Comparison between Solitaire™ AB and Enterprise stent-assisted coiling for intracranial aneurysms

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Received February 15, 2014; Accepted August 6, 2014

DOI: 10.3892/etm.2015.2481

Abstract. The aim of the present study was to analyze the feasibility, rate of procedure-related complications and midterm angiographic follow-up outcomes using the Enterprise (EP) and Solitaire™ AB (ST) stents in the stent-assisted coiling of intracranial aneurysms. In total, 81 patients with 90 aneurysms were included in the study, with the aim to treat 43 aneurysms with the EP stent (47.8%) and 47 aneurysms with the ST stent (52.2%). The 90 aneurysms were successfully stented and subsequently coiled; however, in four patients undergoing treatment with the EP stent, the stent was not navigable; thus, treatment with the ST stent was employed (EP, n=39, 43.3%; ST, n=51, 56.7%). Of the 90 aneurysms, 44 cases were ruptured aneurysms, with 74 located in the anterior circulation and 16 located in the posterior circulation. The stenting success rate of the ST stent was significantly higher compared with the EP stent. However, no statistically significant differences were observed with regard to the packing density, complete occlusion, progressive occlusion, recurrence rate, procedure-related complications, in-stent stenosis and stent migration rates between the two groups. In conclusion, the two common medical devices used for intracranial aneurysms are relatively safe and effective for the treatment of intracranial aneurysms. However, due to the higher stenting success rate of the ST stent, this medical devise was demonstrated to be more flexible and feasible compared with the EP stent.

Introduction

Embolization with Gugliemi detachable coils (GDCs) is considered to be the first-line treatment option for the majority of intracranial aneurysms with small necks (1). However, endovascular treatment for aneurysms of complex morphologies, wide necks or unfavorable dome-to-neck ratios remains a challenge. To improve the efficacy and durability of endovascular treatment for wide-neck aneurysms (2), novel coil designs (including 3D coils) (3) and liquid embolic agents (4) have been developed in the past few years. The efficacy of bioactive coils is controversial, and the development of self-expanding stents has offered more options during the treatment of these aneurysms.

The Enterprise (EP; Codman & Shurtleff, Inc., Miami, FL, USA) is a self-expanding, closed-cell design stent with flared ends in which each end has four radiopaque markers that flare out when fully deployed. The EP stent can be retrieved into the delivery catheter unless more than two-thirds of the entire stent length has been deployed (5). The Solitaire™ AB (ST; ev3 Neurovascular, Irvine, CA, USA) stent is a laser-cut, self-expanding and fully retrievable split-design nitinol device. The distinctive feature of this device is its full retrievability until it is electrically detached from the push wire (6).

During the last decade, these devices have been widely used and are generally accepted as endovascular treatment for intracranial aneurysms. Various studies have reported the characteristics of EP and ST stents (5,7,8); however, to date, there is limited data with regard to the direct comparative benefit of the two stents for stent-assisted coiling (SAC). Consequently, in the present single-center study, the feasibility, rate of procedure-related complications and midterm angiographic follow-up outcomes of the EP and ST stent deployments were analyzed and compared.

Materials and methods

Stent selection. Indications of the two used stents included mainly complex unruptured or ruptured aneurysms, including fusiform, large and/or giant, dissecting or wide-neck aneurysms. In addition, small aneurysms, which may not be embolized by conventional coiling and recurrences, were considered amenable to stent-assisted coiling. EP stents were used for aneurysms arising from a parent vessel with a diameter of 2.5-4 mm, while ST stents were recommended for aneurysms arising from a parent vessel with a diameter of 2.5-5.5 mm. Wide-necked aneurysms were defined as having a neck of ≥4 mm or a dome-to-neck ratio of <2 mm.

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Key words: Solitaire™ AB stent, Enterprise stent, stent-assisted coiling, intracranial aneurysms, endovascular treatment

Patients. The study was approved by the Institutional Review Board of the Zhujiang Hospital, Southern Medical University (Guangzhou, China). Written informed consent was obtained from the patients' families. In total, 81 patients with 90 aneurysms underwent treatment between January 2010 and January 2012. Initially, the aim was to use EP-assisted coiling in 43 aneurysms (47.8%) and ST-assisted coiling in 47 aneurysms (52.2%); however, EP-assisted coiling was not successful in four patients. These patients subsequently underwent treatment with the ST stent and all the aneurysms were successfully stented and coiled (EP, n=39, 43.3%; ST, n=51, 56.7%). The following information was recorded: Patient characteristics, aneurysm demographics, technical and procedure-related complications. Follow-up angiograms, typically obtained at six and 18 months, were reviewed for data on stent patency and aneurysm recurrence. Stent-related complications, including delayed stent migration and in-stent stenosis, were also recorded.

