Online December 29, 2020
Journal of Neuroendovascular Therapy 2021; 15: 301–309
DOI: 10.5797/jnet.oa.2020-0148

Original Article

Intraaneurysmal Neck Plasty: Efficacy of a Super Compliant Double-Lumen Balloon Microcatheter

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Objective: While wide-neck aneurysms can be treated with several methods, we report the specific technique of intraaneurysmal neck plasty (IANP) with a super compliant double-lumen balloon microcatheter (Super-Masamune).
Methods: The Super-Masamune was inflated inside 18 aneurysms. Cases in which the tip of the Super-Masamune was located in the aneurysm were included. Embolization methods were the same as those used in the application of other balloons/stents. The use of the Super-Masamune for the performance of IANP followed two patterns: (1) the Super-Masamune was used not only as a balloon but also for coil insertion (simple IANP); (2) the Super-Masamune was used only as a balloon, and a microcatheter for coil insertion was separately introduced coaxially (coaxial IANP).
Results: The aneurysms were located in the anterior communicating artery (n = 6), middle cerebral artery (MCA; n = 4), anterior cerebral artery (n = 1), internal carotid artery (n = 5), basilar artery (n = 1), and vertebral artery (n = 1). Eight of the aneurysms were ruptured, while 10 were unruptured. Simple and coaxial IANP were both performed in seven cases. Embolization was not performed after inflating the Super-Masamune inside the aneurysm in four cases. Embolization grades following the procedure included eight neck remnants (NRs) and six body fillings (BFs). There was one complication of intraoperative rerupture; however, there was no rupture/rerupture in the follow-up period. Retreatment of the target aneurysm was performed in two cases. The embolization grade assessed in the follow-up period reached complete occlusion for one patient, NR for five, and BF for two patients.
Conclusion: IANP using the Super-Masamune is useful for the treatment of wide-neck aneurysms in which the introduction of a guidewire and/or microcatheter into the branching artery is difficult.

Keywords ▶ intraaneurysmal neck plasty, balloon assist, embolization

Introduction

With the introduction of Guglielmi detachable coil in 1991, embolization has become the standard treatment for cerebral aneurysms.[1)] While this treatment was devised as the insertion of one microcatheter, it has evolved to accommodate the embolization of complexly shaped aneurysms that would have been difficult to treat with the original technique. We commenced the development of a super compliant double-lumen balloon microcatheter (Super-Masamune; Fuji Systems Corporation, Tokyo, Japan) in 2011,[2)] began its clinical application in 2012,[3,4)] and launched it in the market in 2014. This report summarizes cases of patients who underwent intraaneurysmal neck plasty (IANP) with the Super-Masamune catheter since its introduction to the market.

Materials and Methods

Between 2014 and 2020, 670 cases of cerebral aneurysm embolization were performed. Among them, Super-Masamune was used in 42 cases. In 18 of these cases, the balloon was inflated in the aneurysm. While Super-Masamune bulges easily in the aneurysm when overinflated, we only examined cases where the balloon was inflated when the tip of the catheter was inserted into the aneurysm (**Table 1**). There

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Received: July 21, 2020; Accepted: August 28, 2020
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Table 1 Patient profiles

	Age	Sex	Site*	Hunt & Kosnik Grade	Maximum diameter (mm)	Method	Results	Last follow-up		Remarks
1	56	F	BA	0	6.5	Simple	NR	CO	33M	
2	81	M	AcomA	0	5.2	Simple	NR	NR	12M	
3	51	F	MCA	0	4.2	Simple	NR	NR	24M	
4	82	F	MCA	0	8.9	Simple	BF	BF	6M	
5	65	M	AcomA	0	9.7	Simple	NR			Clipping (6M)
6	84	F	AcomA	0	15.1	Simple	BF	BF	7M	
7	50	M	AcomA	4	4.2	Simple	BF			Stent assist coiling (4M)
8	60	M	AcomA	2	8.2	Coaxial	NR	NR	24M	
9	93	F	ICA	2	5	Coaxial	NR		ND	Intraoperative rupture
10	92	F	ICA	3	8.4	Coaxial	NR		ND	
11	83	F	ICA	4	9.3	Coaxial	BF		ND	
12	62	M	AcomA	5	13	Coaxial	NR	NR	2M	
13	58	M	MCA	0	6.1	Coaxial	BF		ND	
14	63	M	MCA	0	9.5	Coaxial	BF	NR	12M	
15	55	F	ICA	0	15	Trial	Switch to balloon assist coiling			
16	72	F	ICA	3	9.2	Trial	Switch to stent assist coiling			
17	66	F	ACA	0	2.7	Trial	Switch to simple coiling			
18	94	F	VA	3	7.9	Trial	Switch to balloon assist coiling			

ACA: anterior cerebral artery; AcomA: anterior communicating artery; BA: basilar artery; BF: body filling; CO: complete obliteration; ICA: internal carotid artery; MCA: middle cerebral artery; ND: not done; NR: neck remnant; VA: vertebral artery

were 7 males and 11 females. The age of subjects ranged between 50 and 93 years old, with a mean age of 70.4 years old.

