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INTERVENTIONAL

Detection of in-stent protrusion (ISP) by intravascular ultrasound during carotid stenting: Usefulness of stent-in-stent placement for ISP

T. Okazaki[1] · S. Sakamoto[1] · K. Shinagawa[1] · N. Ichinose[1] · D. Ishii[1] · T. Matsushige[1] · Y. Kiura[1] · K. Kurisu[1]

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Abstract

Objectives As in-stent protrusion (ISP) during carotid artery stenting (CAS) may cause postoperative embolism, ISP detection is important. Intravascular ultrasound examination (IVUS) is useful for ISP detection because the blood vessel cross-section can be drawn as a tomogram from the lumen. Our objective was to clarify the occurrence of ISP during CAS using IVUS and relevant factors, and to report the usefulness of stent-in-stent placement when treating ISP.

Methods In 142 consecutive patients (128 men, average age 71.7 years; 69 symptomatic) who underwent CAS using dual protection and the blood aspiration method, and subsequent IVUS after stent placement were included. The outcome of CAS, and the occurrence rate of ISP and related factors (plaque characteristics, stent design, intraoperative debris capture rate and postoperative diffusion-weighted imaging (DWI) positive rate) were examined.

Results All CAS procedures were successful and no major adverse events (MAEs) were observed at 30 days. ISP was found in 12% (17/142), and stent-in-stent placement was performed in all cases. Vulnerable plaques were observed in 12 of 17 ISP cases (71%). A closed stent was used in 13 of 17 ISP cases (71%). The intraoperative debris capture rate was 100%, and no neurological symptoms were observed in any patients. A significant increase in ISP susceptibility was related to vulnerable plaques and the intraoperative debris capture rate.

Conclusions Vulnerable plaques and debris capture were significantly correlated with ISP occurrence. In all ISP cases, stent-in-stent placement was performed and good results were obtained.

Key Points

- *ISP detection during CAS using IVUS is important.*
- *ISP-positive patients were correlated with NASCET ≥ 80%, vulnerable plaques and stent length.*
- *Adequate additional treatment of stent in stenting under reliable protection against ISP-positive patients achieved low perioperative complications.*

Keywords Carotid stenosis · Intravascular ultrasound · Stents

Abbreviations

AV	Arteriovenous
CAS	Carotid artery stenting
CC	Close-cell design stent
CCA	Common carotid artery
CEA	Carotid endarterectomy
CREST	Carotid Revascularization Endarterectomy vs. Stenting Trial
DSA	Digital subtraction angiography
DWI	Diffusion-weighted imaging
ECA	External carotid artery
HIS	High-intensity signal
ICA	Internal carotid artery
ISP	In-stent protrusion
IVUS	Intravascular ultrasound
MAE	Major adverse events
NASCET	North American Symptomatic Carotid Endarterectomy Trial
OC	Open-cell design stent
OCT	Optical coherence tomography

✉ T. Okazaki
okazaki@hiroshima-u.ac.jp

[1] Department of Neurosurgery, Graduate School of Biomedical and Health Sciences, Hiroshima University, 1-2-3 Kasumi, Minami-ku, Hiroshima 734 8551, Japan

OFDI	Optical frequency domain imaging
PTA	Percutaneous transluminal angioplasty
TIA	Transient ischaemic attack

Introduction

In 2010, CREST reported that CAS was equal to endovascular carotid endarterectomy (CEA), which promoted the use of CAS. Later, the evolution of protection devices and better methods improved the treatment outcomes of CAS, and the number of CAS procedures increased to more than 7,000 cases per year in Japan [1]. At our facility, we changed to the dual protection + blood aspiration method in November 2009, which reduced the complication rate. Recently, ISP has been suggested to be a cause of embolic complications after CAS. It is important to detect ISP after CAS to prevent embolic complications [2–5]. Since February 2012, the IVUS (Volcano S5 Imaging System, Volcano Corporation) has been routinely employed before and after stent placement, and in-stent protrusion has been found with higher accuracy. ISP during CAS is likely the cause of intraoperative and postoperative embolism, and early response is necessary. As IVUS can monitor blood vessel cross-sections from the lumen, it is useful for detecting ISP. In this study, we evaluated treatment outcome, incidence of ISP and related factors in 142 patients who underwent IVUS after stent placement.