Antiplatelet regimen. All the subjects with unruptured or non-acute ruptured aneurysms had been treated with dual antiplatelet therapy (75 mg clopidogrel and 100 mg aspirin per day) for five days prior to SAC. In the acute phase of the ruptured aneurysms, heparin was injected at the beginning and was maintained for 48 h. Four clopidogrel pills (300 mg) were crushed and injected into the nasogastric tube 2 h prior to surgery. The adequacy of the systemic anticoagulation therapy was monitored by frequent measurements of the activated clotting time (ACT). A baseline ACT was obtained prior to the bolus infusion of 5,000 IU heparin, and hourly thereafter. Clopidogrel (75 mg/day) was administered for six months post-surgery and daily administration of 100 mg aspirin was required for one year.

Endovascular procedure. A biplane flat panel digital subtraction unit (Neurostar or Axiom Artis; Siemens Healthcare, Erlangen, Germany) was used to performed the endovascular procedure. After a 6-French sheath (Terumo, Fujinomiya, Japan) was successfully inserted into the right common femoral artery, the 6-F guide catheter (Envoy; Codman Neurovascular, Miami Lakes, FL, USA) was inserted into the parent vessel. Over a 0.014 inch Transend or Synchro microguidewire (Boston Scientific, Fremont, CA, USA), a microcatheter was delivered into the normal distal artery beyond the aneurysm by 1 to 2 cm. The aneurysm was then embolized once the coiling catheter was navigated within the aneurysm sac. Following the coiling procedure, the stent was pushed through the microcatheter and aligned directly across the neck of the aneurysm. When the appropriate position was achieved, the microcatheter was gently pulled back to unsheathe the stent. The stent would not be fully deployed until the distal markers were completely open. Typically, after full deployment, the position was confirmed by routine diagnostic cerebral angiography. Two stents could be inserted under a necessary position, while for an imperative reposition, repeating the aforementioned processes was required. Microplex coils (MicroVention, Inc., Aliso Viejo, CA, USA), GDCs (Boston Scientific) or Axium coils (ev3 Neurovascular) were delivered via the second catheter into the aneurysm, as reported previously (9). Following an ideal coiling embolization, the stent was detached from the push wire subsequent to routine diagnostic cerebral angiography using a high-resolution biplane angiographic unit.

Packing density. Packing density, also known as the volume embolization ratio, was calculated as the ratio of the volume of the deployed coils to the aneurysm volume. The coil volume was calculated by summing the individual coil volumes, as indicated by the manufacturers. Aneurysm dimensions were measured by 3D images derived from rotational angiography. Subsequently, the aneurysm volume and packing density were calculated using Angiocalc software (available at http://www.angiocalc.com).

Follow-up examination. Angiographic follow-up examinations were performed with conventional angiography at six and 12 months post-surgery, and every year annually thereafter. For follow-up imaging, the patients underwent conventional digital subtraction angiography (DSA) or magnetic resonance angiography, or both. DSA was used for sole analysis whenever available. All the treated aneurysms were graded independently by two interventional neuroradiologists, using several views for each treated aneurysm, including 3D angiography. The angiographic results were classified according to the Raymond-Roy Occlusion Classification (10): Complete occlusion (class 1), neck remnant (class 2) and residual aneurysm (class 3).

Changes in the angiographic outcome were classified as follows: Stable (no change in coil configuration, obliteration grade or contrast filling), improved (progressive occlusion or involution of the neck remnant or contrast filling in the aneurysm) and recanalized (aneurysm recurrence evident due to neck growth, coil compaction, coil extrusion by aneurysm degradation or new sac formation). Additionally, newly visualized or increased contrast filling inside an aneurysm was regarded as recanalization.

Statistical analysis. Data were analyzed using the SPSS 13.0 statistical package (SPSS, Inc., Chicago, IL, USA), and are presented as the mean ± standard deviation. Statistical analyses were performed using the Student's t-test, Fisher's exact test, χ^2 test and analysis of variance, as appropriate, where $P<0.05$ was considered to indicate a statistically significant difference.

Results

Characteristics of the treated aneurysms. In total, 81 patients with 90 aneurysms underwent treatment using EP (n=43) or ST (n=47) SAC at the Department of Neurosurgery, Zhujiang Hospital, between January 2010 and January 2012. The characteristics of all the subjects are shown in Tables I and II. No statistically significant differences were observed with regard to age, gender, aneurysm size and location between the two groups. All the aneurysms (EP, n=39; ST, n=51) were successfully stented and coiled. Of these aneurysms, 74 (82.2%) were located in the anterior circulation, while 16 (17.8%) were located in the posterior circulation (Table III).

