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ORIGINAL ARTICLE - VASCULAR

Predictors of antegrade flow at internal carotid artery during carotid artery stenting with proximal protection

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Abstract

Background Carotid artery stenting (CAS) with proximal occlusion effectively prevent distal cerebral embolism by flow arrest at internal carotid artery (ICA); however, the method can expose antegrade flow at ICA due to incomplete flow arrest. The aim of this study was to identify predictors of antegrade flow during CAS with proximal protection.

Methods We retrospectively analyzed clinical and angiographic data among 143 lesions treated with CAS with proximal protection by occluding the common carotid artery (CCA) and external carotid artery (ECA). Flow arrest or antegrade flow at ICA was confirmed by contrast injection during proximal protection.

Results Antegrade flow at ICA was observed in 12 lesions (8.4%). Compared with lesions in which flow arrest of ICA was achieved, the diameter of the superior thyroid artery (STA) was significantly larger (2.4 ± 0.34 vs. 1.4 ± 0.68 mm, $p < 0.001$), and the rate of ECA branches other than the STA located 0–10 mm above the bifurcation was significantly higher (50 vs. 8.4%, $p < 0.001$). Results of multivariate analysis revealed that a diameter of the STA ≥ 2.3 mm (OR 44, 95% CI 8.1–237; $p < 0.001$) and ECA branches other than the STA located 0–10 mm above the bifurcation (OR 6.0, 95% CI 1.1–32; $p = 0.036$) were independent predictors of antegrade flow.

Conclusions Distal filter protection should be combined with proximal protection for the lesions with antegrade flow to prevent distal migration of the carotid debris.

Keywords Carotid artery stenting · Proximal protection · Incomplete flow arrest · Superior thyroid artery

Abbreviations

CAS	Carotid artery stenting
ICA	Internal carotid artery
CCA	Common carotid artery
ECA	External carotid artery
STA	Superior thyroid artery
EPD	Embolic protection device
MRI	Magnetic resonance imaging
T1W	T1 weighted
rSI	Relative signal intensity
LA	Lingual artery
FA	Facial artery
OA	Occipital artery
ROC	Receiver-operating characteristic

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Introduction

An embolic protection device (EPD) reduces cerebral ischemic complications during carotid artery stenting (CAS) [9]. Among the EPDs that are currently in clinical use, proximal protection has the advantage of providing cerebral embolic protection in all phases of the procedure to occlude the common carotid artery (CCA) and external carotid artery (ECA) [14]. However, whether flow arrest of the internal carotid artery (ICA) is achieved by proximal protection has not be studied; antegrade flow at ICA due to incomplete flow arrest can cause embolic complications. The aim of this study was to identify the predictors of antegrade flow at ICA during CAS with proximal protection.

Materials and methods

Study population

We conducted a retrospective assessment of clinical and angiographic records from September 2012 to December 2016

of all patients who underwent first-time CAS using proximal protection at our hospital. Inclusion criteria were the degree of ICA stenosis, determined by angiography according to the North American Symptomatic Carotid Endarterectomy Trial Criteria: asymptomatic stenosis ≥ 80% and symptomatic stenosis ≥ 50%. Symptomatic was defined as carotid stenosis occurring within 6 months before the procedure, with ischemic minor stroke (Rankin Scale score > 2), transient ischemic attack, or amaurosis fugax. Patients with the following criteria were excluded: lesions with CCA stenosis, ICA stenosis with ECA occlusion or ECA stenosis ≥ 50%, severe peripheral vascular disease preventing femoral access, severe vascular tortuosity or anatomy that would preclude the safe introduction of the guiding catheter, and a contraindication for antiplatelet therapy. Written informed consent was obtained from all patients. This study was approved by the hospital ethics committee.

