

Efficacy and safety of endovascular therapy versus surgical clipping for patients with unruptured middle cerebral artery bifurcation aneurysms

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ABSTRACT

This study aims to evaluate the efficacy and safety of endovascular therapy versus neurosurgical clipping carried out for patients with unruptured middle cerebral artery bifurcation aneurysms (MCABAs). Patients diagnosed with MCABAs were enrolled in this prospective study according to the inclusion and exclusion standard. Enrolled patients were divided into a study group (endovascular therapy) and a control group (neurosurgical clipping), with 65 cases in each group. In terms of efficacy, we found that the proportion of Glasgow Outcome Scale (GOS) grade 1 after treatment in the study group was significantly higher than in the control group ($p<0.001$), while the proportion of GOS grades 2, 3, and 4 after treatment was significantly lower in the study group than in the control group ($p<0.05$). The postoperative brain injury indicators neuron-specific enolase and S100 β in the study group were significantly lower than in the control group ($p<0.001$), and the postoperative life activity score of patients in the study group was significantly higher than in the control group ($p<0.001$). In terms of safety, the postoperative hospital stay of patients in the study group was significantly shorter than in the control group ($p<0.001$), and the incidence rate of postoperative pulmonary and intracranial infections in the study group was significantly lower than in the control group ($p<0.05$). Endovascular therapy for patients with unruptured MCABAs may be effective in improving outcomes and has better safety profile compared with neurosurgical clipping, but may increase the risk of postoperative recurrence.

INTRODUCTION

Intracranial aneurysm is an acquired disease that often leads to devastating effects such as subarachnoid hemorrhage once it ruptures. With the widespread availability of non-invasive imaging, the reported prevalence of intracranial aneurysms is increasing. A meta-analysis of 68 studies, including 1450 unruptured intracranial aneurysms in 94,912 patients from 21 countries, reported an estimated overall incidence of

Significance of this study

What is already known about this subject?

- ⇒ The overall incidence of intracranial aneurysm is estimated to be 3.2%.
- ⇒ Previous studies suggested that neurosurgical clipping is the mainstay of treatment for middle cerebral artery bifurcation aneurysms (MCABAs).
- ⇒ There are many limitations to neurosurgical clipping.

What are the new findings?

- ⇒ Endovascular therapy can significantly improve the clinical efficacy of MCABAs compared with neurosurgical clipping.
- ⇒ The incidence rate of complications after endovascular treatment of MCABAs was low and the recovery rate was faster.
- ⇒ Postoperative levels of neuron-specific enolase and S100 β in the study group were lower than in the control group, suggesting that endovascular treatment has a better effect in protecting the cells of the brain tissue than neurosurgical clipping in patients with MCABAs.

How might these results change the focus of research or clinical practice?

- ⇒ Endovascular therapy for MCABAs may be effective in improving patient outcomes and may have better safety profile compared with neurosurgical clipping, but may increase the risk of postoperative recurrence.



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3.2%.¹ The middle cerebral artery (MCA) is a common site for cerebral aneurysms, accounting for 14.4%–43% of all diagnosed aneurysms.² The most common location of MCA aneurysm is at the MCA bifurcation, which accounts for approximately 63%–90% of cerebral aneurysms, followed by the proximal M1 and then the distal MCA.^{3,4} In addition, middle cerebral artery bifurcation aneurysms (MCABAs) have high morbidity and mortality and seriously

threaten the survival of patients. Therefore, it is of great significance to adopt a timely and effective method to deal with unruptured MCABAs.

Previous studies have suggested that neurosurgical clipping is the mainstay of treatment for MCABAs.⁵ However, there are many limitations to neurosurgical clipping; for example, the wide neck of the aneurysm in most cases of complex MCABAs, the atherosclerotic aneurysm wall and the thrombosis forming in the aneurysm cavity, the presence of calcification in the neck of the aneurysm, and the occupation of the aneurysm in the main branches of the artery, which will interfere with the clipping process. In recent years, with the continuous improvement of endovascular therapy techniques and embolization materials, endovascular therapy has gradually become an important method for treatment of intracranial aneurysms. Some studies indicated that endovascular treatment can effectively treat various complex types of MCABAs, with a low rate of recurrence.^{6,7} However, reports on endovascular treatment of MCABAs at our local clinical practice are scarce.

