



Endoleak management and postoperative surveillance following endovascular repair of internal carotid artery vascular diseases using Willis covered stent



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ABSTRACT

Background: To report the clinical results and experiences of endoleak management and postoperative surveillance following endovascular repair of internal carotid artery vascular diseases (ICAVDs) using Willis covered stents. **METHODS:** Seventy-three patients with ICAVD who received Willis covered stent implantation between November 2013 and September 2018 were retrospectively reviewed. The clinical data of endoleak management and postoperative surveillance were analyzed. **RESULTS:** Seventy-three cases with ICAVD, including 57 aneurysms, 11 carotid-cavernous sinus fistulas (CCF), and 5 surgical injuries, were all successfully installed with covered stents. Total isolation of ICAVDs was achieved in 59 patients (80.8%), and endoleaks were observed in 14 patients (19.2%). Of the 14 patients with endoleaks, 12 had type I endoleaks and 2 had type II; 13 had aneurysms and one had CCF. 10 patients with type I endoleaks received balloon dilatation, and 7 of them underwent a second stent-graft implantation after then. One patient with type II endoleak received embolization of the branch artery, and another one received follow-up observation. Endoleaks resolved in 6 patients and were minimal in 5 patients after balloon dilatation or the second stent implantation. During the follow-up period, minor endoleaks spontaneously resolved in 4 patients and minimal endoleaks were still demonstrated in 4 patients without enlargement of residual lumen and rupture. **CONCLUSIONS:** Endoleaks are the major complication after endovascular repair of ICAVDs and represent one of the limitations of this procedure. Improving the understanding and management of endoleaks can be beneficial in the clinical setting, including the popularization and application of this technique.

1. Introduction

Endovascular repair with Willis covered stents have been widely performed for internal carotid artery vascular diseases (ICAVDs), including aneurysms, carotid-cavernous sinus fistula (CCF), and surgical injury, and preliminary results indicate good flexibility and efficacy.^{1–5} Endoleak development is a major complication of endovascular repair of vascular wall injuries and diseases, which indicates failure to completely isolate diseases; this limits the application of endovascular repair.^{4,6} Therefore, effective endoleak management and postoperative surveillance after endovascular isolation treatment become necessary. The detection and management of endoleaks after endovascular repair of abdominal aortic aneurysms and thoracic aortic aneurysms have been

documented.^{7–12} However, no study has exclusively investigated endoleak management for endovascular repair of ICAVDs with covered stents. In the current study, we performed a retrospective analysis of endoleak management and postoperative surveillance following endovascular repair of ICAVDs treated with Willis covered stents in our institution to elucidate the outcomes and prognosis.

2. Materials and METHODS

Ethical approval The study was approved by the ethics committee of Shanghai Tongji Hospital, Tongji University School of Medicine. All clinical practices and observations were conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from each

Abbreviations: ICAVDs, internal carotid artery vascular diseases; CCF, carotid-cavernous sinus fistulas; SAH, subarachnoid hemorrhage; mRS, modified Rankin scale; WCS, Willis covered stent; BD, balloon dilatation.

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Table 1
Clinical variables of the 73 patients with ICAVDs treated by endovascular repair with Willis covered stent.

Variables	Values
Sex	
Male	32
Female	41
Median Age	64 (19–75)
Location in ICA	
Supraclinoid	19
Clinoid	20
Cavernous	18
Lacerum	16
Pathology	
Aneurysm	57
Aneurysm morphology	
Cystic aneurysm	45
Pseudoaneurysm	9
Dissection	3
Aneurysm size	
<3 mm	14
3–10 mm	24
>10 mm	19
CCF	11
Traumatic	9
Spontaneous	2
Vascular wall injury	5
Clinical Manifestation	
SAH	22
Epistaxis	9
Headache	12
Decreased visual acuity/Diplopia	15
Pituitary dysfunction	2
Pituitary operation related hemorrhage	3
Paranasal sinus operation related hemorrhage	5
Exophthalmos/Conjunctival congestion	11
Tinnitus	6
Strategy	
Covered stent	48
Double covered stent	3
Covered stent plus coils	18
Double covered stent plus coils	4
Outcome	
Complete occlusion	59 (80.8%)
Endoleak	14 (19.2%)
Endoleak Type	
Type I	12
Type II	2
Endoleak Causes	
Poor stent adherence	7
Stent-graft injury	1
Covered stent displaced	2
Insufficient overlap	2
Back flow from the branch vessel	2
Angiography Follow-up	69
Complete occlusion	65
Endoleak	4
Type I/P	3
Type I/D	1
mRS	
0–2	72
>2	1

