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Original Article

The efficacy of Enterprise stent-assisted coil embolization in the treatment of intracranial wide necked aneurysms by magnetic resonance angiography

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Abstract: Use of stent-assisted coil seems to facilitate endovascular treatment of wide-necked intracranial aneurysms, while difficulty of deployment and stent thrombogenicity are the main drawbacks of the system. Thus, the objective of this present study was to assess the role of Enterprise stent-assisted coil embolization using magnetic resonance angiography (MRA) on patients with intracranial wide necked aneurysms. Patients were confirmed by digital angiography and MRA with intracranial wide necked aneurysms (n = 108) after which they were assigned into the Enterprise and non-Enterprise groups. Preoperative digital angiography and MRA examinations were recorded for observing the therapeutic effects, complications and prognosis of the two groups. MRA re-examination was performed post operation, and the sensitivity (Se), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV) of MRA on efficacy of intracranial wide necked aneurysms (efficacy of coil residual blood, aneurysm neck residual blood, parent artery patency, and adjacent artery patency) were calculated using ROC curve in accordance with the digital angiography results. In comparison with the non-Enterprise group, incidence of clinical symptoms including headache, drowsiness, oculomotor nerve palsy, stiff-neck and mental confusion significantly decreased, while the operation time and length of stay were shorter, and the incidences of ruptured aneurysm, shifting, prolapsing and unwinding of spring coil during operation declined in patients of the Enterprise group (all $P < 0.05$). According to the results of MRA re-examination, the postoperative Se, Sp, PPV and NPV of coil residual blood in patients of the Enterprise group were 85.7%, 97.9%, 85.7% and 97.9%, respectively, while the values of aneurysm neck residual blood were 88.9%, 95.6%, 80.0% and 97.7%, separately. The Se and PPV of parent artery patency were 92.6% and 100.0%, respectively, whereas those of adjacent artery patency were 90.0% and 100.0%, respectively. Considering digital angiography as the gold standard, ROC curve results of MRA diagnosing of patients with intracranial wide necked aneurysms were as follows: the area under the ROC curve (AUC) was 0.705, the sensitivity was 84.2%, and the specificity was 56.8%. Our results indicated that the efficacy of Enterprise stent-assisted coil embolization was superior than non-Enterprise stent-assisted coil embolization in treating intracranial wide necked aneurysms, while MRA was of high sensitivity and specificity in predicting the efficacy of Enterprise stent-assisted embolization in the treatment of intracranial wide necked aneurysms and could be used as an important tool and could aid in predicting the efficacy of endovascular interventional therapy for patients with wide necked intracranial aneurysms.

Keywords: Magnetic resonance angiography, Enterprise stent-assisted coil embolization, intracranial wide necked aneurysms, efficacy, complication, sensitivity, specificity

Introduction

Intracranial aneurysm is generally referred to a bulge or dilation caused by bulge in the arterial wall of the cerebral artery lumen and hemodynamics [1]. When neck width of arterial aneurysm is 4 mm or neck-to-body ratio is > 1:2, intracranial aneurysm is considered as intracranial wide necked aneurysms [2]. Rupture of an intracranial aneurysm may lead to subarachnoid space bleeding, along with severe headache, emesis, papilledema, unconsciousness, mental symptoms, and epileptic seizures [3]. As a common cerebrovascular disease, morbidity

of intracranial aneurysm is evident in about 2~5% of the general population [4]. Amongst them, aneurysm rupture accounts for 1~2%, and 68% patients suffering from subarachnoid space hemorrhage are caused by arterial aneurysm rupture, which has a high crippling and fatality rate [5]. At present, clinical diagnosis of intracranial wide necked aneurysms is primarily dependent on imageological examinations, such as CT angiography, digital angiography and magnetic resonance angiography (MRA) [6-8]. Currently, interventional therapy is the preferred treatment option for intracranial wide necked aneurysms, mainly consisting of techniques like balloon-assisted technique, double micro-catheter technique, 3D guglielmi detachable coil (GDC), and intravascular stent implantation [9, 10].

