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Effect and safety of Tubridge flow diverter in the treatment of unruptured intracranial aneurysms

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Abstract

The effect and safety of the Tubridge flow diverting device are unknown in the treatment of intracranial aneurysms after optimization of the device, improvement in the deployment of the device, and accumulation of experience of using the device. This retrospective one-center study was performed to investigate the clinical effect and safety of the Tubridge flow diverting device in the treatment of unruptured intracranial aneurysms. Twenty-three patients with 33 unruptured intracranial aneurysms which were treated with the Tubridge device were retrospectively enrolled. The clinical data, endovascular procedure, complications, and follow-up were analyzed. Twenty-seven Tubridge devices were deployed to treat the 33 aneurysms, and the deployment was failed in 1 case, resulting in the success stenting rate of 96.3%. In 5 (15.2%) aneurysms, coils were loosely packed. Peri-procedural complications occurred in 2 patients (8.7%), including 1 procedure-related complication in which the distal end of a Tubridge device herniated into the aneurysm cavity. In another case, weakness of left upper limb occurred on the second day post procedure, with instent thrombosis being suspected, which was recovered after medication. No other complications occurred. Twenty-three (100%) patients had clinical follow-up 6 months later, with the mRS of 0 in 21 patients, 1 in 1, and 2 in 1. Five (21.7%) patients with 11 aneurysms underwent digital subtraction angiography at 6-month follow-up, with 8 aneurysms being completely occluded (Raymond grade I) and 3 aneurysms still visible (Raymond grade III). The Tubridge flow diverter may be safe and effective in the treatment of unruptured intracranial aneurysms with low perioperative complications and good follow-up outcomes even though multi-center and prospective clinical studies with a large size sample are still needed to validate these results.

Abbreviations: ICA = internal carotid artery, OKM = O'Kelly-Marotta, PED = pipeline embolization device.

Keywords: flow diverter; Tubridge; intracranial aneurysms; unruptured; complications

1. Introduction

With the development of treatment concept, flow diverting devices represented by the pipeline embolization device (PED, Medtronic, Irvine, California) have become an important alternative to conventional coil embolization in the treatment of unruptured intracranial aneurysms.[1–9] For large and giant aneurysms, the 5-year cure rate is more than 95% with the flow diverting device.[10] Recently, different flow diverting devices have been developed including the PED, the Surpass stent (Stryker Neurovascular, Kalamazoo, MI), the Flow-Redirection Endoluminal Device (MicorVention, Tustin, CA), and the Silk flow diverter (Balt Extrusion, Montmorency, France), which have been increasingly applied in over 50 countries.[11] With the capability to change aneurysm hemodynamics, these devices may improve the long-term efficacy, but the current reports of the clinical outcomes varied greatly, with the peri-procedural complication rates and aneurysm occlusion rates ranging 2.8% to 11% and 49% to 93.4%, respectively. The Tubridge flow diverting device is a braided self-expanding stent with flared ends (MicroPort, Shanghai, China) and is made of a nickel-titanium alloy, with the advantages of super-elasticity and shape-holding memory. The device has platinum-iridium radiopaque microfilaments which can improve visualization of the device during endovascular treatment.[11–15] The PARAT clinical trial investigating the clinical effect of the Tubridge device in managing large or giant unruptured cerebral aneurysms in multiple centers reported a 75.34% rate of complete aneurysm occlusion at 6 months of follow-up, which was significantly greater than that for stent-assisted coiling (24.53%).[11] The Tubridge device has different design concept, releasing manner, and sizes, and it may have different endovascular performance in treating intracranial aneurysms compaed with other flow diverting devices. However, no studies have currently been performed to investigate the effect of the Tubridge device in the management of intracranial aneurysms with different sizes ranging 2 mm up in the maximal diameter after optimization of

LL contributed equally to this work.

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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the device, improvement in the deployment of the device, and accumulation of experience of using the device. This study was thus conducted to investigate the effect and safety of the Tubridge device in the treatment of unruptured intracranial aneurysms greater than 2mm in diameter.

2. Materials and methods

This retrospective 1-center study was approved by the ethics committee of our hospital, and all patients had provided signed informed consent to participate. Between April 2018 and January 2019, patients with unruptured intracranial aneurysms treated with the Tubridge device were enrolled. The inclusion criteria were patients with unruptured intracranial aneurysms which were confirmed by imaging examination and treated with the Tubridge device for at least 1 aneurysm. The exclusion criteria were patients with traumatic or infectious intracranial aneurysms, with severe parent artery stenosis, history of endovascular or surgical treatment of intracranial aneurysms, and combination of intracranial tumors or other diseases affecting management of intracranial aneurysms.

