Efficacy and Safety of Willis Covered Stent for Treatment of Complex Vascular Diseases of the Internal Carotid Artery

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Background: Willis covered stents are used in clinical practice for some complex cerebrovascular diseases. However, the performance of the Willis covered stent requires further investigation. In this study, we investigate the safety and efficacy of Willis covered stents for the treatment of complex vascular diseases of the internal carotid artery (ICA).

Methods: Thirteen patients with complex ICA diseases treated with the Willis covered stent system at our institution from October 2016 to January 2018 were analyzed retrospectively. Follow-up observation and digital subtraction angiography (DSA) examination were conducted at about 6−10 months after the treatment.

Results: The complex vascular diseases of the ICA were successfully treated in 12 patients. The technical success rate was 92.3%. Pathologically, 13 lesions included blood blister-like aneurysm ($n = 7$), traumatic pseudoaneurysm ($n = 1$), traumatic carotid artery rupture ($n = 1$), and aneurysm with arteriovenous fistula ($n = 4$). Thirteen patients with complex vascular diseases of the ICA were treated with 15 Willis covered stents. The release sites of Willis covered stents were the C7 ($n = 2$), C6 ($n = 1$), C5 and/or C4 ($n = 9$), and the C2 ($n = 3$) segment of the ICA. DSA performed immediately after stent deployment revealed that complete occlusion of the lesion was achieved in 11 patients and endoleak was observed in 2 patients. Of the 11 patients, postoperative DSA examination indicated that the lesions were occluded completely. Among 2 patients, who had a second stent implantation at the break of the ICA, the traumatic ICA rupture was essentially completely obstructed in 1 patient. The endoleak remained in 1 patient with carotid cavernous sinus fistula because the placement of the second stent system was difficult with his ICA tortuosity. No recurrence of aneurysms, hemorrhagia, and other lesions was observed, and the patients' parent arteries were patent without stenosis. No procedure-related complications or deaths occurred during follow-up.

Conclusions: For the treatment of complex vascular diseases in the ICA, Willis covered stent implantation is safe and effective. However, longer follow-up, large-sample controlled studies, and multicenter studies are needed for further confirmation.

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INTRODUCTION

In this study, the term internal carotid artery (ICA) is used to represent the C1-C7 segments, according to the description of Bouthiller et al.[1] Complex vascular diseases of ICA should be extremely challenging for both routine endovascular treatment and surgical treatment, including blood blister-like aneurysm (BBA), pseudoaneurysm, large or giant aneurysm, and multiple aneurysms. They are associated with high complications and poor efficacy because of their unfavorable morphology and anatomic structure, as well as atherosclerosis. The current surgical strategies for complex cerebrovascular diseases include clipping, wrapping, trapping, clipping with wrapping, suturing, external carotid artery–internal carotid artery (EC-IC) bypass, or ligature of the ICA. However, the bony obstacles and important anatomic structures adjacent to the ICA, such as the cavernous sinus and optical apparatus, pose an enormous challenge for microsurgical treatment. Treatment with surgical methods is associated with intraoperative bleeding and postoperative regrowth rates of up to 23% and 8.3%, respectively.[2]

In recent years, endovascular methods have made some progress in the treatment of complex cerebrovascular diseases. Conventional endovascular methods include coil embolization, the Onyx liquid embolic system, bare stent, stent-assisted coil embolization, or stent-assisted Onyx liquid embolic agent. Nevertheless, with these methods, only 76.5% of patients achieved complete obliteration, while 18.4% of patients needed additional intervention.[3] Moreover, for recurrent aneurysm, reembolization results in a higher risk of coil herniation or thrombus running into the parent vessel, which may result in ischemic stroke.