Herein, our study aims to evaluate the efficacy and safety of endovascular therapy carried out for patients with unruptured MCABAs versus neurosurgical clipping at our location.

MATERIALS AND METHODS

From January 2017 to February 2020, patients with unruptured MCABAs were prospectively enrolled as the research subjects according to the following inclusion and exclusion criteria:

- ▶ Inclusion criteria: (1) patients diagnosed with MCABAs by both cervical digital subtraction angiography and CT angiography; (2) patients judged treatable by both endovascular therapy and neurosurgical clipping; (3) patients with complete clinical data; (4) patients who signed the informed consent, as well as their families; (5) patients with complete follow-up results; and (6) patients with Hunt and Hess Scale grades 0–1.
- ▶ Exclusion criteria: (1) patients with systemic organ failure, acute myocardial infarction, or pulmonary embolism; (2) patients with follow-up time less than 1 year; (3) patients with intracranial arteriovenous malformations; (4) patients who do not comply with treatment or follow-up; (5) pregnant or lactating patients; and (6) patients with Hunt and Hess Scale grades 2–6.

Patients enrolled were divided into a study group (endovascular therapy) and a control group (neurosurgical clipping), with 65 cases in each group, by random number table method. All patients participated in the study voluntarily and signed the informed consent.

Methods

Control group

The procedures for undergoing neurosurgical clipping therapy were as follows: after receiving general anesthesia, according to the results of preoperative imaging, the ipsilateral pterion approach was used for routine craniotomy to expose the brain tissue and then gradually expose the MCABAs. Titanium clamps were used to clamp the neck of the aneurysm. Color Doppler ultrasound was then taken

to evaluate the effect of clamping, and the titanium clamps were adjusted to achieve complete closure. Nimodipine gelatin sponges were used to cope with potential arterial spasm.

Study group

The procedures for undergoing endovascular therapy were as follows: after general anesthesia and heparinization, the femoral artery was punctured using the Seldinger technique and then a 6F arterial sheath was inserted. Subsequently, a catheter was placed at the level of the second cervical vertebra of the internal carotid artery. Rotational angiography was then performed to accurately measure the size of the neck of the MCABA and to evaluate its complexity. Appropriate techniques were implemented according to the results of the measurement, such as coil embolization, balloon-assisted neck reconstruction, micro-guidewire-assisted neck angioplasty, etc. Heparin was given routinely after the operation for anticoagulation, and patients receiving stent-assisted therapy were given oral aspirin. If the patient had symptoms of cerebral ischemia, the anticoagulation time was extended according to the patient's condition. Prompt drainage was performed when subarachnoid hemorrhage or cerebral hemorrhage occurred. If the patient had a large hematoma, prompt evacuation by craniotomy was performed.

Observational index

The main outcomes were as follows: Glasgow Outcome Scale (GOS), daily activity ability, brain injury indexes before and after treatment, postoperative hospital stay, postoperative complications, and recurrence, which were followed for 12 months, and were collected and compared between the two groups.

Glasgow Outcome Scale

GOS⁸ was used to evaluate the prognosis of patients within 12 months after treatment, where grade 1 indicates good prognosis, grade 2 moderate disability, grade 3 severe disability, grade 4 vegetative survival, and grade 5 death.

Activity ability

Barthel Index⁹ was used to evaluate the activities of daily living before and after treatment. The scale included a total of 10 items, with a score of 10 points for each item and with the score ranging from 0 to 100 points. The activities of daily living were divided into three levels—good, moderate, and poor—according to the Barthel Index score, where >60 is good with mild dysfunction, 41–60 with moderate dysfunction, and ≤40 poor with severe dysfunction.

Indicators of brain injury

The indicators of brain injury were preoperative and postoperative serum levels of neuron-specific enolase (NSE) and astrocyte-derived protein (S100β).¹⁰ The processes were as follows: 3–5 mL of blood were drawn from the cubital venous of the patient just before treatment and at 24 hours after treatment and these were then centrifuged and stored in a refrigerator at –30°C. NSE and S100β were both detected by double-antibody sandwich ELISA.