Five days prior to endovascular treatment, dual antiplatelet therapy was administered for every patient with clopidogrel (75 mg/d) and aspirin (100 mg/d). Thromboelastography was carried out to test the response of antiplatelet medications, and the dosage of medications was adjusted according to the test results. Under general anesthesia and heparinization, a T-track stent catheter (MicroPort) was sent to the distal segment of the parent artery, and a Tubridge device was selected and navigated to the right position before deployed. In the endovascular procedures with poor stent opening, prolonged procedural time, and thrombosis formation, Tirofiban was used intravenously with the initial injection dose of 5 μg/kg injected within 3 minutes before dripping in the dose of 0.05 $\mu g/kg^{-1}/min^{-1}$. After the endovascular treatment was finished, Tirofiban was continued for 24 to 36 hours, and clopidogrel (75 mg/d) and aspirin (100 mg/d) were administered in all patients for 3 months before long-term use of aspirin (100 mg/d).

The patient was followed up at the clinics or with digital subtraction angiography. The Raymond grading system was used to evaluate the embolization effect of the Tubridge device, and the clinical prognosis was assessed with the modified Rankin scale scores. The occlusion degree of aneurysm was assessed with the O'Kelly-Marotta (OKM) grading system,[16] which divided the aneurysm filling degree as: grade A – complete (>95%), B – incomplete (5%–95%), C – neck remnant (<5%), and D – no filling (0%).

2.1. Statistical analysis

The SPSS software was used for statistical analysis. The measurement data were presented as mean ± standard deviation, and enumeration data were presented as number and percentage.

3. Results

Twenty-three patients with 33 unruptured intracranial aneurysms met the inclusion criteria and were enrolled, including 7 male and 16 female patients, with an age range of 40 to 77 years (mean 60) (Table 1). Eight (34.8%) patients harbored multiple aneurysms and the other 15 (65.2%) patients had 1 aneurysm each. Fourteen (60.9%) patients experienced headache or dizziness, 3 (13.0%) had ischemic cerebral vascular diseases, and the other 6 (26.1%) patients were incidentally found. Twenty-eight (84.8%) aneurysms were located at the C4-C7 segments of the internal carotid artery (ICA), 4 (12.1%) at the V4 segment of the vertebral artery, and 1 (3.0%) at the petrous segment of ICA. Eighteen (54.5%) aneurysms were between 2 and 5 mm in size, 9 (27.3%) between 5 and 10 mm, and 6 (18.2%) greater than 10 mm. Twenty-eight (84.8%) aneurysms were saccular, and 5 (15.2%) were dissecting or fusiform.

Twenty-seven Tubridge devices were deployed to treat the 33 aneurysms (Figs. 1 and 2; Table 1), including 5 Tubridge devices with a 3.5 mm diameter, 5 with a 4.0 mm diameter, ten with a 4.5 mm diameter, 3 with a 5.0 mm diameter, 2 with a 5.5 mm diameter, 1 with a 6.5 mm diameter, and 1 with a 2.5 mm diameter. In 1 case with a 4-mm aneurysm at the tortuous paraclinoid segment of the ICA, the distal end of the Tubridge device (4.5 mm × 30 mm) herniated into the aneurysm cavity when the micro-guide wire was withdrawn (Fig. 1), and repeated attempts did not succeed in navigating the micro-guide wire into the distal segment of the parent artery, resulting in failure of correct deployment and the success rate of stenting of 96.3% (26/27). After the procedure, the case was treated with intravenous pumping of Tirofiban (6 mL/h) for 9 days. All the other cases had successful stenting. Eighteen aneurysms in 8 patients were also completely covered by the Tubridge devices. In 5 (15.2%) aneurysms, coils were loosely packed in the aneurysm cavity.

Peri-procedural complications occurred in 2 patients (8.7%), including 1 (4.3%) procedure-related complication in which the distal end of a Tubridge device herniated into the aneurysm cavity. The patient was conscious after the procedure, and the contralateral muscle strength was grades II to III. At 3-month follow-up, the patient remained conscious and walked independently. In another case (4.3%) with a 3.7 mm × 4.0 mm aneurysm at the ophthalmic segment of the right ICA, weakness of left upper limb occurred on the second day after the embolization procedure, with the muscle strength of grade II. Instent thrombosis was suspected, and Tirofiban of 10 mL was injected intravenously followed by intravenous pumping of Tirofiban at the dose of 6 mL/h. The muscle strength recovered within 24 hours after medication. No other complications occurred.