ICA, internal carotid artery; CCF, carotid-cavernous sinus fistulas; SAH, subarachnoid hemorrhage; Type I/P, blood flow from stent proximal site; Type I/D, blood flow from stent distal site; mRS, modified Rankin Scale.

patient before the study was conducted. Written informed consent was obtained from all patients for publication of these case reports and any accompanying images.

2.1. Patients

Seventy-three patients who presented with ICAVD and were treated with Willis covered stent implantation between November 2013 and September 2018 were retrospectively reviewed. Seventy-three cases with

ICAVD included aneurysms in 57 patients, CCF in 11 patients, and skull base surgical injuries in five patients. The clinical and preliminary radiological data of 57 of these 73 patients have been reported previously. 4 Of the 73 patients, 32 were men and 41 were women, and their age ranged from 19 to 75 years (mean 64 years). The demographic and clinical data of the 73 patients are summarized in [Table 1](#).

At presentation, the clinical manifestations were subarachnoid hemorrhage (SAH) in 22 cases (ruptured aneurysms in 19, pituitary operation-related hemorrhage in three), epistaxis in nine cases (nasopharyngeal carcinoma radiotherapy in four, traumatic injury in two, paranasal sinus operation-related hemorrhage in three), headache in 12 cases, visual defect and/or diplopia in 15 cases, pituitary endocrine abnormalities in two cases, exophthalmos/conjunctival congestion in 11 cases, and tinnitus in six cases. Of the 57 aneurysms, 45 were saccular aneurysms, nine were pseudoaneurysms, and three were dissection aneurysms. Of the 11 CCF cases, nine were traumatic and three were spontaneous.

2.2. Endoleak-Type classifications

According to the source of blood flow causing the leak, the endoleak-type intracranial aneurysms after deployment of the covered stent are classified as types I to IV.^{7,8} Type I endoleaks result from blood flow that originates from the proximal (type Ia) or distal (type Ib) endograft attachment sites. Type II endoleaks represent retrograde blood flow through the branch artery at the membrane-covered area into the aneurysm sac. Type III endoleaks occur when there is a structural failure of the stent graft, which includes stent-graft fractures, holes that develop in the fabric of the device, or disconnection of the graft compounds, resulting in direct blood flow endoleaks. Type IV endoleaks are caused by the stent-graft porosity.

2.3. Endovascular procedures

All patients were treated with endovascular isolation under general anesthesia. According to the characteristics of vascular disease, different strategies of endovascular repair treatment were performed, including single covered stent implantation, double covered stent implantation, and covered stent plus coils, which are summarized in [Table 1](#). In principle, a single covered stent was used first, and then a double-covered stent or covered stent plus coils would be considered when the width of the aneurysm neck was greater than 12 mm or the aneurysm crossed the bend section, in order to decrease the incidence of endoleak. The strategy selection was as follows:

2.4. Conventional technique

A 6-Fr long sheath (Cook, Bloomington, USA) or an 8-Fr guiding catheter (Envoy, Codman Neurovascular, USA) was initially positioned into the cervical segment of the ICA via the right femoral artery approach. A 6-Fr Neuron (Penumbra, Alameda, California, USA) or Navien (Ev3/Covidien, USA) support catheter was advanced approximately to the target lesion. A 300- or 205-cm-long and 0.014-inch diameter micro-guidewire (Transcend, Boston Scientific, USA) was navigated into the distal segment of the parent artery. The Willis covered stent (MicroPort, Shanghai, China) is available in various diameters (3.5–4.5 mm) and lengths (7–16 mm). The selected stent should be 0.5 mm wider at most in diameter than the target artery and at least 4 mm longer than the lesion neck. Under the guidance of the roadmap, the stent was advanced over the micro-guidewire and bridged the lesion orifice. Multiple control angiograms were obtained to confirm the position of the stent and to avoid covering any important side branch. The stent was deployed at 5–6 atm pressure. Angiography was performed immediately after deflation of the balloon to confirm the correct placement of the stent and satisfactory occlusion of the lesion.