In comparison with the traditional microsurgery clipping operative treatment, interventional therapy of intracranial aneurysm has various advantages such as minimal trauma, rapid recovery, low recurrence rate, and high security [11]. Primitive intravascular interventional therapy is limited for its postoperative syndrome, yet with the improvement of intervention materials and transporting devices, a variety of new interventional therapies have been developed that provide more and efficient methods in treating intracranial wide necked aneurysms [1]. Enterprise stent (produced by Cordis Company, USA) is a type of nitinol self-expanding stent, with advantages such as strong elasticity, access to circuitous and remote blood vessels, moderate aperture, recoverability of some parts and accurate placement [12]. MRA can show the existence of blood flow upward, as well as directly and clearly show the size, location, shape, parent artery of arterial aneurysm, and the overall situation of arterial aneurysm by multi-angle observation [13]. Thus, the MRA is significantly valuable during diagnosis of cerebrovascular diseases, thus can aid in providing a new approach in the treatment of intracranial wide necked aneurysms [14]. Therefore, the purpose of this study is to evaluate the efficacy of Enterprise stent-assisted coil embolization for patients with intracranial wide necked aneurysms using MRA.

Materials and methods

Ethical statement

This study was conducted in conformity to medical ethical standards, was performed with approval of the Ethics Committee of China-Japan Union Hospital of Jilin University. Informed consents were from all participants or their family members.

Subjects

A sum of 108 patients confirmed with intracranial wide necked aneurysms and admitted in China-Japan Union Hospital of Jilin University between February 2013 and June 2015 were selected for this study, consisting of 46 males and 62 females. The age range for the included study subjects was 28 to 73 years old, with a mean age of 48.19 ± 11.48 years old, among which 16 patients suffered from hemorrhage, wile 92 patients did not have an hemorrhages. Location distributions of arterial aneurysm were as follows: basilar artery aneurysm (n = 7), posterior communicating aneurysms (n = 50), anterior communicating aneurysms (n = 28), and internal carotid artery-ophthalmic artery aneurysm (n = 23). All 108 patients were informed about the treatment modalities, advantages and disadvantages, costs and postoperative conditions. Then corresponding treatments were chosen according to the patient's wishes and the doctor's advice. All patients were divided into the Enterprise (54 patients performed with Enterprise stent-assisted coil embolization) and non-Enterprise (54 patients performed with non-Enterprise stent-assisted coil embolization) groups.

MRA and digital angiography examinations

All patients underwent MRA and digital angiography examinations and were confirmed with wide-necked aneurysm. Three dimensional time of flight magnetic resonance angiography (3D-TOF MRA) inspection was employed, and head coil was selected, and all imaging was conducted on the GE SIGNA 1.5 T superconducting MR scanner. GRASS sequential scanning was performed, with the repetition time (TR) at 48 m, echo time (TE) at 2.5 m, flip angle at 20 degree, matrix at 512 × 512, 1.2 mm thickness × 40 slices × 2 slabs (overwrap 8 slices), field of view (FOV) at 24 cm × 18 cm and the number of acquisition (NOA) for once, for a scanning time of 5~10 min. After scanning, the maximum intensity projection image (maximum, intensity, projection, MIP) was reconstructed on MRI host. Next, the magnetic resonance image data line was transmitted to

Table 1. Baseline characteristics of patients between the Enterprise and non-Enterprise groups

	Enterprise group (n = 54)	Non-Enterprise group (n =54)	*P* value
Age (years)	48.43 ± 11.47	47.94 ± 11.59	0.826
Gender			
Male	24 (44.4%)	22 (40.7%)	0.846
Female	30 (55.6%)	32 (59.3%)	
Course of disease (month)	2.65 ± 0.25	2.71 ± 0.28	0.242
BMI index	23.18 ± 2.36	23.87 ± 3.02	0.189
Tumor diameter			0.513
4~9 mm	21	26	
10~25 mm	29	23	
> 25 mm	4	5	
Family history of cancer (n)	6 (11.1%)	4 (7.4%)	0.507
History of hypertension	23 (42.6%)	19 (35.2%)	0.554
History of coronary heart disease	14 (25.9%)	16 (29.6%)	0.830
Blood glucose (mmol/L)	6.03 ± 1.15	5.96 ± 1.17	0.755
Onset with hemorrhage (n)	10 (18.5%)	6 (11.1%)	0.417
Location of arterial aneurysm			
Basilar artery aneurysm	3 (5.6%)	4 (7.4%)	0.966
Anterior communicating aneurysm	14 (25.9%)	14 (25.9%)	
Posterior communicating aneurysm	26 (48.1%)	24 (44.4%)	
Internal carotid artery ophthalmic artery segmental aneurysm	11 (20.4%)	12 (22.2%)	
Hunt-Hess grading			
0	45 (83.3%)	47 (87.0%)	0.650
I	6 (11.1%)	4 (7.4%)	
II	2 (3.7%)	3 (5.6%)	
III	1 (1.9%)	0 (0%)	