Materials and methods

Patients

Between February 2012 and January 2017, 142 consecutive patients (male, n=128; mean age, 71.7 years; symptomatic, n=69) with internal carotid artery (ICA) stenosis underwent 142 CAS procedures in our hospital. In five patients with access route difficulties, we used the transbrachial artery approach. In three patients, we used the distal balloon protection method with a balloon wire system (GuardWire; Medtronic). In 137 of the 142 patients, CAS procedures were performed by the dual protection (simultaneous flow reversal and distal filter) and blood aspiration method as described previously [6, 7]. In all patients, IVUS was performed after stent deployment and in-stent protrusion was assessed. If ISP was detected by IVUS after stenting, an additional stent was implanted. In these cases, IVUS was repeated at the end of the procedure and added the stent until ISP disappeared completely. Since the horizontal resolution of the IVUS is 0.2 mm, the ISP minimum size was defined as 0.2 mm or more (Fig. 1).

CAS procedure (combined dual protection and blood aspiration)

Antiplatelet drugs (clopidogrel 75 mg/day; aspirin 100 mg/day; and/or cilostazol 200 mg/day) were administered for at least 1 week before CAS. The same neurointerventionist performed CAS under local anaesthesia, and an activated clotting time of > 275 s was maintained using heparin.

A 9-F sheath was placed into the femoral artery, and a 4-F sheath was placed into the femoral vein. A 9-F occlusion balloon-guiding catheter (OPTIMO; Tokai Medical Products) was introduced into the common carotid artery (CCA). The proximal end of the 9-F occlusion balloon-guiding catheter was connected to the 4-F sheath inserted into the femoral vein via the blood filter to capture debris, and an external arteriovenous (AV) shunt line was created. The line was also created to aspirate blood manually using a 50-ml syringe from the AV shunt line. Next, a balloon wire system was introduced into the external carotid artery (ECA), which was continuously occluded during the procedure. After inflation of the occlusion balloons in the CCA and ECA, we confirmed that blood flowed through the AV shunt line into the venous circulation by the difference between arterial and venous pressures (flow reversal). Under flow-reversal conditions, a filter wire (FilterWire EZ, Boston Scientific) crossing the stenotic lesion was deployed into the high cervical ICA. Dual protection was performed with simultaneous flow reversal and a distal filter. Initial IVUS imaging was carried out before pre-dilatation. The stent and post-dilatation balloon diameters were determined according to the IVUS findings. The ICA was pre-dilated under dual protection, and approximately 30 ml of blood was manually aspirated through the AV shunt line using a 50-ml syringe. The CCA balloon was then deflated to reduce the duration of brain ischaemia. The CCA balloon was again inflated, and under dual protection, a self-expanding stent (Carotid Wallstent; Boston Scientific, PRECISE; Johnson & Johnson, Protégé; ev3 Inc.) was deployed from the distal portion of the stenotic ICA to the CCA, and post-dilation proceeded. Thereafter, approximately 30 ml of blood was manually aspirated through the AV shunt line using a 50-ml syringe. An aspiration catheter (Export aspiration catheter; Medtronic) was advanced towards the filter over the wire using the wire of the distal filter. The tip of the aspiration catheter was first placed in the stent and blood was repeatedly aspirated manually. The CCA balloon was deflated after confirming the absence of debris in the aspirated blood. The tip of the aspiration catheter was advanced just proximal to the distal filter and blood was repeatedly aspirated manually. The aspiration catheter was withdrawn after confirming the absence of debris in the blood aspirated from the ICA. A total of 142 CAS procedures was performed using IVUS between February 2012 and January 2017. In-stent protrusion was assessed by IVUS. ISP was defined as observation