Therefore, there is still no ideal therapeutic strategy to treat those diseases. One of the main advances is the use of the Willis covered stent, which has emerged as a promising therapeutic option in the management of complex cerebrovascular diseases. In 2006, Li et al.[4] first reported the use and technical aspects of Willis covered stents developed specifically for intracranial vasculature for the treatment of two pseudoaneurysms secondary to the successful exclusion of direct carotid cavernous fistula in the ICA. The Willis covered stent consists of three parts: a bare stent, an expandable polytetrafluoroethylene (ePTFE) membrane, and a balloon catheter. The bare stent is made from a strand of cobalt chromium super alloy wire, which is 0.06 mm in diameter. The wire is cut into a sinusoidal wave pattern using a laser. The whole body of the stent is radiopaque to facilitate precise placement. The ePTFE membrane is extremely thin and in a tubular configuration (30- to 50-μm thick). The delivery system is a rapid-exchange balloon catheter system with a working length of 145 cm. Willis covered stents with diameters of 3.0 to 5.0 mm and lengths of 7 to 19 mm are available.[5]

In recent years, covered stents have been applied more frequently in the treatment of various complicated cerebrovascular diseases of the ICA, with encouraging short-term to midterm clinical outcomes.[5,6] The mechanism of Willis covered stent results in immediate exclusion of aneurysms from the intracranial circulation, while preserving the patency of the parent artery. In addition, the Willis covered stent reconstructs the intracranial arterial wall and alleviates the mass effect.[6] Despite these advantages, the performance of the Willis covered stent requires further investigation. Data on the safety and efficacy with regard to complex vascular diseases in the ICA treated with the Willis covered stent remain inadequate.[7,8] In this study, we report our experience with and the efficacy and safety of the Willis covered stent in a retrospective analysis of 13 patients with ICA disease treated with this stent at our institution.

METHODS AND MATERIALS

Human Rights Statement

All the human studies in our program were approved by the ethics committee of Union Hospital, Huazhong University of Science and Technology. Written informed consent was obtained from all patients before endovascular procedures and related clinical data collection.

Patients

Between October 2016 and January 2018, a total of 13 cases were treated by implantation of the Willis covered stents at our institution, including BBA (Blood blister-like aneurysm often occurs in the unbranched part of the upper segment of the internal artery, which is small in size and is generally less than 10 mm in diameter. Its vascular wall is only an outer membrane, and there is a lack of elastic intima and middle membrane.) in 7 patients, traumatic pseudoaneurysm in 1 patient, traumatic carotid artery rupture in 1 patient, and aneurysm with arteriovenous fistula in 4 patients. Of the 13 patients, 4 were male and 9 were female, and the mean patient age was 51.1 ± 11.7 years (range, 17–64 years). The clinical manifestations were

Table I. Endovascular treatment, outcome, and follow-up data for 13 patients treated with Willis covered stents

Case no. /sex/age	Diagnosis	Clinical presentation	Location	Size (mm)	Stent size (mm)	Immediate angiographic result	Angiography months	Follow-up occlusion result	mRS score
1/F/57	BBA	Headache, vomiting	L,C5	5.7 × 4.8	4.0 × 10	Occlusion	6	Complete	0
2/F/54	BBA	Headache	L,C7	2.4 × 2.5	3.5 × 7.0	Occlusion	8	Complete	0
3/F/44	BBA	Headache	L,C4-C5	5.0 × 6.0	3.5 × 10	Occlusion	6	Complete	0
4/M/62	BBA	Headache	R,C4	2.4 × 3.7	3.5 × 7.0	Occlusion	9	Complete	0
5/F/49	BBA	Headache, vomiting	L,C6	8.7 × 9.4	3.5 × 10	Occlusion	10	Complete	0
6/F/60	BBA	Headache	L,C4	12 × 11	4.0 × 13	Occlusion	6	Complete	0
7/F/51	BBA	Headache	R,C7	3.5 × 4.4	4.0 × 10	Occlusion	6	Complete	0
8/M/17	Pseudotrauma	Epistaxis	L,C4-C6	3.5 × 10	4.0 × 16	Occlusion	6	Complete	0
9/M/44	Traumatic ICA rupture	Coma	L,C2		3.5 × 10 4.0 × 10	Occlusion	6	Complete	1
10/F/60	Aneurysm with AVF	Headache	R,C7 R,C2	2.5 × 3.0	4.0 × 10	Occlusion	8	Complete	0
11/F/54	Aneurysm with AVF	Proptosis	R,A2 L,C4-C5	2.0 × 3.0	3.5 × 10	Minimal endoleak	6	Minimal endoleak	1
12/F/48	Aneurysm with AVF	Proptosis bruit	L,C7 L,C4	3.2 × 4.0	3.5 × 10	Occlusion	6	Complete	0
13/M/64	Aneurysm with AVF	Bruit	R,C6 R,C4-C5	4.3 × 5.5	3.5 × 7.0 3.5 × 10	Occlusion	6	Complete	0