the workstation hard disk, and finally transmitted to the CT host for post-processing. Digital angiography system (OEC9600) (General Electric Company, USA) was adopted during the digital angiography inspection, and Seldinger technology was used for puncturing the percutaneous femoral arterial puncture. Selective angiography was conducted in various branches of cerebral blood vessels (bilateral neck, external artery and vertebral artery) by a 5F catheter, followed by taking anteroposterior and lateral film, each in 6~12 frames/s. All MRA and digital angiography images were independently assessed by two neurosurgeons (Zhao Hang and Yu Weidong, Department of Neurosurgery of China-Japan Union Hospital).

Neighboring arteries refer to arteries adjacent to the targeted artery. In this study, the artery was a wide necked intracranial. Carotid coil remnant represented residual aneurysm, containing residual neck and residual dome. Residual neck indicated that projections can be seen of any part of the original defect in the arterial wall, but the aneurysmal sac was not opaque, while residual dome represented any opacification of the sac [15].

Therapy strategies

Therapies in the Enterprise group were as follows: (1) Femoral artery puncture performed by Seldinger's method with indwelling of 6F or 8F arterial catheter sheaths. (2) Prior to operation, aortocranial angiography was performed by an angiographic catheter, from which the size, the width of intracranial wide necked aneurysms and the diameter of parent artery were measured and obtained. (3) The appropriate angle, route, Enterprise stent, and coil were selected according to the location of intracranial wide necked aneurysms and the condition of parent artery. (4) After administrating general anesthesia, an ENVOY catheter (6F or 8F) was indwelled

Table 2. Efficacy, intraoperative and postoperative complications of patients between the Enterprise and non-Enterprise groups

	Enterprise group (n = 54)	Non-Enterprise group (n = 54)	*P* value
Time of operation (min)	50.47 ± 4.22	65.37 ± 5.62	*P* < 0.001
Time of hospitalization (d)	8.13 ± 1.74	13.50 ± 1.95	*P* < 0.001
Modified Rankin Scale			0.308
Rankin 0 point	35 (64.8%)	39 (72.2%)	
Rankin 1 point	9 (16.7%)	10 (18.5%)	
Rankin 2 point	7 (13.0%)	5 (9.3%)	
Rankin 3 point	3 (5.5%)	0 (0.0%)	
GOS score evaluation			0.004
Good	47 (87.0%)	34 (63.0%)	
Bad	7 (13.0%)	20 (37.0%)	
Total intraoperative complications			0.023
Yes (n, %)	5 (9.3%)	14 (25.9%)	
No (n, %)	49 (90.7%)	40 (74.1%)	
Intraoperative complications			
Rupture of aneurysms	1 (1.8%)	8 (14.8%)	0.031
Coil shifting, prolapse and unwinding during operation	0 (0.0%)	6 (11.1%)	0.027
Intraoperative ischemic of arterial aneurysm	3 (5.6%)	0 (0.0%)	0.243
Cerebral angiospasm	3 (5.6%)	1 (1.9%)	0.618
Total postoperative complications			0.024
Yes (n, %)	8 (14.81%)	19 (35.19)	
No (n, %)	46 (85.19%)	40 (64.81)	
Comparison of postoperative complications			
Progressive headache	5	15	0.024
Drowsiness	3	14	0.008
Oculomotor paralyses	2	10	0.029
Nuchal rigidity	3	15	0.004
Confusion	2	10	0.029

in arteria femoralis, along with perfusion of high-pressure saline water tin order o prevent thrombosis and air incoming through the catheter. (5) The stent was indwelled in the parent artery under the optimal route along with microguide wire. The transporting guide wire was removed, followed by pushing the length exchange guide wire. The "0.021" PROWLER SELECT Plus micro-catheter was extracted, and the micro-catheter compatible with the spring coil was pushed, during which mesh technology and parallel technology were adopted to perform intravascular embolization of arterial aneurysm. (6) After the intravascular embolization, an aortocranial angiography was performed again.