The detection reagents were purchased from Shanghai Hengyuan Technology Company.

The Hunt and Hess Scale

Grade 1 is described as asymptomatic or minimal headache and slight neck stiffness with a predicted 70% survival rate.

Postoperative complications

Postoperative complications included cerebral hernia, intracranial infection, and pneumonia. Whether it was associated with a cerebral hernia was comprehensively judged according to changes in patients' consciousness, existence of unilateral and pupillary dilatation, diminished or absent light reflex, and imaging characteristics.

Follow-up

All patients were observed for recurrence and rerupture of intracranial aneurysm for at least 12 months after the operation. Recurrence of intracranial aneurysms was defined as follows: compared with the original aneurysm, the tumors and the residual parts of the neck were larger than those before treatment, and there was a contrast end leak and the new aneurysms at other sites were excluded. Rerupture of aneurysm met the following criteria: exposed contrast medium was found during intraoperative coil placement, or increased bleeding was shown on postoperative imaging examination or confirmed by craniotomy or angiography.

Statistical analysis

All the data collected in this study were analyzed by SPSS V.22.0 software. Normally distributed measurement data were expressed as mean \pm SD and comparisons were examined by a Student's t-test. Non-normally distributed measurement data were expressed as median (IQR) and comparisons were examined by Wilcoxon test. One-way analysis of variance was used for comparison between multiple groups. Categorical data were expressed as n (%) and differences between the two groups were examined by χ^2 analysis. Correlation analysis was performed using Spearman's correlation coefficient. Statistical significance level was set at 0.05 for a two-sided test.

RESULTS

Baseline characteristics

A total of 130 patients with MCABAs were prospectively enrolled in this study. Patients in the study group were 25–67 years old, with an average age of 48.93 ± 8.91 years old, with 19 men and 46 women. Patients in the control group were 26–68 years old, with an average age of 48.89 ± 8.45 years old, with 18 men and 47 women. Of the 130 patients, 105 had single aneurysms and 25 had multiple aneurysms. Of the patients, 21 had two aneurysms and 4 had three aneurysms. In the study group, 12 patients were treated with the spin-coil embolization technique, 9 patients were treated with balloon-assisted neck remodeling surgery, 8 patients were treated with micro-assisted neck plasty, and 7 patients were treated with stent-assisted coil embolization of aneurysms. Gender, age, left/right side, smoking history, hypertension history, Glasgow Coma Scale (GCS) score, and outcome of the modified Fisher classification were comparable in the two groups ($p>0.05$) (table 1).

Comparison of GOS grading

The proportion of GOS grade 1 after treatment in the study group was significantly higher than in the control group ($p<0.001$). The proportion of GOS grades 2, 3, and 4 after treatment in the study group was significantly lower than in the control group ($p_2=0.024$, $p_3=0.001$, $p_4=0.012$) (table 2).

Comparison of activity ability

There were no significant differences in the life activity score of patients before treatment ($p>0.05$). The postoperative life activity score of patients in the study group was significantly higher than in the control group ($p<0.001$) (table 3).

Comparison of indicators of brain injury

There were no significant differences in serum levels of NSE and S100 β before treatment ($p>0.05$). The postoperative serum level of NSE in the study group was significantly lower than in the control group ($p<0.001$). The postoperative serum level of S100 β in the study group was significantly lower than in the control group ($p<0.001$) (table 3).

Comparison of postoperative hospital stay and complications

The postoperative hospital stay of patients in the study group was significantly shorter than in the control group ($p<0.001$). The incidence rate of postoperative pulmonary infection in the study group was significantly lower than in the control group ($p=0.002$). The incidence rate of postoperative intracranial infection in the study group was significantly lower than in the control group ($p<0.001$). There was no significant difference in the incidence of brain herniation between the two groups ($p=0.730$) (table 4).

