CASE REPORT

Successful dilation using a Non-Slip Element Percutaneous Transluminal Angioplasty Scoring Balloon to treat in-stent restenosis of carotid artery stenting with inadequate dilation during balloon angioplasty : A case report

Manabu Yamamoto[1, 3], Shigeomi Yokoya[1], Takuma Kato[2, 3], and Hidesato Takezawa[2, 3]

Departments of [1]Neurosurgery and [2]Neurology, [3]Neuroendovascular Therapy, Saiseikai Shiga Hospital, Imperial Gift Foundation Inc., Shiga, Japan.

Abstract : *Background* : Carotid artery stenting (CAS) is commonly performed to treat internal carotid artery (ICA) stenosis ; however, it is associated with high recurrence rates. The treatment of in-stent restenosis (ISR) following CAS poses several challenges, and percutaneous transluminal angioplasty (PTA) is a possible treatment option. Scoring balloons used in the cardiovascular field can prevent slipping and plaque incisions during balloon expansion ; however, their efficacy in treating cervical ICA ISR remains uncertain. *Case description* : An 81-year-old man underwent CAS for carotid artery stenosis and subsequently developed ISR. Initial PTA with a noncompliant balloon failed to achieve sufficient dilation. However, the employment of a non-slip-element (NSE) PTA scoring balloon for additional expansion resulted in successful dilation, indicating its effectiveness in treating cervical ICA ISR. The patient was discharged postoperatively without any new neurological deficits, although magnetic resonance imaging revealed new ischemic lesions. *Conclusion* : The NSE PTA balloon could be considered as a valuable and effective treatment option for ISR when conventional balloon catheters face challenges in achieving dilation, although potential risks such as debris embolization should be considered. J. Med. Invest. 71 : 303-305, August, 2024

Keywords **:** *carotid artery stenting (CAS), in-stent restenosis (ISR), non-slip element (NSE), percutaneous transluminal angioplasty (PTA)*

INTRODUCTION

Carotid artery stenting (CAS) is actively performed to treat internal carotid artery (ICA) stenosis ; however, it is associated with high recurrence rates. Although treatment methods for in-stent restenosis (ISR) following CAS have not been fully established, percutaneous transluminal angioplasty (PTA) is considered an option.

Scoring balloons are commonly used to prevent slips during balloon expansion in the cardiovascular field (heart and limb arteries) using resin-based elements. These scoring balloons prevent slipping and incisions in the plaque during expansion (1, 2). However, the effectiveness of scoring balloons for treating cervical ICA ISR remains uncertain.

Herein, we present a case in which we initially used a noncompliant balloon at high pressure for an extended period, but did not achieve sufficient dilation ; however, upon employing a non-slip element (NSE) PTA scoring balloon for additional expansion, successful dilation was ultimately achieved, demonstrating its effectiveness in treating cervical ICA ISR.

CASE DESCRIPTION

Herein, we describe the case of an 81-year-old man with a right ICA ISR who had been hospitalized for acute myocardial infarction two years prior, at which point symptomatic severe-grade stenosis (89% stenosis as defined in the North American Symptomatic Carotid Endarterectomy Trial) (Figure A) was noted. CAS was performed via the right radial approach as treatment. A 7-Fr guiding catheter (Fubuki Hard ; Asahi Intec, Nagoya, Aichi, Japan) was placed in the right common carotid artery. A balloon protection device (GuardWire ; Boston Scientific, Marlborough, MA, USA) was used for distal embolic protection. The balloon (Shiden 4.0 × 30 mm, Kaneka, Osaka, Japan) was inflated at 8 atm for 30 s for pre-dilation. CAS was performed with a Carotid Wallstent 8.0×21 mm (Boston Scientific, Marlborough, USA) because the diameter of the carotid bifurcation was measured as 5.79 mm. Consequently, a balloon (Shiden 4.0×30 mm, Kaneka, Osaka, Japan) was inflated at 6 atm for 30 s for post-dilation. Carotid angiography confirmed the resolution of the stenosis (Figure B). Postoperative carotid echosonography confirmed a reduction in the systolic peak flow at the stenotic site to 1.2 m/s. The patient continued dual-antiplatelet therapy (prasugrel and aspirin) for 3 months, followed by aspirin monotherapy after CAS. However, the patient ultimately required retreatment for ISR because echosonography, performed two and a half years after the initial CAS, revealed that the systolic peak flow at the stenotic site within the carotid stent had increased to 4.0 m/s, suggesting ISR.