L, left; R, right; AVF, arteriovenous fistula.

headache caused by subarachnoid hemorrhage (SAH) in 8 cases, including Hunt and Hess grade I in 5 cases, grade II in 2, and grade III in one. The remaining patients were characterized by proptosis and/or intracranial bruit in 3 cases, epistaxis in 1 case, and coma in 1 case. Clinical and angiographic features of 13 patients are summarized in Table I. All subjects had no previous surgical procedures involving ICA C1—C7 segments.

Head computed tomography (CT) scanning is indispensable before the surgical procedure. Digital subtraction angiography (DSA) was performed in all patients after admission so that we could further confirm the diagnosis, the relationship between the lesions and the side branches, the collateral circulation of the cerebral vessels, and the degree of vascular tortuosity. Three-dimensional (3D) reconstruction DSA was performed to measure the diameter of the parent artery, the size of the aneurysm, and the width of the aneurysm neck.

Surgical Procedure

All operations were carried out under local anesthesia, except in 3 patients. A 6F long sheath (Cook Medical, Bloomington, IN, USA) was initially positioned into the diseased ipsilateral C1 segment of the ICA via a right femoral approach. Catheterization of the ICA was then performed using a 6F Neuron (Penumbra, USA) or Navien (ev3/Covidien, USA) guide catheter. A microguidewire of 300-cm length and 0.014-inch diameter (Transcend; Boston Scientific, USA) was navigated into the distal segment of the parent artery or other lesions with or without a microcatheter, using roadmap guidance. The Willis covered stent system™ that was developed by MicroPort® Medical Co. (Shanghai, China) was then advanced over the microguidewire, and the proximal and distal ends of the stent bridged the aneurysm orifice of the patent artery. According to the results of angiography and 3D reconstruction, we chose the proper stent. It is worth noting that the Willis covered stent must extend at least 2 mm beyond the neck of the aneurysm on both sides and 0.5 mm larger in diameter than the target artery. As to carotid cavernous sinus fistula, the covered stent was placed at the proper proximal and distal ends of the cavernous fistula point of the ICA along an exchange microguidewire. Multiple control angiograms were obtained during the procedure to confirm lesion orifice coverage by the stent. The stent was then deployed according to recommended pressure.

If the aneurysm orifice or fistula was not completely covered and an obvious endoleak was

observed, the balloon was reinflated to improve stent apposition and to eliminate the endoleak. If the endoleak persisted or worsened, another covered stent could be employed. However, no further treatment was conducted if angiography demonstrated only slow or slight endoleak under the assumption that spontaneous thrombosis would eventually occur over time. In addition, artery dissection or perforation, acute thrombosis, and stent migration were also recorded. Unenhanced head CT and neurological examinations were performed routinely after the procedure to exclude any intracranial hemorrhage or ischemic event. DSA is the golden standard for the diagnosis of cerebrovascular diseases, and it can clearly show the shape of aneurysms. In addition, CT angiography/magnetic resonance angiography images are blurred because of constructed defect caused by the stents.