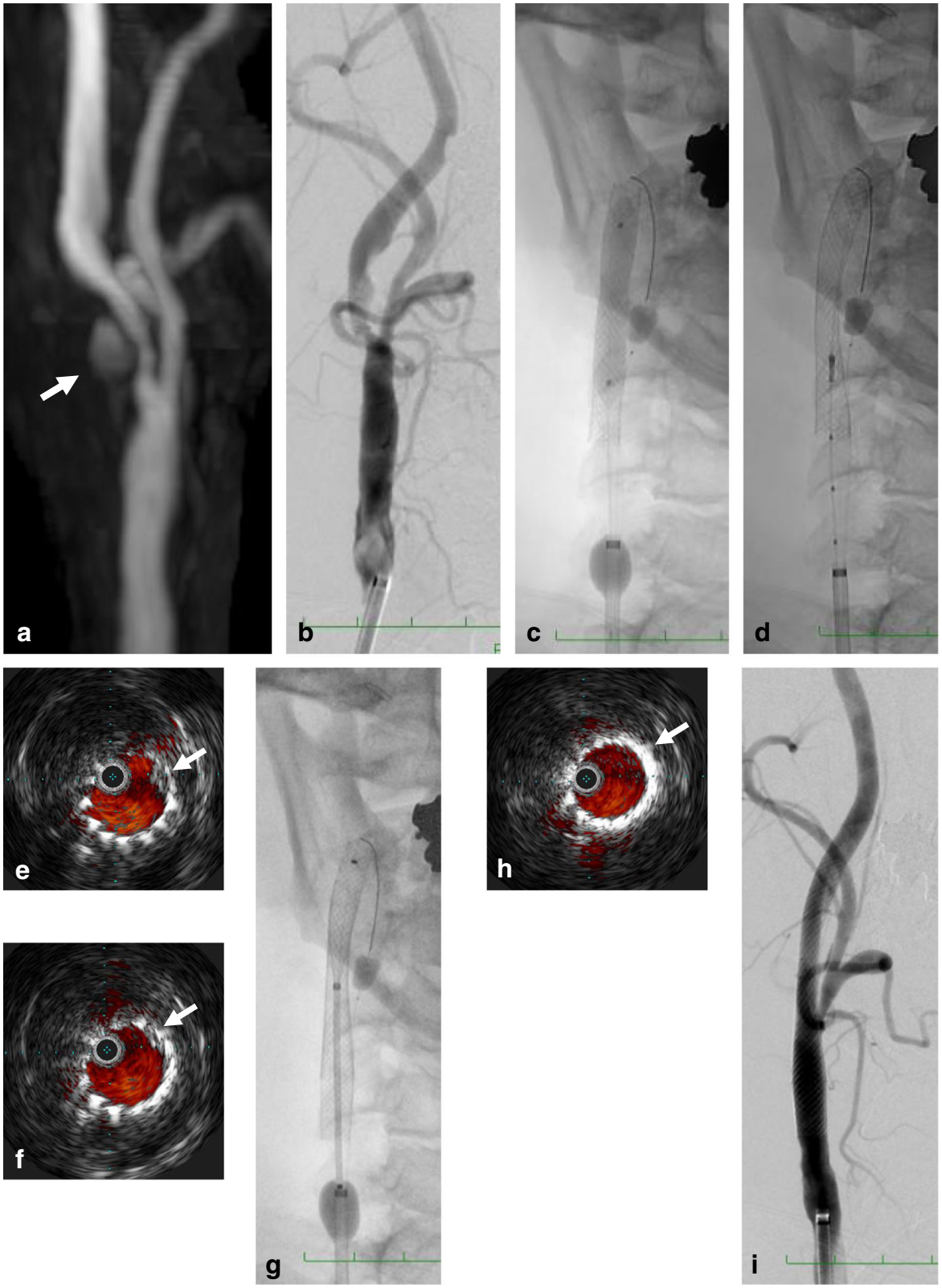

Fig. 1 Representative case. Preoperative magnetic resonance angiography indicated high signal intensity in the plaque (arrow) (**a**). A lateral view of the digital subtraction angiogram shows severe stenosis in the right ICA before stenting (**b**). After inflation of the occlusion balloons in the CCA and ECA, we performed the CAS procedure under flow-reversal conditions (**c**). After post-dilatation, ISP was detected by IVUS (**d, e**). After the first stent-in-stenting, ISP was detected by IVUS and further stent-in-stenting was performed (**f, g**). After stent-in-stenting, the ISP was compressed, which was also reconfirmed by IVUS and angiogram (**h, i**). Debris captured in the distal filter and blood filter (**j, k**). One high-intensity spot was observed on DWI in the contralateral frontal lobe 1 day after CAS (**l**)