External appearance of the Super-Masamune catheter is shown in **Fig. 1**. It has a length of 150 cm, distal outer diameter of 2.8 F, and proximal outer diameter of 3.4 F. The tip length is 2 mm and the balloon length is 4.0 mm. The balloon expands to a diameter of 7.0 mm with the recommended injection volume of 0.2 mL and to 8.0 mm with the maximum injection volume of 0.36 mL. Its compatible guidewire is 0.014 inch in width. A total of three radiopaque markers are provided at the tip and proximal end of the balloon, as well as at 3 cm proximal from the tip. The method of employing the Super-Masamune catheter does not differ remarkably from that using other balloons/stents. Although the approach to antiplatelet therapy differs for ruptured and unruptured cases, the variance does not depend on the device.

We examined two conditions in this study: (1) the balloon was used not only as a balloon but also as a coil-guiding microcatheter (simple IANP); and (2) the balloon was used only for protection, while a coil-guiding microcatheter was inserted separately (coaxial IANP). Simple IANP was performed if the tip of the Super-Masamune was facing the main lumen of the aneurysm. There should be some distance between the tip of Super-Masamune and the aneurysmal wall to avoid perforation. As the lumen diameter of a guiding catheter that is compatible with Super-Masamune is ≥0.059 inch, a guiding catheter with a diameter of ≥6 F is needed for simple IANP; a guiding catheter with a diameter of ≥8 F is needed for coaxial IANP. DSA was performed if it could be confirmed by fluoroscopy or road map that the balloon had inflated only inside the aneurysm, that the parent artery had not been occluded, and that the coil had been appropriately inserted. Coils used in IANP were softer ones without strong shape-memory to avoid perforation. For each insertion of the coil, we repeated the operation of inflating the balloon immediately before the coil entered the aneurysm, deflating the balloon after completing the insertion, and detaching the coil after checking the condition of the artery that was meant to be preserved. As IANP is the last resort when other balloons/stents cannot be used, we aimed to pack the distal two-thirds of the aneurysm and did not focus on the treatment of the neck. The absence of the estimated rupture site and bleb from angiograms served as another indicator in rupture cases.

Results

The sites of the target aneurysms included the anterior communicating artery (AcomA; n = 6), middle cerebral artery

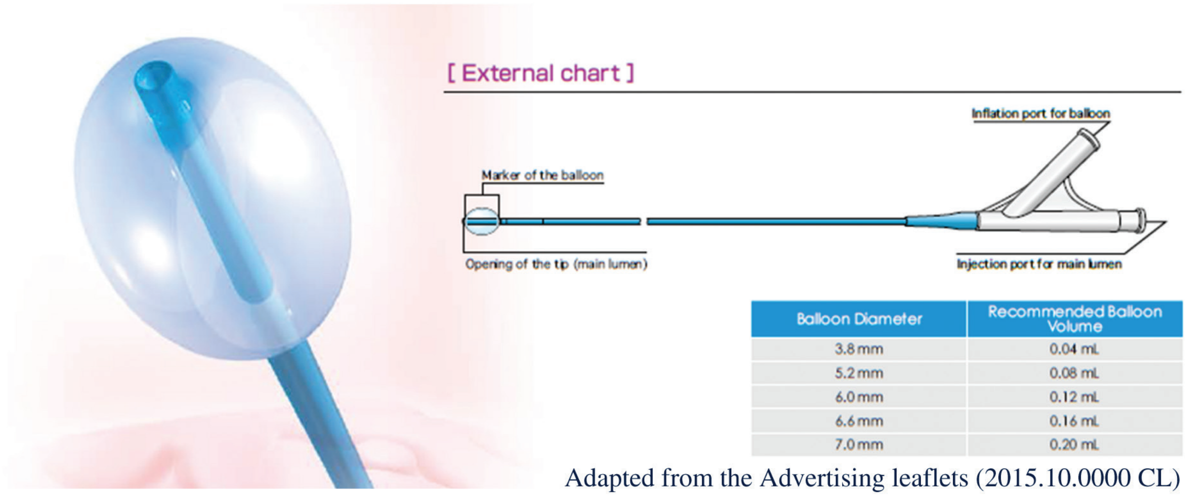

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Fig. 1 External appearance of the Super-Masamune.

(MCA; n = 4), anterior cerebral artery (n = 1), internal carotid artery (n = 5), basilar artery (BA; n = 1), and vertebral artery (n = 1). The sizes of the aneurysms ranged between 2.7 and 15.1 mm, with a mean size of 8.2 mm. There were eight rupture cases with a Hunt & Kosnik (H&K) grade of 2 in 2, 3 in 3, 4 in 2, and 5 in 1. Simple IANP was performed in seven cases, and coaxial IANP was performed in seven other cases. Embolization was not performed after inflating the Super-Masamune inside the aneurysm in four cases. Those were treated by the other method as shown in **Table 1**. Eight cases had neck remnant (NR), and six had body filling (BF). There was one case of intraoperative rupture, which occurred upon coil insertion during coaxial IANP; however, the incident did not cause neurological deterioration. Additional treatments included one case of stent-assist coiling and one case of clipping. Follow-up of 6 months or longer was possible in eight cases; complete obliteration (CO) was observed in one case, NR in five, and BF in two.