Imaging assessment

Diameter of the CCA, ICA, STA, and most stenotic lesion were measured by angiography using biplane system (BRANSIST Safire, Shimadzu, Kyoto, Japan), and each diameter was calculated referring the diameter of a guiding catheter. Calcification was defined that calcified lesion was extended over a half of the carotid artery circumference by computed tomography or ultrasound. Carotid magnetic resonance imaging (MRI) using a 3-T imaging machine (MAGNETOM Verio; Siemens, Erlangen, Germany) was performed before the procedure. T1 weighted (T1W) images of the carotid artery, including the area with the highest rate of stenosis and plaque, were obtained. T1W image parameters were as follows: repetition time 500; echo time 13; and slice thickness, 2.0. The relative signal intensity (rSI) of plaque components was calculated in relation to the sternocleidomastoid muscle, and rSI > 1.25 was defined as "high," meaning unstable.

CAS procedures

CAS with proximal protection was performed using a guiding catheter with a temporary occlusion balloon or Mo.Ma Ultra proximal protection device (Medtronic, Minneapolis, MN, USA). In Japan, the Mo.Ma Ultra proximal protection device was firstly approved by the Ministry of Health, Labour and Welfare in January 2013. We mainly used a guiding catheter with a temporary occlusion balloon. However, from January 2014, the Mo.Ma Ultra proximal protection device was used for lesions with a safe access. Dual oral antiplatelets were administered beginning at least 5 days before the CAS procedure. Local anesthesia was provided for all patients to allow continuous monitoring of their level of consciousness and motor function. Systemic anticoagulation was achieved by administrating heparin to maintain an activated clotting time of at least 275 s.

In 109 lesions, an 8 or 9-French (F) sheath and an 8F or 9F guiding catheter with a temporary occlusion balloon (Optimo; Tokai Medical Products, Aichi, Japan, or Cello; Fuji System Corp., Tokyo, Japan) were navigated to the CCA from the femoral artery. Additionally, a PercuSurge Guardwire (Medtronic) was navigated to the ECA to occlude it by inflating the device to 4–6 mm. In 34 lesions, the Mo.Ma Ultra proximal protection device was navigated to occlude the CCA and ECA.

The ECA was occluded about 10 mm above the carotid bifurcation, and branches of the ECA such as the superior thyroid artery (STA), lingual artery (LA), facial artery (FA), and occipital artery (OA) were occluded as much as possible while paying attention to slip-back of the balloon into the CCA.

The arterial pressure line was connected to the guiding catheter, or Mo.Ma Ultra proximal protection device, and the mean systemic blood pressure was measured by deflating the CCA balloon. After occluding the ECA and CCA, the mean stump pressure was measured, and 5 mL of contrast medium were injected to verify flow arrestor antegrade flow at ICA (Fig. 1). Neurological intolerance was defined as the presence of conscious disturbance, motor paresis, or aphasia during proximal occlusion test within 1 min. In patients with neurological intolerance, the CCA balloon was immediately deflated to restore cerebral blood flow. A 0.014-in guidewire or distal filter protection device such as the Filter wire EZ (Stryker, Natick, MA, USA) or Spider FX (Medtronic) was crossed over the stenotic lesion under proximal protection. Filter protection device was combined with proximal protection for patients with neurological intolerance, antegrade flow at ICA, and unstable plaque. Pre-dilatation was performed using a balloon catheter (3.0–5.0 mm), and then a stent system, the Precise (Cordis, Miami Lakes, FL, USA), Protege (Medtronic), or Carotid Wallstent (Stryker), was deployed, and post-dilatation was performed by using a 4.0- to 7.0-mm balloon catheter. Then, a manual aspiration of 60 mL of blood was performed, and the aspirated blood was returned to the central venous circulation through an external filter to capture debris in the continuous blood return system [6], or filtered through sieves to check visible debris. After which the temporary occlusion balloon in the CCA was deflated to restore ICA flow. The presence of any neurological deficits during the procedure was also defined to neurological intolerance. Diffusion-weighted (DW)-MRI was performed within 1–3 days after the procedure.