Antithrombotic Regimen

Before the procedure, patients received dual antiplatelet therapy with oral aspirin (100 mg/day) and clopidogrel (75 mg/day) for 3 consecutive days or a loading dose of aspirin (300 mg) and clopidogrel (300 mg) for emergency operation patients before the operation. Furthermore, a 50 Units heparin bolus per kilogram of body weight was intravenously injected before stent insertion, and an additional 1000 Units bolus was added every hour to maintain heparinization. However, for patients with acute SAH, extraordinary precautions are required when using the double antiplatelet protocols because the use of aspirin and clopidogrel in patients with SAH could increase the risk of intracranial rebleeding. For these patients, the double antiplatelet medication should be administered through a nasogastric tube before the procedure.

After the procedure, low-molecular-weight heparin was subcutaneously injected at a dosage of 50 Units heparin bolus per kilogram of body weight/12 hours for at least 3 days, and nimodipine (20 mg) diluted in 30-mL saline was transfused intravenously to prevent intracranial vasospasm. Dual antiplatelet medication of clopidogrel 75 mg/day and aspirin 100 mg/day was maintained for at least 6 months after the operation to avoid thrombosis and in-stent stenosis in those patients whose intracranial lesions were completely excluded with stents. Thereafter, patients were instructed to follow a single antiplatelet (aspirin, 100 mg/day) regimen for at least 2 years. Blood pressure is one of the most important hemodynamic parameters. We keep the systolic blood pressure within 160 mm Hg, but not too low. The mean arterial pressure should be above 90 mm Hg to maintain enough cerebral perfusion pressure.

Clinical and Imaging Follow-up

Follow-up examinations including clinical and DSA examinations were performed after the procedure. Whenever neurological symptoms deteriorated, intracranial hemorrhage recurrence or acute stroke was suspected and head CT was conducted immediately. The modified Rankin Scale (mRS) was applied to evaluate the treatment outcomes during clinical follow-up. The status of the aneurysms or fistula was assessed by DSA to exclude the possibility of residual endoleak or shunt recurrence and in-stent stenosis during imaging follow-up. Angiography data were collected immediately after the procedure and reviewed by three experienced neuroradiologists.

Statistical Analysis

SPSS version 16.0 (IBM SPSS Software, USA) was used to perform the statistical analysis of the data. Continuous variables are presented as mean ± standard deviation. Categorical variables are presented as percentages.

RESULTS

Primary Procedural Results

Demographic data combined with clinical and DSA findings of the program are summarized in Table I. The ICA aneurysm or arteriovenous fistula treatment with covered stents was technically successful in 12 of 13 patients. The procedure was successful on the first time in 11 of 12 patients (representative images: Fig. 1). A case with traumatic ICA rupture was essentially completely obstructed after second stent implantation at the break of the ICA (Fig. 2). Another patient with aneurysm combined with carotid cavernous sinus fistula still had residual shunt after the first stent implantation. However, the second stent system in place was difficult with his ICA tortuosity.

Moreover, there were no procedure-related complications such as vessel dissection, vessel perforation, acute in-stent thrombosis, or stent migration. The head CT scans also showed that patients had no occurrence of evident intracranial hemorrhage or ischemic stroke immediately after the procedure.