Representative example 1: Case 1 (Fig. 2)

A 56-year-old female patient was found to have a BA aneurysm upon detailed examination following the presentation of vascular murmur. The aneurysm straddled the right posterior cerebral artery, and simple IANP was performed. The outcome immediately after treatment was NR, but CO was observed at the 21-month and 33-month follow-ups.

Representative example 2: Case 4 (Fig. 3)

An 82-year-old female patient was referred to our hospital after MRI performed to investigate her headache revealed a cerebral aneurysm. Embolization was performed despite her advanced age due to the size of the aneurysm in the periphery of MCA being approximately 9 mm and at the patient's insistence. A branching artery derived from the body of the aneurysm featured a hairpin-curve form. As this was a peripheral aneurysm in an elderly patient, we chose to perform a simple IANP, which yielded an outcome of BF with no medical complications. Angiography performed 6 months later revealed that there were no changes to the embolized state.

Representative example 3: Case 7 (Fig. 4)

A 51-year-old male patient was urgently transported to our department in a comatose state. The patient was diagnosed with H&K grade 4 subarachnoid hemorrhage, and embolization was performed for an AcomA aneurysm, which was identified as the source of the bleeding. The left A2 segment had branched from the body of the aneurysm, and simple IANP was performed to preserve this artery. Despite the outcome being BF, it was possible to embolize the tip of the aneurysm. After providing acute phase treatment, the patient was transferred to a rehabilitation hospital. Angiography performed 4 months later revealed coil compaction; hence, additional treatments were administered. A stent was placed between the Lt A2 and Rt A1 segments, which resulted in CO.

Representative example 4: Case 14 (Fig. 5)

A 63-year-old male patient with lung cancer was found to have a right MCA aneurysm after having undergone MRI to investigate possible brain metastasis of the cancer. The