Statistical analysis

Variables are expressed as absolute numbers and percentages or mean ± standard deviation. Comparisons were made using

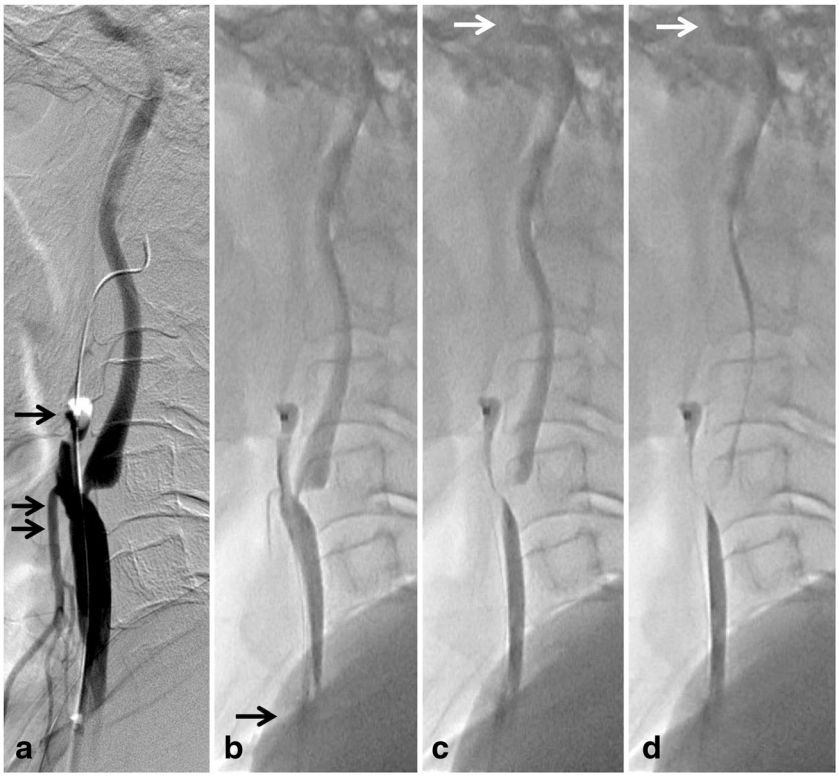

Fig. 1 Representative case of carotid stenosis revealing antegrade flow at internal carotid artery during proximal protection. **a** Pre-procedural angiogram in the lateral view. External carotid artery (ECA) is occluded by balloon (arrow) about 10 mm above the carotid bifurcation. Superior temporal artery (double arrows) is patent, and its inner diameter is 2.6 mm. **b**–**d** During occlusion of ECA and common carotid artery (arrow in **b**) by balloons, the contrast medium injected from the guiding catheter slowly flows from the carotid stenotic lesion into the intracranial ICA (white arrow in **c**, **d**)

the *t* test for unpaired samples or the chi-squared test as appropriate. To identify the diameter of the STA that provided the best cutoff for predicting antegrade flow at ICA, we chose the values in which the sum of the specificity and sensitivity was the highest. This value was obtained using receiver-operating characteristic (ROC) curve analysis. Multivariate analysis was performing to identify predictors of antegrade flow at ICA using factors with a p value < 0.10 in univariate analysis. For all tests, a p value < 0.05 was considered statistically significant. All statistical analyses were performed with the R 3.4.0 statistical software (R foundation for Statistical Computing, Vienna, Austria).

Results

A summary of the baseline and lesion characteristics according to the occurrence of antegrade flow at ICA is shown in Table 1. Lesions with antegrade flow were observed in 8.4% of the patients. Notably, lesions with antegrade flow were significantly affected by the diameter of the STA and ECA branches other than the STA located 0–10 mm above the bifurcation. No differences between the two groups were observed with respect to the stenotic ratio and contralateral occlusion or stenosis.

A summary of the intraprocedural data and the clinical outcomes is shown in Table 2. No differences between the two groups were observed with respect to the stump pressure and neurological intolerance. Technical success was achieved in all patients. Permanent neurological deficits were seen in two patients in the flow arrest group; one had major cerebral infarction that occurred 3 days after CAS due to stent thrombosis, and the other had cerebral hemorrhage 3 weeks after the procedure due to hyperperfusion syndrome. The rates of permanent and transient neurological deficits were not different between the two groups.