Therapies in the non-Enterprise group were as follows: Seldinger's method was employed to puncture the femoral artery, and 6F catheter sheaths were indwelled. Patients underwent digital subtraction angiography by 5F angiographic catheter, and were confirmed for intracranial wide necked aneurysms. Patient's conditions were fully evaluated, a single coil was employed without Enterprise stent, and an aortocranial angiography was performed as well.

Three to five days prior to operation, patients were prescribed oral tablets of 100 mg enteric-coated aspirin and 75 mg clopidogrel, which were ingested every day. During the operation, daily dosages of the same amount of the prescribed medicines were administered through nasal feeding. After the operation, the same dosage was again ingested orally every day. Six months later, they were only prescribed oral

Figure 1. MRA and digital angiography images of patients with arterial aneurysm after operation for 6 months. Note: A (a), no obvious arterial aneurysm remnant evident by MRA in the Enterprise group, the black arrow points to the stent, and the white arrow points to where no arterial aneurysm remnant exits; A (b), no arterial aneurysm remnant in the right cerebral hemisphere was shown by digital angiography in the Enterprise group, the black arrow points to the stent, and the white arrow points to where no arterial aneurysm remnant exits; B (a), a few arterial aneurysm remnants were found in the non-Enterprise group by MRA, the black arrow points to the remnants, and no stent exists; B (b) a few posterior communicating aneurysms remnants in the left cerebral hemisphere were found in the non-Enterprise group by digital angiography, the white arrow points to the remnants, and no stent exists; MRA, magnetic resonance angiography.

tablets of 100 mg enteric-coated aspirin tablet for the rest of their lives.

Follow-up

All follow ups were calculated at the time of discharge, and the clinical outcomes of the two groups were observed using Glasgow Outcome Scale (Glasgow GOS) (GOS score > 3 meant good recovery; GOS score ≤ 3 meant poor recovery). Meanwhile, treatment-related parameters and intraoperative complications of both groups were observed and analyzed. Meanwhile, all patients were observed and followed up for 6 months, which ended on March 30th, 2016. The Modified Rankin Scale [16], as well as MRA and digital angiography re-examinations of the patients were analyzed every three months.

Statistical analysis

Data was processed using SPSS 21.0 software (SPSS Inc, Chicago, IL, USA). Enumeration data was presented in ratio or percentage, and chi-square test was highlighted for group comparisons. Measurement data were presented as mean ± standard deviation (SD), and the mean values between groups were analyzed by *t* test. The result of digital angiography was used as a reference, and ROC curve was adopted to evaluate the accuracy of the predictive value of MRA in the efficacy of Enterprise stent-assisted coil embolization. The two-sided test was employed in all examinations, and $P < 0.05$ was considered statistically significant difference.

Results

Baseline characteristics of patients in the Enterprise and non-Enterprise groups

Baseline *characteristics of all patients* were collected and analyzed (Supplementary Data). There was no statistical difference in terms of age, gender, history of hypertension, coronary heart disease, smoking and alcohol, blood glucose level, onset with hemorrhage, location of arterial aneurysm and Hunt-Hess Grade between the patients of the Enterprise and non-Enterprise groups (all $P > 0.05$) (**Table 1**), which implied that the two groups were comparable.

Efficacy, intraoperative and postoperative complications of patients in the Enterprise and non-Enterprise groups

As shown in **Table 2**, the operation time and length of stay of patients in the Enterprise

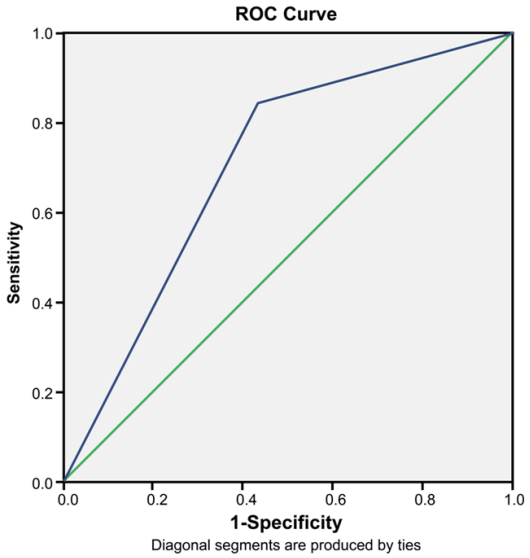

Figure 2. ROC curve of MRA diagnosing patients with intracranial wide necked aneurysms. Note: MRA, magnetic resonance angiography.