Procedural feasibility of the stents. Inability to position the delivery system occurred with greater frequency in the EP

Table I. Baseline demographics of the patients with aneurysms treated by stent-assisted coiling using the EP or ST stent.

Variable	Total	EP	ST	P-value
Age, years[a]	53±13.1	52±14.6	53±11.3	0.712
Female gender, n (%)	45 (55.6)	19 (52.8)	26 (57.8)	0.661
Aneurysm size, mm[a]	9.5±6.0	9.3±6.3	9.7±5.3	0.962
Ruptured aneurysms, n (%)	44 (48.9)	20 (51.3)	24 (47.1)	0.832
Packing density[a]	34.3±14.4	33.9±16.3	35.6±14.5	0.338

[a]Data are presented as the mean ± standard deviation. EP, Enterprise; ST, Solitaire™ AB.

Table II. Patient presentations.

Symptom	Total (n=90)	EP (n=39)	ST (n=51)	P-value
Subarachnoid hemorrhage, n (%)	40 (44.4)	18 (46.2)	22 (43.1)	0.280
Cranial nerve palsy, n (%)	14 (15.6)	5 (12.7)	9 (17.6)	1.000
Ischemic attack, n (%)	7 (7.8)	4 (10.3)	3 (5.9)	0.698
Headache, n (%)	12 (13.3)	4 (10.3)	8 (15.8)	0.533
Asymptomatic, n (%)	17 (18.9)	8 (20.5)	9 (17.6)	0.243

EP, Enterprise; ST, Solitaire™ AB.

Table III. Stented aneurysm locations.

Location	Total (n=90)	EP (n=39)	ST (n=51)	P-value
Anterior circulation, n (%)	74 (82.2)	32 (82.1)	42 (82.4)	1.000
ICA cavernous	10 (11.1)	4 (10.3)	6 (11.8)	1.000
ICA ophthalmic	10 (11.1)	3 (7.7)	7 (13.7)	0.505
ICA supraclinoid	18 (20.0)	7 (17.9)	11 (21.6)	0.793
MCA	5 (5.6)	2 (5.1)	3 (5.9)	1.000
AcomA	4 (4.4)	2 (5.1)	2 (3.9)	1.000
PcomA	27 (30.0)	14 (35.9)	13 (25.5)	0.355
Posterior circulation, n (%)	16 (17.8)	7 (17.9)	9 (17.6)	1.000
Basilar tip	7 (7.8)	2 (5.1)	5 (7.8)	0.694
PCA	2 (2.2)	2 (5.1)	0 (0)	0.185
Vertebral artery	6 (6.7)	2 (5.1)	4 (5.9)	0.694
PICA	1 (1.1)	1 (2.6)	0 (0)	0.433

ICA, internal carotid artery; MCA, middle cerebral artery; AcomA, anterior communicating artery; PcomA, posterior communicating artery; PICA, posterior inferior cerebellar artery; PCA, posterior cerebral artery; EP, Enterprise; ST, Solitaire™ AB.

group when compared with the ST group (P=0.022). In addition, the rate of technical complications in the EP group was significantly higher compared with that in the ST group (14.0 and 0%, respectively). Thus, the ST stent was more feasible to deploy (100%) compared with the EP stent (90.7%; Table IV).

Of the 43 aneurysms intended to be treated by SAC using EP stents, 39 (90.7%) were successfully stented and coiled. Two stent migrations occurred in the EP group following final deployment; in both patients this was managed by implantation of a second ST stent. In the remaining four cases where the EP stent was not navigable, the ST stent was successfully navigated without complications during subsequent coiling. In one of the four patients, the EP stent was unable to be expanded as desired, and the body of the stent experienced deformation towards the aneurysm sac subsequent to the stent being detached from the push wire (Fig. 1).

Table IV. Procedural feasibility and procedure-related morbidity in patients treated with stent-assisted coiling.

Complications	Total	EP	ST	P-value
Technical, n (%)	6/90 (6.7)	6/43 (14.0)	0/47 (0)	0.022[a]
Failed to deploy	4 (4.4)	4 (9.3)	0 (0)	0.048[a]
Stent migration	2 (2.2)	2 (4.7)	0 (0)	0.478
Procedure-related, n (%)	6/90 (6.7)	1/39 (2.6)	5/51 (9.8)	0.228
Thromboembolic events	2 (2.2)	1 (2.6)	1 (2.0)	1.000
Intraprocedure rupture	1 (1.1)	0 (0)	1 (2.0)	1.000
Post-procedure rupture	3 (3.3)	0 (0)	3 (5.9)	0.255

[a]P<0.05. EP, Enterprise; ST, Solitaire™ AB.