In the ROC curve analysis, a diameter of STA of 2.3 mm was determined as the most reliable cutoff value for antegrade flow (Fig. 2).

ECA branches other than the STA located 0–10 mm above the bifurcation were observed in 18/143 (13.0%) lesions, and 6/18 (33%) lesions among them had antegrade flow.

Multivariate analysis identified that a diameter of the STA ≥ 2.3 mm and ECA branches other than the STA located 0–10 mm above the bifurcation were independent predictors of lesions with antegrade flow (Table 3). A dot chart of the relationship between the diameter of the STA, the presence of ECA branches other than the STA located 0–10 mm above the bifurcation, and the antegrade flow is shown in Fig. 3.

Discussion

Our study demonstrated the following. (1) An injection of contrast medium to verify flow arrest or antegrade flow at ICA showed that the occurrence of antegrade flow was 8.4%

Table 1 Baseline patient and lesion characteristics in antegrade flow and flow arrest groups

Characteristic	Total	Antegrade flow	Flow arrest	*p* value
Patients	*n* = 143	*n* = 12	*n* = 131	
Age, years	72 ± 7.3	72 ± 9.1	71 ± 7.2	0.91
Males	126 (88)	12 (100)	114 (87)	0.39
Hypertension	113 (79)	9 (75)	104 (79)	0.71
Diabetes	46 (32)	4 (33)	42 (32)	1.00
Symptomatic	90 (63)	10 (83)	80 (61)	0.28
Contralateral ICA severe stenosis/occlusion	23 (16)	3 (25)	20 (15)	0.41
Stenosis, 80–99%	19 (13)	2 (17)	17 (13)	
Occlusion	4 (2.8)	1 (9)	3 (2)	
Lesions				
Calcification	15 (10)	0 (0)	15 (11)	0.61
Plaque MRI-T1W, hyper	79 (55)	7 (58)	72 (55)	1.00
Stenotic ratio, %	74 ± 14	74 ± 15	74 ± 14	0.95
Ulceration	76 (53)	7 (58)	70 (53)	1.00
Diameter of CCA, mm	7.8 ± 0.94	8.0 ± 1.1	7.8 ± 0.93	0.47
Diameter of distal ICA, mm	5.0 ± 0.93	5.0 ± 0.85	5.0 ± 0.94	0.87
Diameter of most stenotic lesion, mm	1.4 ± 0.84	1.3 ± 0.81	1.4 ± 0.85	0.68
STA				
Position				0.98
10 mm above the bifurcation	5 (3)	0 (0)	5 (4)	
0–10 mm above the bifurcation	63 (44)	6 (50)	57 (44)	
Under the bifurcation	64 (45)	6 (50)	58 (44)	
None or occlusion	11 (8)	0 (0)	11 (8)	
Diameter, mm	1.4 ± 0.66	2.3 ± 0.34	1.4 ± 0.68	< 0.001
ECA branch 0–10 mm beyond the bifurcation	18 (13)	6 (50)	12 (9)	< 0.001
LA	12 (8)	3 (25)	9 (7)	
LA + OA	3 (2)	1 (8)	2 (2)	
LA + FA + OA	1 (1)	1 (8)	0 (0)	
LA and STA common trunk	1 (1)	0 (0)	1 (1)	
OA	1 (1)	1 (8)	0 (0)	

Values are presented as the number of patients (%) unless indicated. Mean values are presented ± SD

ICA internal carotid artery, *T1W* T1 weighted, *CCA* common carotid artery, *STA* superior thyroid artery, *ECA* external carotid artery, *LA* lingual artery, *OA* occipital artery, *FA* facial artery

of the lesions underwent CAS with proximal protection. (2) A diameter of the STA ≥ 2.3 mm and ECA branches other than the STA located 0–10 mm above the bifurcation were independent predictors of antegrade flow. (3) Antegrade flow was not associated with an increased risk of post-procedural cerebral ischemic events by combining the use of a distal filter with proximal protection.

