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Original Article

A 6-Fr guiding catheter (Slim Guide®) for use with multiple microdevices

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Abstract

Background: We developed a new 6-Fr guiding catheter (Slim Guide®) that features a large lumen (0.072 inch) for performing advanced techniques as are required in patients with wide-necked aneurysms whose treatment with a single microcatheter is difficult.

Methods: The Slim Guide was used to address 30 saccular and 20 dissecting aneurysms. All 50 patients presented with subarachnoid hemorrhage. To perform the advanced techniques we used SL-10® or Excel 14® and Hyperform® balloon microcatheters.

Results: Of the 30 patients with saccular aneurysms, 20 were treated with the double microcatheter- and the other 10 with the balloon assist technique. All 20 patients with dissecting aneurysms were treated with the double microcatheter technique. We encountered slight interference during the treatment of one saccular aneurysm with the balloon assist technique using the Slim Guide guiding catheter; another patient with a saccular aneurysm treated with the balloon assist technique suffered a minor transient ischemic complication.

Conclusions: With the Slim Guide, the risks inherent in the application of advanced techniques may be decreased. Its use facilitates the coil embolization of aneurysms that pose treatment challenges.

Key Words: Embolization, guiding catheter, interventional neurosurgery

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INTRODUCTION

Although effective techniques have been developed for aneurysmal embolization, aneurysms with a wide neck or a large neck-to-fundus ratio require advanced techniques such as the double microcatheter-, the balloon assist-, and the stent support technique to prevent coil protrusion into the parent artery.[2,7-10,13,14]

Advanced techniques that involve the use of multiple devices require a large single guiding catheter or multiple guiding systems. To meet this need, we developed a 6-Fr guiding catheter, the Slim Guide®, which features a large inner lumen (0.072 inch) to accommodate multiple devices. Results of our experimental studies confirmed the usefulness of a two-microdevice technique using the Slim Guide (Kai *et al*., submitted elsewhere). Although the inner diameter of the Slim Guide is only slightly larger than the diameter of the Launcher® and Envoy® guiding catheters (0.071 and 0.070 inch, respectively), it significantly increased the combination of microdevices that could be used for the coil embolization of aneurysms that pose treatment challenges. Although the Slim Guide provides greater flexibility than the other two guiding catheters, it keeps kink resistance than the Launcher® and Envoy® guiding catheters.

Here we describe our initial experience using the Slim Guide to treat patients with aneurysms that were difficult to treat with conventional techniques.

MATERIALS AND METHODS

We developed the Slim Guide guiding catheter in collaboration with Medikit Co. Ltd. (Tokyo, Japan). Its inner diameter is 0.072 inch, its length is 95 cm, and the outer diameter of its tip is 6 Fr (2.03 mm). The flexible polyamide catheter tube is kink-resistant and harbors a wire blade.

Between April 2006 and July 2010, 50 patients with saccular (n=30) or dissecting aneurysms (n=20) underwent interventional surgery using the Slim Guide at Kumamoto University Hospital. Prior written informed consent for participation in this clinical trial was obtained from all patients or their legal representatives. The Slim Guide was used in the application of double microcatheter- and balloon assist techniques. The indication for the double microcatheter technique was the presence of a wide-necked saccular or dissecting aneurysm; the balloon assist technique was used to address only wide-necked saccular aneurysms. The study protocol was approved by the clinical investigation committee of Kumamoto University.

The 50 patients ranged in age from 35 to 78 years (mean age 57.6 years); they were 23 males and 27 females. All presented with subarachnoid hemorrhage (SAH); 13 manifested Hunt–Hess grade I, 16 were grade II, 15 were grade III, and 6 were grade IV. The 30 saccular aneurysms were located on the internal carotid- (n = 15), the anterior communicating- (n = 4), and the basilar artery (n = 11). Their size ranged from 3.5 to 18 mm (mean 7.5 mm) and the aneurysmal neck from 3.8 to 6.3 mm (mean 4.6 mm). Almost all of the saccular aneurysms had a wide neck (diameter > 4 mm) or an unfavorable neck-to-fundus ratio (> 0.7); consequently, stable occlusion by embolization with the single microcatheter technique was difficult. All 20 dissecting aneurysms arose on the vertebral artery.

Embolization in the interventional angiography suite was with high-resolution digital subtraction angiography and a road-mapping technique. We used the transfemoral approach with the patients under general anesthesia. After inserting a 6-Fr sheath into the femoral artery we acquired a diagnostic angiogram using a 5-Fr diagnostic catheter. Then we inserted the 6-Fr Slim Guide guiding catheter (95 cm in length) and a coaxial 4-Fr catheter (JB-2, length 117 cm) with a 0.035-inch guidewire through the sheath. The Slim Guide was perfused with heparinized saline and connected to a double Y-type connector (MX336®; SHEEN MAN, Osaka, Japan) [Figure 1].