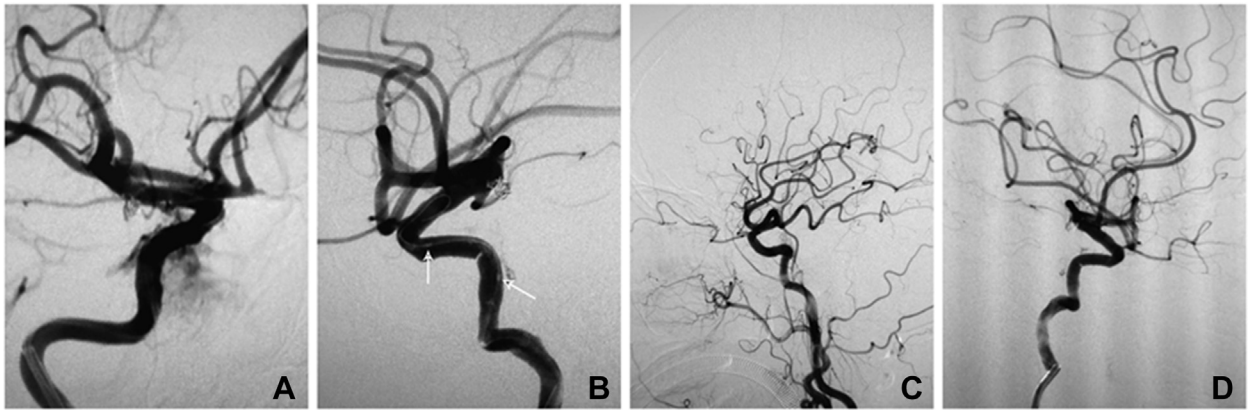

Fig. 1. A 60-year-old woman with a right arteriovenous fistula of the ICA. **(A)** Right ICA angiography shows anterior choroidal artery aneurysm and arteriovenous fistula of the ICA at the C2 segment, which steals the flow drained into the inferior petrosal sinus. **(B)** The Willis covered stent was successfully passed through the support catheter and precisely bridged the ostium of the fistula. The two markers at the proximal and distal ends of the Willis covered stent are shown by the *arrows*, which help us confirm the positioning of the covered stent. **(C)** Immediate angiography after deployment of the Willis covered stent showed occlusion of the fistula and preservation of the internal carotid artery. **(D)** Follow-up angiogram at 6 months showed the fistula was completely occluded.

Angiographic Follow-up Results

The follow-up results are presented in Table I. DSA data were obtained from 13 patients after a mean follow-up period of 6.8 ± 1.3 months (range, 6—10 months). One patient with aneurysm combined with carotid arteriovenous fistula, whose fistula was not totally occluded previously, showed no change. The other 12 patients with complete exclusion were stable. Overall, during the average follow-up periods, complete exclusion was achieved in 12 (92.3%) of 13 patients, and 1 patient maintained a minimal shunt. We found no recurrence or occlusion of the parent artery during the follow-up period in any patients.

Clinical Follow-up Results

Clinical follow-up data were collected from 13 patients. The follow-up period ranged from 3 to 15 months after the operation. No ischemic or hemorrhagic event was reported by any patient during the follow-up period. At the end of follow-up, no patient had aggravated symptoms. The mRS score at follow-up was 0 in 11 patients and 1 in two patients.

DISCUSSION

Conventional surgical procedures, such as clipping, wrapping, trapping, EC-IC bypass suturing, or ligature of ICA, have been used for the management of complex vascular diseases of the ICA, such as BBA, traumatic pseudoaneurysm, and aneurysm combined with carotid arteriovenous fistula.[9] However, these strategies tend to result in severe bleeding and even death intraoperatively.[10] One of the key reasons for the failure of surgical procedures is the limit of the morphology and structure of the aneurysm and arteriovenous fistula. In addition, the series of important structures around the lesion are also significant reasons.

Although the placement of coils (Axium; Medtronic, USA), detachable balloons (HyperGlide, Medtronic, USA), bare stents (LVIS; Microvention, USA), and Onyx liquid embolic system (Medtronic, USA) improves the success rate of aneurysm or carotid arteriovenous fistula embolization, it is still associated with some serious problems, such as a high recurrence rate and obvious mass effect.[7,8] Considering the drawbacks of surgery and embolization therapies, the use of Willis covered stents to achieve reconstruction of the parent artery in the treatment of complex vascular diseases of the ICA has evolved as one of most promising advances in recent years.[11,12] The emergence of Willis covered stents has completely changed the traditional concept of procedural manipulations in the aneurysm sac. Willis covered stents are intended to reconstruct the parent artery, and reconstruction is hypothesized to occur in such a way that the aneurysm or carotid arteriovenous fistula is isolated from