Twenty-three (100%) patients experienced clinical follow-up 6 months later, with the mRS of 0 in 21 (91.3%) patients, 1 in 1 (4.3%), and 2 in 1 (4.3%). Five (21.7%) patients with 11 aneurysms underwent digital subtraction angiography at 6-month follow-up (Fig. 2), with 8 (72.7%) aneurysms being completely occluded (Raymond grade I) and 3 (27.3%) aneurysms still visible (Raymond grade III). In thirteen (56.5%) more patients with 16 aneurysms who were followed up with digital subtraction angiography 11 to 22 (median 16) months after embolization, complete occlusion was achieved in 15 (93.75%) aneurysms and neck remnant was demonstrated in 1 (6.25%).

4. Discussion

In this study, it was found that the Tubridge flow diverter may be safe and effective in the treatment of unruptured intracranial aneurysms, with low perioperative complications and good follow-up outcomes even though multi-center and prospective clinical studies with a large size sample are still needed to validate these results. Compared with the Tubridge device used in the PARAT clinical trial,[11] the Tubridge device used in this study has been optimized in the delivery system, adherence ability to the arterial wall, and braiding structure, with expanded indications of intracranial aneurysms to include small aneurysms rather than just large wide-necked aneurysms. Moreover, cumulative experience in operating this device has greatly facilitated successful treatment of intracranial aneurysms. This is why we did this study and summarized the clinical effect and safety in applying this device.

In our study with 23 patients harboring 33 aneurysms, 27 (81.8%) aneurysms were less than 10 mm, and only 1 aneurysm with 4 mm in diameter failed the procedure. At 6-month angiographic follow-up of 5 patients with 11 aneurysms, 8 aneurysms were completely occluded. This indicated the advantage of the

Table 1

Clinical data and endovascular treatment.

Variables	Data
M/F	7/16
Age (yr)	40–78 (mean 60 ± 8)
No. of aneurysm	33
Patients with multiple aneurysms (n)	8 (34.8%)
Patients with 1 aneurysm (n)	15 (65.2%)
Clinical symptoms (n)	
Headache or dizziness	14 (60.9%)
Ischemic symptoms	3 (13.0%)
Incidentally found	6 (26.1%)
Aneurysm location (n)	
ICA C4-C7 segment	28 (84.8%)
Vertebral artery V4 segment	4 (12.1%)
ICA Petrous segment	1 (3.0%)
Aneurysm size (n)	
2–5 mm	18 (54.5%)
5–10 mm	9 (27.3%)
>10 mm	6 (18.2%)
Aneurysm morphology (n)	
Saccular	28 (84.8%)
Dissecting or fusiform	5 (15.2%)
Tubridge devices deployed (n)	27
Success rate of stenting	96.3% (26/27)
Tubridge deployed only	28 (84.8%)
Tubridge combined coiling	5 (15.2%)
Complications (n)	
Technique related	1 (4.3%)
Instent thrombosis	1 (4.3%)
Clinical follow-up time	6 mo
Follow-up mRS	
0	21 (91.3%)
1	1 (4.3%)
2	1 (4.3%)
Angiographic follow-up at 6 mo (n)	5 (21.74%)
No. of aneurysms	11
grade I	8 (72.7%)
Raymond grade III	3 (27.3%)
Angiographic follow-up at 11–22 mo (n)	13 (56.52%)
No. of aneurysms	16
Raymond grade I	15 (93.75%)
Raymond grade II	1 (6.25%)

mRS = modified Rankin scale score.

Tubridge device in treating small intracranial aneurysms, without the necessity of complex microcatheter shaping, complex operation with multiple microcatheters, or puncture of aneurysm wall leading to aneurysm rupture during endovascular operation.

In 1 case with a procedure-related complication, the causes were multiple. The anchoring distance of the Tubridge device was insufficient, and a sufficient anchoring distance should be ensured to prevent the braided stent to shorten proximally, especially in tortuous or curved arteries. The Tubridge device was relatively soft with weaker radial support force and could be easily affected or displaced by movement of micro-guide wires or microcatheters in tension. Inexperience in operating the flow diverting device was another factor, and with increasing experience, the technique-related complications would certainly be decreased with increased clinical effect.[17] Soft slow maneuver of the device could decrease relevant technique-related complications, and after the Tubridge device had been deployed, it was not necessary to pass a micro-guide wire or a microcatheter through the deployed stent to prevent possible stent displacement.