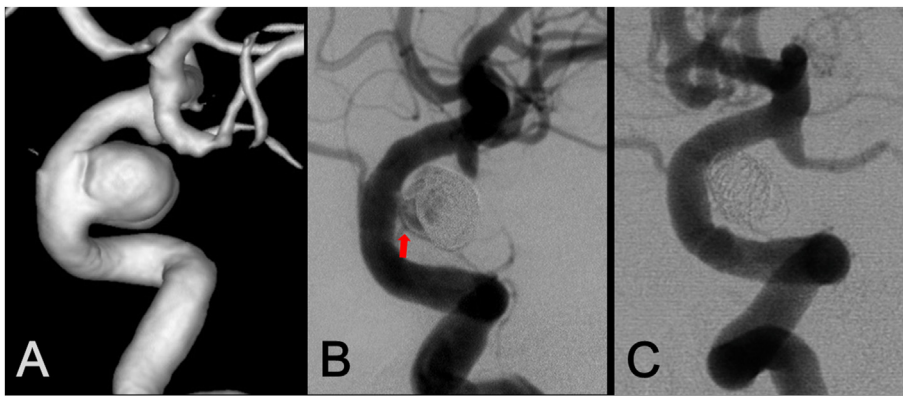


Fig. 1. A large aneurysm on the clinoid segment of the internal carotid artery treated with the Willis covered stent plus coils. (A). Pre-procedural three-dimensional rotational view shows a large (10.0mm×9.0mm) aneurysm on the clinoid segment of the internal carotid artery. (B). Cerebral angiogram immediately after stent-assisted coil embolization shows near total occlusion of the aneurysm with mild endoleak (indicated by arrow). (C). Eighteen-month follow-up DSA image shows complete disappearance of the aneurysm with patency of the parent artery.