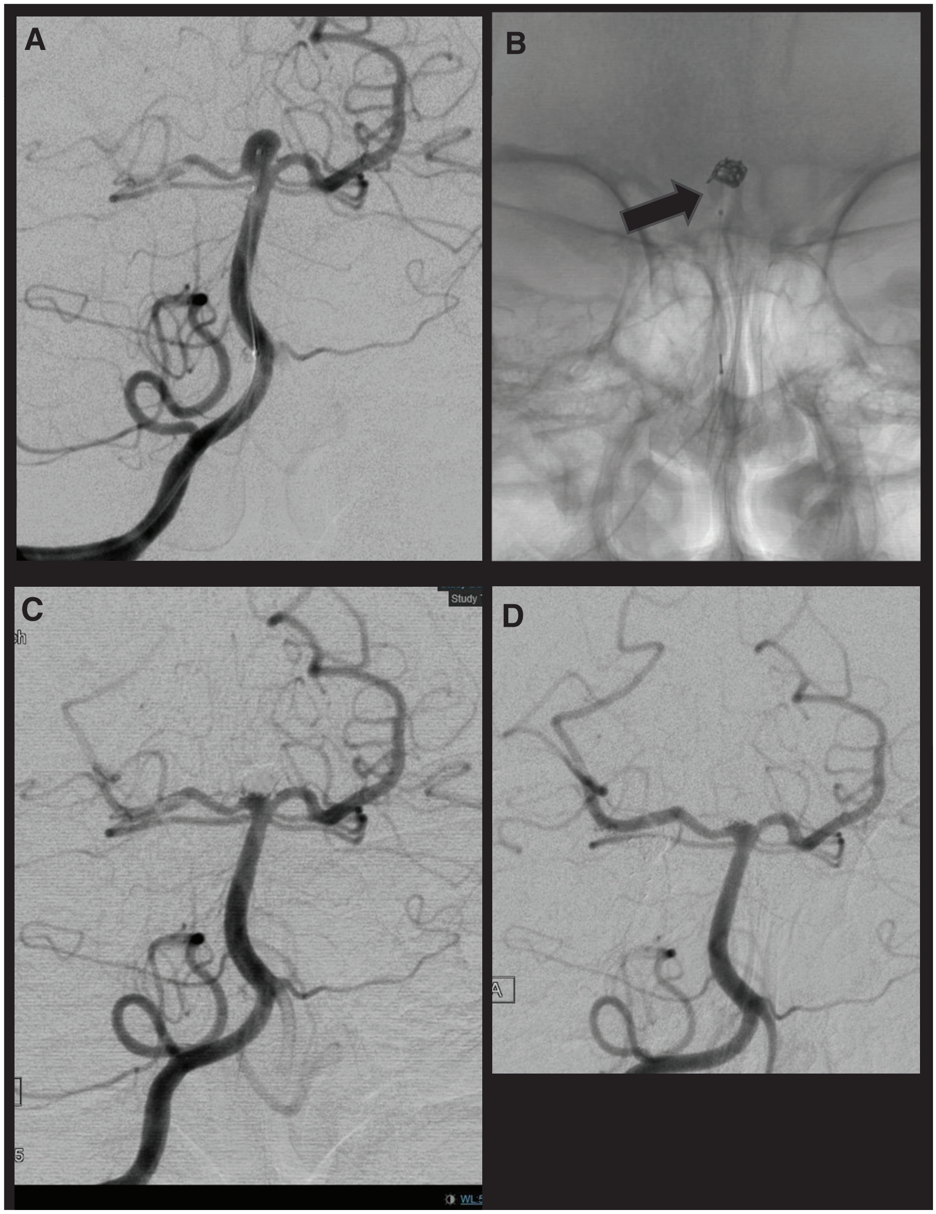

Fig. 2 Antero-posterior view of the right vertebral artery angiogram in Case 1. (**A**) An angiogram obtained just prior to embolization. Right PCA originates from the aneurysm dome. The Super-Masamune is already introduced. Note that the marker of the tip is inside the aneurysm, and the marker of the proximal end of the balloon indicates the distal portion of the basilar artery. (**B**) Skull X-p during coil insertion. The arrow shows the balloon inflated in the aneurysm. (**C**) An angiogram just after embolization showing the NR. (**D**) Follow-up angiogram performed 33 months after embolization shows CO with good patency of right PCA. CO: complete obliteration; NR: neck remnant; PCA: posterior cerebral artery

aneurysm was 9.5 mm in size, and we decided to perform embolization in consideration of the primary disease. Coaxial IANP was performed, as the catheter tip could not be positioned in the proper location with simple IANP. While the outcome immediately after treatment was BF, it improved to NR by the 12-month follow-up. The patient was lost to follow-up due to exacerbation of the primary disease.

Discussion

Balloon assist[5–8] and stent assist[9–12] embolization are representative techniques used to treat cerebral aneurysms with wide neck. Although they feature superior efficacy and widespread use, they are implemented in the parent artery rather than the aneurysm. While the technique of bulging

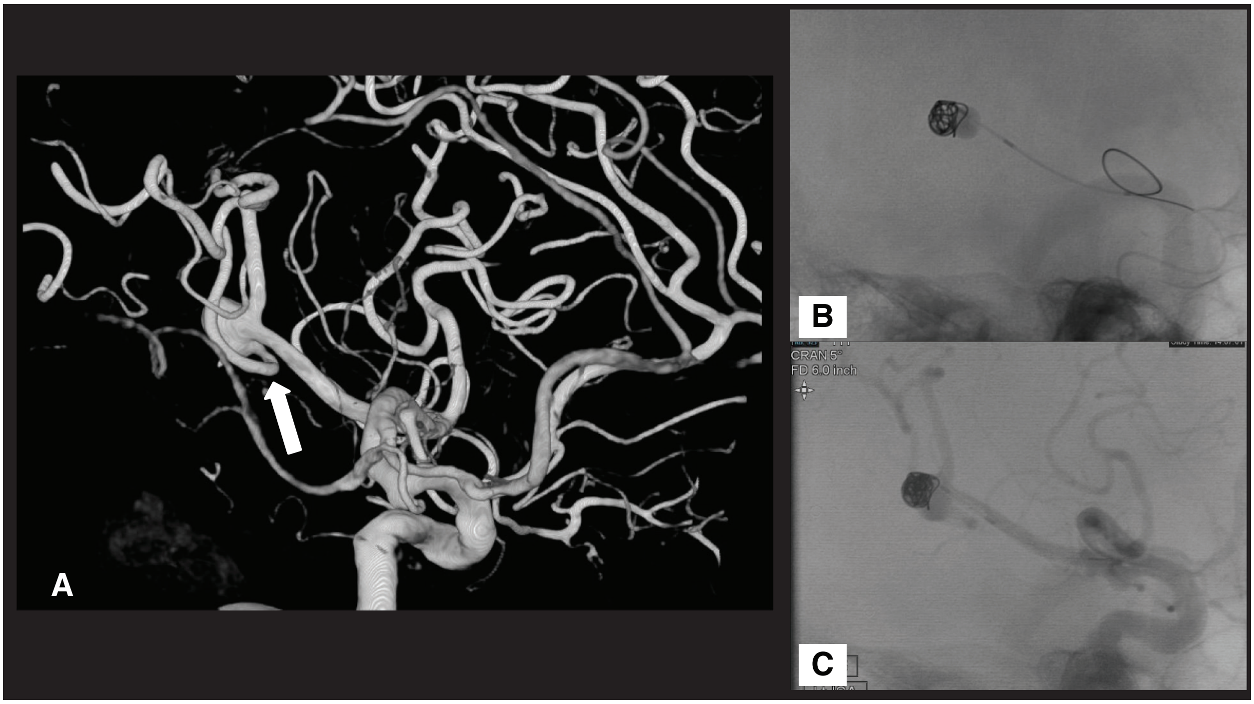

Fig. 3 Lateral oblique view of left internal carotid angiogram in Case 4 showing a large MCA aneurysm. (**A**) A 3D DSA just prior to embolization. The white arrow indicates a branching artery originating from the aneurysm dome with a hairpin curve. (**B**) Skull X-p during coil insertion. Note that the balloon is inflated in the aneurysm. (**C**) An angiogram just after insertion of the last coil. Both the MCA branches are completely preserved. MCA: middle cerebral artery