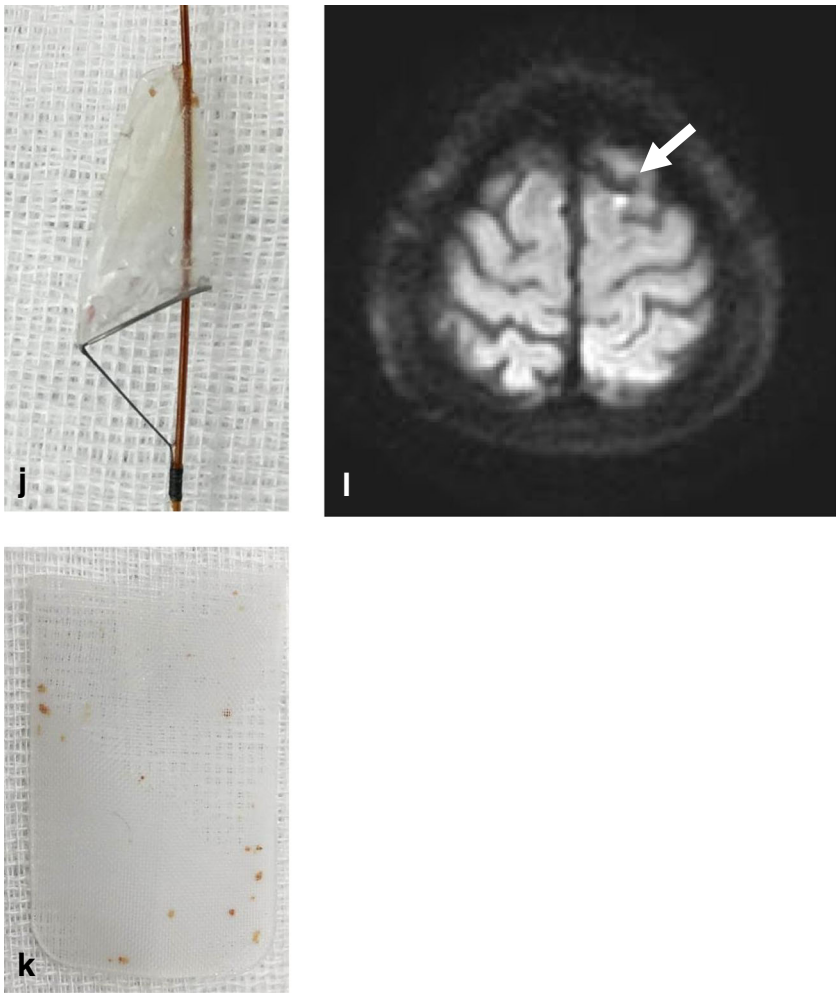

Fig. 1 (continued)

of plaque inside the stent lumen. If in-stent protrusion was detected by IVUS after stenting, an additional stent was implanted using the same kind of stent. IVUS and stent-in-stent placement were repeated after confirming the disappearance of the in-stent protrusion. If absent, the CCA balloon was inflated again and the distal filter was retrieved under flow reversal to prevent migration of debris captured in the distal filter. The ECA and CCA balloons were deflated, completing the CAS procedure.

Argatroban (2.5 mg/h) was continued for 12 h after CAS. Dual antiplatelet drugs were administered for 3 months and a single antiplatelet drug was prescribed indefinitely.

Time-of-flight MR angiography

Preoperative MRI to evaluate ICA plaques was performed 3 days before CAS with a clinical 3T MR unit (Signa Excite HD 3.0T; General Electric) using an eight-channel NeuroVascular phase array coil. Maximum intensity projection images from TOF-MRA were obtained using the following parameters: repletion time: 20 ms; echo time: 3.4 ms; flip angle: 18°; field of view: 240 × 240 mm; matrix: 256 × 160 (recon 512 × 512); and slice thickness: 2.4 mm.

Ultrasonography (US)

Preoperative US evaluation of the ICA plaques was performed 3 days before CAS. Two-dimensional B-mode and colour Doppler images of the affected carotid bifurcation were obtained using US (LOGIQ 7 system, GE Yokogawa Medical Systems) with a 3–10 MHz broadband linear array transducer. US was performed by an experienced sonographer certified by the Japan Academy of Neurosonology.

Definition of vulnerable plaques in this study

When high-intensity signal (HIS) in the ICA plaque was confirmed on preoperative TOF-MRA by two or more authors, the plaque was judged to be vulnerable, and when preoperative US of the ICA plaque exhibited a mobile component that was not synchronised with the heartbeat, the plaque was also judged to be vulnerable. Thus, ICA plaques with a mobile

component on US and/or HIS on TOF-MRA were defined as vulnerable.