Embolization was performed with the double microcatheter- or the balloon assist technique. In all patients we used an SL-10® or Excel 14® microcatheter (Boston Scientific, Fremont, CA, USA) and a Hyperform® balloon (4 × 7 mm) microcatheter (eV3, Irvine, CA, USA). All patients received an intravenous (i.v.) bolus of 5000 U of heparin just before balloon inflation. This was followed by the i.v. infusion of 500 - 1000 U/hr for the duration of the procedure to ensure that the activated coagulation time was maintained at 2 x baseline. Heparinization was used in all patients even those with SAH at onset.

In patients with saccular aneurysms we used the double microcatheter technique under fluoroscopic and roadmap guidance.[5] The two microcatheters were inserted into the aneurysmal sac at different sites. We used different types of detachable coils including Guglielmi detachable coils (GDC; Boston Scientific). The first two coils were simultaneously deployed through the two microcatheters; they were detached when they were fixed and stable in

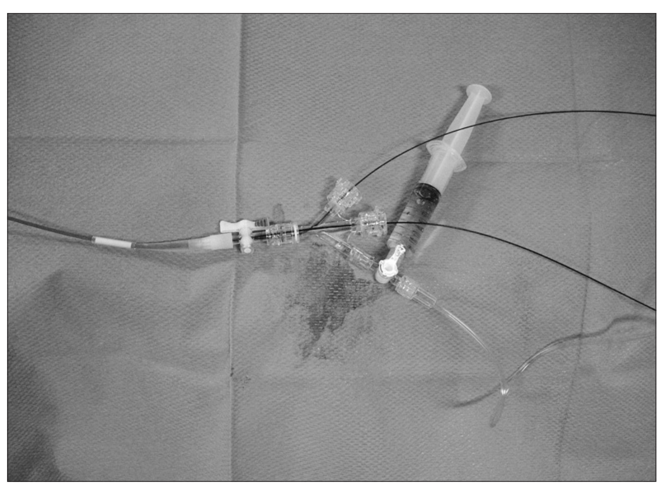

Figure 1: Connection of the double Y-type connector that allows continuous flushing of the Slim Guide while introducing the double microdevices

the aneurysmal sac without protrusion into the parent artery. When framing of the coils was complete we deployed coils to fill the intra-aneurysmal space through each microcatheter.

When we used the double microcatheter technique to address the 20 dissecting aneurysms, we carefully positioned one microcatheter at a level just distal to the dissection site and the other proximal to the site of dissection. The distal and proximal sites of the dissecting aneurysm were simultaneously embolized using GDCs.[6] After obstructing the dissecting aneurysms with the coil trapping method we acquired angiographic confirmation that there was no filling of the dissection site through the contralateral vertebral artery.

The balloon assist technique was used in wide-necked aneurysms. At first, we usually placed the balloon catheter at the aneurysmal neck. Then we inserted the microcatheter into the aneurysmal sac and deployed the first framing coil; if it protruded into the parent vessel, we inflated the balloon and re-deployed the coil. If the coil was not fixed in the aneurysmal sac, the second Slim Guide guiding catheter was inserted into the contralateral femoral artery and the second microcatheter was navigated into the aneurysmal sac. In this way, we were able to perform the double microcatheter- and the balloon assist technique. When the coils ceased to move in the aneurysmal sac they were detached and the balloon was temporarily deflated. After confirming the stable placement of the coils in the aneurysm we continued with dense coil packing. The balloon was appropriately inflated during coil deployment.

In the course of embolization we acquired repeat angiograms to confirm vessel patency and adequate aneurysmal packing and to identify complications such as clot formation. This treatment was followed by 24 - 48 hr of systemic anticoagulation with heparin to maintain a partial thromboplastin time (PTT) at approximately twice the normal value. Saccular aneurysms were graded based on the occlusion rate as complete (no residual space post-embolization), nearly complete (minor residual space or a neck remnant less than 2 mm), and partial (large residual space or a neck remnant larger than 2 mm). The management outcome was evaluated using the modified Rankin scale (mRS) at 6-month follow-up. Evaluations were performed by two neurologists (TH, MW). We obtained post-embolization follow-up cerebral angiograms at 3 months and 1 and 2 years and used multiple projections with selective contrast injections to define any residual lesions. Angiograms were graded on the basis of a modified 3-point Raymond scale (Raymond 1 = complete obliteration of aneurysm including the neck; Raymond 2 = contrast filling the neck of the aneurysm without opacification of aneurysm sac; and Raymond 3 = contrast filling the sac of the aneurysm).[15] Patients with major coil compaction that failed to disappear and patients in whom minor- progressed to major compaction in the course of 2 years after the first embolization underwent repeat coil treatment.