The effect of flow diversion is closely related to correct selection of the flow diverter.[18] The selection of appropriate diameter of the stent is very important. The closer the stent diameter is to the true diameter of the vessel, the easier it is to open and the better it will adhere to the wall. The expanding range of the Tubridge device is 0.5 mm, indicating that this device will have good wall adherence and flow diversion in arteries with the diameter equaling to the stent calibration diameter ±0.5 mm. Generally, the larger proximal diameter of the parent artery is used as the selection criteria, and the stent with a slightly smaller diameter can be chosen to cover the proximal artery. If the vascular condition is good and the neck of the aneurysm is not very wide, the stent with a smaller diameter can be selected. If the vascular condition is tortuous or the neck of the aneurysm is very wide (2 times larger than the diameter of the parent artery), a stent with a larger diameter can be selected in order to better anchor the stent. For the length of the Tubridge stent, both ends of the stent should have over 6 mm for anchoring after deployment, however, according to the actual experience, degree of tortuosity of blood vessels, and size of aneurysm neck, it will be relatively safe to ensure a 10 mm anchoring length at both ends. Especially when the aneurysm neck is very wide, the anchorage length of the distal end should be ensured because the stent will be shortened after the stent is fully expanded at the aneurysm neck. So, the total length of the stent should be chosen according to the proximal and distal anchoring length and the aneurysm neck size. It should be noted that when calculating the neck size of aneurysms with wide necks or of fusiform aneurysms, the stent will be significantly shortened when it is fully opened at the wide aneurysm neck, and it will be relatively safe if the stent length at the aneurysm neck is 1.5 times that of the neck actual size. For those who used the Tubridge stent in the early stage, it is better to use a longer rather than a shorter stent.

The release process of the Tubridge stent was completed by "pushing the stent" combined with "withdrawing the microcatheter." Our experience was to withdraw the microcatheter as the main method and to push the stent as the auxiliary method, so as to ensure that the catheter was located in the middle axis of the blood vessel or on the small bending side of the arterial curve. When approaching the proximal end, releasing part of the microcatheter tension will make the stent automatically spring open. Compared with the Pipeline device, the microcatheter should be reduced in tension during the process of releasing the Tubridge stent which is soft and has a certain degree of self-expansion. Compared with the low-profile visualized intraluminal support stent (MicroVention, Tustin, California), the Tubridge stent needs more pushing force to achieve good wall adherence because the Tubridge stent has more braided wires, greater pushing resistance, and marked shortening. The Tubridge device has a similar releasing process to that of the low-profile visualized intraluminal support stent but has good opening and wall adherence at vascular bends.

In our study, 1 patient had experienced an ischemic complication (4.3%), which was lower than 9.76% in the PARAT study.[11] This lower ischemic complication rate probably attributed to adequate antiplatelet therapy before the procedure, good wall adherence of the stent after deployment, and application of small doses of Tirofiban (6 mL/h) in pumping during and 24 to 48 hours after the procedure even if the preoperative thromboelastogram met the requirement. The use of Tirofiban will not increase hemorrhagic risk but can significantly decrease ischemic complications in patients with cerebral aneurysms treated with stent-assisted embolization.[19]

In a study investigating the safety and efficacy of flow diversion for cerebral aneurysms beyond the Willis circle including 28 patients with 28 aneurysms treated with 5 PED and 25 Tubridge devices,[20] perioperative complications were noticed in 2 patients (7.1%), delayed complications in 3.6% of patients (1/28), complete or near complete occlusion was present in 16 patients (61.5%), incomplete occlusion in 6 cases (23.1%), and unchanged status of occlusion in 4 cases (15.4%). Their conclusion is that the flow diversion is reliable in the treatment