the balloon or stent into the aneurysm has been previously introduced, it is ineffective unless the artery branches from a site near the neck of the aneurysm. The double-catheter technique is a representative adjunctive technique that can be performed inside the aneurysm.[13,14] However, this approach was devised merely to supplement the performance of the microcatheter and is not as effective as the use of balloons or stents.

The IANP methodology examined in the present report inflates the balloon inside the aneurysm and has the potential to prompt a paradigm shift in the treatment of cerebral aneurysms. Inflating the balloon inside the aneurysm had not been tested thus far for several reasons. The first concerns its safety. Although the capacity of coils to adjust to the aneurysm walls makes them safer than balloons, this difference in performance does not indicate that the process of inflating a balloon in the aneurysm is extremely risky approach. Indeed, challenging techniques like treating aneurysms using a balloon had been tested before coils earned widespread practical use. Hence, balloons have not been inflated inside aneurysms because they were no balloons on the market that could be applied in this manner, not because they are unsafe. The current balloons commercially available to assist aneurysm embolization are intended for application to the parent artery; their shapes and compliance are unsuitable for inflation inside aneurysms. As the Super-Masamune balloon features a double lumen, it does not require a sealing wire. Furthermore, as its nose is short, the tip of the balloon and the tip of the microcatheter are adjacent: this structure cannot be found in other balloons. The Super-Masamune is also super compliant relative to other balloons and only inflates in an open space. For this reason, the balloon inflates well inside the aneurysm, even if the inflation is initiated when it is positioned across the neck of an aneurysm.

All cases examined in the present study found that treatments with balloons/stents were difficult or impossible. As aforementioned, conventional balloons/stents need to be led into the artery that is meant to be preserved, but this can be compromised by problems such as the inappropriate branching angle of the artery. However, as the branch that is meant to be preserved originates from near the neck of the aneurysm, the insertion of Super-Masamune into the origin of the branch is a simple process; that is, while it is difficult to direct the guidewire/microcatheter of conventional balloons/stents to the target artery from the origin of the branch, this operation is not required when the Super-Masamune is used. In this respect, the Super-Masamune is an epochal device.

The guidewire does not remain when the balloon is inflated during simple IANP, wherein the Super-Masamune