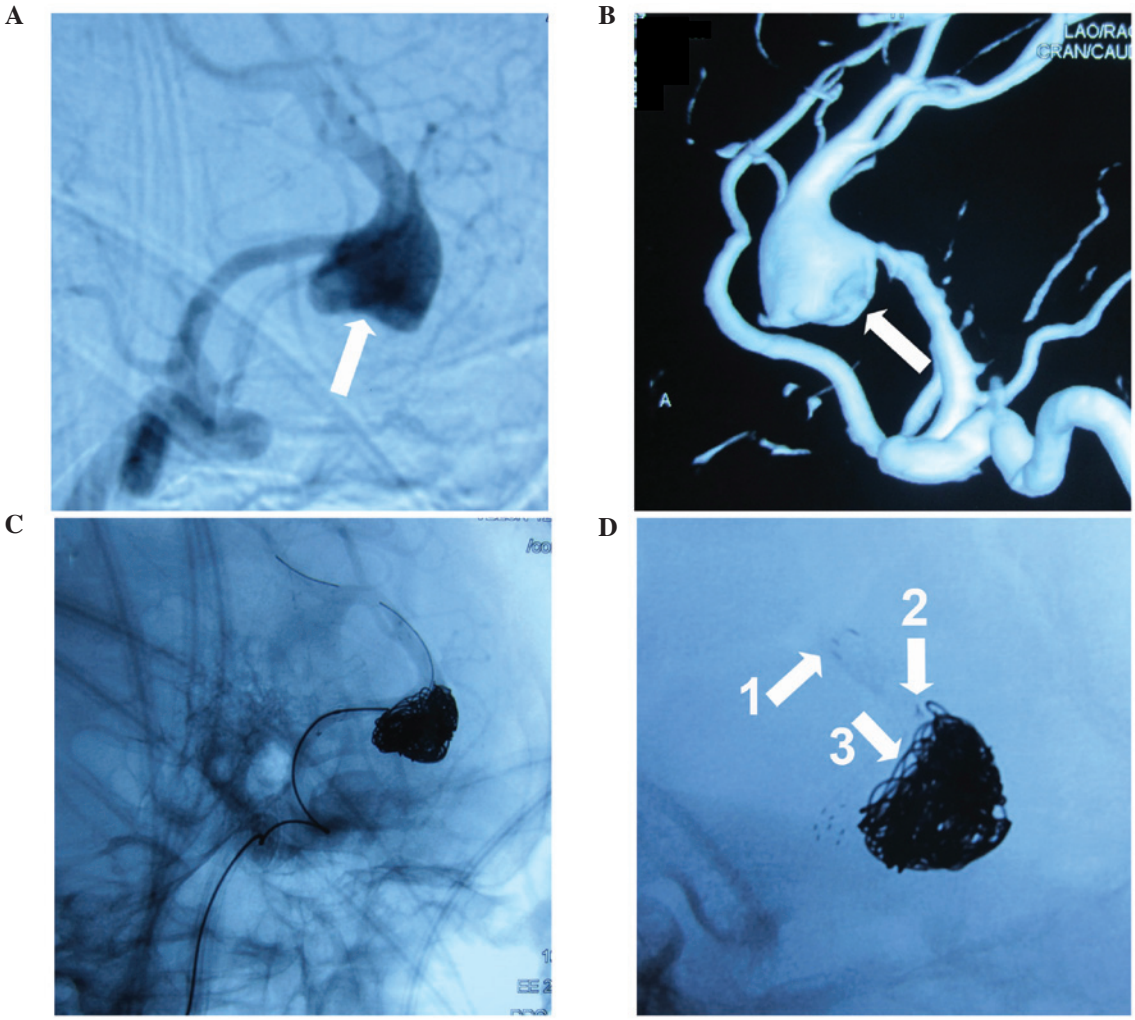

Figure 1. (A) Conventional and (B) three-dimensional angiograms of a 44-year-old male without subarachnoid hemorrhage revealed a left dissecting middle cerebral artery (MCA) aneurysm (white arrows). (C) Deployment of a second Enterprise (EP) stent in the left MCA. (D) The proximal 4.5x22 mm EP stent was unable to be expanded as desired (white arrow 2); thus, the body of the stent deformed and moved into the aneurysm sac after the stent had detached from the push wire (white arrow 3). The white arrow 1 is the 4.5x28 mm EP stent.

Of the 47 aneurysms intended to be treated with the ST stent, all were successfully deployed with subsequent coiling. The total success rate of ST-assisted coiling was 100%. However, in two patients, the stent required retrieval and repositioning subsequent to the initial full deployment. No patients experienced stent migration following the final placement in the ST group.