Postoperative evaluation

Clinical outcomes

We assessed hyperintense areas on DWI on 3-T scanners, and defined major adverse events (MAEs) as major stroke, myocardial infarction or death after CAS. Stroke was defined as new neurological deficits lasting > 24 h. Minor and major strokes were defined as new neurological deficits that were completely resolved within 30 days and ≥ 30 days of follow-up, respectively. DWIs acquired within 3 days before and after CAS were compared to evaluate CAS-related hyperintense areas. Two or more neuroimaging specialists assessed the DWI on 3-T.

Definition of captured visible debris

We assessed the call strainer that passed the aspirated blood, the distal filter and the blood filter in the flow reversal line after CAS. When debris was confirmed by two or more authors, we considered the debris to have been captured. The findings were confirmed by two or more cerebral endovascular treatment specialists.

Statistical analysis

Continuous variables are expressed as mean ± SD. Categorical data are summarised as percentages and were compared using Fisher's exact test. Comparisons of continuous variables between cohorts were performed using the unpaired Student's t test. A p-value < 0.05 was considered significant, and all statistical analyses were performed using JMP software V. 10.

Results

The patients' mean age was 71.7 ± 6.7 years, and 128 were male. The mean stenosis rate was 69.1 ± 24.7% according to the NASCET method. Among all patients, 80 (56.3%) had right-side lesions, 69 (48.6%) had symptomatic stenosis, 64 (45.4%) had vulnerable plaques, 88 (65.7%) had calcification on the internal carotid artery wall, 107 (75.9%) had hypertension, 103 (73.1%) had dyslipidaemia, 60 (42.6%) had diabetes mellitus, 14 (9.9%) had peripheral artery disease and 34 (24.1%) were smokers. Statins were administered from 1 month before CAS for 129 (91.5%) patients. The DWI positive rate was 28% (39/139) and the debris capture rate was 58% (82/142).

The right brachial artery was used for five patients. Four procedures were performed using a filter wire, and one using a balloon-wire system. All remaining CAS procedures were performed from the femoral artery in the manner described above. Pre-dilatation was performed for 139 patients, and the mean diameter of the pre-dilatation balloon was 3.1 ± 0.4 mm. Post-dilatation was performed for 140 patients, and the mean diameter of the post-dilatation balloon was 5.7 ± 0.8 mm. Carotid wall stents were used in 121 (85.8%) patients. Precise stents and Protégé stents were used in ten (7.1%) patients each. The mean stent diameter and length were 8.6 ± 1.0 mm and 26.4 ± 7.7 mm, respectively.

Outcomes of the procedure at 30 days (Table 1)

All patients were followed in our hospital. Ipsilateral ischaemic stroke occurred within 30 postoperative days in three patients (2.1%), and all were minor strokes. Transient ischaemic attack (TIA) occurred in one patient (0.7%). There were no cases of postoperative myocardial infarction or death. In two patients, ischaemic symptoms were observed the day after operation. In one patient, ischaemic symptoms were observed immediately after the operation. TIA symptoms of unilateral spatial neglect and dysarthria occurred immediately and disappeared within 2 h post-operation.

ISP incidence on IVUS and risk factors for ISP

Table 2 shows the patient's baseline clinical characteristics. In 17 patients, ISPs were detected by IVUS after post-dilatation, and visible debris was observed in the aspirated blood, the distal filter and the blood filter in the flow reversal line after CAS in all 17. We performed stent-in-stent placement in all ISP-positive patients and confirmed the disappearance of ISP with IVUS. Symptomatic complications were not observed in ISP-positive patients. ISP-positive patients had significant differences in plaques of NASCET 80% or more (p=0.0367), vulnerable plaques (p=0.0084) and stent length (p=0.0189).

Table 1 Outcomes of the procedure at 30 days

Outcomes of the Procedure at 30 days	Values are n (%)
Technical success	142/142 (100)
30-day major adverse event rate	0/142 (0)
Stroke	3/142 (2.1)
· Major stroke	0/142 (0)
· Minor stroke	3/142 (2.1)
Transient ischaemic attack	1/142 (0.7)
Myocardial infarction	0/142 (0)
Death	0/142 (0)