The patient underwent carotid artery PTA via a right radial approach. Carotid angiography performed prior to the procedure confirmed restenosis (Figure C). A 5-Fr guiding catheter (Axcel guide, 98 cm ; Medikit Co., Ltd., Tokyo, Japan) was placed in the right common carotid artery, and a filter device (Spider FX, 4 mm ; Covidien, Irvine, CA, USA) was used for distal embolic protection. Angioplasty was attempted using a balloon (Coyote NC 4.0 mm × 30 mm ; Boston Scientific, Marlborough, MA, USA) at 20 atm for 120 seconds (Figure D). However, intravascular

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Address correspondence and reprint requests to Shigeomi Yokoya, MD, PhD, Department of Neurosurgery, Saiseikai Shiga Hospital, Imperial Gift Foundation Inc., 2-4-1 Ohashi, Ritto-city, Shiga 520-3046, Japan and Fax : +81-77-553-8259. E-mail : yokoya@ks.kyorin-u.ac.jp

ultrasound (IVUS) using the VOLCANO system (Volcano Japan Corp., Tokyo, Japan) and an IVUS catheter (Eagle Eye Platinum ; Volcano Japan Corp.) performed immediately after the first PTA revealed a thick intimal hyperplasia (Figure E, F). We thus determined that simple PTA could provide insufficient stenosis dilation.

We subsequently deployed a scoring balloon (NSE PTA 4.0 × 20 mm ; Nipro, Osaka, Japan) for the second PTA. First, an NSE PTA scoring balloon was inflated into the lesion at 14 atm for 30 s, and then at 16 atm for 60 s (Figure G, H). IVUS, performed immediately after the second PTA using the NSE PTA scoring balloon, revealed the disappearance of the thick intimal hyperplasia (Figure I). We ultimately concluded that the NSE PTA balloon achieved sufficient dilation of the intimal hyperplasia. The filter retrieved following the procedure had captured large amounts of microscopic debris, although the levels of debris from using the NSE PTA scoring balloon and a normal balloon could not be compared as we did not retrieve the filter before the NSE PTA balloon was used.

Postoperative carotid echosonography revealed that the systolic peak flow at the stenotic site had reduced to 2.4 m/s, indicating likely amelioration of the lesion. Although diffusion-weighted magnetic resonance imaging performed the day after surgery revealed new ischemic lesions (Figure J), the patient showed no neurological deficits and was ultimately discharged on the second postoperative day.

DISCUSSION

The NSE PTA scoring balloon contains several non-slip elements that have been said to increase the risk of vessel rupture or dissection, meaning that the indication for carotid arteries should be carefully considered, and this device is not recommended in lesions involving distal to stents or broken stents. However, we considered that it could be used in this case, as the