Procedure-related morbidity and mortality rates. No statistically significant differences were observed in the

Table V. Immediate angiographic results.

Occlusion grade[a]	Total (n=90)	EP (n=39)	ST (n=51)	P-value
Class 1, n (%)	45 (50.0)	19 (48.7)	26 (51.0)	1.000
Class 2, n (%)	28 (31.1)	13 (33.3)	15 (29.4)	0.819
Class 3, n (%)	17 (18.9)	7 (17.9)	10 (19.6)	1.000

[a]According to the Raymond-Roy Occlusion Classification (10). EP, Enterprise; ST, Solitaire™ AB.

Table VI. Follow-up angiographic results.

Parameter	Total (n=65)	EP (n=29)	ST (n=36)	P-value
Mean follow-up, months	15.1±9.8	15.9±11.4	14.0±6.8	0.418
Stable, n (%)	37 (56.9)	16 (55.2)	21 (58.3)	0.807
Progressive occlusion, n (%)	24 (36.9)	11 (37.9)	13 (36.1)	1.000
Recurrence, n (%)	4 (6.2)	2 (6.9)	2 (5.6)	1.000
In-stent stenosis, n (%)	2 (3.1)	1 (3.4)	1 (2.8)	1.000

EP, Enterprise; ST, Solitaire™ AB.

procedure-related complication rates (P=0.228) and procedure-related mortality rates (P=1.000) between the EP and ST groups (Table IV). In the EP group, there was one case of a procedure-related complication (thromboembolic event), which occurred in the cavernous segment of the internal carotid artery and resulted in lower limb fatigue thereafter. In response, thrombolytic therapy was administered immediately following identification intraoperatively with urokinase. However, the patient exhibited little neurological improvement after six weeks of hospitalization.

In the ST group, five patients (9.8%) had aneurysms that were associated with procedure-related complications. The events included one thromboembolic event, one intraprocedure rupture, which was possibly caused by mechanical irritations during stent deployment, and three hemorrhages following SAC within one month, which were possibly associated with antiplatelet therapy and high blood pressure. Of these five patients, the patient who suffered the intraprocedure rupture succumbed, two patients with early hemorrhage events succumbed following surgery for non-endovascular events, while the other two patients (one thromboembolic event and one hemorrhage) survived.

Immediate angiographic results. Immediate angiographic results on the occlusion grade following the SAC were analyzed and the results are summarized in Table V. Complete occlusion was obtained in 19/39 (48.7%) of the EP group and 26/51 (51.0%) of the ST group. Neck remnants were present in 13/39 (33.3%) of the EP group and 15/51 (29.4%) of the ST group. In addition, a residual aneurysm was present in 7/39 (17.9%) of the EP group and 10/51 (19.6%) of the ST group. No statistically significant differences were identified between the two groups (P>0.05). Furthermore, the two groups achieved a high packing density, and no statistically significant difference was observed between the EP and ST groups (P=0.338).

Follow-up angiographic results. At the most recent angiographic follow-up post-embolization, 29/39 (74.4%) of the EP group and 36/51 (70.6%) patients in the ST group underwent cerebral angiography. The mean follow-up times in the EP and ST groups were 15.9±11.4 and 14.0±6.8 months, respectively. Changes in the angiographic outcomes in the EP group were as follows: Stable in 16/29 patients (55.2%), progressive occlusion in 11/29 patients (37.9%) and recurrence in 2/29 patients (6.9%). Changes in the angiographic outcomes in the ST group were as follows: Stable in 21/36 patients (58.3%), progressive occlusion in 13/36 patients (36.1%) and recurrence in 2/36 patients (5.6%). In total, 24/65 (36.9%) aneurysms that were followed-up underwent progressive occlusion (Table VI). In the four cases that demonstrated an aneurysm sac, recanalization was observed without further treatment since the recanalization was minor. Each group had one patient that presented with an in-stent stenosis at the follow-up (EP, Fig. 2; ST, Fig. 3). The conditions of the two patients were observed during the first 12 months of the follow-up period and were asymptomatic; thus, further intervention was not required.