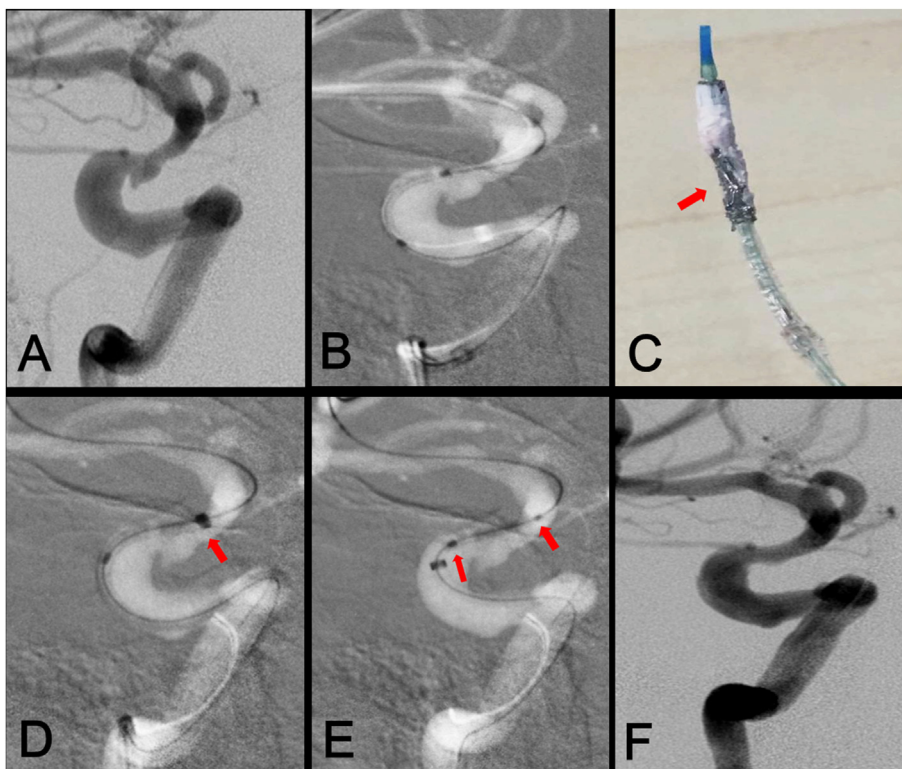


Fig. 2. Navigation of the Willis covered stent with a support catheter. (A). The pre-procedural digital subtraction angiography (DSA) image shows a dissecting aneurysm on the ophthalmic segment of the internal carotid artery (ICA). (B). A support catheter (Navien) is positioned in the cavernous segment of the ICA. (C). Willis covered stent is damaged during the navigation process because of the tortuous vessel (arrow). (D). The support catheter exceeds lesion location (indicated by arrow). (E). The Willis covered stent is successfully passed through the support catheter and precisely bridge the location of the aneurysm (arrows). (F). Immediate post-procedural angiography shows exclusion of the aneurysm.

2.5. Special operation

¹ For large (10–25 mm) or giant (>25 mm) aneurysms, or lesions located in curved segments or closely related to the perforating vessel, before the covered stent is deployed, coils could be inserted into the cavity through another microcatheter (Fig. 1).² If the lesion location beyond the cavernous segment or the parent artery was seriously tortuous, the support catheter (Neuron or Navien) should be pushed across the segment of the lesion by the coaxial technique, then the stent was pushed through the support catheter to the correct position and the support catheter was pulled back to reveal the covered stent, which would avoid membrane damage of the stent during the delivery process (Fig. 2).³ After covered stent deployment, if angiography demonstrated an endoleak that originated from the proximal or distal endograft attachment sites, the proximal or distal end should be dilated with the balloon again (Fig. 3), or implanted with another covered stent. If immediate angiography demonstrated only slow and slight filling of the aneurysm, balloon post-dilation could be avoided, and further

observation could be a better choice (Figs. 1 and 4)⁴; endoleak could result from the backflow from the branch vessel at the membrane-covered area (type II), such as the posterior communication artery, which has traffic compensation with the posterior circulation artery. If a covered stent was implanted in the supraclinoid segment, vertebrobasilar arteriography was performed. Once the type II endoleak occurs, embolization of the branch artery with coils can be considered (Fig. 5).

2.6. Antithrombotic treatment

Before the procedure, patients with unruptured aneurysms or CCF were treated with daily doses of 100 mg of aspirin and 75 mg clopidogrel for at least 3 days, and then a thromboelastogram was used to confirm the patients' nonresistance to aspirin and clopidogrel. For urgent operations, such as SAH, hemorrhage, and epistaxis caused by ruptured aneurysms, pseudoaneurysms, or vascular wall injuries, a loading dose of 300 mg clopidogrel and 300 mg aspirin was administered through a nasogastric