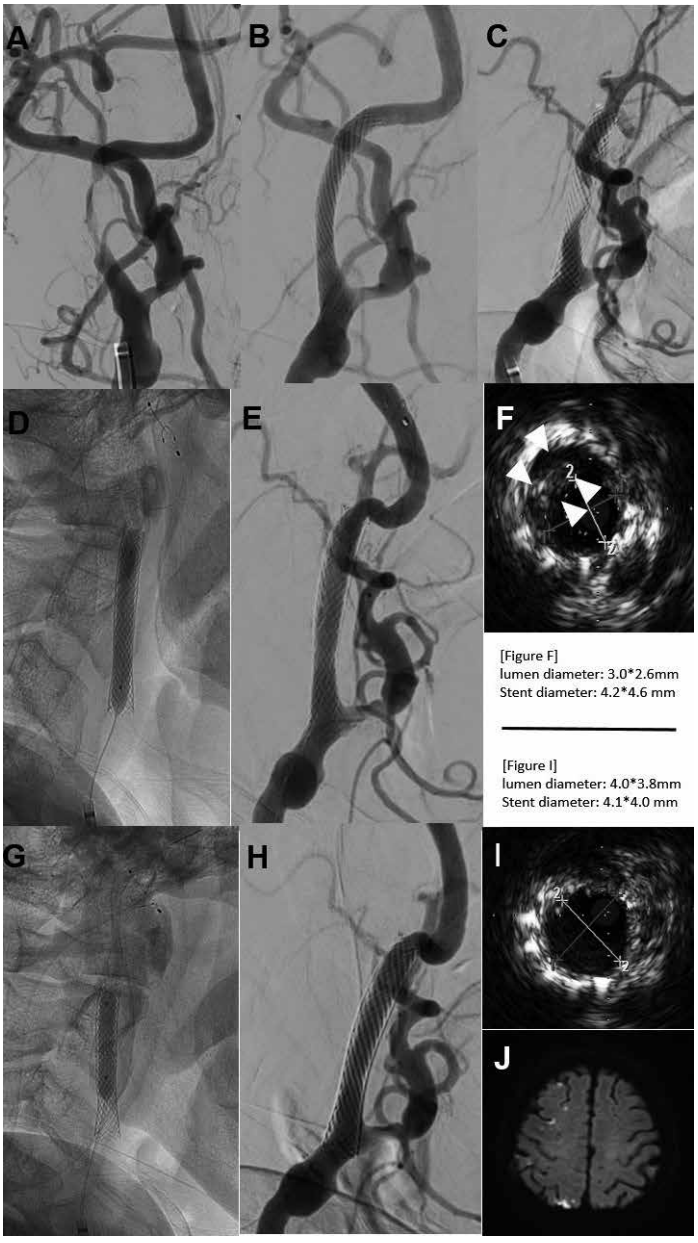

Figure 1.
(A) The right cervical carotid angiography (CAG) before carotid artery stenting (CAS), in the lateral view, showing severe carotid stenosis.
(B) Post-CAS angiography, lateral view, showing good blood flow and disappearance of the stenosis.
(C) Right CAG, obtained two and a half years after CAS, showing in-stent restenosis.
(D) In-stent percutaneous transluminal angioplasty (PTA) with the non-compliant balloon, Coyote NC (20 atm for 120 s) was attempted.
(E and F) Right carotid angiography obtained immediately after the PTA with Coyote NC showing apparent alleviation of in-stent restenosis. However, intravascular ultrasound performed at the same time revealed that the lumen was still narrowed by thick intimal hyperplasia (indicated by paired arrows).
(G) In-stent dilation with the non-slip element (NSE) percutaneous transluminal angioplasty (PTA) scoring balloon (14 atm for 30 s, and 16 atm for 60 s) was attempted.
(H) Right carotid angiography, obtained just after the PTA using an NSE PTA scoring balloon, revealed that in-stent restenosis was alleviated.
(I) Intravascular ultrasound just after the PTA using NSE PTA scoring balloon demonstrated denudation of thick intimal hyperplasia and the lumen to be secured.
(J) Diffusion-weighted magnetic resonance imaging, one day after the procedure, showing scattered fresh cerebral infarctions.

stent was not damaged, and the risk of injury to the vessel was considered low because the elements did not contact the vessel wall when in contact with the stent. In our case, although the noncompliant balloon, Coyote NC, expanded at high pressure for a long duration (20 atm for 120 s), it did not expand sufficiently. Subsequently, additional dilation was performed using an NSE PTA balloon at relatively low pressures (14 atm for 30 s and 16 atm for 60 s), resulting in successful dilation.