CAS with proximal protection reduces embolic complications. Its principal advantages include the establishment of cerebral protection before lesion crossing and the removal of debris during the procedure. It theoretically overcomes the ability of capturing debris better than by a distal filter in terms of unprotected lesion crossing and migration into the cerebral artery of particulate debris that are smaller than the filter pores [6]. However, a recent meta-analysis comparing proximal protection and distal filter protection demonstrated no statistical differences concerned to cerebrovascular events and post-procedural DW-MRI findings [2, 12]. The main disadvantage of neurologic intolerance from proximal protection due to insufficient cerebral collateralization has been studied, and its predictors were clarified to be low stump pressure and contralateral ICA occlusion [5]. The use of distal filter combined with proximal protection and short procedure time have been effective in decreasing ischemic events for the patients with neurologic intolerance [5]. However, other disadvantages of incomplete flow arrest at ICA have not been well investigated. Our study demonstrated preoperative predictors of antegrade flow at ICA. In this study, permanent and transient neurological deficits and a post-procedural positive signal on DW-MRI were not significant in the two groups. The reason

Table 2 Intraprocedural data and clinical outcomes related to antegrade flow

Factor	Total $n = 143$	Antegrade flow $n = 12$	Flow arrest $n = 131$	p value
Procedure features				
Mo.Ma use	37 (26)	4 (33)	33 (25)	0.51
Patent STA	127 (89)	12 (100)	115 (88)	0.37
Mean systemic blood pressure, mmHg	90 ± 10	92 ± 4.9	90 ± 11	0.47
Mean stump pressure, mmHg	38 ± 18	44 ± 8.3	37 ± 18	0.17
Stump/mean blood pressure, %	42 ± 19	48 ± 9.4	41 ± 20	0.25
Occlusion neurological intolerance	25 (17)	2 (17)	23 (18)	1.00
Combined use of a distal filter	122 (85)	12 (100)	110 (84)	0.21
Closed-cell stents	66 (46)	7 (58)	59 (45)	0.55
Dilatation of the maximum balloon size, mm	4.9 ± 0.8	4.8 ± 0.6	5.0 ± 0.8	0.57
Outcomes				
DW-MRI, positive	25 (17)	4 (33)	21 (16)	0.22
Any neurological deficits	5 (3)	0 (0)	5 (4)	0.89
Transient neurological deficits	3 (2)	0 (0)	3 (2)	
Permanent neurological deficits	2 (1)	0 (0)	2 (2)	

Values are presented as the number of patients (%) unless indicated. Mean values are presented ± S

Mo.Ma Mo.Ma proximal protection device, *STA* superior thyroid artery, *DW* diffusion weighted

for this was thought to be because the distal filter device was combined with proximal protection for the lesion with antegrade flow to prevent distal migration of the carotid debris.

This combined protection can prevent distal embolization for patients with antegrade flow at the ICA, because full protection likely cannot be achieved by proximal protection alone, and migrated debris can be captured via the distal filter instead of through proximal protection. Therefore, this combined proximal protection method should be applied for lesions that have preoperative predictors of antegrade flow and in those where antegrade flow is verified by contrast injection during proximal protection. The combined protection may even be applied for patients with neurological intolerance and unstable plaque, which allows intermittent proximal protection for patients with neurological intolerance who cannot tolerate prolonged balloon occlusion of the CCA and prevents distal debris migration for patients with unstable plaque who have a high risk of distal emboli. Previously, we reported that visible debris captured by distal filter were observed in 17.3% of the patients despite combined protection of flow reversal and distal filter during CAS. If the stent system is passed through a guiding catheter using the rapid exchange technique, then there would be insufficient space in the guiding catheter, which might cause antegrade flow and migration into the cerebral artery despite proximal protection; this likely occurred in our previous study [6].