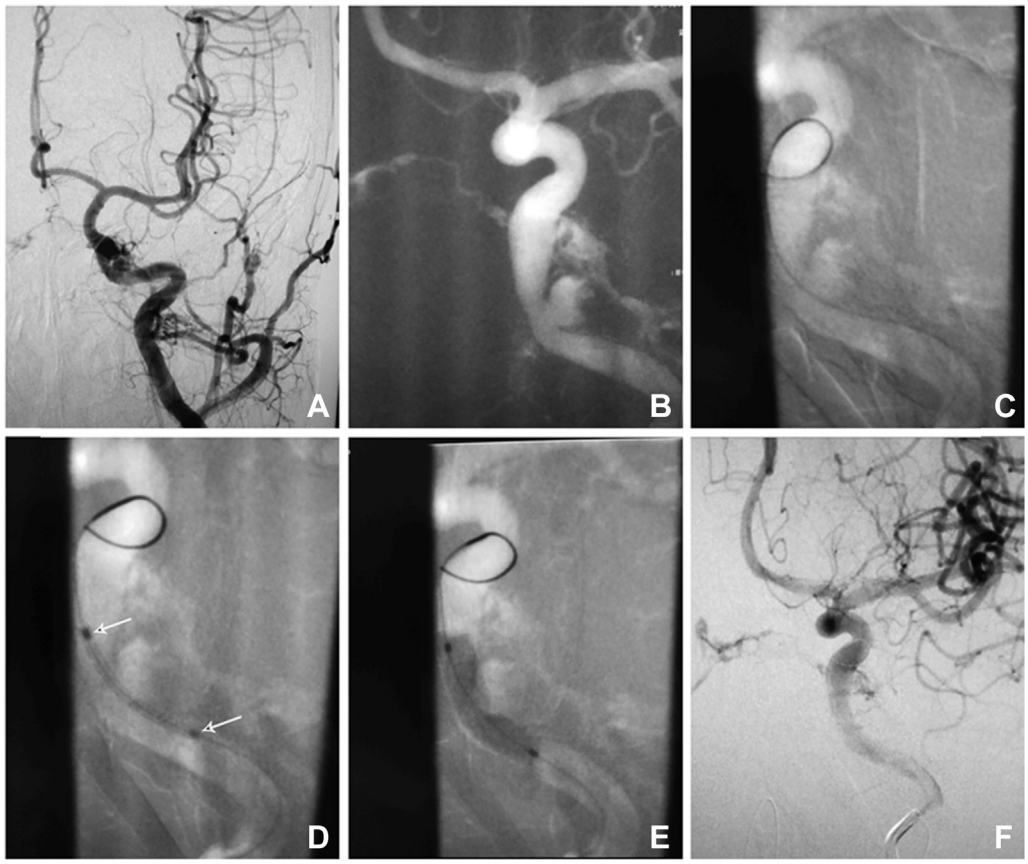

Fig. 2. A 44-year-old man with a left traumatic ICA rupture. **(A)** The preprocedural DSA image showed that a rupture was located at the C2 segment of the left ICA. **(B)** Three-dimensional (3D) angiography showed the relationship between the location of ICA rupture and the surrounding anatomy. **(C)** The microguidewire successfully passed through and reached the distal end of the lesion. **(D)** The Willis covered stent was successfully deployed, with proximal and distal ends (*arrows*) of the stent covering the ostium of the ICA rupture on both sides. **(E)** Balloon reinflation at the proximal and distal ends of the stent. There was residual shunt after balloon reinflation. **(F)** Cerebral angiogram immediately after the second stent deployment showed near-total occlusion of the ICA rupture with mild endoleak.

the flow, followed by intraaneurysmal thrombosis formation progressively or occlusion of the ostium of the fistula.

Isolation of the aneurysm or occlusion of the fistula ostium with the covered stent can result in immediate exclusion of the aneurysm from the circulation with none of the procedural manipulations occurring in the aneurysm lumen or fistula, which reduces procedure-related rupture or rebleeding. In addition, no or few embolization materials are deployed into the aneurysm sac, so the procedure does not cause mass effects or affect aneurysm shrinkage after complete exclusion.[13,14] Compared with surgical procedures, Willis covered stent placement is technically simple, and the procedure is swift, safe, and results in only a small wound. Arterial reconstruction with Willis covered stents is reliable, and recanalization and recurrence are less likely.[15] The greatest advantage of Willis covered stents is that they can achieve a true anatomical cure immediately and permanently exclude aneurysm and arteriovenous fistula from circulation.