group were much shorter than those in the non-Enterprise group (all $P < 0.001$). Prognostic effects of patients in both groups were evaluated by the Modified Rankin Scale. No significant difference was observed in the postoperative score between the two groups ($P > 0.05$), which indicated that Enterprise stent-assisted coil embolization did not impact the prognosis of the patients. The incidences of complications, including ruptured aneurysm, shifting, prolapsing, and unwinding of spring coil during operation significantly reduced in the Enterprise group ($P < 0.05$), and no difference in incidence of intraoperative ischemic of arterial aneurysm and cerebral angiospasm was observed between the two groups (both $P > 0.05$). In comparison with the non-Enterprise group, postoperative complications such as headache, drowsiness, oculomotor nerve palsy, stiff-neck, and mental confusion were much lower and insignificant in the Enterprise group (all $P < 0.05$) (**Figure 1**).

Digital angiography and MRA re-examinations for evaluating postoperative efficacy of patients in the Enterprise and non-Enterprise groups

Patients underwent digital angiography and MRA postoperative re-examinations six months post operation. No patients experienced discomfort during the MRA examination process and only two patients experienced nausea and dysphoria after undergoing digital angiography. Postoperative re-examination showed that both the number of coil remnant and aneurysm neck remnant patients in the Enterprise group was less than the non-Enterprise group (**Figure 2**).

The results of digital angiography re-examination indicated that 7 patients and 9 patients from the respective groups had residual blood within the coil and neck of intracranial wide necked aneurysms, while 47 and 45 patients had no residual blood within the coil and neck in the Enterprise group. The MRA re-examination found 6 cases and 8 cases with residual blood within coil and neck of intracranial wide necked aneurysms separately and 46 and 43 cases without residual blood within coil and neck. In addition, via digital angiography re-examination, unblocked parent arteries and adjacent arteries were 54 strips and 90 strips, separately, while MRA re-examination found 50 and 81 strips of unblocked parent arteries and adjacent arteries. No in-stent restenosis was observed in patients after undergoing digital angiography and MRA re-examinations. According to MRA results, the postoperative sensitivity (Se), specificity (Sp), positive predictive value (PPV) and, negative predictive value (NPV) of coil residual blood in the Enterprise group patients were 85.7%, 97.9%, 85.7% and 97.9%, respectively, while the values of aneurysm neck residual blood were 88.9%, 95.6%, 80.0% and 97.7%, separately. The Se and PPV of parent artery patency were 92.6% and 100.0%, respectively, while those of adjacent artery patency were 90.0% and 100.0%, respectively (**Table 3**). Since there were no false positive or true negative cases in both parent artery and adjacent artery patencies, the Sp or NPV was not calculated.

ROC curve for evaluating the efficacy in diagnosing intracranial wide necked aneurysms

Considering digital angiography as the gold standard, ROC curve results of MRA diagnosis of patients with intracranial wide necked aneurysms were as follows: the area under the ROC curve was 0.705, the sensitivity was 84.2%, and the specificity was 56.8%, which was indicative of that MRA was effective in diagnosing intracranial wide necked aneurysms (**Figure 2**).

Table 3. Digital angiography and MRA re-examinations for evaluating postoperative efficacy of patients in the Enterprise and non-Enterprise groups

		Imaging parameters			
		Coil residual blood	Aneurysm neck residual blood	Parent artery patency	Adjacent artery patency
Digital angiography	Presence (P)	7	9	54	90
	Absence (A)	47	45	0	0
MRA	True positive (TP)	6	8	50	81
	False negative (FN)	1	1	4	9
	False positive (FP)	1	2	0	0
	True negative (TN)	46	43	0	0
	Se (%)	85.7	88.9	92.6	90.0
	Sp (%)	97.9	95.6		
	PPV (%)	85.7	80.0	100.0	100.0
	NPV (%)	97.9	97.7		

Note: digital subtraction angiography; MRA, magnetic resonance angiography; Se, sensitivity; Sp, specificity; PPV, positive predictive value; NPV, and negative predictive value.