This case suggests that the NSE PTA balloon may be useful for treating ISR following CAS. The NSE PTA balloon can induce cracks in a lesion and expand them by concentrating the dilatation pressure on its surface elements. To the best of our knowledge, there have been very few reports on the use of scoring balloons in the carotid region (2), and its efficacy thus remains unclear. Furthermore, no reports have yet compared noncompliant balloon catheters with dilatation pressure.

In the present case, the NSE PTA balloon was able to dilate the lesion at 70-80% of the pressure of the noncompliant balloon, which failed to achieve sufficient dilation. The lower dilatation pressure with NSE may have contributed to a reduction in the risk of vascular damage associated with high-pressure dilation. In fact, several reports have been published which indicate a lower incidence of arterial dissection during angioplasty of the superficial femoral artery when using the NSE PTA scoring balloon compared to when using conventional balloons (1). Moreover, in cases of calcified lesions, ordinary balloons often have difficulty expanding ; however, scoring balloons have the potential to induce cracks and achieve overexpansion.

One might argue that, in contrast to native arteries, the benefit of low-pressure dilation for ISR is unclear. However, we considered that the scoring balloon used in our case was able to achieve dilation at a lower pressure and in a shorter time (14atm x30seconds and 16atm x60seconds) compared with the non-compliant balloon (20atm x120seconds), resulting in inadequate dilation, indicating that the scoring balloon may provide effective dilation in more cases, including ISR, as in our study.

This case also suggests that IVUS can provide useful information regarding balloon selection ; scoring, and conventional balloons. In the present case, since the intimal hyperplasia observed on IVUS showed isoechogenicity and was considered fibrotic, we considered that better dilation was achieved with an NSE PTA scoring balloon than with a non-compliant balloon. In our case, the intimal hyperplasia was considered to sufficiently hard and could not be expanded sufficiently even with a high-pressure balloon, resulting in our ultimate use of the NSE PTA scoring balloon, which has been indicated as appropriate for complex diffuse fibro-calcific atherosclerotic lesions due to their ability to reduce slippage (3).

Our case also suggests that an NSE PTA scoring balloon may increase the risk of debris embolization, although it is not clear exactly what caused the postoperative cerebral infarction as we used both a non-compliant balloon and a scoring balloon in this case. Furthermore, to the best of our knowledge, no studies have yet compared the conventional and scoring balloons in terms of peripheral embolic complications. As a practical consideration, although our patient remained asymptomatic, scattered fresh infarctions were observed on postoperative magnetic resonance imaging, despite the fact that embolization as a surgical complication is unlikely to occur during the treatment of intimal hyperplasia. Debris is generated when intimal hyperplasia is disrupted during balloon expansion. Concerns may arise from the possibility of an increased risk of neurological complications if a significant amount of debris is present. Despite employing balloon protection during CAS, one report revealed the occurrence of periprocedural neurological complications in 5.2% of the patients (4). Overall, we recommend enhancing embolic protection, which can be achieved by adding flow reversal technique, regardless of the tissue characteristics observed in IVUS, when employing an NSE PTA scoring balloon.

CONCLUSION

The NSE PTA balloon, which is used as a rescue option, may be a valuable and effective treatment option for ISR when conventional balloon catheters encounter dilatation difficulties.

CONFLICT OF INTEREST

The authors report that there are no competing interests to declare.

The authors have no relevant financial or nonfinancial interests to disclose.

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Ethical approval and consent to participate : All procedures in this study were performed in accordance with the 1964 Declaration of Helsinki. A series of treatments was performed after obtaining appropriate written informed consent from the patients. The requirement for additional written consent for inclusion in this study was waived by the Ethics Committee of Saiseikai Shiga Hospital because of the retrospective and observational nature of the study.

Author contributions : All authors contributed to the conception and design of the study. Material preparation and data collection were performed by all authors. Data analysis was performed as described by Yamamoto *et al*.. The first draft of the manuscript was written by Shigeomi Yokoya, and all authors commented on the previous versions of the manuscript. All the authors have read and approved the final version of the manuscript.

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