In our series, 15 Willis covered stents were implanted into the target artery of 13 patients receiving endovascular treatment. Both the immediate angiographic results and the final angiographic follow-up results demonstrated complete exclusion in 12 patients, with patency of ICA in all 13 patients. The clinical follow-up demonstrated a full recovery in 11 patients and improvement in 2 patients. As shown in our results, the Willis covered stents have been proved to be safe and efficient for the treatment of complex vascular diseases. Giant

aneurysms, BBA, and pseudoaneurysm beyond the petrous segment of the ICA are difficult to embolize with coils. In addition, it is difficult to introduce a microguidewire into a sac microaneurysm. In these cases, the use of a Willis covered stent not only decreases the difficulty and risk of operation but also reduces the cost. Moreover, the artery beyond the petrous segment of the ICA is relatively straight.

Nevertheless, there are also some limitations in the clinical application of covered stents. They had a poor target arrival rate in passing the tortuous intracranial vasculature, especially in the siphon segment of the ICA. Because of this composition and construction, rigidity is a main shortcoming of this stent. Willis covered stents are not flexible or conformable enough to fully act in accordance with the configuration of the tortuous targeted arteries, leading to poor apposition of the stent to the vessel wall.[9] Therefore, the excessive tortuosity of the parent artery should be regarded as a contraindication to Willis covered stent.[16] The learning curve of this stent system is 200 cases of cerebral angiography and 50 cases of interventional surgery for cerebrovascular disease.

Endoleak

Although the Willis covered stent had a high rate of immediate aneurysm exclusion, endoleak remained a frequent issue. Endoleak, which is defined as persistent perfusion of the space between the stent graft and the parent vessel wall, is the most common procedural failure of endovascular repair. Endoleaks usually develop immediately after stent deployment and rarely during follow-up.

In our study, transient endoleaks were observed in 3 of 13 patients (23.1%) immediately after the first stent deployment. The proximal and distal parts of the stent were reinflated by balloon to eliminate the endoleak in one patient. Another two patients required deployment of additional graft stents. The endoleak in one of the patients disappeared after the second stent deployment (Fig. 2). However, a residual endoleak remained in the other patient because the second stent system in place was difficult because of the extreme tortuosity of the cerebral vasculature.

The potential causes of endoleak after deployment of the Willis covered stent included a size mismatch between the covered stent and the parent vessel, the nonhomogeneous lumen of the blood vessel, incomplete coverage of the aneurysm orifice, transient vasospasm, stent migration, and rupture of the covered membrane.[16,17] According to our experience, if immediate angiography showed only slow and slight filling of the aneurysm and minor endoleaks were not resolved by aggressive intervention at the time of the initial procedure, further observation could be an advisable choice, which might offer a chance for spontaneous occlusion of endoleaks with minimal slow residual filling. But this strategy may pose a higher risk of aneurysm rupture until the endoleak is completely occluded and the aneurysm lumen has completely thrombosed, especially in patients with acute SAH.

Therefore, angiographic follow-up was indispensable for monitoring changes in endoleak and aneurysm cavity thrombosis in those patients who had a minor endoleak after the procedure. It is also important to select a covered stent of adequate size based on the estimation of the size of the parent artery and the aneurysm.

Side Branch Occlusion

The major concerns about the covered stent placement in the cerebral vasculature are the closure of important side branches or perforating arteries stemming from the covered artery segment. This limits the application of this procedure to certain anatomic locations of the ICA, such as the most common C5-C7 segment, from which four common and critical side branches—the ophthalmic artery, anterior choroidal artery, the posterior communicating artery, and the superior hypophyseal artery—originate.