RESULTS

We addressed saccular and dissecting aneurysms endovascularly using the double microcatheter- or the balloon assist technique. Of 30 patients with saccular aneurysms, 20 were treated with the double microcatheter and 10 with the balloon assist technique. All 20 dissecting aneurysms were treated with the double microcatheter technique [Table 1]. We did not encounter displacement of the microcatheter in any of the 50 patients subjected to the combined techniques using the Slim Guide although in one patient undergoing the balloon assist technique there was slight microcatheter movement and the balloon catheter moved during microcatheter manipulation.

Based on the modified 3-point Raymond scale (mRS), of the 30 patients with saccular aneurysms, 14 had grade 1, 10 had grade 2, and 6 had grade 3 [Table 2]. In all 20 patients with dissecting aneurysms we obtained complete occlusion of the dissecting site. One patient with a saccular aneurysm treated with the balloon assist technique suffered a minor ischemic complication that resulted in transient mild left hemiparesis. We encountered no other intra-procedural complications.

Table 1: Combination of the devices used in balloon assisted- or double microcatheter techniques that employ the Slim Guide®

Combination of devices	Case number	Interference
Double microcatheter technique	40	
0.010 inch / 0.010 inch	16	No
0.010 inch / 0.014 inch	13	No
0.014 inch / 0.014 inch	11	No
Balloon assist technique	10	
0.010 inch / Hyperform (4*7mm)	8	1 case
0.014 inch / Hyperform (4*7mm)	2	No

Table 2: Treatment outcomes and the obliteration- and complication rate in patients with aneurysms addressed with the balloon assist- or double microcatheter technique using the Slim Guide

	Embolization of aneurysm			Complication
	Raymond scale 1	Raymond scale 2	Raymond scale 3	
Saccular aneurysm	14	10	6	1
Dissecting aneurysm	20	0	0	0

At 6-month follow-up, the mRS was 0 - 1 in 35-, 2 in 8-, and 3 in 6 patients; it was 5 in one patient. During the 2-year follow-up period, only one patient suffered re-bleeding. There were 3 saccular aneurysm patients with coil compaction; they underwent a second embolization procedure.

Representative case

This 70-year-old woman presented with grade III SAH. Conventional angiography demonstrated a basilar tip aneurysm with a wide neck and a large neck-to-fundus ratio; its treatment required the use of multiple devices [Figure 2]. After introducing a 6-Fr sheath in the bilateral femoral arteries, we catheterized the bilateral vertebral arteries using the 6-Fr Slim Guide (Medikit) as the guiding catheter. An SL-10- (Boston Scientific) and a 4 × 7 mm Hyperform microcatheter (MicroTherapeutics, Irvine, CA, USA) were placed from the guiding catheter in the left vertebral artery. Another SL-10 microcatheter was placed from the guiding catheter in the right vertebral artery [Figure 3]. The aneurysm was carefully embolized using GDC-10 coils. The first coils deployed from the two SL-10® microcatheters were 4 mm × 6 cm and 3 mm × 4 cm; both coils were deployed simultaneously under Hyperform balloon inflation. The final angiogram confirmed complete occlusion of the aneurysm [Figure 4]. Upon awakening, her neurological examination returned normal findings and she was discharged 3 weeks after treatment.

DISCUSSION

Although many aneurysms can be treated with conventional techniques, wide-necked aneurysms and those with a large neck-to-fundus ratio require advanced techniques such as the double microcatheter-, balloon assist-, and stent support technique to prevent coil protrusion into the parent artery.[1,4,12,14,16-18]

Advanced techniques can be carried out through single groin access using a 6- or 7-Fr catheter or by introducing two guiding catheters (5 Fr or 6 Fr) through separate groin sites. Although the manipulation of two such guiding catheters is neither difficult nor risky, the methods may produce complications associated with thromboembolic- or flow disturbances in the parent artery. Also, as the number and size of the guiding catheters increases, so does the risk for complications. Luzardo *et al.*[11] reported that the Envoy 6-Fr guiding catheter (inner diameter 0.070 inch; Codman, Raynham, MA, USA) can simultaneously accommodate both the microcatheter and the balloon microcatheter for balloon-assisted coiling. According to others,[3,19] the 5-Fr shuttle sheath (inner diameter 0.074 inch; Cook Medical Inc., Bloomington, IN, USA) also accommodated both a microcatheter and a balloon catheter and allowed the acquisition of excellent control angiograms and roadmap