Comparison of results of follow-up

All patients were followed up for at least 12 months, with an average follow-up time of 13.24 ± 1.03 months. The results of imaging re-examination 1 year after operation were as follows: in the study group, there were five cases of aneurysm recurrence, with a recurrence rate of 7.7%, and no residual aneurysm neck existed; in the control group, there was one case of aneurysm recurrence and nine cases of residual aneurysm neck, with a recurrence rate of 1.5%, which is lower than in the study group ($p=0.104$).

DISCUSSION

Patients with unruptured MCABAs lack the typical clinical symptoms. When the size of the arterial ring increases, the nerves or blood vessels become compressed and then the effects of the mass occur. The incidence of intracranial aneurysm in the population is higher than that of subarachnoid hemorrhage. Therefore, in the management of unruptured intracranial aneurysms, it is essential to offer patients the best treatment option. Once the aneurysm ruptures, it induces severe symptoms of intracranial hemorrhage. Age, gender, and smoking history are all important factors associated with rupture of the intracranial artery.¹¹ Most of the ruptured MCABAs had the following characteristics: diameter of 7–14 mm, irregular wall shape,

Table 1 Patient characteristics

Patient characteristics	Study group (n=65)	Control group (n=65)	χ^2/t	P value
Age at treatment (years)	48.93±8.91	48.89±8.45	0.038	0.846
Female sex, n (%)	46 (71)	46 (72)	0.026	0.979
Left side, n (%)	33 (51)	34 (52)	0.031	0.861
Smoking history, n (%)	21 (32)	18 (28)	0.330	0.566
History of arterial hypertension, n (%)	48 (74)	51 (78)	0.381	0.537
Mean GCS score	14.01±1.23	14.92±1.19	−1.460	0.147
Hunt and Hess Scale, n (%)			0.135	0.713
Grade 0	43 (66)	41 (63)		
Grade 1	22 (34)	24 (37)		
Modified Fisher classification, n (%)				
Grade 0	21 (32)	17 (26)	2.757	0.599
Grade 1	9 (14)	6 (9)		
Grade 2	13 (20)	11 (17)		
Grade 3	15 (23)	13 (20)		
Grade 4	7 (11)	8 (12)		
Site of aneurysm, n (%)				
Posterior communicating artery	30 (46)	32 (49)	1.025	0.599
Middle cerebral artery	9 (14)	12 (18)		
Anterior communicating artery	26 (40)	21 (32)		
Shape of aneurysm, n (%)				
Cystic	41 (63)	43 (66)	0.836	0.841
Spindle	11 (17)	14 (21)		
Lobulated	12 (18)	9 (14)		
Multiple forms	21 (32)	23 (35)		
Diameter of aneurysm, n (%)				
<5 mm	41 (63)	40 (62)	0.537	0.764
5–15 mm	21 (32)	20 (31)		

GCS, Glasgow Coma Scale.

accompanied by asci, and height to width ratio greater than 1.¹² Ruptured aneurysms with a diameter <7 mm are also present in clinical presentations, which may be associated with a history of more than 5 years or an unstable growth.¹¹ Some authors believed that the rate of rupture of MCABAs accounts for the highest proportion, 38.0%–68.4%, of MCA aneurysms in clinical practice and the cause of the rupture may be related to the hemodynamic features of blood flow and the pressure distribution along the MCA.¹³ Compared with the distal MCA, MCA bifurcation is characterized by high pressure and strong shear force on the vessel wall and so the incidence and the rate of rupture of MCABAs are higher.

Table 2 Comparison of GOS grading

GOS grade	Study (n=65) n (%)	Control (n=65) n (%)	χ^2	P value
Grade 1	53 (82)	23 (35)	28.509	<0.001*
Grade 2	10 (15)	21 (32)	5.125	0.024
Grade 3	2 (3)	15 (23)	11.437	0.001*
Grade 4	0 (0)	6 (9)	6.290	0.012*
Grade 5	0	0		

*Difference is statistically significant at $p<0.05$.
GOS, Glasgow Outcome Scale.

