with stent implantation: (1) Before surgery, the location and degree of vascular stenosis, and its relationship with clinical symptoms need to be confirmed by angiography, clarifying whether patients are compliant to the

Table 7. Recurrence of stenosis and univariate analysis

Items	Patients with postoperative restenosis (n = 8)	Patients without postoperative restenosis (n = 90)	χ^2	P
Ages ≥70 years (n)	7	17	18.703	<0.001
Male (n)	7	60	1.475	0.225
Preoperative Stenosis rate (%)	83.47±6.68	82.48±12.01	0.229	0.819
Preoperative MRS score (points)	2.2±0.6	2.1±0.7	0.391	0.679
Preoperative NIHSS score (points)	4.3±1.4	4.2±1.2	0.223	0.824
The Type of Stent (n)			0.102	0.749
Wingspan stent	3	39		
Apollo stent	5	51		
Preoperative collateral circulation (n)			0.955	0.329
Grade 2	5	70		
Grades 3-4	3	20		
Circulation site (n)			0.232	0.631
Anterior circulation	2	30		
Posterior circulation	6	60		
Postoperative administration of anticoagulant (n)			0.033	0.856
Aspirin	4	48		
Clopidogrel	4	42		
Regular administration of atorvastatin after operation (n)			0.054	0.816
Present	6	64		
Absent	2	26		
History of hypertension (n)	8	60	3.843	0.049
History of diabetes (n)	7	21	14.823	0.000
History of smoking (n)	6	59	0.293	0.588
History of coronary heart disease (n)	7	15	21.174	<0.001
Type B Mori classification (n)	5	28	3.241	0.072
Combined with other underlying disease (n)	4	37	0.774	0.379

Note: MRS: modified Rankin scale; NIHSS: National Institute of Health stroke scale.

Table 8. The value of variable

Variables	The value of variable
Age	<70 year = 0, ≥70 years = 1
Present with the history of diabetes or not	Absent = 0, present = 1
Present with the history of hypertension	Absent = 0, present = 1
Present with the history of coronary heart disease or not	Absent = 0, present = 1

Table 9. Logistic regression analysis

Variable	β	SE	Wald	P	OR	95% CI
Advance age	0.08	0.04	18.443	<0.001	30.06	11.34-39.37
The history of coronary heart disease	0.16	0.11	22.358	<0.001	5.00	2.41-14.38

indications of stent implantation. (2) Stent implantation may be considered for patients with type A or B Mori classification, while contraindicated for patients with type C Mori classification. (3) It is also necessary to evaluate the benefits of patients that are obtained after implantation. It was reported that patients with reduced blood flow reserve capacity in the

responsible vascular area could benefit more from surgery when compared with those with normal reserve capacity [22, 23].

In this study, the incidence of complications was 3.03%, which was lower than that in a similar study [24]. In our study, 2 patients suffered from intraparenchymal hemorrhage, and 1 patient died (0.8%). As one of the most serious complications after stent implantation, cerebral hemorrhage endangers the life of patients once it occurs. The possible reason may be that guide wire, catheter, and stent implantation cause mechanical damage to blood vessel during the operation. Therefore, there are high requirements on the surgical proficiency of physicians performing a surgery like this. In addition, 2 patients had symptomatic cerebral infarction during the perioperative period. After reoperation and local arterial thrombolysis, their symptoms were significantly improved. In our opinion, we should monitor the condition of patients in the perioperative period closely and take corresponding measures immediately for those with complications. By doing so, the adverse consequences caused by complications are relieved.

The short- and long-term benefits of patients are the focus of clinical attention. Our results showed that the degree of vascular stenosis and blood flow were significantly improved after patients were treated with intravascular stenting for 1 year. Moreover, their neurological function was significantly restored. There were no significant differences on various indicators between 1-year and 2-year postoperative patients. These results suggest that intravascular stenting can release the stenosis of diseased arteries, resulting in improved neurological function and blood flow velocity, and accelerated restoration of normal blood supply to patients' blood vessels. In this way, ideal short- and long-term efficacy was obtained [25, 26]. Postoperative restenosis is one of the key factors influencing the medium-long term efficacy. In our study, 8 patients had restenosis, with a restenosis rate of 8.16%. The results of multivariate analysis displayed that advanced age (≥70 years) and the history of coronary heart disease were independent risk factors contributing to postoperative restenosis. For patients with advanced age or the history of coronary heart disease, therefore, it is necessary to actively control their underlying disease before performing surgical treatment or involve the age factor in the determination of patients' benefits to choose a more appropriate treatment.

However, there are two shortcomings in this study. Firstly, this is a single-centered study carried out in a small number of patients. Secondly, inflammatory factors are not detected, not to mention the analysis of changes in the levels of these factors. Accordingly, it is difficult to discuss the effect of surgery from the perspective of the inflammatory response. There is still a need to conduct subsequent study to further explore the short- and long-term efficacy of intravascular stenting.

In summary, the short- and long-term efficacy of intravascular stenting in the treatment of intracranial artery stenosis is significant. In addition, it is necessary to pay attention to patients' perioperative complications. Moreover, the history of coronary heart disease and advanced age (≥70 years) are independent risk factors that affect the occurrence of postoperative restenosis.

Disclosure of conflict of interest

None.

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