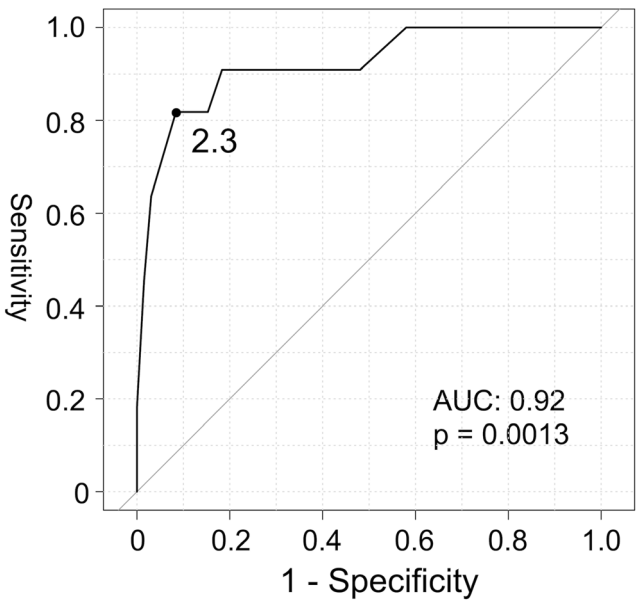

Fig. 2 Receiver-operating characteristic curve analysis indicates that a diameter of the superior temporal artery of 2.3 mm is the most reliable cutoff value for predicting antegrade flow at ICA. AUC area under the curve

Table 3 Multivariative analysis for factors related to antegrade flow

Variable	Adjusted OR	95% CI	p value
STA diameter ≥ 2.3 mm	44	8.1–237	< 0.001
ECA branches other than the STA 0–10 mm above the bifurcation	6.0	1.1–32	0.036

STA superior thyroid artery, *ECA* external carotid artery, *OR* odds ratio, *CI* confidence interval

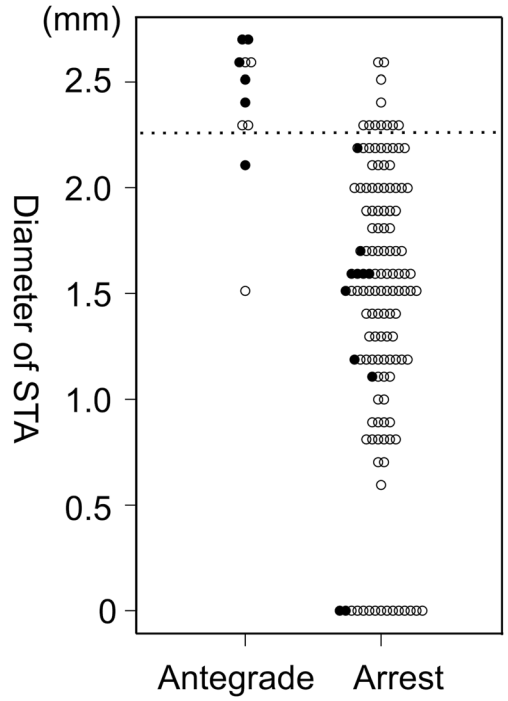

Fig. 3 Dot plot of the diameter of the superior temporal artery (STA) in antegrade flow and flow arrest groups. A broken line indicates a cutoff value (2.3 mm) for antegrade flow. Block dots indicates lesions with external carotid artery branches other than the STA located 0–10 mm above the bifurcation

Occlusion of the ECA at a lower position from the carotid bifurcation reduces patent ECA branches and prevents antegrade flow at ICA. In particular, the STA and other proximal ECA branches should be occluded for patients with antegrade flow at ICA. However, occlusion of the STA is commonly difficult, because occlusion of the ECA at a position just distal from the carotid bifurcation can cause slip-back of the balloon into the CCA. In fact, STA was patent in 96% (127/132) of the lesions by proximal protection in this study. Therefore, the ECA should be occluded as much as possible at about the position where the branches of the ECA are occluded, while also paying attention to slip-back of the balloon into the CCA. In this study, the STA originated from CCA in 48% (64/132) and ECA in 52% (68/132) of the lesions, excluding non-STA lesions. Among them, the STA originated 10 mm above the bifurcation in only 5% (7/132). Previous anatomical studies about origin of the STA showed similar results that the STA originated from the ECA in 25–51% of the lesions, whereas it originated from the bifurcation and CCA in 49–75% of the lesions [1, 11, 13], and the mean distance between the bifurcation and the origin of the STA was 3.3–5.9 mm distal to the bifurcation [1, 10, 13].