Discussion

Previous studies have analyzed the procedural feasibility, initial grade of occlusion and complication rates associated with each stent individually. A wide range of results have been reported for each stent with regard to the stenting success rates, with a range of 93.9-100% for the EP stent (11,12), and 93.3-100% for the ST stent (13,14). However, there are limited data directly comparing these two stents. In the present study,

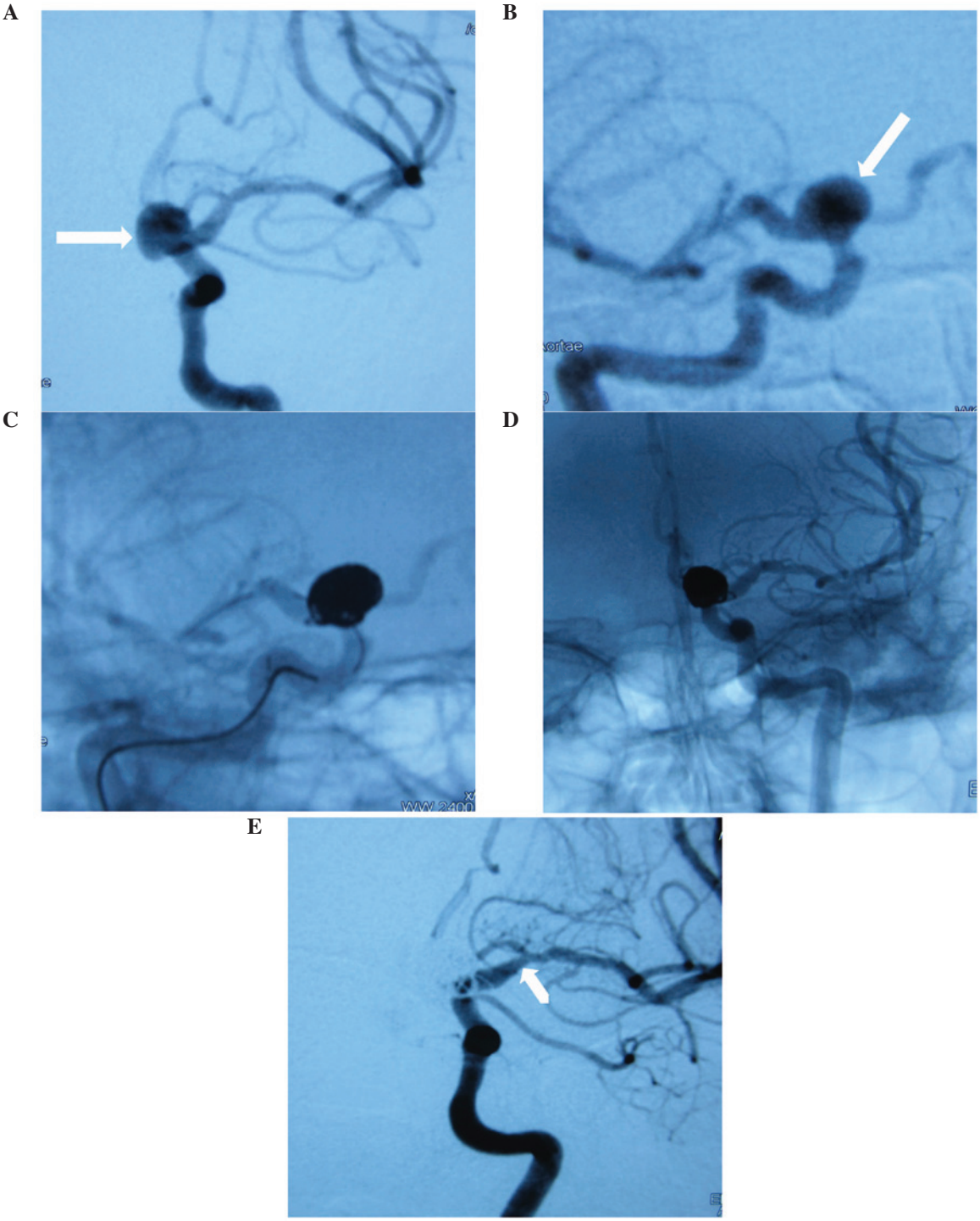

Figure 2. (A and B) Cerebral angiography of a 55-year-old female without subarachnoid hemorrhage revealed a left ophthalmic internal carotid artery (ICA) aneurysm (white arrows). (C and D) The aneurysm was treated successfully with Enterprise stent-assisted coiling. (E) After the 12-month follow-up period, angiography revealed a stenosis in the proximal supraclinoid segment ICA (white arrow).

success rates of 90.7 and 100% were achieved in the EP and ST groups, respectively. Notably, in the four cases where EP placement had failed, the ST stent was successfully deployed without complications during subsequent coiling. The results indicated that the ST stent is extremely flexible and technically easy to deploy, and can be easily and safely manoeuvred through severe tortuous vessels.