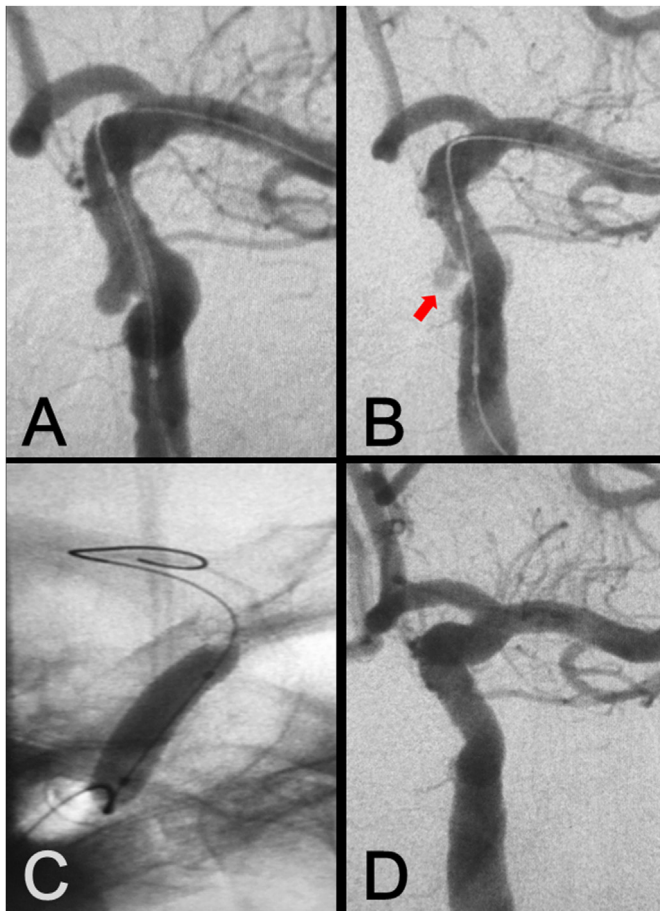


Fig. 3. Balloon post-dilatation for type I endoleak. (A). Digital subtraction angiography (DSA) image shows an aneurysm on the ophthalmic segment of the internal carotid artery. (B). Immediate post-procedural angiography shows an endoleak that originated from the proximal endograft attachment site (arrow). (C). The proximal endograft attachment site is dilated with the balloon again. (D). Endoleak is eliminated after balloon post-dilatation.

tube before the procedure. All patients received systemic intravenous heparin during the procedure, maintaining an activated clotting time between 250 and 300 s. During the procedure, tirofiban was infused intravenously with a bolus dose of 10 ug/kg, followed by an intravenous infusion at a rate of 0.15 ug/kg/min for 48 h to prevent acute thrombosis or thromboembolism. After the procedure, the patients were instructed to take the dual antiplatelet regimen for 6 months, and aspirin alone was continued for at least 2 years.

2.7. Angiographic and clinical follow-up

Angiographic and clinical follow-ups were scheduled at 3 and 6–12 months after the endovascular procedure, and annually thereafter. Any deterioration in neurological symptoms necessitated the patient to return to the hospital, and a brain CT or MRI was performed if necessary. The modified Rankin Scale (mRS) was used to evaluate the clinical status of the patients. The status of the lesion was assessed by DSA to exclude the possibility of residual endoleak, aneurysm regrowth, and in-stent stenosis. Data from the initial and final angiographic results and clinical outcomes were retrospectively collected and analyzed by two authors in consensus (C. F and H-Q. T).

3. RESULTS

3.1. Primary procedural results

Seventy-three cases with ICAVD, including 57 aneurysms, 11 CCF, and five surgical injuries, were successfully installed with covered stents. Among the 73 patients who underwent endovascular repair of ICAVD, 48 patients received single covered stent implantation, three patients underwent double covered stent implantation, 18 patients received single covered stent implantation plus coil embolization, and four patients underwent double covered stent implantation plus coil embolization.

Immediately, total isolation of ICAVDs was achieved in 59 patients (80.8%), and endoleaks were observed in 14 patients (19.2%), including mild residual filling of the aneurysm in seven patients (intraluminal retention of contrast media). Of the 14 patients with endoleaks, 12 had type I endoleaks, two had type II endoleaks, 13 had aneurysms, and one had CCF. Ten patients with type I endoleaks underwent balloon repositioning, and seven of them simultaneously underwent a second stent-graft implantation. One patient with type II endoleak had embolization of the branch artery, and another patient underwent follow-up observation. Endoleak resolved in six patients and was minimal in five patients after balloon dilation or after the second stent implantation. Demographic data and angiographic and clinical findings of all patients are summarized in [Tables 1 and 2](#).