Due to the complexity of aneurysm shape, location, and size in clinical practice, the decision for treatment of MCABAs has been controversial.^{14–15} One study¹⁶ reported that MCABAs treated with neurosurgical clipping had a complete occlusion rate of 98.3% and a postoperative complication rate of 5.3%, while endovascular treatment had a complete occlusion rate of 53.2% and a rate of postoperative cerebral ischemia of up to 10.4%. In another study, the proportion of patients with GOS grade 1 after endovascular treatment was 81.4%, while the corresponding proportion of patients in the neurosurgical clipping group was 50%.¹⁷ A study reported by Berro *et al*¹⁷ confirmed that endovascular treatment of intracranial aneurysms has the characteristics of being minimally invasive and particularly suitable for elderly patients. Another study¹⁸ demonstrated that the incidence of postoperative complications in patients with MCABAs treated with endovascular therapy was significantly lower than those treated with neurosurgical clipping (11.11% vs 32.35%). Surgical therapy is still linked to higher rates of immediate and long-term complete occlusion. There are now a variety of endovascular devices available, allowing for the best approach and treatment based on the patient's characteristics (age and comorbidities) and aneurysm morphology (neck size, shape, and dimension). The gap between the two techniques is narrowing. One meta-analysis¹⁹ suggested

Table 3 Comparison of activity ability and indicators of brain injury

	Study group (n=65)	Control group (n=65)	t	P value
Mean activity score				
Before treatment	43.59±4.29	44.83±4.02	-1.7	0.092
After treatment	73.29±6.39	66.94±5.98	5.85	<0.001*
Mean NSE, µg/L				
Before treatment	41.98±6.93	42.12±7.01	-0.115	0.909
After treatment	11.02±4.08	19.38±3.87	-11.986	<0.001*
Mean S100β, µg/L				
Before treatment	18.98±2.39	19.08±2.41	-0.238	0.812
After treatment	4.03±0.38	8.38±0.42	-61.92	<0.001*

*Difference is statistically significant at $p<0.05$.

NSE, neuron-specific enolase; S100β, astrocyte-derived protein.

that the coiling method had lower mortality, while another meta-analysis in the modern era²⁰ indicated that treatment-related complications and mortality were comparable between surgical clipping and endovascular coiling. Compared with surgery, the endovascular approach seems to increase the probability of good functional outcome after treatment. However, one original article²¹ showed that microsurgical clipping had a significantly higher technical success rate than endovascular treatment. In the mean time, the rate of major ischemic stroke and functional outcome were comparable between both groups. From anatomical considerations, aneurysms in the distal arterial segments are often not amenable to endovascular therapy,²² and surgical therapy may be preferred in these circumstances. Endovascular treatment is often the preferred technique for posterior circulation aneurysms, which are accessible by angiogram but harder to get to surgically.²³ Aneurysms at the MCA trifurcation are difficult to coil without complication and surgery may be preferred for these lesions. The treatment of wide-neck intracranial aneurysms is the most challenging either by neurosurgical or by endovascular approach. The main limitation of endovascular surgery for complex and wide-neck aneurysms has been the risk of recurrence and the risk associated with compromise of the parent artery and/or arterial branches incorporated in the neck of the aneurysm. Rapid technological advances in endovascular neurosurgery have shaped the treatment of intracranial aneurysms in the past three decades. Numerous devices, including remodeling balloons^{24–26} and stents,²⁷ have been developed to assist in the endovascular treatment of wide-neck aneurysms. However, perioperative antiplatelet treatment is mandatory to prevent instant

thrombosis, which is a major concern in patients with acute subarachnoid hemorrhage (SAH). One study suggests that temporary placement of the Solitaire AB stent during coiling was a feasible and effective treatment for acutely ruptured wide-neck aneurysms, which had a higher rate of adequate postoperative occlusion than standard coiling, with comparable safety,²⁸ and had the advantage to overcome antiplatelet therapy. This approach, which does not need preoperative antiplatelet medication, might be a beneficial option for treating such lesions when balloon remodeling is either not an option or fails.¹⁵ Treatment-related complications and mortality are comparable among these techniques and the risk of aneurysm rupture seems very low for all strategies. In comparison with surgery, the endovascular method appears to enhance the likelihood of a positive functional result after treatment.¹⁵ The current study showed that the proportion of postoperative GOS grade 1 in the study group was significantly higher than in the control group, suggesting that endovascular therapy can significantly improve the clinical efficacy of MCABAs compared with neurosurgical clipping. The improved prognostic effect of endovascular treatment may be due to the continuous advancement of endovascular embolization techniques and its own minimally invasive nature. In the current study, we found that the study group had shorter postoperative hospital stays and the rates of complications such as pulmonary and intracranial infections were lower than those in the control group, suggesting that the incidence rate of complications after endovascular treatment of MCABAs was low while the recovery rate was faster. However, the results reported by some authors²⁹ are different from the current results, indicating that the