Certain studies have reported their initial experiences of stent migration in SAC using EP and ST stents (8,15). Heller and Malek (16) hypothesized that the possible reason was the lack of complete stent apposition to the wall, which may contribute to this phenomenon by decreasing the surface in contact with the vessel wall or increasing the exposure of stent elements. In the present study, two stent migrations occurred in the EP group and required a second stent, while no stent migration was observed in the ST group. This may be associated with the following reasons. Firstly, the ST stent is laser-cut from a nitinol plate into a folded honeycomb pattern

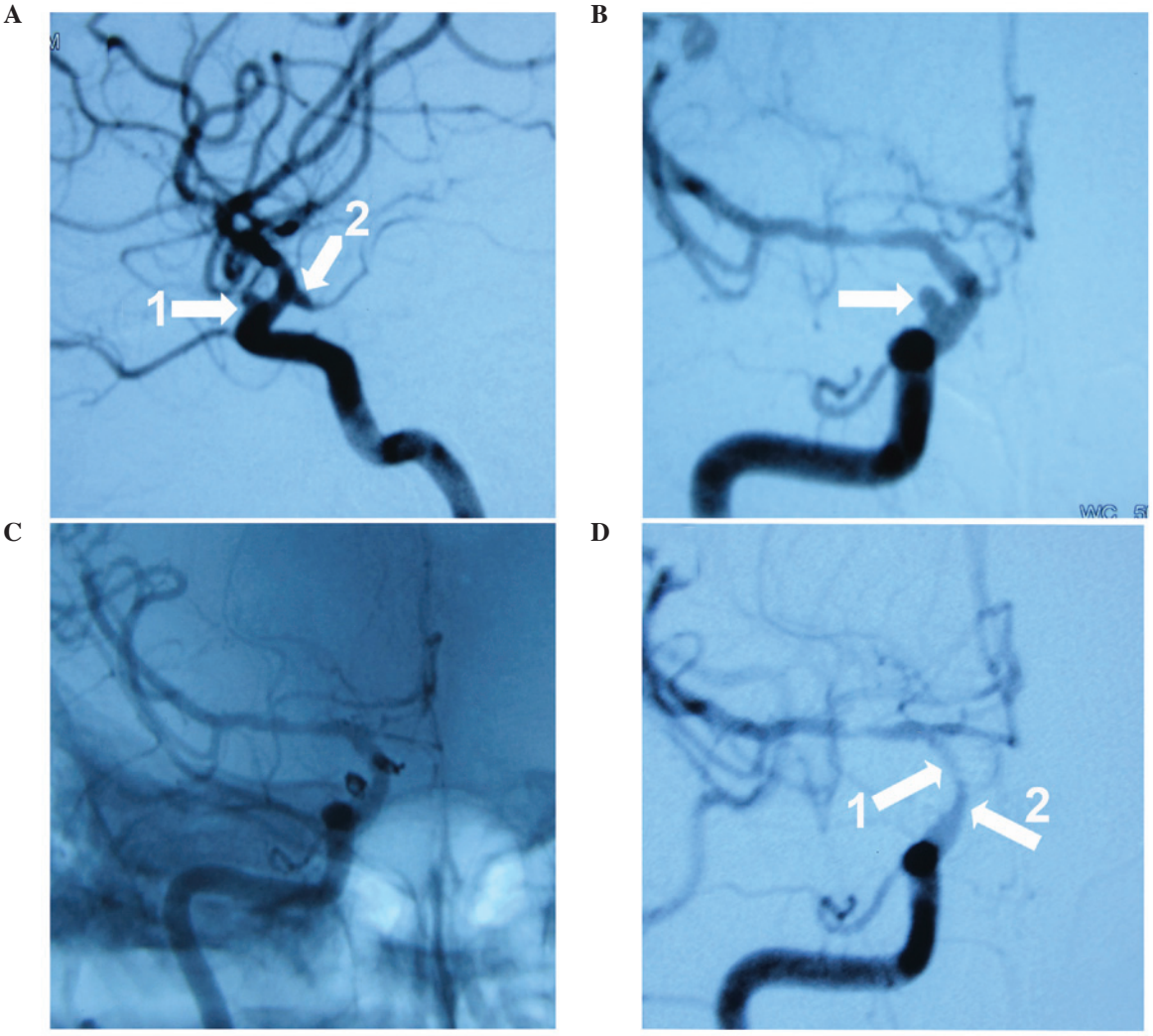

Figure 3. (A) Cerebral angiography of a 46-year-old female with subarachnoid hemorrhage revealed a right ophthalmic internal carotid artery (ICA) aneurysm (white arrow 1) and posterior communicating artery aneurysm (white arrow 2). (B) Cerebral angiography revealed a right ophthalmic ICA aneurysm (white arrow). (C) The aneurysm was treated successfully with Solitaire™ AB stent-assisted coiling. (D) After the 12-month follow-up period, angiography revealed a stenosis in the supraclinoid segment ICA (white arrow 1 and 2).

that allows the stent to have a higher apposition to the wall of the vessel in large or small vessels. Secondly, the EP stent has two different diameters along its length, and the flared ends have a 4.5-mm diameter to anchor within the parent artery, whereas the stent itself has a 4-mm diameter. In small vessels, the EP stent can anchor tightly with small diameters within the vessels by its flared ends without migration. However, in larger vessels, a decreased contact area and higher central flow velocities may induce a possible stent migration, which may explain the relative increase in delayed migration of the EP stent.