3.2. Angiographic and clinical follow-up results

The mean follow-up period was 9 months (range 6–24 months). Follow-up angiographies were performed in 69 patients, complete exclusion of the aneurysms was observed in 65 patients, minor endoleaks spontaneously resolved in four patients, and minimal endoleaks were still demonstrated in four patients; however, enlargement of the residual lumen and rupture occurred in one patient. Sixty-four patients showed good parent artery patency, while the other five patients showed mild to

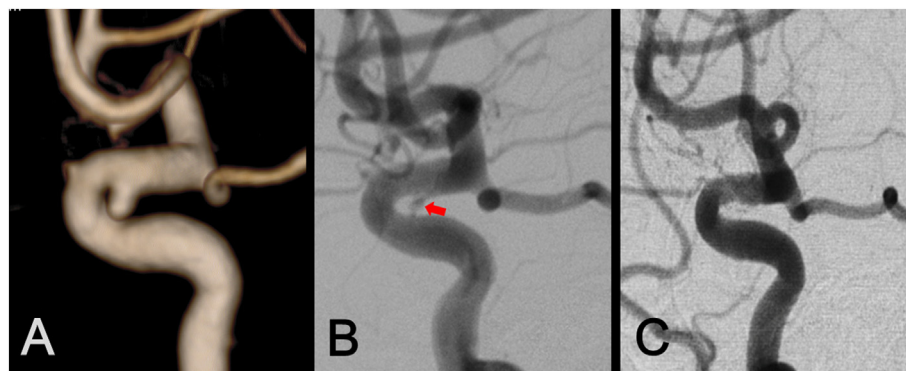


Fig. 4. Follow-up observation for minor endoleak. (A). Digital subtraction angiography (DSA) image shows an aneurysm on the ophthalmic segment of the internal carotid artery. (B). Immediate post-procedural angiography shows a minor endoleak that originated from the distal endograft attachment site (arrow). (C). Twelve-month follow-up DSA image shows disappearance of endoleak.

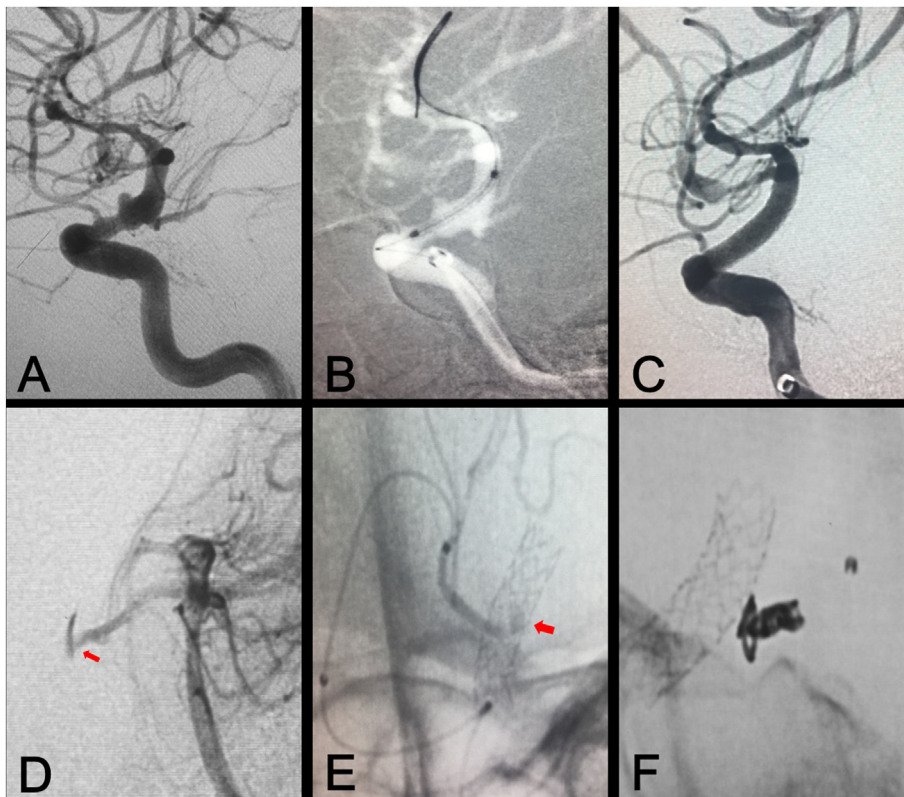


Fig. 5. Embolization of branch artery for type II endoleak. (A). Pre-procedural digital subtraction angiography (DSA) image shows an aneurysm on the ophthalmic segment of the internal carotid artery (ICA). (B). A Willis covered stent is positioned at the location of the aneurysm. (C). Immediate post-procedural angiography shows exclusion of the aneurysm. (D, E). Vertebral arteriography shows that contrast agent displays on the outside of the stent, representing a type II endoleak resulting from the backflow from posterior communication artery (arrows). (F). Embolization of posterior communication artery with coils.