Table 4 Comparison of results of follow-up

	Study group (n=65)	Control group (n=65)	χ^2/t	P value
Postoperative hospital stay (days)	17.65 (1.29)	23.0 (1.32)	-23.501	<0.001*
Pulmonary infection, n (%)	12 (18)	28 (43)	9.244	0.002*
Intracranial infection, n (%)	2 (3)	42 (64)	54.968	<0.001*
Brain herniation, n (%)	4 (6)	5 (8)	0.119	0.730

*Difference is statistically significant at $p<0.05$.

incidence of postoperative complications in the treatment of ruptured MCAs by neurosurgical clipping and endovascular interventional embolization is similar. This may be due to the different populations included in these studies. In addition, the results of the current study showed that the postoperative life activity score in the study group was significantly higher than in the control group, suggesting that endovascular treatment can improve the life activity of patients with MCABAs compared with neurosurgical clipping. This may be due to the reduced risk of complications, reducing the damage to the cranial nerve function, which is conducive to promoting early recovery and improving living ability.

NSE is an enzyme in neuronal cells which can indicate the degree of injury of nerve cells. When neuronal cells are injured, NSE will be released into the blood and the level of NSE in the serum will be significantly increased.³⁰ S100 β is a type of marker protein in the glial cell, which is mainly present in brain astrocytes. Serum levels of NSE and S100 β can reflect the extent of brain injury.³¹ There is a lack of studies on the detection of brain injury markers in patients with MCABAs by endovascular therapy. The postoperative levels of NSE and S100 β in the study group were lower than in the control group, as shown in the current study, suggesting that endovascular treatment has a better effect in protecting the cells of the brain tissue than neurosurgical clipping in patients with MCABAs. The reason for this phenomenon is that, on the one hand, endovascular treatment can achieve better hemostatic effect by mechanical tamponade and interfering with local hemodynamics, and on the other hand the endovascular treatment itself is minimally invasive, which can better reduce the occurrence of brain injury and protect the brain tissue during treatment, compared with neurosurgical clipping.

There is a constant risk of recurrence of intracranial aneurysms after endovascular treatment of MCABAs. Data³² show that the recurrence of intracranial aneurysms after embolization was closely related to the contraction and degeneration of the coiling, as well as the degree of embolization, location of aneurysm, and the materials. The current study reached similar results, in which the recurrence rate in the study group was higher than in the control group. International studies³³ suggested that stent-assisted coil double plug was beneficial to the forming of intracranial aneurysm thrombosis and could reduce the rate of recurrence of aneurysms. In addition, some authors believed that endovascular therapy is more suitable for complex unruptured MCABAs, with lower recurrence rate, but there is a risk of stent deformation, stenosis, and stent thrombosis in the long term.³⁴

The limitations of this study should be taken into account. One was that the patients included were strictly restricted, resulting in a small sample size, which affected the external validity of the conclusions of this experiment and thus may weaken the generalizability of the results. Other limitations included the lack of blinding, which may increase bias caused by subjective judgment, and the short-term follow-up, which may affect the prognosis and

postoperative functional results. Additionally, intraoperative and postoperative hemorrhagic/ischemic stroke were not studied, which may weaken the power of the conclusion.

In conclusion, endovascular therapy for MCABAs may be effective in improving patient outcomes and may have better safety profile compared with neurosurgical clipping, but may increase the risk of postoperative recurrence.

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Correction: *Efficacy and safety of endovascular therapy versus surgical clipping for patients with unruptured middle cerebral artery bifurcation aneurysms*

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