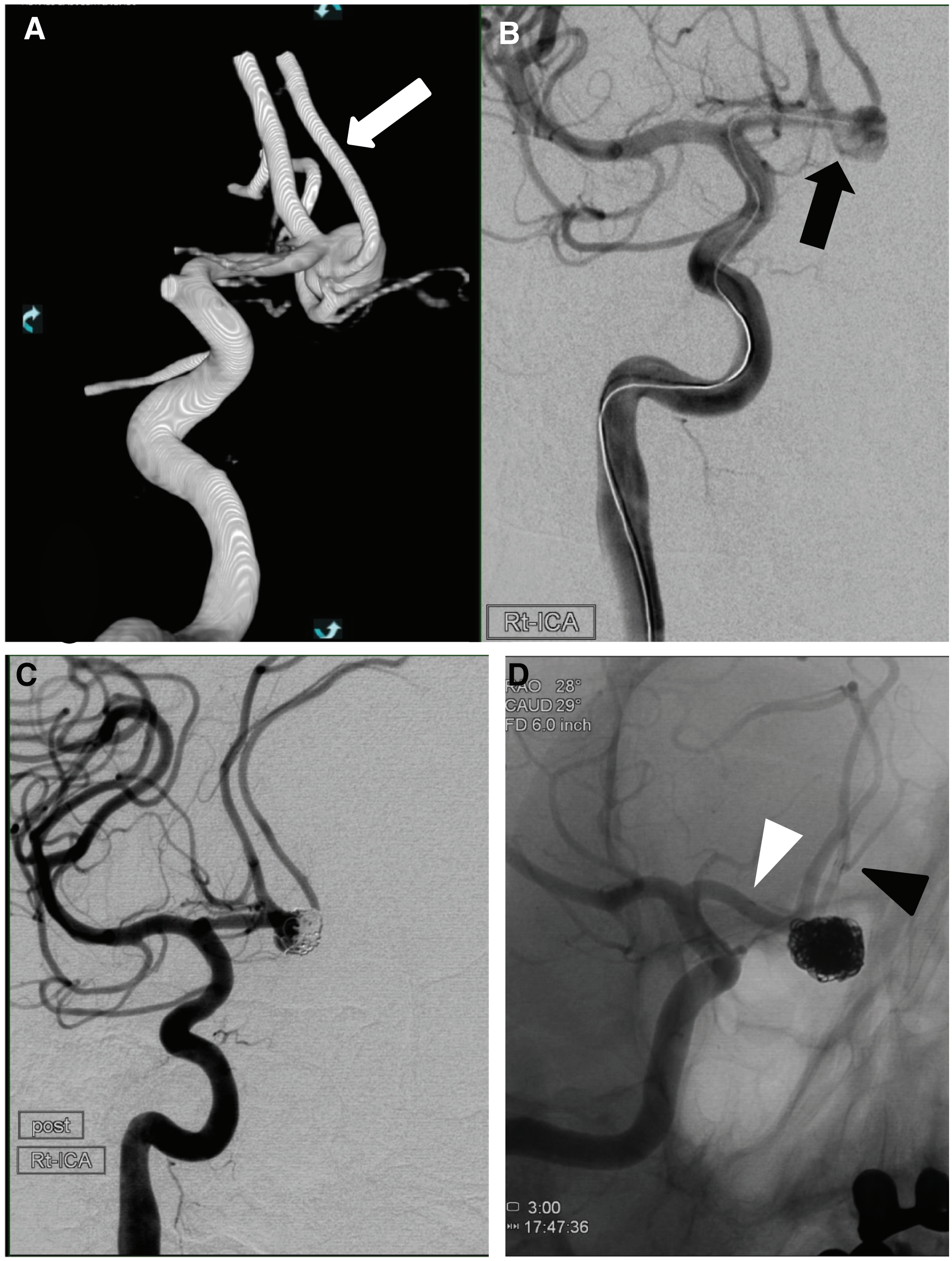

Fig. 4 Left (**A, B, C**) and right (**D**) anterior oblique view of the right internal carotid artery angiograms in Case 7. (**A**) A 3D DSA just prior to embolization showing an anterior communicating artery aneurysm. Note that the left A2 originates from the aneurysm dome (white arrow). (**B**) An angiogram performed just after the introduction of the Super-Masamune. The arrow indicates the inflated Super-Masamune inside the aneurysm. (**C**) An angiogram obtained just after coiling. The left A2 is completely preserved, though the embolization was graded as BF. (**D**) An angiogram performed just after stent assist coiling 4 months later. The black and white arrowheads indicate the distal and proximal ends, respectively, of an Enterprise stent. BF: body filling

is also used as a microcatheter for coil insertion. During coaxial IANP, a separate microcatheter is used for coil insertion, and the balloon can be inflated while the guidewire remains in the main lumen; this feature improves the stability of the balloon. Since the Super-Masamune has two markers intended for coil insertion, simple IANP makes full use of the characteristics of the Super-Masamune. Hence, the Super-Masamune can be used for elderly patients for whom coaxial catheterization is difficult. All patients who underwent simple IANP had aneurysms in the periphery of MCA or AcomA and were generally older. It is conceivable that coaxial catheterization would be too difficult to perform