Table 2
Endovascular treatment and follow-up results of 14 patients with endoleak.

Case no	Age (y)	Disease category	Disease status		Treatment strategy	Endoleak type	Endoleak treatment	Outcome	Follow-up	
			Size (mm)	Location					Time (months)	Endoleak outcome
1	50s	Aneurysm/SAH	3.0 × 2.5	Supraclinoid	WCS	Type I/D	Observation	–	12	None
2	50s	Aneurysm	2.5 × 3.0	Clinoid	WCS	Type I/D	BD + WCS	Disappeared	12	None
3	30s	Aneurysm	10.0 × 9.0	Clinoid	WCS + Coils	Type I/D	Observation	–	18	None
4	60s	Aneurysm/SAH	6.0 × 7.5	Supraclinoid	WCS + Coils	Type I/D	BD	Disappeared	12	None
5	40s	CCF	–	Clinoid	WCS	Type I/P	BD + WCS	Diminished	9	Slight
6	50s	Aneurysm/SAH	9.0 × 7.0	Cavernous	WCS + Coils	Type I/D	BD + WCS	Disappeared	18	None
7	60s	Aneurysm/SAH	8.0 × 12.0	Supraclinoid	WCS + Coils	Type I/P	BD + WCS	Disappeared	9	None
8	50s	Aneurysm	3.0 × 4.5	Cavernous	WCS	Type I/D	BD	Disappeared	12	None
9	20s	Aneurysm	9.0 × 7.5	Cavernous	WCS	Type I/P	BD + WCS	Diminished	15	Slight
10	20s	Aneurysm	16.0 × 18.0	Lacerum	WCS	Type I/D	BD + WCS	Diminished	7	Slight
11	60s	Aneurysm	8.0 × 12.0	Clinoid	WCS + Coils	Type II	Observation	–	8	None
12	40s	Aneurysm/SAH	3.0 × 2.0	Supraclinoid	WCS	Type I/D	BD	Diminished	12	Slight
13	50s	Aneurysm/SAH	2.0 × 2.0	Supraclinoid	WCS	Type II	Branch vessel embolization	Disappeared	9	None
14	40s	Aneurysm	18.0 × 20.0	Clinoid	WCS + Coils	Type I/D	BD + WCS	Diminished	9	None

Y, year; SAH, subarachnoid hemorrhage; CCF, carotid-cavernous sinus fistulas; WCS, Willis Covered Stent; Type I/P, blood flow from stent proximal site; Type I/D, blood flow from stent distal site; BD, balloon dilatation.

moderate asymptomatic in-stent stenosis. Telephone follow-ups were conducted for the remaining patients. During the follow-up period, no

ischemic or hemorrhagic events were reported by any of the patients. The mRS score at follow-up was 0–2 in 72 patients and 3 in one patient.

4. Discussion

Endoleak is a common phenomenon in the isolation treatment with covered stents, which implies failure to exclude the diseases and carries a high risk of recurrence of lesions; thus, it has become a nonnegligible issue during endovascular repair of ICAVDs. Endoleak management and postoperative surveillance following endovascular repair of ICAVDs with covered stents have become essential. Generally, endoleaks are caused by incomplete occlusion of the disease orifice using the covered stent and can be classified into types I to IV according to the source of blood flow.^{7,8} There are various causes of endoleaks after deployment of the covered stent.^{6,13–15} The different types and causes of endoleaks determine different treatment strategies.