Figure 2: Left vertebral angiogram (anteroposterior view) showing a wide-necked and multilobular aneurysm at the top of the basilar artery

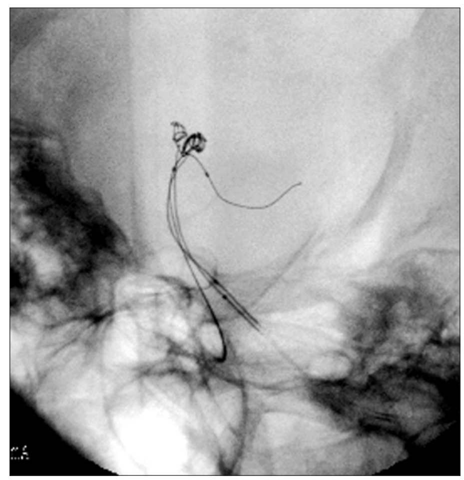

Figure 3: Intra-procedural plain radiograph (anteroposterior view) shows placement of the balloon microcatheter and of one microcatheter through the left- and another through the right vertebral artery

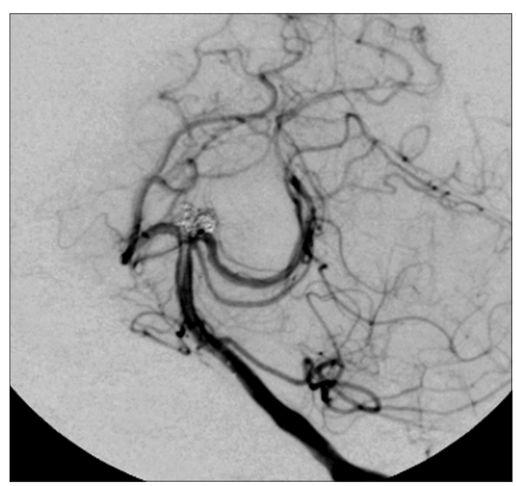

Figure 4: Left vertebral angiogram (anteroposterior view) shows complete obliteration of the aneurysm at the top of the basilar artery

views during the procedures. While the 5-Fr shuttle system involves a smaller access site and features a larger lumen than the 6-Fr Envoy catheter, there are limitations to its use; the shuttle catheter's soft, atraumatic tip renders its navigation into tortuous vessels and vessels with tortuous aortic arches difficult.

According to Luzardo *et al*.,[11] the quality of angiograms during embolization obtained by using the 6-Fr Envoy guiding catheter was comparable to images acquired through a 7-Fr guiding catheter. However, with the 6-Fr Envoy guiding catheter, they encountered more resistance to contrast injection and in some cases there was a slight increase in friction between the double microdevices and the guiding catheter. This makes a single guiding system with a large inner lumen that allows the easy passage of multiple devices desirable in patients whose aneurysms require advanced interventional techniques.

Our Slim Guide catheter makes it possible to carry out procedures that require multiple microdevices. Its outer diameter is that of 6-Fr catheters and its inner lumen measures 0.072 inch. Conventional 6-Fr guiding catheters feature an inner lumen of 0.071 inch (Launcher) and 0.070 inch (Envoy). Characteristic features of the Slim Guide® are the greater flexibility and kink-resistance of the catheter compared with the Launcher®- and Envoy® guiding catheters. Moreover, other advantages such as the low infusion pressure of the injection volume, make it possible to inject a greater volume of contrast medium when two microdevices are inserted. Our clinical trial of the Slim Guide yielded good results and facilitated the acquisition of sharp angiographic and road-mapping images in the course of aneurysmal embolization procedures. Also, when the Slim Guide is the guiding catheter, various combinations of multiple microdevices can be inserted. When we used Envoy or Launcher as the guiding catheters and the microballoon catheter as the microdevice, we did not need to introduce the Excelsior® or Fas-Tracker 10® microcatheter as a second microdevice. With this combination, our use of the Slim Guide created no problems. In the current series, we encountered slight motion of the microcatheter during balloon catheter movement in only one patient with a saccular aneurysm who was treated with the balloon assist technique. In the other 49 patients there was no movement of the microcatheter during movement of another microcatheter and only one patient with a saccular aneurysm manifested slight, transient ischemic complications. The treatment outcomes were satisfactory in all 50 patients except for one patient who suffered re-bleeding.

CONCLUSION

Use of the Slim Guide may reduce the risks raised by the application of advanced embolization techniques and it may represent a valuable tool for the coil embolization of difficult aneurysms. With the Slim Guide, the risks inherent in the use of advanced techniques to address aneurysms that pose treatment challenges may be decreased.

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