Table 2 The patient's baseline clinical characteristics

	ISP(+), n=17	ISP(-), n=125	*p*-value
Age, mean±SD, y	73.4±5.7	71.5±6.9	0.363
Male, n (%)	16 (94.1)	112 (89.6)	1
right side, n (%)	8 (47.1)	72 (57.6)	0.444
Stenosis, mean±SD, %	79.8±16	67.67±25.3	0.0584
Stenosis (NASCET>80%), n (%)	11 (64.7)	46 (34.1)	0.0367*
Hypertension, n (%)	15 (88.2)	92 (74.2)	0.363
Dyslipidemia, n (%)	15 (88.2)	88 (71)	0.157
Diabetes mellitus, n (%)	9 (52.9)	51 (41.1)	0.436
Pre-operative statin treatment, n (%)	15 (88.2)	114 (91.9)	0.639
Smoker, n (%)	5 (2.9)	29 (23.4)	0.558
Symptomatic, n (%)	12 (70.6)	57 (45.6)	0.07
Vulnerable plaque, n (%)	13 (76.5)	51 (41.1)	0.0084*
Calcification, n (%)	11 (64.7)	77 (64.7)	0.578
Closed cell stent, n (%)	13 (76.5)	108 (87.1)	0.265
Pre-dilatation balloon diameter, mean±SD, mm	3.06±0.24	3.07±0.40	0.742
Stent diameter, mean±SD, mm	8.52±0.87	8.64±1.03	0.651
Stent length, mean±SD, mm	31.76±12.03	25.67±6.67	0.0189*
Post-dilatation balloon diameter, mean±SD, mm	6±0.71	5.7±0.85	0.0919
Debris capture, n (%)	17 (100)	65 (52.4)	<0.0001*
DWI positive, n (%)	7 (41.2)	32 (25.8)	0.249
Stent			
Carotid wall stent, n (%)	13 (76.5)	108 (87.1)	
Protégé stent, n (%)	4 (23.5)	6 (4.8)	
Precise stent, n (%)	0 (0)	10 (8.1)	

*Significant

Discussion

The detection of ISP is important in order to lower the complication rate of CAS procedures. Hayashi confirmed ISP with digital subtraction angiography (DSA) and IVUS immediately after CAS, and added percutaneous transluminal angioplasty (PTA). ISP disappeared, but diffuse cerebral infarction appeared in the right parietal lobe after operation. The patient developed left hemiparesis and configuration apraxia [8]. Kuroiwa et al reported that ISP was immediately found after CAS with IVUS, confirmed the increase in ISP size during postoperative follow-up observation (postoperative days 2 and 6), and applied stent-in stent placement. They confirmed mobile plaque protrusion with IVUS during the second CAS procedure [9]. Wehman et al also confirmed ISP with the IVUS immediately after CAS, and after re-examining the IVUS 10 min later, they found that the ISP had disappeared and the distal embolic protection device had successfully captured the debris [10]. Kotsugi et al reported ISP in 27 (7.8%) of 354 consecutive carotid atherosclerotic stenosis patients using IVUS during CAS. According to their report, five out of nine patients who developed ISP on both DSA and IVUS were followed without further treatment such as PTA or stent-in-stent placement. In 80% (4/5), postoperative stroke occurred. One was major stroke. They added stent-in-stent placement in four patients with ISP and in two with delayed ISP, and confirmed the disappearance of ISP [11]. Of 77 CAS procedures, Shinozaki et al confirmed ISP in six (7.8%), and added PTA in two and stent-in-stent placement in four patients, confirming the disappearance of ISP in all. Post-operative symptomatic complications were not observed [12]. From these past reports, it was demonstrated that reliable detection of ISP during the CAS procedure and secure correspondence of PTA and stent-in-stent placement are necessary for reducing perioperative complications.

In a previous report on the ISP detection rate, the frequency was low at 0.4–2.6% on DSA and 7.8% on IVUS [11–13]. In this study, ISP was observed in 12% (17/142). This is a slightly higher incidence than in other reports. As mentioned above, we have determined post-PTA balloon and stent sizes based on IVUS measurements. We chose the largest balloon size possible without exceeding the vessel diameter of the distal ICA. The post-dilatation balloon diameter was also somewhat

large, at 5.7 ± 0.8 mm on average. The reason for choosing a larger size was to prevent delayed stroke from occurring due to plaques that later protrude from the mesh of the stent. It is possible to prevent distal embolism even if ISP occurs during the procedure by squeezing the plaque during the operation with a large balloon. We define endovascular CEA as CAS using reliable protection and a large PTA balloon. There was no significant relationship between ISP and post-dilatation balloon diameter.