A number of studies have reported that SAC procedures are associated with higher rates of procedure-related complications compared with coiling procedures that are performed without the use of a stent (7,17-20). However, the observations of the present study indicated that there were no statistically significant differences in the overall procedure-related complication rate and procedure-related mortality rate between the EP and ST groups. This phenomenon may be explained by the relatively unfavorable anatomical access, the subarachnoid hemorrhage-related hypercoagulable state, vasospasm and the long duration of the procedure. Furthermore, there is also a potential selection bias in selecting the ST stent versus the EP stent for a particular aneurysm.

Although the two groups achieved a high packing density and complete occlusion, there was no statistically significant difference in the packing density or occlusion grade between the two stents in the present study. The observations regarding the packing density and immediate aneurysm occlusion grade in the present study were similar to results of previous studies with a larger series of aneurysms treated with stent assistance (7,8,11). The closed-cell design of these two stents is hypothesized to play a role in these two aspects.

The use of a stent may contribute to the progression of thrombosis of aneurysms. Izar *et al* (19) reported 14 months of angiographic follow-up data in 61 aneurysms treated with SAC embolization. The study demonstrated an improvement in progressive occlusion in 36% of the followed-up aneurysms. In a series of 104 aneurysms treated with ST stents, Clajus *et al* (8) reported that 39.2% of the followed-up aneurysms exhibited an improvement in progressive occlusion following 13.6 months of angiographic follow-up.

The mechanisms underlying progressive occlusion and the low recurrence rate of aneurysms treated with SAC may be due to the technical and physiological properties of the two stents. Primarily, stents provide a mechanical scaffold for coils within an aneurysm, particularly in wide-necked or giant aneurysms, allowing for increased packing density, improved neck coverage and the prevention of coil protrusion into the parent artery (21). Furthermore, the stent has flow-diverting properties, resulting in the modifications of the intra-aneurysmal hemodynamics. Subsequently, the flow within the aneurysm becomes disordered, which may lead to spontaneous and delayed aneurysm thrombosis, reduced coil compaction in the region of the inflow zone and a decrease in the wall shear stress and subsequent growth of the aneurysm that remains untreated (22,23). Finally, the stent may provide a structural basis for neointimal proliferation at the aneurysm neck, resulting in permanent separation of the aneurysm from the parent vessel lumen (24).

In the present study, the in-stent stenosis rate was relatively low, with only one patient from each group presenting with a stenosis during the follow-up period. The two patients were asymptomatic; thus, no further intervention was required. Certain studies have reported that the in-stent stenosis rates remain relatively low following EP and ST SAC, ranging between 6.9 and 22% (25,26). The deployment of a stent inevitably causes endothelial injury over the treated vascular segment. The proliferation and activation of regional smooth muscle cells occur, resulting in stenosis within the stent (27). The degree of neointimal hyperplasia and in-stent stenosis following SAC may be associated with the severity of endothelial injury during the stent deployment, as well as further manipulations affecting the stent stability during the initial procedure. These results indicate that the two devices can be well-positioned at the aneurysm neck without inducing major endothelial injuries.

On the basis of previous observations and experiences, the EP stent was preferentially selected when the diameter of the parent artery was <4 mm. In particular, the EP stent was selected for small arteries, including the A2 segment, M2 segment and posterior inferior cerebellar artery, where the ST stent was relied on as an easy-to-deliver backup for SAC. By contrast, the ST stent was preferable when the diameter of the parent artery was >4 mm.

There are a number of limitations that require addressing with regard to the present study. Firstly, the study was a retrospective analysis; thus, was subject to the inherent biases of the study design. Secondly, the patients were recruited from a single institution (patient-selection bias), and the sample size involved in the present study was relatively small, therefore further studies are required. Therefore, definitive conclusions are unable to be drawn.

In conclusion, the results of the present study demonstrated that the two stents are relatively safe and effective for the treatment of intracranial aneurysms. The two stents achieved high packing densities, complete occlusion, high progressive occlusion and low recurrence rates. However, there were more procedure-related complications in the ST group when compared with the EP group. Therefore, due to the higher stenting success rate of the ST stent, this device was demonstrated to be more flexible and feasible compared with the EP stent. However, further studies are required, particularly with a longer follow-up period and a larger study size population.

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