Some reports show that the ophthalmic artery can be sacrificed if necessary as reconstruction of the ophthalmic artery from the external carotid artery collaterals is possible.[8] However, Zhu et al.[17] reported an acute right-side visual loss caused by the covering of the right ophthalmic artery with covered stent, which might have been due to a deficiency in the compensation of lateral branches from the ipsilateral external carotid artery. The anterior choroidal artery primarily feeds the area of the optic tract, internal capsule, and cerebral peduncle.[18] Extreme caution should be taken not to cover the anterior choroidal artery origin when the covered stent is placed into the ICA. The posterior communicating artery can be sacrificed if necessary, in cases in which the vessel is not of the fetal-type posterior cerebral artery and there are no other fetal variations.[13] The superior hypophyseal artery is a complex of vessels that can vary in number from one to four. The arterial branches' anastomosis with hypophyseal artery branches arising from the other side and the posterior communicating arteries form a circum infundibulum network, which supplies the pituitary stalk, optic nerve, and chiasm. It

plays a very important role in the blood supply of the optic nerve. Serious visual impairment could be caused by the covering of the superior hypophyseal artery.[19]

In our series, the ophthalmic artery, anterior choroidal artery, and fetal-type posterior cerebral artery were not occluded by the covered stent, which may be attributed to appropriate case selection and careful evaluation of the location of the perforating arteries from multiple angles as well as the assistance of the two markers that point to the two ends of the Willis covered stent.

In-stent Stenosis

One of the most important and growing clinical long-term complications of stent graft placement is stent restenosis with increased stent implantation in intervention neurosurgery. The reported mechanism of in-stent stenosis includes inadequate stent expansion, chronic stent recoil, in-stent thrombosis, and neointimal hyperplasia. Neointimal hyperplasia is the main pathological basis for in-stent stenosis.[20]

Antiplatelet therapy has been demonstrated to play an essential role in the inhibition of in-stent neointimal hyperplasia.[21] Poor adherence to dual antiplatelet therapy after the procedure has been proven to be an independent predictor of in-stent stenosis.[22] Tan et al.[6] reported that in-stent stenosis was associated with the stent deployment pressure. A lower deployment pressure led to less endothelial injury, which has been thought to be closely related to neointimal growth and the incidence of in-stent stenosis. Zhu et al.[17] observed that a greater graft area of covered stents may inevitably increase the tissue hyperplasia reaction that tends to result in intimal hyperplasia. In this study, no patients showed in-stent stenosis or ICA occlusion, as confirmed by follow-up angiography. Possible reasons could be that all patients followed stringent dual antiplatelet therapy and appropriate cases were selected to implant stents.

Comparison with the Flow Diverts

In recent years, the clinical application of flow diverts such as Pipeline has been a major breakthrough in endovascular therapy of cerebral aneurysm. However, compared with the covered stent, some advantages and disadvantages exist. The complete aneurysm occlusion rate of using the Pipeline embolization device was lower than that of using a covered stent, especially for patients with acute SAH. Therefore, patients may run a higher risk of rehemorrhage after receiving subsequent antiplatelet treatment.[17] Flow diverts also run the high risk of side branch occlusion because of their high metal surface area coverage (approximately 30−35%), although this is much less likely than with a covered stent.[23] Because of the destabilization of the aneurysmal wall after flow diverts placement, the redirection of the aneurysm inflow jet, and an alteration of intraaneurysmal shear forces to new points, the aneurysm may rupture or grow again.[17] With regard to the cost, the Willis covered stent is cheaper than the Pipeline device.

Limitations

There were some limitations in our study. First, long-term follow-up and large-scale studies are relatively insufficient, so some complications such as regrowth, ICA occlusion, and in-stent stenosis cannot be adequately evaluated. Second, this study lacked a comparison group that received other treatments, such as coils embolization and surgical procedures. Third, our study was not a randomized controlled trial.

CONCLUSION

The treatment of patients with complex vascular diseases of the ICA by Willis covered stent placement resulted in satisfactory clinical outcomes. Willis covered stent can serve as a safe and effective solution for complex aneurysm and arteriovenous fistula of the ICA by reconstruction and preservation of the ICA. These findings need to be further confirmed by longer follow-up and controlled studies with larger samples.

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