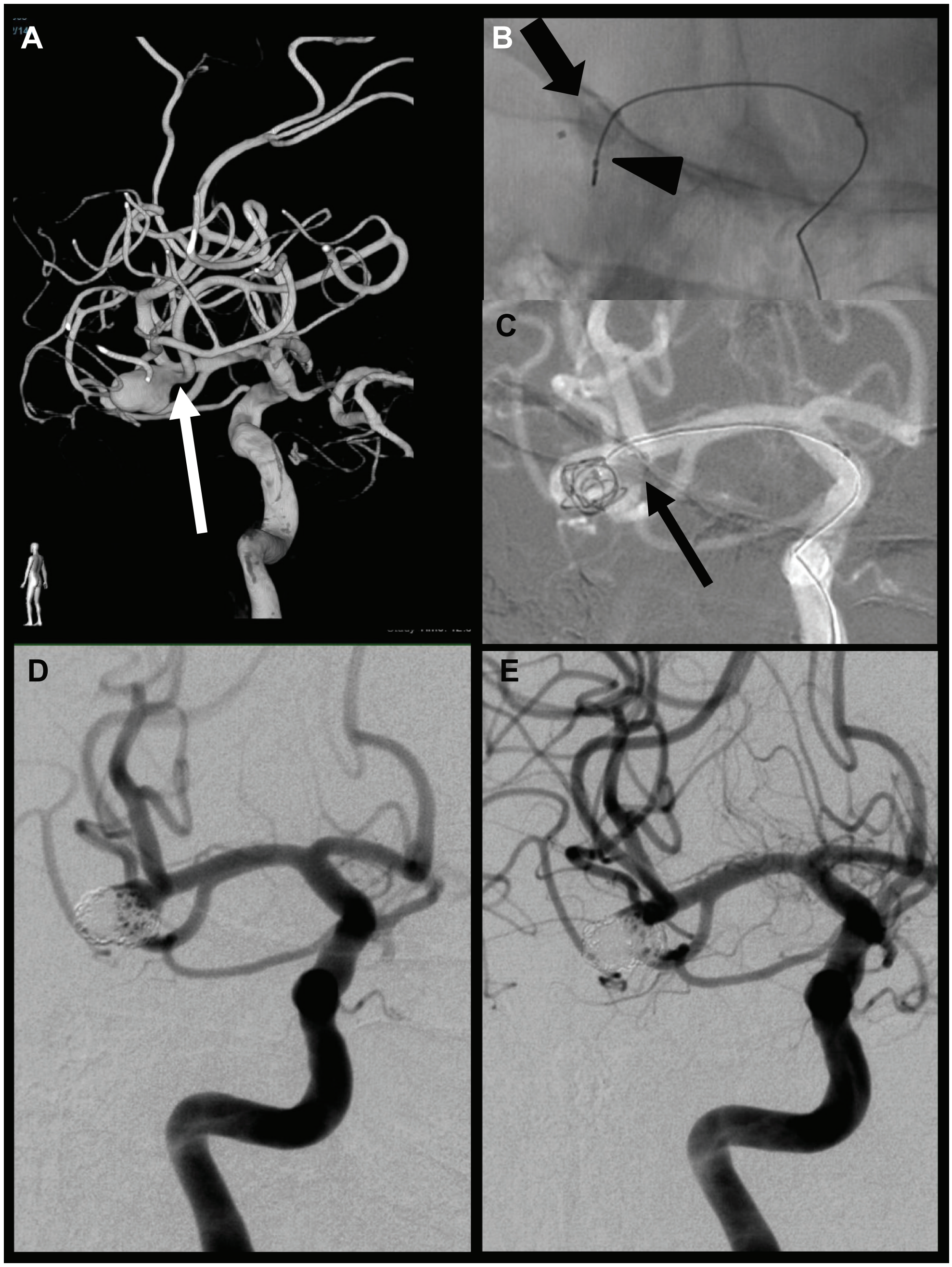

Fig. 5 Left anterior oblique views in Case 14. (**A**) A 3D DSA obtained just prior to embolization showing an MCA aneurysm. The long white arrow indicates a branching artery originating from the aneurysm dome. (**B**) Skull Xp obtained just prior to embolization. The arrow indicates the Super-Masamune inflated inside the aneurysm, and an arrowhead indicates another microcatheter used for the insertion of the coils. (**C**) Screenshot of road mapping performed during the insertion of the coil. Note that the Super-Masamune is inflated inside the aneurysm (long arrow) to prevent the protrusion of the coils. (**D**) An angiogram obtained just after embolization shows BF with the preservation of the MCA branches. (**E**) An angiogram obtained 12 months later shows the NR with the preservation of the MCA branches. BF: body filling; MCA: middle carotid artery; NR: neck remnant

in these cases. On the other hand, the optimal placement of the Super-Masamune would differ depending on its application as a balloon catheter or microcatheter for coil insertion. If coaxial catheterization is possible, the use of coaxial IANP would thus achieve more reliable embolization. Aside from one case, all ruptured aneurysms were treated by coaxial IANP, and placement of the coil was likely given greater consideration in these cases.

The present study included many high-risk cases: seven patients were older than 80 years of age, seven had aneurysms whose size exceeded 9 mm, and three had H&K grade 4 or 5 aneurysms. These circumstances account for the preference of coiling over craniotomy. Performing embolization yielded no outcomes of CO, seven of NR, and six of BF; however, considering that CO was impossible by the time IANP was performed and that none of aneurysms ruptured after embolization, these results are acceptable. In our hospital, we have avoided the combined use of stents to treat acute rupture cases as much as possible. Instead, we apply the combined use of stents to the treatment of aneurysms in the subacute phase of rupture and focus on improving curability.[15] In other words, emergency treatments are prioritized during the acute phase, while full-scale treatment is administered from the subacute phase onwards. Although stent assist coiling was performed during the chronic phase for Case 7, the purpose in the initial phase of treatment—as outlined by the aforementioned policy—had been achieved with this approach. Furthermore, although the treatment of Case 14 resulted in BF, the condition of this patient improved to NR by the 12-month follow-up, indicating that the clinical course varies case by case. For Case 17, we used the Super-Masamune to perform simple IANP. However, as the coil protruded into the parent artery when the balloon was deflated, embolization with simple catheterization was achieved using the Super-Masamune as a microcatheter rather than a balloon and inserting it by pressing on the coil from the front. As we were able to perform a trial occlusion that could not be performed with the microcatheter alone, our strategy was more effective than simply inserting an ordinary microcatheter.