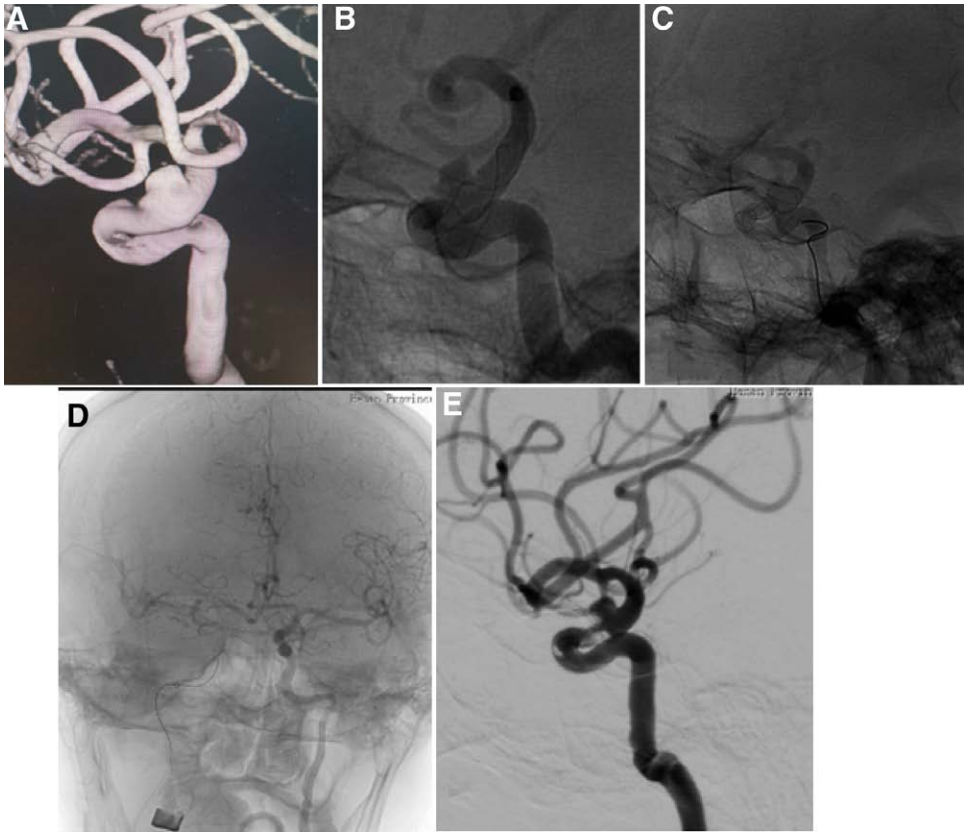

Figure 1. A technical complication occurred in a patient with a wide-necked aneurysm at the ophthalmic segment of right ICA. (A) Before embolization, angiogrpahy revealed a wide-necked aneurysm at the ophthalmic segment of right ICA. (B) A Tubridge device (4.5 mm × 30 mm) was deployed to treat the aneurysm. (C) When a J-type micro-guide wire was used to "massage" the Tubridge device, the distal end of the device herniated into the aneurysm cavity. (D) After repeated attempts, the micro-guide wire still could not be navigated into the distal artery through the Tubridge device. Contralateral circulation was shown to partially compensate for the blood flow. (E) Digital subtraction angiography 1 h later demonstrated instent thrombosis and blood flow in the distal artery. ICA = internal carotid artery.

of distal aneurysms with a high technical success rate and low permanent disability rate. In a study investigating telescoping flow diverters for 20 complex intracranial aneurysms using the Tubridge (in 15 patients) and PED devices (in 5 patients),[21] the technical success rate of stenting was 100%, the immediate occlusion results were OKM grade A (35.0% or 7 cases), OKM grade B (55.0% or 11 cases), and OKM grade C (10.0% or 2 cases), and no perioperative complications occurred. At clinical follow-up of 20 patients (100%) 6 to 96 months later, 1 patient developed massive infarction and the other 19 patients had the mRS between 0 and 2. Angiographic follow-up in 17 patients (85%) 6 to 27 months later revealed the occlusion results of OKM grade B in 1 case (5.9%), OKM grade C in 6 cases (35.29%), and OKM grade D in 10 cases (58.8%). However, 2 patients (11.8%) developed occlusion of the patent artery. Their conclusion was that telescoping flow diverters showed low perioperative complications and high aneurysm occlusion rate when treating complex intracranial aneurysms. Liang et al[13] reported the treatment of 8 complex middle cerebral artery aneurysms using the Tubridge device, with no intra-procedural complications, no morbidity or mortality at a mean follow-up of 11.3 ± 3.6 months, suggesting safety and efficacy of endovascular treatment of the middle cerebral artery aneurysms using the Tubridge flow diverter. Because the Tubridge device is still at the initial stage of clinical application, most studies are only composed of a small series of patients as demonstrated in the above studies. Even with such a small series of cases, safety, efficacy and good outcomes have been proved in the use of the Tubridge devices for the treatment of cerebral aneurysms. However, prospective, multi-center studies with significantly more patients should be performed to confirm the safety and efficacy of the Tubridge device.