The digital angiography and MRA diagnostic results were examined by Kappa, with a reference value of 0.47 ($P < 0.01$), highlighting the consistency between the two sets of results.

Discussion

In this study, patients with intracranial wide necked aneurysms underwent Enterprise and non-Enterprise stent-assisted coil embolization separately, and the results indicating that the symptoms of patients in the Enterprise group were improved compared to the non-Enterprise group.

GDC embolization has been proven to be the primary procedure in treating intracranial aneurysms because of high safety, small trauma and low recurrence rate [17]. However, application of the GDC embolization by itself may face difficulties during treatment since the coil tends to prolapse or block the parent artery, thus making it difficult to establish pyknotic embolization, while also increasing the recurrence rate of arterial aneurysm [18]. Moreover, the implantation of stent can promote the formation of embolization within the arterial aneurysm and the coverage of aneurysmal neck membranes through vessel reestablishment, thus reducing the recurrence rate of arterial aneurysm [19]. At present, intracranial aneurysm stent used in clinical treatment mainly comprise of Solitaire stent, Neuroform stent, LEO stent, and Enterprise stent [20, 21], among which the Enterprise stent is characterized by convenient transportation, perfect compliance, little damage to vascular wall, and high technical success rate [22, 23].

This study conducted a comparative analysis regarding the treatment-related indexes and intraoperative complications between the Enterprise and non-Enterprise groups. The results indicated that the intraoperative complications of arterial aneurysm decreased with respect to re-rupture and bleeding of arterial aneurysm as well as shifting and prolapse of coil, while the incidences of ischemic events and cerebral angiospasm increased in the Enterprise group compared to the non-Enterprise group. By performing Enterprise stent therapy on 116 patients with un-ruptured intracranial wide necked aneurysms, a success rate up to 94% were found [24]. On the basis of statistical analyses on 37 pairs of patients with intracranial aneurysm, it was highlighted that stent-assisted technology can significantly improve the long-term treatment effect of intracranial aneurysm, decrease its recurrence rate, and is beneficial for the formation of thrombus in arterial aneurysm [25].

The result of this study indicated that MRA, as an examination, plays an important role in identifying aneurysm. MRA is a noninvasive and rapid diagnostic procedure for intracranial wide necked aneurysms. Intra-arterial signal reduction by magnetic susceptibility artifact or radio

frequency shielding may limit the use of TOF-MRA as a follow up tool for intracranial stenting [26]. MRA can eliminate the artifacts caused by irregular blood and intuitive images. Moreover, MRA can scan the entire intracranial areas and produce images, thus improving the specificity, sensitivity and accuracy while treating intracranial wide necked aneurysms [27]. MRA has been proven to be capable of improving the efficiency of inspection after Enterprise stent-assisted coil embolization and reduce the risk of follow-up by this study. In conformity with digital angiography results of this study, it's also found that MRA had high sensitivity and specificity in its evaluation of Enterprise stent-assisted coil embolization in patients with intracranial wide necked aneurysms.

It has been suggested by scholars that MRA should be the primary diagnostic procedure, and digital angiography should be employed when large arterial aneurysm residual cavity or recanalization ahs been found by MRA [15]. However, there remain some obstructions in MRA. Firstly, rapid cerebral blood flow cycling speed will interrupt intracerebral artery imaging by vein signals, thus causing diagnostic errors; besides, since the spatial resolution of MRA is lower than the traditional digital angiography, which will impact the efficiency of MRA as the specificity and sensitivity will decrease for tumor bodies whose diameters are smaller than 3 mm. Therefore, MRA cannot completely replace digital angiography in some areas [28, 29]. Nevertheless, with the increased application of MRA and development of new MRA technologies, MRA will be an excellent technique in screening of aneurysms and may replace some conventional arteriography in some cases [30], consequently making it applicable for a wider array of applications and establishing more prominent clinical value in the field of vascular disease diagnosis.

To conclude, Enterprise stent-assisted coil embolization has superior clinical efficacy compared to non-Enterprise stent-assisted coil embolization in the treatment of intracranial wide necked aneurysms, while MRA is highly sensitivity in the evaluation of the Enterprise stent-assisted coil embolization while treating intracranial wide necked aneurysms, which is of instructive significance in clinical treatment.

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Disclosure of conflict of interest

None.

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