The inner diameter of the STA was 1.72 mm in cadaver specimens, as reported by Cavalcantii et al. [3]. In this study, the mean inner diameter measured by angiography was 1.68 mm, which was similar to that reported in Cavalcantii et al.'s study. A diameter of the STA ≥ 2.3 mm was the most reliable cutoff value for antegrade flow, and this was shown in 16% (21/132) of the lesions, excluding those with no STA and occlusion of the STA.

In the proximal portion of the ECA, the LA and FA originated from the frontal side. Mean distances between the bifurcation and the LA and FA origins were 12–15 mm [1, 4, 8, 13] and 20–22 mm [1, 10, 13], respectively. In this study, the LA and FA were observed at 0–10 mm above the bifurcation in 12 and 0.7% of the lesions, respectively. The OA typically originated from the posterior side of the ECA. Hayashi et al. reported that 57% of the OAs originated from above the level of the origin of FA, 32% from between the level of the LA and FA, and 11% from below the level of the FA in a cadaver study [7]. Acar et al. reported that the distance from the bifurcation to the origin of the OA was 21 mm [1]. In this study, the OA originated 0–10 mm above the bifurcation in 2.8% of the lesions. Ascending pharyngeal artery (APA) originated mainly from the posterior side of the ECA with many variance. Cavalcanti et al. reported that in 20 cases of the cadavers, the APA arose from the ECA in 80% and OA, bifurcation, and common trunk of the LA and FA in 5% each, and it was located 15.3 ± 8.3 mm above the bifurcation [3]. Hayashi et al. reported 66% of the APA arose from above the level of LA, 31% from below the level of LA, 2% from the bifurcation, and 2% from ICA [7]. In this study, the origin of the APA was not 0–10 mm above the bifurcation, as assessed by angiography.

The stump pressure by proximal protection was affected by back pressures of ICA, STA, and other non-occluded ECA branches. The stump pressure was significantly related to neurological intolerance due to cerebral blood flow insufficiency by proximal protection [5]. In this study, stump pressure was not related to antegrade flow. We assumed that stump pressure was more likely affected by back flow pressure from the ICA than that of the STA and other non-occluded ECA branches.

This study has several limitations. First, this was a single-center study with a limited number of patients. The selected lesions were biased in safe access from a femoral artery and non-stenotic ECA. Second, patency of the ECA branches such as LA, FA, and OA was confirmed in only pre-procedural angiography with ECA occlusion. It was sometimes difficult to confirm that the ECA branches were occluded or not because of insufficient contrast filling by occlusion of main trunk of ECA. Furthermore, during proximal protection, occlusion of the STA and ECA branches might not confirmed by contrast injection due to the back flow from the patent STA and ECA branches. The patency of the ECA branches could change if the position of the balloon to occlude ECA was even just a little moved.

Conclusions

Antegrade flow occurred in 8.4% of the lesions undergoing proximal protected CAS. A diameter of the STA ≥ 2.3 mm and ECA branches other than the STA located 0–10 mm above the bifurcation were independent predictors of antegrade flow; therefore, ischemic complication due to distal embolization could occur. Distal filter protection should be combined with proximal protection to prevent embolic complications for the lesions with antegrade flow.

Compliance with ethical standards

Conflict of interest None.

Ethical approval For this type of study, formal consent is not required.

Informed consent Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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Comments

Carotid artery stenting (CAS) with proximal occlusion is theoretically the most effective procedure to prevent distal cerebral embolism by flow arrest at internal carotid artery (ICA). However, existence of antegrade flow at ICA during proximal protection may cause embolic stroke. The authors clearly demonstrated occurrence rate (8.4%) and predictors of the antegrade flow in this interesting report. Additionally, their strategy using distal filter device in addition to proximal balloon protection can prevent distal cerebral embolism even in presence of the antegrade flow. This report is interesting and will give an important information for the readers.

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