In this study at 30 days after the procedure, minor stroke was observed in 2.1% (3/142) and TIA in 0.7% (1/142). We used the proximal protection method to occlude the common carotid artery and the external carotid artery with a balloon and filter protection device in the internal carotid artery. We performed this procedure with flow reversal and confirmed the capturing of debris in all 17 patients with ISP by this method. We believe that the method of CAS known as endovascular CEA reduces perioperative complications. Kotsugi et al reported that in 357 consecutive CAS procedures, filter protection was used in 79%, the open-cell design stent (OC) was used in 67%, with major stroke occurring in 3.1%, minor stroke in 2.5% and TIA in 2.5% [11]. Donato et al reported the results of ISP detection using OCT (Optical Coherence Tomography) in 40 consecutive CAS procedures. The ISP incidence rate was 23.3% for the closed-cell design stent (CC) and 68.6% for OC, which was significantly higher [14]. Kotsugi et al reported significantly more ISP incidences with OC. CC is used in 86% of patients and this may have resulted in the reduced stroke incidence after CAS [11]. In our study, CC was used in 85.2% and we obtained good outcomes.

Yoshimura et al detected ISP using OCT. It was reported that the ISP detection rate by OCT was 17.6% (6/34), whereas it was 0% with IVUS. In our report, it was 12% (17/142), indicating that the detection rate is higher with OCT than with IVUS. This may be because the horizontal resolution is smaller in OCT than in IVUS (OCT: 12–18 μm, IVUS: 150–200 μm) [15]. If the size of the plaque causing ISP is less than 150 μm, it is difficult to detect with IVUS. This is one of the limitations of IVUS. The recently developed optical frequency domain imaging (OFDI) technique provides faster image acquisition speed, greater penetration depth and higher quality image resolution compared with the conventional time-domain OCT. Yamada et al evaluated ISPs by OFDI after stent placement in patients diagnosed with vulnerable plaques with black blood T1-weighted MRI images, and found ISPs in 86% (32/37) [16]. In this study, ISPs were observed in 20% (13/64) in the vulnerable plaque group. Thus, the ISP detection capability of OFDI is very high. Unfortunately, clinical use of the CAS procedure of OFDI is not allowed in Japan. The above-mentioned study is being conducted in clinical research. How much ISP for additional treatment is a topic for future study.

Stenosis, vulnerable plaque of NASCET 80% or more, vulnerable plaques and stent length were related to ISP positivity. Shinozaki et al reported that ISP occurrence significantly increased in cases of severe stenosis with delayed filling. We confirmed the localisation of plaque using IVUS before stent placement and selected the length of the stent so that the stent went from a normal to a normal vessel. Therefore, when we confirmed long plaque lesion we chose a long stent. It has been speculated that the stenosis rate and stent length are related to high plaque volume. Yoshimura et al found that there was significantly more intra-plaque bleeding when a high intensity signal was observed in plaques with time-of-flight MRA. In patients with high intensity signals in plaques, the postoperative DWI positive rate was significantly high (35.1% vs. 65.8%) [17]. Ischaemic complications are more likely to occur during CAS procedures if patients have a high stenosis rate, long plaque lesion and vulnerable plaques.

The debris capture rate

Stent-in-stent placement was performed for 17 ISP-positive patients, and we confirmed debris capture in all. The average debris capture rate was 58% (82/142). In ISP-positive patients, the debris capture rate was higher. The DWI prevalence rate was as high as 41.7%, but not significantly different from that in ISP-negative patients. It was suggested that adequate additional treatment of stent-in-stenting with reliable protection against ISP-positive patients prevented a significant increase of the DWI prevalence rate.

Study limitations

The study design was retrospective and conducted at a single centre with a small number of patients. A volume of 142 consecutive CAS procedures over 5 years is quite low and might impact on peri-procedural events. A larger multicentre study and randomised controlled trials are needed to confirm these results. There were no ISP-positive patients after completing CAS. Furthermore, we speculated on the relationship between ISP positivity and complications based on previous reports.

Conclusions

The ISP incidence on IVUS was 12%. Stent-in-stent placement was performed in all with good results. The occurrence of ISP is associated with vulnerable plaques, NASCET 80% or more, and stent length. In order to reduce the risk of post-operative stroke, it is necessary to ensure protection during CAS procedures to ensure capture of debris.

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Compliance with ethical standards

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Statistics and biometry No complex statistical methods were necessary for this paper.

Informed consent Written informed consent was waived by the Institutional Review Board.

Ethical approval Institutional Review Board approval was obtained.

Methodology
- Retrospective
- Case-control study
- Performed at one institution

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