Some limitations existed in this study, including retrospective and single center study design, enrollment of Chinese patients only, and no control, which may all affect the generalization of the outcome. Future studies will have to solve these issues for better outcomes.

The flow diverting devices have a good therapeutic effect on refractory or highly recurrent aneurysms and can simplify the endovascular operation and reduce the risk of operation for common intracranial aneurysms. The Tubridge flow diverter may be safe and effective in the treatment of unruptured intracranial aneurysms, with low perioperative complications and good follow-up outcomes even though multi-center and prospective clinical studies with a large size sample are still needed to validate these results.

Author contributions

Agreement to be accountable for all aspects of the work: all authors.
Approval of the article: all authors.
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Revision of the original version: Bu-Lang Gao.
Study design: Li Li, Tiao-Xiao Li.
Study supervision: Zi-Liang Wang, Kun Zhang.
Writing of the original version: Li Li.

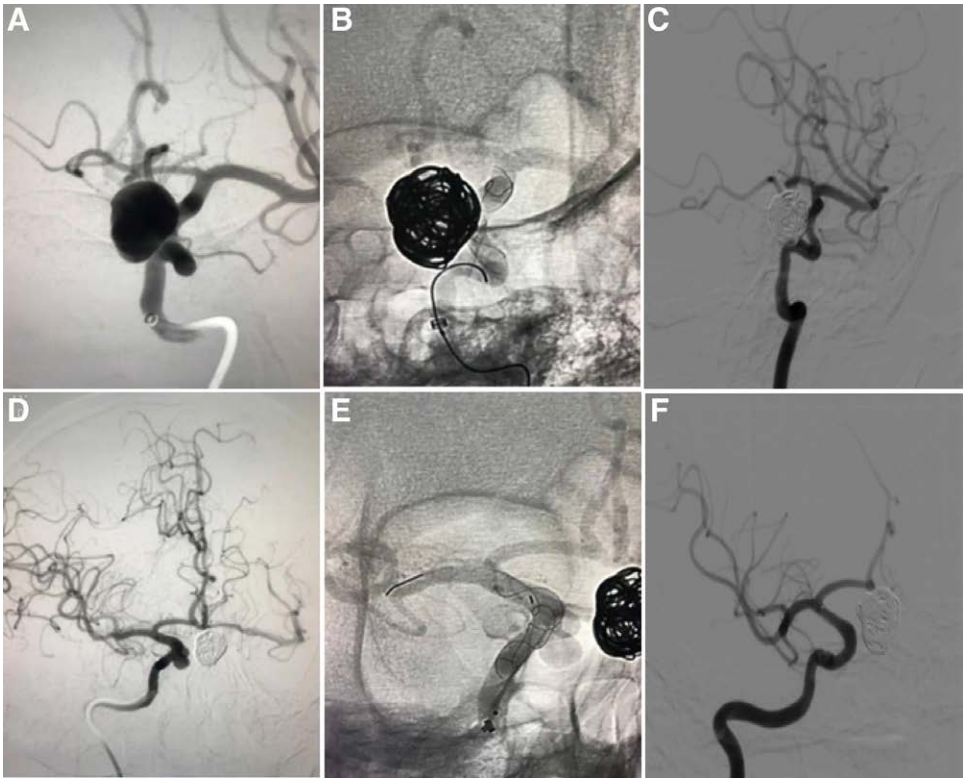

Figure 2. The Tubridge device was used to treat a patient with intracranial aneurysms on bilateral internal carotid arteries. (A) A large aneurysm with the greatest diameter of 15 mm was shown on the siphon segment of left ICA. (B) A Tubridge device (4.5 mm × 25 mm) was deployed followed by coil embolization of the aneurysm. The device had good adherence to the artery wall immediately after deployment, and the aneurysm was loosely packed with coils. (C) At 6-mo follow-up, the aneurysm was completely occluded. (D) Two tandem aneurysms were demonstrated at the siphon segment of the right ICA, with the greatest diameter of aneurysm dome of 6.8 and 5 mm, respectively. (E) A Tubridge device (4.5 mm × 20 mm) was deployed to cover the 2 aneurysms, and the device had good adherence to the arterial wall immediately after deployment. (F) At 6-mo follow-up, the aneurysm was completely occluded with patent parent artery. ICA = internal carotid artery.

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