4.1. Classification of endoleak causes

The causes of endoleaks after deployment of the covered stent can be classified into three types, according to our experience as follows¹: vascular anatomy correlation: because of the tortuosity of the ICA, especially the siphon segment of the ICA, the balloon-dilated covered stent has poor vascular compliance, leading to poor adhesion and is prone to endoleak at the curved vessel, which usually results in a type I endoleak, and the ICA has many branches, such as the ophthalmic artery and posterior communication artery, which has traffic compensation with the external carotid artery and posterior cerebral artery. The backflow from the branch artery at the membrane-covered area could result in type II endoleaks (Fig. 5)²; device material correlation: fabric tears, graft disconnection, or disintegration of the fabric resulting from stent rubbing against the wall of the vessel during the delivery process may result in type III or IV endoleaks³; operation technique correlation: covered stent may fail to cover the whole lesion resulting from the stent size deviation and stent shifting during the process of release or balloon retracement, which may lead to type I endoleak.

4.2. Treatment strategy for endoleak

There are two treatment strategies for endoleaks after isolation treatment, immediate treatment and follow-up observation, depending on the following situations⁵: immediate treatment: stent failed to completely cover the lesion segment; anterograde blood flow endoleak from the proximal end of the stent or the direct endoleak from the damaged material of the stent (i.e., type III or IV endoleak),¹⁶ and no contrast agent was retained in the lumen at the late stage²; follow-up observation: the retrograde flow endoleak at the distal end of the stent; the contrast agent was retained in the lumen at the late stage or there was a slow and slight filling of the aneurysm lumen; in this group, minor endoleaks were spontaneously eliminated in four patients during the follow-up period.

For type II endoleak treatment, our experience is limited because of the limited number of cases. We report two cases of type II endoleaks caused by the posterior communication artery by traffic compensation with the posterior circulation artery and the ophthalmic artery by traffic compensation with the external carotid artery. With endovascular isolation treatment of thoracic and abdominal aortic aneurysms with covered stents, it is recommended that type II endoleaks should be treated immediately to prevent the risk of aneurysm rupture.^{9,17} However, we believe that if the blood flow of the endoleak is minimal, follow-up observation may be considered. In this study, one patient underwent embolization of the branch artery, and another underwent follow-up observation, and the endoleak eventually disappeared in both patients. Further controlled studies with larger samples and longer follow-up periods are needed to determine the most appropriate treatment for type II endoleaks. Moreover, it is suggested that endoleaks overlapped with double-covered stents usually need to be further observed because of the slow blood flow of this type of endoleak.

4.3. Strategy selections for endoleak control

Compared with previous studies, some new strategies were first used in this group to reduce and avoid the occurrence of endoleaks. The incidence of endoleaks decreased significantly and the lumen occlusion improved.^{6,18} The different types of endoleaks can be reduced and avoided by the following strategies¹: type I endoleak: carefully evaluate the size of the parent artery in order to select an adequate size of the covered stent; the inflation pressure should be maintained during the deployment procedure until full stent apposition, and negative pressure should be maintained while gently removing the balloon during the removal procedure; tension is added if the bending part is at the distal end of the lesion or tension is reduced if the bending part is at the proximal end of the lesion during the releasing period; if the endoleak originated from the proximal or distal endograft attachment sites, the proximal or distal site should be dilated again with balloon or implanted with another covered stent²; type II endoleak: delivery of a microcatheter towards the branch artery to embolize with coils; if the blood flow of endoleak is minimal, follow-up observation may be considered³; type III or IV endoleak: the coaxial technique should be considered if the lesion location beyond the cavernous segment or the parent artery is seriously tortuous, which could avoid fabric tears, graft disconnection, or disintegration of the fabric during the delivery process.

5. Conclusion

The successful use of endovascular isolation techniques for ICAVDs has improved the efficacy of some refractory and high-risk diseases. However, this technique also has some defects that are related to the existing materials and the anatomy particularity of the ICA. Improving the understanding and management of endoleaks could be beneficial in the clinical setting, including the popularization and application of this technique, although this still needs to be further confirmed by multi-center clinical research.

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Declaration of Competing Interest

The authors declare that they have no conflict of interest.

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