One case of intraoperative rupture was observed as a complication. The coil perforated during coil placement in the performance of coaxial IANP. There is only small space in the aneurysm in IANP, so perforation of aneurysm by coils should be paid attention more than in other method. We use softer coils without strong shape-memory in IANP. Troubleshooting was possible by adding a coil from the Super-Masamune, and no consequent neurological deterioration was observed. No other medical complications nor any adverse effects caused by inflating the balloon inside the aneurysm were noted in any case. The above observations suggest that the safety of using the Super-Masamune to perform IANP is acceptable. However, in terms of health insurance applicability, the Super-Masamune is meant to be placed in the parent artery to seal the neck of the aneurysm, much like other balloons, to assist aneurysm embolization. So, IANP does not follow the instruction strictly. It is a form off-label use. We performed IANP in this series in the doctor's discretion with an informed consent to patient and/or his/her families. Our hospital has established clinical ethics committee in this year of 2020. IANP was submitted to the clinical ethics committee and was accepted. IANP is now permitted by clinical ethics committee in our hospital.

When using the Super-Masamune in the case of a small contrast space, the injection pressure of the contrast agent will have the same effect as pressing on the balloon syringe, which can inflate the balloon slightly during DSA. To avoid this, it is recommended that a parent catheter whose size is 1F wider than that of the minimum guiding catheter be used.

Although IANP using the Super-Masamune may not yet constitute a first-choice treatment, it would be effective in preserving the artery that is difficult to guide to the periphery.

Conclusion

The Super-Masamune is a super compliant balloon that can be inflated inside an aneurysm. IANP performed with the Super-Masamune would, therefore, be a highly useful treatment option for aneurysms.

Acknowledgment

We would like to thank Editage (www.editage.com) for English language editing.

Disclosure Statement

We declare no conflicts of interest.

References

1) Guglielmi G, Viñuela F, Dion J, et al: Electrothrombosis of saccular aneurysms via endovascular approach. Part 2: Preliminary clinical experience. *J Neurosurg* 1991; 75: 8–14.
2) Ezura M, Kimura N, Uenohara H: Super-Masamune: developing process and animal study. *JNET J Neuroendovasc Ther* 2015; 9: 187–191. (in Japanese)
3) Ezura M, Kimura N, Uenohara H: Super-Masamune: initial clinical experience. *JNET J Neuroendovasc Ther* 2015; 9: 192–196. (in Japanese)
4) Kimura N, Ezura M, Uenohara H: Intraaneurysmal neck plasty with the Super-Masamune, a super-compliant, double-lumen balloon microcatheter. *JNET J Neuroendovasc Ther* 2016; 10: 44–48.
5) Takahashi A, Ezura M, Yoshimoto T: Broad neck basilar tip aneurysm treated by neck plastic intra-aneurysmal GDC embolisation with protective balloon. *Interv Neuroradiol* 1997; 3: 167–170.

6) Moret J, Cognard C, Weill A, et al: The “Remodelling Technique” in the treatment of wide neck intracranial aneurysms. Angiographic results and clinical follow-up in 56 cases. *Interv Neuroradiol* 1997; 3: 21–35.

7) Ezura M, Matsumoto Y, Takahashi A: Intraaneurysmal embolization using Hyperform balloon occlusion system. *Surg Cerebral Stroke* 2006; 34: 270–273. (in Japanese)

8) Gory B, Kessler I, Seizem Nakiri G, et al: Initial experience of intracranial aneurysm embolization using the balloon remodeling technique with Scepter C, a new double-lumen balloon. *Interv Neuroradiol* 2012; 18: 284–287.

9) Henkes H, Bose A, Felber S, et al: Endovascular coil occlusion of intracranial aneurysms assisted by a novel self-expandable nitinol microstent (neuroform). *Interv Neuroradiol* 2002; 8: 107–119.

10) Park SY, Oh JS, Oh HJ, et al: Safety and efficacy of low-profile, self-expandable stents for treatment of intracranial aneurysms: initial and midterm results - a systematic review and meta-analysis. *Interv Neurol* 2017; 6: 170–182.

11) Iosif C, Piotin M, Saleme S, et al: Safety and effectiveness of the Low Profile Visualized Intraluminal Support (LVIS and LVIS Jr) devices in the endovascular treatment of intracranial aneurysms: results of the TRAIL multicenter observational study. *J Neurointerv Surg* 2018; 10: 675–681.

12) Satow T, Ikeda G, Takahashi JC, et al: Coil Embolization for unruptured intracranial aneurysms at the dawn of stent era: results of the japanese registry of neuroendovascular therapy (JR-NET) 3. *Neurol Med Chir (Tokyo)* 2020; 60: 55–65.

13) Kwon OK, Kim SH, Kwon BJ, et al: Endovascular treatment of wide-necked aneurysms by using two microcatheters: techniques and outcomes in 25 patients. *AJNR Am J Neuroragiol* 2005; 26: 894–900.

14) Kim DJ, Kim BM, Park KY, et al: Coil embolization of overwide and undertall small intracranial aneurysms with double microcatheter technique. *Acta Neurochir (Wien)* 2014; 156: 839–846.

15) Ezura M, Morita T, Haryu S, et al: Stent-assisted embolization for acutely ruptured aneurysms. *Surg Cerebral Stroke* 2021; 49: 34–37. (in Japanese)